SCHEME : J

Name : _____

Roll No. : _____ Year : 20___ 20___

Exam Seat No. : _____

LABORATORY MANUAL FOR

PHARMACEUTICS (20051)

FIRST YEAR D.PHARMACY

MAHARASHTRA STATE BOARD OF TECHNICAL EDUCATION, MUMBAI
(Autonomous) (ISO 9001: 2015) (ISO/IEC 27001:2013)

VISION

To ensure that the diploma level technical education constantly matches the latest requirements of technology and industry and includes the all-round personal development of students including social concerns and to become globally competitive, technology led organization.

MISSION

To provide high quality technical and managerial manpower, information and consultancy services to the industry and community to enable the industry and community to face the challenging technological & environmental challenges.

QUALITY POLICY

We, at MSBTE are committed to offer the best-in-class academic services to the students and institutes to enhance the delight of industry and society. This will be achieved through continual improvement in management practices adopted in the process of curriculum design, development, implementation, evaluation and monitoring system along with adequate faculty development programmes.

CORE VALUES

MSBTE believes in the following:

- ✓ Skill development in line with industry requirements.
- ✓ Industry readiness and improved employability of Diploma holders.
- ✓ Synergistic relationship with industry.
- ✓ Collective and Cooperative development of all stake holders.
- ✓ Technological interventions in societal development.
- ✓ Access to uniform quality technical education.

LABORATORY MANUAL OF

PHARMACEUTICS

(20051)

First Year

Diploma in Pharmacy

Maharashtra State Board of Technical Education, Mumbai.

(Autonomous)

(ISO 9001:2015) (ISO/IEC27001:2013)

PCI ER-2020/'J' Scheme Curriculum

Maharashtra State Board of Technical Education, Mumbai

(Autonomous) (ISO 9001:2015) (ISO/IEC27001:2013)

4th floor, Government Polytechnic Building, 49, Kherwadi, Bandra (E), Mumbai- 400 051

(Printed on – July 2024)

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MAHARASHTRA STATE BOARD OF TECHNICAL EDUCATION, MUMBAI

CERTIFICATE

This is to certify that Mr. /Ms. _____

Roll No. _____ of First Year Diploma in Pharmacy studying at

_____

has completed the practical work satisfactorily in Pharmaceutics (20051) for the academic year 20 - 20 as prescribed in the PCI ER 2020 syllabus.

Date: _____ Enrollment No.: _____

Place: _____ Exam Seat No.: _____

Course Teacher **Principal**

External Examiner

Seal of the Institute

MAHARASHTRA STATE BOARD OF TECHNICAL EDUCATION MUMBAI

PROGRAM OUTCOMES

1. **Pharmacy knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy.
2. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
3. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.
4. **Professional identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
5. **Pharmaceutical ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
6. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
7. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
8. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
9. **Life-long learning:** Recognize the need for and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis

COMPETENCIES FOR THE INDIAN D. PHARM HOLDERS

Competency is defined as "A distinct composite of knowledge, skill, attitude and value that is essential to the practice of the profession in real life contexts".

The candidates who successfully complete the Diploma in Pharmacy (D. Pharm) program of Education Regulations 2020 (ER-2020), from the institutions approved by the Pharmacy Council of India are expected to attain the following professional competencies.

1. Review Prescriptions: The student should receive and handle prescriptions in a professional manner and be able to check for their completeness and correctness. Also, the prescribers should be contacted for any clarifications & corrections in the prescriptions with suggestions if any.

2. Dispense Prescription / Non-Prescription Medicines: The student should be able to dispense the various scheduled drugs / medicines as per the implications of the Drug & Cosmetic Act and Rules thereunder. Also, the non-prescription medicines (over-the-counter drugs) should be dispensed judicially to the patients as required.

3. Provide Patient Counselling / Education: The student should be able to effectively counsel / educate the patients / caretakers about the prescription / non-prescription medicines and other health related issues. Effective communication includes using both oral and written communication skills and various communication techniques.

4. Hospital and Community Pharmacy Management: The student be able to manage the drug distribution system as per the policies and guidelines of the hospital pharmacy, good community pharmacy practice and the recommendations of regulatory agencies. Also, be able to manage the procurement, inventory, and distribution of medicines in hospital / community pharmacy settings.

5. Expertise on Medications: The student should be able to provide an expert opinion on medications to health care professionals on safe and effective medication – use, relevant policies and procedures based on available evidence.

6. Proficiency on Pharmaceutical Formulations: The student should be able to describe the chemistry, characteristics, types, merits and demerits of both drugs and excipients used in pharmaceutical formulations based on her/his knowledge and scientific resources.

7. Entrepreneurship and Leadership: The student should be able to acquire the entrepreneurial skills in the dynamic professional environments. Also, be able to achieve leadership skills through teamwork and sound decision-making skills.

8. Deliver Primary and Preventive Healthcare: The student should be able to contribute to various healthcare programs of the nation including disease prevention initiatives to improve public health. Also contribute to the promotion of national health policies.

9. Professional, Ethical and Legal Practice: The student should be able to deliver professional services in accordance with legal, ethical, and professional guidelines with integrity.

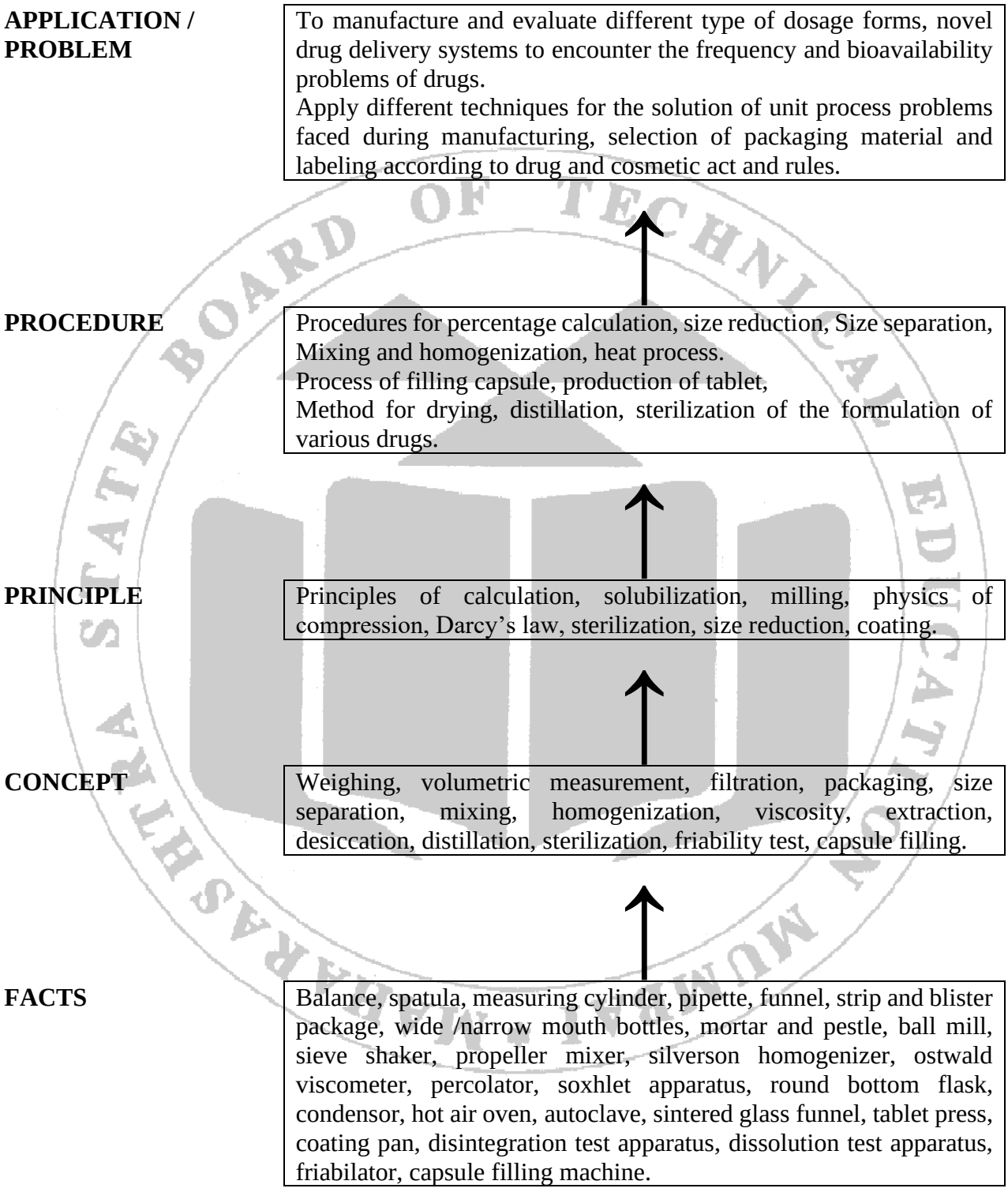
10. Continuing Professional Development: The student should be able to recognize the gaps in the knowledge and skills in the effective delivery of professional services from time to time and be self-motivated to bridge such gaps by attending continuing professional development programs.

COMPETENCY MAPPING WITH THE COURSE

Competencies	Pharmaceutics
1.Review Prescriptions	✓
2. Dispense Prescription / Non-Prescription Medicines	✓
3.Provide Patient Counselling / Education	✓
4.Hospital and Community Pharmacy Management	
5.Expertise on Medications	✓
6.Proficiency on Pharmaceutical Formulations	✓
7.Entrepreneurship and Leadership	✓
8.Deliver Primary and Preventive Healthcare	
9.Professional, Ethical and Legal Practice	✓
10.Continuing Professional Development	✓

GRAPHICAL STRUCTURE OF SUBJECT AREA

PHARMACEUTICS (20051)



PHARMACEUTICS – PRACTICAL

Course Code: ER20-11P/20051 **75 Hours (3 Hours /Week)**

Scope: This course is designed to train the students in formulating and dispensing common pharmaceutical dosage forms.

Course Objectives: This course will discuss and train the following aspects of preparing and dispensing various pharmaceutical dosage forms

1. Calculation of working formula from the official master formula
2. Formulation of dosage forms based on working formula
3. Appropriate Packaging and labelling requirements
4. Methods of basic quality control tests

Course Outcomes: Upon successful completion of this course, the students will be able to

1. Calculate the working formula from the given master formula
2. Formulate the dosage form and dispense in an appropriate container
3. Design the label with the necessary product and patient information
4. Perform the basic quality control tests for the common dosage forms

Practicals

1. Handling and referring the official References: Pharmacopoeias, Formularies, etc. for retrieving formulas, procedures, etc.
2. Formulation of the following dosage forms as per monograph standards and dispensing with appropriate packaging and labelling
    - **Liquid Oral:** Simple syrup, Piperazine citrate elixir, Aqueous Iodine solution
    - **Emulsion:** Castor oil emulsion, Cod liver oil emulsion
    - **Suspension:** Calamine lotion, Magnesium hydroxide mixture
    - **Ointment:** Simple ointment base, Sulphur ointment
    - **Cream:** Cetrimide cream
    - **Gel:** Sodium alginate gel
    - **Liniment:** Turpentine liniment, White liniment BPC
    - **Dry powder:** Effervescent powder granules, Dusting powder
    - **Sterile injection:** Normal Saline, Calcium gluconate Injection
    - **Hard Gelatine Capsule:** Tetracycline capsules
    - **Tablet:** Paracetamol tablets
3. Formulation of at least five commonly used cosmetic preparations e.g. cold cream, shampoo, lotion, toothpaste etc
4. Demonstration on various stages of tablet manufacturing processes
5. Appropriate methods of usage and storage of all dosage forms including special dosage such as different types of inhalers, spacers, insulin pens
6. Demonstration of quality control tests and evaluation of common dosage forms viz. tablets, capsules, emulsion, sterile injections as per the monographs

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period i.e., a minimum of THREE assignments per student)

1. Various systems of measures commonly used in prescribing, compounding and dispensing practices
2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, their generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical
3. Overview of various machines / equipment's / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.
4. Overview of extemporaneous preparations at community / hospital pharmacy vs. manufacturing of dosage forms at industrial level
5. Basic pharmaceutical calculations: ratios, conversion to percentage fraction, alligation, proof spirit, isotonicity

Field Visit

The students shall be taken for an industrial visit to pharmaceutical industries to witness and understand the various processes of manufacturing of any of the common dosage forms viz. tablets, capsules, liquid orals, injectables, etc. Individual reports from each student on their learning experience from the field visit shall be submitted.

STRATEGY FOR IMPLEMENTATION

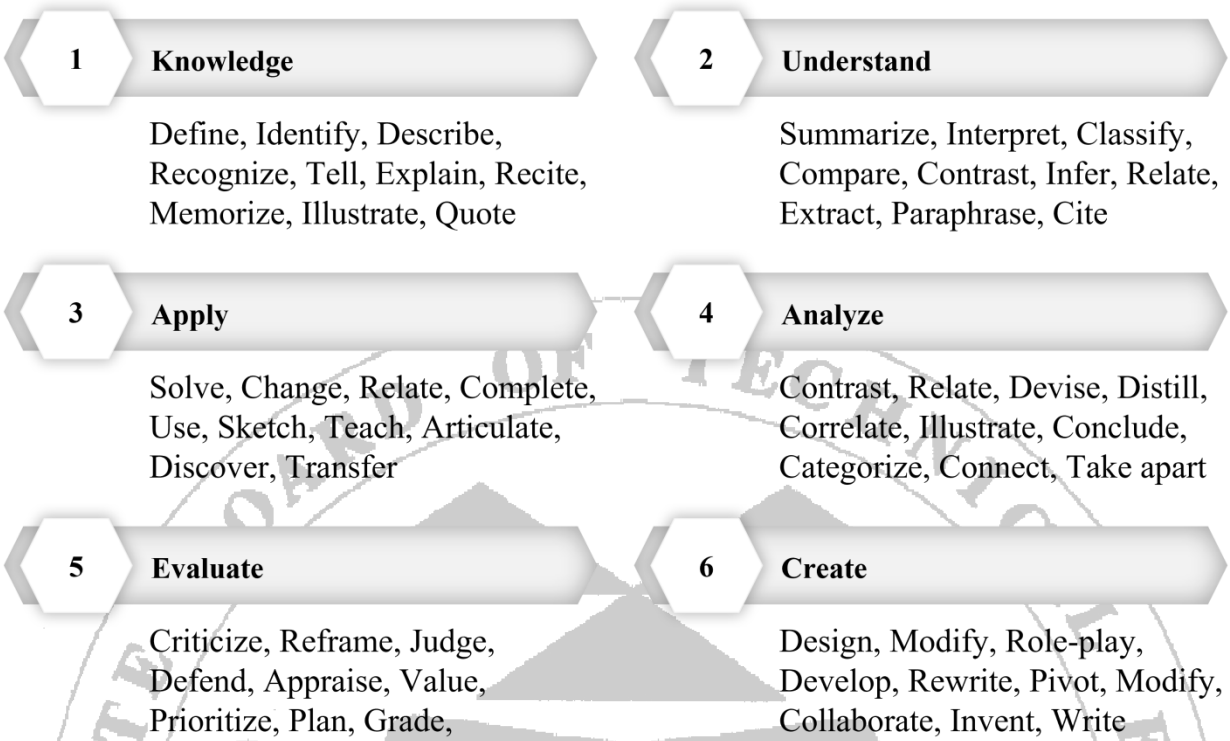
It is suggested that 32-35% experiments shall be completed before every sessional exam.

GUIDELINES FOR TEACHERS

Teacher shall explain the following points to the students before starting of the practical:

1. **Learning Objectives:** To foster better understanding of the subject and to inculcate the skills and attitude related practicals.
2. **Graphical structure:** In graphical structure topics and subtopics are organized in systematic way so that ultimate purpose of learning the subject is achieved. This is arranged in the form of fact, concept, principle, procedure, application and problem.
3. **Elementary Guide to work in Laboratory:** The methods and other finer details of the equipment including equipment specifications should be explained to avoid equipment breakages, create conducive environment for proper organizing of the practical work with the time schedule.
4. Teachers should verify and check the work conditions of the equipment and request the students to follow the standard operating procedures (SOP).
5. Before starting the practical, Teachers should explain the strategies of the experiment.
6. Teachers should ensure the active participation of students while performing the experiment.
7. Observations should be checked individually and each student should be given a chance to perform the experiment.
8. Teachers should ask the students to complete the questions which are given at the end of the experiment accordingly.
9. Assessment of manuals should be done according to the assessment norms. Proper marks should be distributed according to the performance of the individuals.
10. Teachers should explain the competencies that student should achieve, in detail with their importance to students after completion of their course.
11. Apart from the syllabus, teachers should provide and cover extra topics which are beneficial for the students.
12. Explanation about various equipment with some interesting videos, reagents, chemicals, glasswares should be given to students prior to commencing of the practical.
13. Teachers should observe the students when students are performing practicals in groups, proper contributions of the individual student should be there and record of observation should be noted by all of them.
14. Teachers should also organize a visit to the pharmaceutical industries where students get a brief idea about the manufacturing processes of common dosage forms such as tablets, capsules, liquid orals, injectables, etc.
15. Teachers should also ask them to gather information about each type of dosage forms, their generic name, branded names and label contents.
16. Teachers may suggest the students to refer to sources of information such as literature, research papers, books, attending conferences, seminars for the updation of knowledge.
17. According to the professional competencies given by PCI, teachers should develop the professional skills of the students.
18. Teacher should construct different types of sessions for students such as quiz, group discussions projects on different topics, etc.
19. Teachers should ensure that revised CIAAN – 2017 norms or the latest norms given by MSBTE are followed simultaneously and implemented.
20. Teachers should follow the guidelines given by PCI & MSBTE from time to time.

BLOOMS TAXONOMY LEVELS



INSTRUCTIONS FOR STUDENTS

Students should follow the instructions given below for better understanding of the subject from a theoretical and practical concept of view.

1. As per the instructions, the students should wear an apron, cap, mask, gloves and slippers before entering the lab.
2. The students should keep their important things in the locker which is provided by the college.
3. While entering the laboratory, the students should carry manual, rough book and practical requirements as instructed.
4. Students should attend the practical regularly throughout the year, so as to understand the subject properly, and to develop the skills for performing the experiments and attaining the competencies.
5. The students should carry out the experiment individually and perform the experiment atthe allotted specific work area.
6. The practical applications of every experiment should be noted by the students.
7. Students should answer the questions asked in the practicals and should ask the teacher about their difficulties without any hesitation.
8. After completion of practicals students should write the answers of the question given at the end of the experiment.
9. Students should develop different types of competencies to become competent Pharmacists.
10. Students should actively participate in group discussions, activities, etc. and strive to achieve the knowledge, skills, and attitude.
11. Student should submit the manual for assessing regularly on the scheduled date.
12. After completing the practical, the student should clean the platform and glassware that he has used.

LABORATORY MANUAL OF PHARMACEUTICS

MAPPING OF COURSE OUTCOMES

Exp. No.	Title of Experiment	CO1	CO2	CO3	CO4
1.	Handling of Indian Pharmacopoeia	✓			✓
2.	Handling of National Formulary of India			✓	✓
3.	Preparation and Evaluation of Simple Syrup IP	✓	✓	✓	✓
4.	Preparation and Evaluation of Piperazine Citrate Elixir IP	✓	✓	✓	✓
5.	Preparation and Evaluation of Aqueous Iodine Solution IP	✓	✓	✓	✓
6.	Preparation and Evaluation of Cod Liver Oil Emulsion	✓	✓	✓	✓
7.	Preparation and Evaluation of Castor Oil Emulsion	✓	✓	✓	✓
8.	Identification and Quality Control Tests for Emulsions				✓
9.	Preparation and Evaluation of Calamine Lotion IP				
10.	Preparation and Evaluation of Magnesium Hydroxide Mixture BP	✓	✓	✓	✓
11.	Preparation and Evaluation of Simple Ointment IP	✓	✓	✓	✓
12.	Preparation and Evaluation of Sulphur Ointment IP	✓	✓	✓	✓
13.	Preparation and Evaluation of Cetrimide Cream BP	✓	✓	✓	✓
14.	Preparation and Evaluation of Sodium Alginate Gel	✓	✓	✓	✓
15.	Preparation and Evaluation of Turpentine Liniment IP	✓	✓	✓	✓
16.	Preparation and Evaluation of White Liniment BP	✓	✓	✓	✓
17.	Preparation and Evaluation of Sodium Phosphate Effervescent Granules USP	✓	✓	✓	✓
18.	Preparation and Evaluation of Zinc Oxide Salicylic Acid Dusting Powder	✓	✓	✓	✓
19.	Preparation and Evaluation of Sodium Chloride Injection IP	✓	✓	✓	✓
20.	Preparation and Evaluation of Calcium Gluconate Injection IP	✓	✓	✓	✓
21.	Demonstration of Quality Control Tests for Injections				✓
22.	Preparation and Evaluation of Tetracycline Hydrochloride Capsule	✓	✓	✓	✓
23.	Demonstration of Quality Control Tests for Capsules.				✓
24.	Formulation and Evaluation of Paracetamol Tablets IP	✓	✓	✓	✓
25.	Demonstration of Tablet Manufacturing Process		✓		
26.	Demonstration of Quality Control Tests for Tablets				✓
27.	Formulation and Evaluation of Cold Cream	✓	✓	✓	✓
28.	Formulation and Evaluation of Vanishing Cream	✓	✓	✓	✓
29.	Formulation and Evaluation of Clear Shampoo	✓	✓	✓	✓
30.	Formulation and Evaluation of Body Lotion	✓	✓	✓	✓
31.	Formulation and Evaluation of Toothpaste	✓	✓	✓	✓
32.	Demonstration of Use of Special Dosage Forms		✓		

LIST OF EXPERIMENTS AND RECORD OF PROGRESSIVE ASSESSMENT

Expt. No	Title of Experiment	Page No.	Date of Performance	Date of Submission	Assessment Max. Marks 10	Sign of Teacher
	Handling and referring the official References: Indian Pharmacopoeia and National Formulary of India					
1	Handling of Indian Pharmacopoeia	1				
2	Handling of National Formulary of India	11				
	Formulation of dosage forms: Introduction to monophasic liquid dosage form: Syrup, Elixir, Solution					
3	Preparation and Evaluation of Simple Syrup IP	21				
4	Preparation and Evaluation of Piperazine Citrate Elixir IP	25				
5	Preparation and Evaluation of Aqueous Iodine Solution IP	29				
	Introduction to biphasic liquid dosage form: Emulsion					
6	Preparation and Evaluation of Cod Liver Oil Emulsion	35				
7	Preparation and Evaluation of Castor Oil Emulsion	40				
8	Identification and Quality Control Tests for Emulsion	44				
	Introduction to biphasic liquid dosage form: Suspension, Lotion.					
9	Preparation and Evaluation of Calamine Lotion IP	53				
10	Preparation and Evaluation of Magnesium Hydroxide Mixture BP	58				
	Introduction to semisolid dosage form: Ointment					
11	Preparation and Evaluation of Simple Ointment IP	66				
12	Preparation and Evaluation of Sulphur Ointment IP	70				
	Introduction to semisolid dosage form: Cream, Gel.					
13	Preparation and Evaluation of Cetrimide Cream BP	76				
14	Preparation and Evaluation of Sodium Alginate Gel	82				
	Introduction to Liniments					
15	Preparation and Evaluation of Turpentine Liniment IP	87				
16	Preparation and Evaluation of White Liniment BP	92				
	Introduction to solid dosage form: Dry Powders					

Expt. No	Title of Experiment	Page No.	Date of Performance	Date of Submission	Assessment Max. Marks 10	Sign of Teacher
17	Preparation and Evaluation of Sodium Phosphate Effervescent Granules USP	97				
18	Preparation and Evaluation of Zinc Oxide Salicylic Acid Dusting Powder	101				
	Introduction to sterile dosage form: Injectables					
19	Preparation and Evaluation of Sodium Chloride Injection IP	108				
20	Preparation and Evaluation of Calcium Gluconate Injection IP	112				
21	Demonstration of Quality Control Tests for Injection	116				
	Introduction to solid unit dosage form: Capsules					
22	Preparation and Evaluation of Tetracycline Hydrochloride Capsules	125				
23	Demonstration of Quality Control Tests for Capsules	129				
	Introduction to solid unit dosage form: Tablets					
24	Formulation and Evaluation of Paracetamol Tablets IP	138				
25	Demonstration of Tablet Manufacturing Process	143				
26	Demonstration of Quality Control Tests for Tablets	149				
	Introduction to cosmetics: Cream, Shampoo, Lotion, Toothpaste					
27	Formulation and Evaluation of Cold Cream	163				
28	Formulation and Evaluation of Vanishing Cream	167				
29	Formulation and Evaluation of Clear Shampoo	171				
30	Formulation and Evaluation of Body Lotion	175				
31	Formulation and Evaluation of Toothpaste	180				
	Introduction to special dosage forms.					
32	Demonstration of Use of Special Dosage Forms.	185				

I) PRACTICAL RECORD MARKS*:

Sessional Exam	Experiment No.		Total no. of experiments conducted	Average marks obtained for the experiments conducted. (out of 10)	Teacher's Signature
	From	To			
First Sessional					
Second Sessional					
Third Sessional					

*Sessional wise marks should be considered for internal assessment of practical sessional examinations (out of 10M)

II) ASSIGNMENT MARKS#:

Sr. No.	Title of Assignment	Marks out of 05#	Assignment Marks (Average of three)	Teacher's Signature
1				
2				
3				

#Marks should be transferred from Appendix -1 A typical format for assessment of an assignment.

III) FIELD VISIT REPORT MARKS$:

Sr. No.	Title of Field Visit	Marks out of 05$	Field Visit Marks (Average of three)	Teacher's Signature
1				
2				
3				

$ Marks should be transferred from Appendix -2 A typical format for assessment of an assignment.

Average Sessional Mark out of 10	Assignments Mark out of 05 (Average of three)	Field Visit Mark out of 05 (Average for the reports)	Total Marks out 20	Teacher's Signature

PHARMACOPOEIA

The word "pharmacopoeia" is derived from the Greek words 'pharmakon' meaning 'a drug' and "poieo" meaning 'make'. Pharmacopoeia is the official standard book, which is published by the Government of that country.

Definition: "Pharmacopoeia is an official comprehensive book published by the government containing information about composition, preparation, standards for drugs and other related substances in the form of monographs, with legal standards of purity, quality and strength".

Classification:

The drug-compendia are classified as:

A. Official compendia.
B. Unofficial compendia (also known as non-official).

OFFICIAL COMPENDIA:

Official compendia are the compilation of drugs and other related substances which are recognised as legal standards of purity, quality, and strength by a government agency of the respective countries of their origin.

e.g., British Pharmacopoeia (BP), British Pharmaceutical Codex (BPC), Indian Pharmacopoeia (IP), United States Pharmacopoeia (USP), Pakistan Pharmacopoeia, European Pharmacopoeia (EP), National Formulary (NF), The State Pharmacopoeia of USSR and Pharmacopoeias of other countries.

Significance of Pharmacopoeia:

1. Pharmacopoeias ensure that medications are both safe and effective for use by establishing standards for the production, quality control, and testing of medications.
2. Avoid adulteration drugs.
3. Gives complete information on drugs and their dosage forms.
4. Enforce the quality of drugs by the regulatory authorities.
5. Provide specifications and test methods for drugs.
6. Maintain uniformity and control the standards of the drugs available in the market.

INDIAN PHARMACOPOEIA:

Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules 1945 thereunder. IP is recognized as the official book of standards for the drugs being manufactured and/or marketed in India. IP contains a collection of authentic procedures of analysis and specifications of drugs for their identity, purity and strength. The standards of the IP are reliable in nature and are enforced by the regulatory authorities for ensuring the quality of drugs in India. During quality assurance and at the time of dispute in the court of law the IP standards are legally acceptable.

History of Indian pharmacopoeia:

The history of the IP began in the year 1833 when a committee of the East Indian Company's Dispensary recommended the publication of a Pharmacopoeia. Bengal Pharmacopoeia and General Conspectus of Medicinal Plants was published in 1844, which mainly listed most of the commonly used indigenous remedies. This was followed by IP 1868, which covered both the drugs of British Pharmacopoeia (BP) 1867 and indigenous drugs used in India, with a supplement published in 1869 incorporating the vernacular names of indigenous drugs and plants. However, from 1885 the BP was made official in India. A Drug Enquiry Committee appointed in 1927 by the government recommended the publication of a National Pharmacopoeia.

After independence, the Indian Pharmacopoeia Committee was constituted in 1948, for publication of IP as its main function. The Indian Pharmacopoeia editions are as follows:

Sr. No.	Editions	Year of Publication	Supplements / addendum	No. of Volume	Chairman of Committee
1	First	1955	1960	One	Dr. B. N. Ghosh
2	Second	1966	1975	One	Dr. B. Mukerjee
3	Third	1985	1989, 1991	Two	Dr. Nityanand
4	Fourth	1996	2000, 2002, 2005	Two	Dr. Nityanand
5	Fifth	2007	2008	Three	Dr. Nityanand
6	Sixth	2010	2012	Three	Dr. Raman Mohan Singh
7	Seventh	2014	2015, 2016	Four	Mr. P. K. Pradhan
8	Eighth	2018	2019	Four	Shri. C. K. Mishra
9	Ninth	2022	2024	Four	Shri. Rajesh Bhushan

INDIAN PHARMACEUTICAL CODEX:

This book contains detailed information about indigenous drugs of India. It was prepared by Pharmaceuticals and Drugs Research Committee under the chairmanship of B. Mukerjee and was published in 1953 by Council of Scientific and Industrial Research, 1953.

BRITISH PHARMACOPOEIA (BP):

British pharmacopeia is a pharmacopoeia for the United Kingdom published annually by the British Pharmacopoeia Commission. Under the Medical Act 1858, the General Council of Medical Education and Registration published first British pharmacopeia in1864. Second edition of BP was published in 1867. Third edition of BP was published in 1885. Fourth and fifth editions of BP were published in 1898 and 1914. During 1953, the eight edition of BP was published, and edition titles of drugs& preparation were changed in English instead of Latin and metric system. The BP Committee published BP at every year interval. In BP 2007 monographs were introduced for material specially used in preparation of traditional Chinese medicines. BP 2008 contained approximately 3100 monographs for substance, preparations and articles used in practice. BP 2007-2009 were given in 6 volumes i.e., Volume I to Volume VI. Volume I & II contain medicinal substances. Volume III contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homeopathic preparations. Volume IV contains supplementary chapters, IR spectra etc. Volume V contains veterinary. Volume VI contains a CD ROM version. The latest British Pharmacopoeia (BP) 2021 supersedes the BP 2020 containing 4000 monographs.

BRITISH PHARMACEUTICAL CODEX (BPC):

The British Pharmaceutical Codex was compiled by a committee of experts, working under the direction of the Council of the Pharmaceutical Society of Great Britain. It helps pharmacists and physicians to obtain trustworthy information concerning drugs and medicinal preparations. The British Pharmaceutical Codex (BPC) was first published in 1907, several editions of BPC were published till date.

UNITED STATES PHARMACOPOEIA (U.S.P.):

In 1817, Dr. Lyman Spalding of New York proposed a plan to the Medical Society of the country at New York for publishing a National Pharmacopoeia. The first edition of United States Pharmacopoeia was compiled, edited and published on 15th December 1820 which had 217 drugs in about 272 pages. Subsequent editions of USP appeared after the gap of ten years. In 1905, the ninth edition of USP was published. However, it was given the title USP VIII, to show that it was the eighth revision. USP considers 25°C as the standard temperature for specific gravity and solubility statements. In 1940 the convention directed that the pharmacopoeia must be revised every 5 years. On July 5, 1974, unification of the USP and NF (National Formulary) was announced. Since then, the subsequent editions consolidate USP and NF into a single volume. All drug substances and drug products were covered in USP whereas NF is devoted exclusively to pharmaceutical ingredients. The 22nd edition of USP combined with the 17th edition of NF was published in January 1990. The 42nd edition of USP combined with the 37th edition of NF was published in 2019.

INTERNATIONAL PHARMACOPOEIA:

The International Pharmacopoeia (Ph. Int.) constitutes a collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances and dosage forms.

The history of The International Pharmacopoeia (Ph.Int.) dates back to 1874 when the need to standardise terminology and to specify dosages and composition of drugs led to attempts to produce an international pharmacopoeial compendium. The first conference, called by the Belgian Government and held in Brussels in 1902, resulted in the Agreement for the Unification of the Formulae of Potent Drugs, which was ratified in 1906 by 19 countries. A second agreement, the Brussels Agreement, was drawn up in 1925 and ratified in 1929. This 41-article agreement stipulated that the League of Nations would be responsible for the administrative work to produce a unified pharmacopoeia. General principles for the preparation of galenicals, maximal doses, nomenclature and biological testing of arsenobenzones were included in the articles of this agreement, as was a table of dosage strengths and descriptions for 77 drug substances and preparations.

The Health Organization of the League of Nations set up a Technical Commission of Pharmacopoeial Experts in 1937. In 1947 the Interim Commission of the World Health Organization (WHO) took over the work on pharmacopoeias previously undertaken by the Health Organization of the League of Nations. In 1948 the First World Health Assembly approved the establishment of the Expert Committee by the Interim Commission. In 1951 this became the Expert Committee on the International Pharmacopoeia; and subsequently, in 1959, the Expert Committee on Specifications for Pharmaceutical Preparations. The panel has always been named the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

The First Edition was published in two volumes (1951 and 1955) and a supplement (1959) in English, French and Spanish, and was also translated into German and Japanese. The Second Edition was published in 1967, Third Edition was published in 1975, Fourth Edition was published in 2006, Fifth Edition was published in 2015, there were several editions published between 2015 to 2020, now the tenth edition was published in 2020.

EUROPEAN PHARMACOPOEIA:

The purpose of the European Pharmacopoeia is to promote public health by the provision of recognised common standards for the quality of medicines and their components. Such standards are to be appropriate as a basis for the safe use of medicines by patients. In addition, their existence facilitates the free movement of medicinal products in Europe and beyond.

European Pharmacopoeia monographs and other texts are designed to be appropriate to the needs of:

- regulatory authorities.
- those engaged in the quality control of medicinal products and their constituents.
- manufacturers of medicinal products and their individual components.

The European Pharmacopoeia is widely used internationally.

The first edition was published in 1967, second edition was published in 1980, third edition was published in 1997, several editions were published between 1997 to 2020, latest eleventh edition was published in 2022.

UNOFFICIAL COMPENDIA:

The book other than official drug compendia which are used as secondary reference sources for drugs and other related substances are known as non-official drug compendia.

e.g. Merck Index, Extra Pharmacopoeia (Martindale), United State Dispensatory, Remington's Pharmaceutical Science.

EXTRA PHARMACOPOEIA:

The Extra Pharmacopoeia, originally produced by William Martindale in 1883 and now published by the Pharmaceutical Society of Great Britain, contains information on the drugs presently used in Great Britain. It is still known as 'Martindale'. It lists some 6,000 drugs and medicines used throughout the world, including details of over 125,000 proprietary preparations. It also includes almost 700 disease treatment reviews.

THE MERCK INDEX:

The Merck Index has been regarded as the most authoritative and reliable source of key physical, pharmacological and historical information on chemicals, drugs and biologicals. Since 2013, it has been updated by the Royal Society of Chemistry. The first edition was published in 1889 by the German chemical company Emanuel Merck and was primarily used as a sales catalogue for Merck's growing list of chemicals it sold. Several editions were published between 1889 to 2013, the latest fifteenth edition was published in 2013.

REMINGTON'S PHARMACEUTICAL SCIENCE:

Remington has been the definitive reference for all aspects of the science and practice of pharmacy and is used for pharmaceutics, therapeutics, and pharmacy practice courses in primary curricula. Remington: The Science & Practice of Pharmacy is the most widely used textbook and reference work on pharmaceutical sciences. Publication of the text was begun as Practice of Pharmacy in 1886 by Joseph Price Remington, Professor and later Dean at the University Remington has provided a comprehensive source of knowledge about the science and practice of pharmacy. The book provides information to help both students and practitioners to serve effectively as members of the health professions team. The 22nd edition was published in 2012.

NATIONAL FORMULARY OF INDIA

The National Formulary of India is essentially meant for the guidance of the members of the medical and pharmaceutical profession; medical students, nurses and pharmacists etc. working in hospitals, dispensaries and in sales establishments. In the preparation of this Formulary, the expert opinion of medical practitioners, teachers in medicine, nurses, pharmacists etc. has been obtained. The selection of drugs for inclusion in the National Formulary has been made taking into consideration the relative advantages and disadvantages of the various drugs used in current medical practice and their availability in the country. Thus, the National Formulary of India represents a broad consensus of expert opinion in respect of drugs and their formulations and provides the physicians with carefully selected therapeutic agents of proven effectiveness which form the basis of rational drug therapy.

The National Formulary of India is an authoritative guide to prescribing, dispensing and administering medicines for healthcare professionals. It will be useful for framing national drug policies in the country. The Ministry of Health and Family Welfare, Govt. of India vide its notification F. No. X. 11035/2/06-DFQC, dated 8th May 2008 assigned this mandatory responsibility to the Indian Pharmacopoeia Commission, Ghaziabad to publish NFI on regular basis. The IPC has published three consecutive editions of National Formulary of India since its formation. The Indian Pharmacopoeia Commission has published the 4th Edition, 5th Edition and 6th Edition of NFI.

Importance of National Formulary of India:

1. The National Formulary of India helps to understand the impact and side effects of different medicines.
2. It promotes the rational use of different medicines in the country.
3. It is beneficial and of great help to the healthcare professionals while prescribing the medicines to the patients.

Chronology of National Formulary of India (NFI):

The Chronology of Publication National Formulary of India is as follows: -

1. The First Edition of NFI – National Formulary of India, 1960.
2. The Second Edition of NFI –National Formulary of India, 1966.
3. The Third Edition of NFI – National Formulary of India, 1979.
4. The Fourth Edition of NFI – National Formulary of India, 2011.
5. The Fifth Edition of NFI – National Formulary of India, 2016.
6. The Sixth Edition of NFI (Current Edition) – National Formulary of India, 2021.

Experiment No. 01

Handling of Indian Pharmacopoeia

1. Aim

To handle and refer Indian Pharmacopoeia to perform the activities mentioned in the experiment.

2. Practical Significance

The practical significance of referring to the Indian Pharmacopoeia lies in ensuring regulatory compliance, maintaining quality assurance, supporting research and development, guiding pharmacy practice, and safeguarding consumer safety in the pharmaceutical industry and healthcare sector.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Explain the content of Indian Pharmacopoeia.	CO1 & 4	BTL2
2	List various publications of Indian Pharmacopoeia.	CO1 & 4	BTL1
3	Use Indian Pharmacopoeia to find a specific test for a dosage form.	CO1 & 4	BTL3
4	Collaborate and communicate with a team.	CO1 & 4	BTL5

4. Relevant Theoretical Background

Indian Pharmacopoeia: The Indian Pharmacopoeia is a compendium of official standards for the drugs manufactured and /or marketed in India.

Contents of Indian Pharmacopoeia:

A. Introduction: The Scientific Director of Indian Pharmacopoeia Commission (IPC) approves the introduction part. This part explains edition, salient features, and additions and omissions from the previous editions.

B. General notices: The General Notices provide the basic guidelines for the interpretation and application of the standards, tests, assays, and other specifications of the Indian Pharmacopoeia (IP), as well as to the statements made in the monographs and other texts of the Pharmacopoeia.

C. Monographs: It is a complete explanation of a particular pharmaceutical that contains nomenclature, classification, physical properties.

a. **General monographs:** General monographs on dosage forms include requirements of general application and apply to all preparations within the scope of the Introduction section of the general monograph, except where a preamble limits the application. The requirements are not necessarily comprehensive for a given specific preparation; additional requirements may sometimes be given in the individual monograph for it.

1. **Production**: Statements given under the heading Production relate to aspects of the manufacturing process and are not necessarily comprehensive. However, they are mandatory instructions to manufacturers.
2. **Manufacture of drug products**: The opening definitive statement in certain monographs for drug products is given in terms of the active ingredient(s) only. Any ingredient(s) other than those included in the statement, must comply with the general notice on Excipients and the product must confirm to the Pharmacopeial requirements.

3. **Excipients**: Any substance added in preparing an official preparation shall be innocuous, shall have no adverse influence in the therapeutic efficacy of the active ingredients and shall not interfere with the tests and assays of the Pharmacopoeia.

b. **Individual monographs**: Drug products that are the subject of an individual monograph are also required to comply with the tests given in the general monographs.

1. **Titles**: The main title for a drug substance is the International Non-proprietary Name (INN) approved by the World Health Organization. Subsidiary names and synonyms have also been given in some cases where included, they have the same significance as the main title.
2. **Chemical formulae**: When the chemical structure of an official substance is known or generally accepted, the graphic and molecular formulae are normally given at the beginning of the monograph for information.
3. **Atomic and molecular weights**: The atomic weight or molecular weight is shown, as and when appropriate at the top right-hand corner of the monograph. The atomic and molecular weights and graphic formulae do not constitute analytical standards for the substances described.
4. **Definition**: The opening statement of a monograph is one that constitutes an official definition of the substance, preparation or other article that is the subject of the monograph. In certain monographs for pharmaceutical preparations the statement is given in terms of the principal ingredient(s).
5. **Statement of content**: The limits of content stated are those determined by the method described under Assay.
6. **Category**: The statement of category is provided for general information only and is indicative of the medical or pharmaceutical basis for recognition in the Pharmacopoeia.
7. **Dose**: Doses mentioned in the Pharmacopoeia are intended merely for general guidance and represent, unless otherwise stated, the average range of quantities that are generally regarded as suitable for adults when administered by mouth.
8. **Usual strength**: The statement on the usual strength(s) of a preparation given in the individual monograph indicates the strength(s) usually marketed for information of the pharmacist and the medical practitioner.
9. **Description**: The statements under the heading Description are not to be interpreted in a strict sense and are not to be regarded as official requirements.
10. **Solubility**: Statements on solubility are given in popular terms in IP under general notices and are intended as information on the approximate solubility at a temperature between 15° and 30°, unless otherwise stated, and are not to be considered as official requirements.
11. **Test Methods**: References to general methods of testing are indicated by test method numbers in brackets immediately after the heading of the test or at the end of the text.
12. **Identification**: The tests given under the heading Identification are not necessarily sufficient to establish absolute proof of identity. They provide a means of verifying that the identity of the material under examination is in accordance with the label on the container.
13. **Tests and assays**: The tests and assays are the official methods upon which the standards of the Pharmacopoeia depend. The requirements are not framed to consider all possible impurities. It is not to be presumed, for example, that an impurity that is not detectable by means of the prescribed tests is tolerated.
14. **Tests**: Unless otherwise stated, the assays and tests are carried out at a temperature between 20° and 30°.

15. **Other tests**: In the monographs on dosage forms and certain preparations, under the sub-heading 'Other tests' it is stated that the article complies with the tests stated under the general monograph of the relevant dosage form or preparation.
16. **Limits**: The limits given are based on data obtained in normal analytical practice. They consider normal analytical errors, of acceptable variations in manufacture and of deterioration to an extent that is acceptable.
17. **Quantities**: Unless otherwise stated, the quantities to be taken for assays, the limit tests and the other tests are of the Substance under examination.
18. **Apparatus**: Measuring and weighing devices and other apparatus are described in the chapter entitled 'Apparatus for Tests and Assays'.
19. **Reagents and solutions**: The reagents required for the tests and assays of the Pharmacopoeia are defined in the various chapters showing their nature, degree of purity and the strengths of the solutions to be made from them.
20. **Indicators**: Where the use of an indicator solution is mentioned in an assay or test, approximately 0.1 ml of the solution shall be added, unless otherwise directed.
21. **Reference substances**: Certain monographs require the use of chemical reference substances or a biological reference preparation or a reference spectrum.
22. **Test animals**: The animal experiments are carried out in accordance with the provisions of The Prevention of Cruelty to Animals Act, 1960' and 'CPCSEA Guidelines to prevent the infliction of unnecessary pain, suffering and prevention of cruelty to animals.
23. **Calculation of results**: In determining compliance with a numerical limit in assay or test, the result should be calculated to one decimal place more than the significant figures stated and then rounded up or down as follows: if the last figure calculated is 5 to9, the preceding figure is increased by 1; if it is 4 or less, the preceding figure is left unchanged.
24. **Storage containers**: In general, an article should be packed in a well-closed container i.e., one that protects the contents from contamination by extraneous solids, liquids, moisture or vapours and from loss of the article under normal conditions of handling and storage and preserves the properties of the drug.
25. **Labelling**: The labelling of drugs and pharmaceuticals is governed by the Drugs and Cosmetics Rules, 1945. The statements that are given in the monographs under the side-heading 'Labelling' are not comprehensive.
26. **Storage**: Statements under the side-heading Storage constitute non-mandatory advice. The articles of the Pharmacopoeia are to be stored under conditions that prevent contamination and, as far as possible, deterioration. Precautions that should be taken in relation to the effects of the atmosphere, moisture, heat and light are indicated, where appropriate, in the individual monograph. The storage conditions are defined by the following terms:
    - Store in a dry, well-ventilated place at a temperature not exceeding 30°C.
    - Store in a refrigerator (2°C to 8°C).
    - Store in a freezer (-2°C to-18°C).
    - Store in a deep freezer (Below-18°C).
    - Storage conditions not related to temperature are indicated in the following terms:
        - Store protected from light.
        - Store protected from light and moisture.

D. Test methods: It contains common and relevant test methods for quality recognition of drugs and other related substances. The reference of the test method is given in the individual monograph by mentioning the test method number in the bracket after the test heading. It contains

apparatus, biological methods, chemical methods, physical and physicochemical methods, pharmaceutical methods, herbal products, vaccines, blood and blood-related products.

E. Reference data: Contains the standard spectra and chromatograms of the drug substances.

F. Reagents and solutions: The methods of preparing different buffers, reagents and standard solutions are included in this section. It also specified the materials to be used as indicators, as well as the method for preparing indicator solutions.

G. General tests: In this section, guidelines have been provided for cleaning of glassware, use of biological indicators, sterilisation techniques, removal of residual solvents and controlling impurities in drug substances, use of pharmaceutical waters, applications of statistics and reference substances.

H. Primary packages for pharmaceuticals: This chapter deals with the specific requirements, guidance and information on containers used for packaging of the pharmaceutical article. The material used to manufacture containers, particularly plastic containers, the raw materials, the additives used, and the formulations employed should be agreed upon with the users of the containers.

Details of Indian Pharmacopoeia:

Editions	Year of Publication	Content
First	1955	• It covers 986 monographs. • The title of monographs has been given in Latin language. Abbreviated titles for use in prescription have been given immediately below the Latin title. • The English title has also been given below the abbreviation title. • The weights and measures have been given in the metric system.
Second	1966	• The titles of monographs have been changed from Latin to English. • The words of the title have been transposed to give the name of the drug first e.g. Injection of Aminophylline has been changed to Aminophylline Injection. • It covers 890 monographs.
Third	1985	• New analytical techniques such as flame photometry, electrophoresis, hemoglobinometry were introduced. • Disintegration test amended with modification. • A microbial limit test prescribed for some drug. • Pyrogen test revised. • Gas liquid chromatography is used for alcohol determination. • New appendix “water for pharmaceutical use” has been introduced.
Fourth	1996	• It contains 1149 monographs and 123 appendices. • The fourth edition includes 294 new monographs while 110 monographs have been deleted from the third edition. • Computer generated structural formulas were added. • Infra-red and UV Spectrophotometric tests added alternatives to chemical tests. • HPLC used for analysis e.g bioassay of insulin replaced with HPLC. • Bioassay provided for the vaccine. • ORS-Citrate formula recommended by WHO introduced.

Editions	Year of Publication	Content
Fifth	2007	• The Indian Pharmacopoeia 2007 is presented in three volumes. • Volume I contain the general notes, preface, the structure of the IPC, Introduction and general chapters. • Volume II deals with general monographs on drug substances, dosage forms and pharmaceutical aids. • Volume III contains monographs on drug substances, dosage forms, pharmaceutical aids, vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and veterinary products. • General chemical tests for identification have been almost eliminated and more specific infrared and ultraviolet spectrophotometric tests have been given. • The test for pyrogens involving the use of animals has been virtually eliminated. A test for bacterial endotoxins has been introduced. • Labelling and storage are featured at the end of a monograph. • Limits of bacterial contamination have been introduced for controlling the microbial quality of all medicinal products.
Sixth	2010	• Sixth edition of Indian Pharmacopoeia 2010 is presented in three volumes. • Volume I contain the Notices, Preface, the Structure of the IPC, Acknowledgments, Introduction, and the General Chapters. • Volume II contains the General Notice, General Monographs on Dosage Forms, Monographs on drug substances, dosage forms and pharmaceutical aids (A to M). • Volume III contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z) followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products. • Monographs of Vaccines and Immunosera are also upgraded in view of development of the latest technology in the field. • A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is added. • A chapter on NMR is incorporated in Appendices. • The chapter on microbial contamination is also updated.
Seventh	2014	• Seventh edition of Indian Pharmacopoeia 2014 is presented in four volumes. • The IP 2014 incorporates 2548 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms, antibiotic monographs, insulin products and herbal products etc. • 19 New Radiopharmaceutical Monographs and 1 General chapter is first time being included in this edition. • The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations

Editions	Year of Publication	Content
Eighth	2018	• Eighth edition of Indian Pharmacopoeia 2018 is presented in four volumes. • It contains 220 New monographs • 170 New chemical monographs • 49 API • 64 Formulations • 53 Fixed dose formulations • 02 Excipients • 02 Antibiotics • 15 New herbs and Herbal products monographs • 03 New Radiopharmaceutical monographs. • 14 New veterinary non-biological monographs. • 18 New Biological monographs • 02 Vaccines and Immunosera for human use • 06 Biotechnology derived therapeutic products. • 10 Blood and Blood related products.
Ninth	2022	• Ninth edition of Indian Pharmacopoeia 2022 is presented in four volumes. • Containing 92 new monographs for drugs. • 12 new general chapters. • 1245 monographs for formulations. • 930 monographs for active pharmaceutical ingredients (APIs). • Dissolution specifications for all prolonged release drugs.

5. Requirements

Various editions of Indian Pharmacopoeia.

6. Procedure

Search the monograph of specific drug/or dosage form and note the observation in the given activity table.

Activities: Search for the monograph of the following dosage form of any drug from I.P. and complete the following activities.

Activity-I: Edition and Year of publication of I.P.:	
Dosage form: Capsule	
Volume of I.P. used	
Page number/s	
Title of Monograph	
Statement of content	

Identification test	
Dissolution test Procedure	
Assay Procedure	

Activity-II: Edition and Year of publication of I.P.:	
Dosage form: Injection	
Volume of I.P. used	
Page number/s	
Title of Monograph	
Statement of content	
Usual strength	
Identification test	
Assay Procedure	
Storage	

Activity-III: Edition and Year of publication of I.P.:	
Dosage form: Suspension	
Volume of I.P. used	
Page number/s	
Title of Monograph	
Statement of content	
Identification test	
Assay Procedure	
Storage	
Labelling	

Activity-IV: Edition and Year of publication of I.P.:	
Buffer; Reagents; Standard solution.	
Volume of I.P. used	
Name of buffer	
Page number/s	
Procedure for preparation of buffer	
Name of reagent	
Page number/s	

Procedure for preparation of reagent	
Name of standard solution	
Page number/s	
Procedure for preparation of standard solution	

7. Result

Indian pharmacopoeias are referred, and activities mentioned were completed.

8. Conclusion

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9. References

a. Indian Pharmacopoeias 1996, 2007, 2014, and 2022.
b. United State Pharmacopeia (USP)
c. British Pharmacopoeias (BP)

10. Practical Related Questions

a. Define Pharmacopoeia.
b. Write the salient features of the fourth edition of pharmacopoeia.
c. Enlist the parts of the individual monograph.
d. What are the requirements of the labelling section in an individual monograph?

(Space for Answers)

11. Assessment Scheme:

Particular	Performance of Activities (Motor skill)	Answers Written	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**03**	**02**	**01**	**04**	**10**	

Experiment No. 02

Handling of National Formulary of India

1. Aim

To handle and refer to the National Formulary of India to perform the activities mentioned in the experiment.

2. Practical Significance

The National Formulary of India (NFI) is significant as it serves as a comprehensive reference for the standards and specifications of drugs and pharmaceuticals used in the country. It helps ensure the quality, safety, and efficacy of medicines available to the public, promoting better healthcare outcomes and regulatory compliance.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Explain the content of National Formulary of India.	CO4	BTL2
2	Search the information related to rational use of drug	CO4	BTL3
3	Search the pharmacological information of specific drugs.	CO4	BTL3
4	Collaborate and communicate with a team.	CO1 & 4	BTL5

4. Relevant Theoretical Background

The National Formulary of India (NFI) is a publication that provides comprehensive information on drugs and their formulations approved for use in India. It serves as a reference for healthcare professionals regarding the standardization, quality, and use of medicines in the country.

Features of The National Formulary of India (NFI):

a. **Quality Assurance:** It ensures that drugs and pharmaceutical products meet established standards for quality, safety, and efficacy, reducing the risk of substandard or counterfeit medications.

b. **Regulatory Compliance:** Healthcare professionals and pharmaceutical manufacturers can use the NFI to comply with regulatory requirements set by government authorities, such as the Drugs and Cosmetics Act in India.

c. **Standardisation:** NFI promotes standardisation in drug manufacturing, formulation, and labelling, facilitating consistency in product quality and patient care across different regions and manufacturers.

d. **Clinical Guidance:** Healthcare practitioners rely on the NFI for evidence-based information on drug dosages, indications, contraindications, and interactions, aiding in prescribing decisions and patient management.

e. **Education and Training:** The NFI serves as an educational resource for pharmacists, physicians, and other healthcare professionals, helping them stay updated on current drug information and best practices in pharmacotherapy.

f. **Public Health:** By ensuring the availability of safe and effective medications, the NFI contributes to improving public health outcomes and reducing the burden of disease in the population.

The monographs of the National Formulary of India (NFI) typically cover detailed information on pharmaceutical substances, including their pharmacological properties, indications, dosage

forms, and usage guidelines. These monographs serve as comprehensive references for healthcare professionals and researchers in India.

Publications of National Formulary of India:

Sr. No.	Edition	Year of Publication
1	First	1960
2	Second	1966
3	Third	1979
4	Fourth	2011
5	Fifth	2016
6	Sixth	2021

The salient feature of NFI sixth edition 2021 includes:

- 34 therapeutic categories chapters including 591 drug monographs and 23 appendices are included in this edition.
- Important Web Links related to NLEM, Drugs banned in India, NHP, Drugs banned in sports, Immunization schedule, wherever necessary are provided for information to readers.
- Only indications approved by the Indian drug regulator (CDSCO), clinically relevant and as per standard care are included
- The term 'availability' is now replaced with 'dosage forms and usual strength'
- Only the clinically relevant precautions and contraindications are included.
- The common or the serious and clinically relevant adverse effects are included
- Storage conditions for medicines are included for special cases only
- Chapter on Medicines banned in sports in previous edition has been considered under appendices in this edition
- Considering the prevalence of diabetes in the country a separate Chapter on Management of Diabetes is included after revising completely
- New appendix on Good Distribution Practices is incorporated
- The Appendix on the National Immunization Schedule and IAP Immunization Schedule is revised as per current schedule.

Monograph:

Monograph of NFI includes following sections:

- **Schedule of drug**: It appears at the right upper corner of the monograph. The drugs are classified into various schedules under Drug and Cosmetics Act 1940 and Rules 1945 are
  - **Schedule G**: Drug is to be administered under supervision of registered medical practitioner.
  - **Schedule H**: Drug requires prescription.
  - **Schedule H1**: Prescription drug is abusive and requires maintenance of record after selling.
  - **Schedule K**: Drug can be sold without license.
  - **Schedule X**: Drug is narcotic or psychotropic substance.
- **Indications**: It mentions the health issues which can be treated with the drug under consideration.
- **Availability/Dosage forms and usual strength**: It indicates various available dosage forms of the drug under consideration and their strength.
- **Dose**: The dose of the drug for different health problems in patients with different ages using available dosage forms is given in this section.

- **Contraindications**: This section specifies the medical conditions that make the use of drugs possibly inadvisable.
- **Pregnancy category:**

Category	Risk	Examples
A	No risk in controlled human studies	Levothyroxine, Folic Acid, Liothyronine
B	No risk in other studies	Metformin, Cyclobenzaprine, Amoxicillin
C	Risk not ruled out	Gabapentin, Amlodipine, Trazodone.
D	Positive evidence of risk	Losartan, Phenytoin
X	Contraindicated in pregnancy	Atorvastatin, Simvastatin, Methotrexate, Finasteride

- **Precautions**: It indicates measures to be taken to prevent anything harmful or unpleasant from occurring during the administration of the drug. It also includes the warning of something dangerous or unpleasant that could happen after administration of a drug.
- **Adverse effects**: The unwanted or undesirable effects that may occur due to the drug are given in this section.
- **Storage**: It states the required storage condition for the drug or its formulation.

  The additional information related to the healthcare professionals is given in the appendices of NF1.

5. Requirements

National Formulary of India.

6. Procedure

Search the monograph of a specific drug and note the observation in the given activity table.

Activities: Search the monograph of the following drug from NFI and complete the following activities.

Activity-I: Complete the monograph of any one NSAID drug.	
Edition and Year of publication of NFI:	
Page number/s	
Title of Monograph	
Pregnancy category	
Schedule	

Indication	
Availability	
Dose	
Contraindication	
Precaution	
Adverse effect	
Storage	

Activity II: List the category and examples of drugs		
Category	**Examples of drugs**	
Pregnancy category A		
Pregnancy category B		
Pregnancy category C		
Pregnancy category D		
Pregnancy category X		
Schedule H drugs		
Schedule X drugs		

Activity III: Write drug- drug interaction and their effect			
Sr. No.	**Drug**	**Interacting drug**	**Interaction details (effect)**
1			
2			
3			

7. Result

National Formulary of India is referred, and activities mentioned are completed.

8. Conclusion

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9. Reference:

a. National formulary of India 2016 edition.
b. https://qps.nhsrcindia.org.
c. www.ipc,gov.in/IPC.

10. Practical Related Questions

a. Write about the importance of NFI.
b. Write the different pregnancy categories.
c. What is schedules H and H1, G and X as per D & C Act 1940?
d. List the editions with year of publication of NFI.

(Space for Answers)

11. Assessment Scheme

Particular	Performance of Activities (Motor skill)	Answers Written	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**03**	**02**	**01**	**04**	**10**	

LIQUID DOSAGE FORMS

Liquid dosage forms are homogeneous liquid preparations containing one or more active ingredients with or without additives dissolved in a suitable vehicle, meant for oral administration.

Classification of liquid dosage form:

1. **Monophasic liquid dosage form:**
   a. Internal used monophasic liquid dosage form:
      i. Syrup
      ii. Elixir
      iii. Solution
   b. External used monophasic liquid dosage form:
      i. Mouthwash
      ii. Gargle
      iii. Linctus
2. **Biphasic liquid dosage form:**
   E.g. Emulsion, Suspension, Dry powder for reconstitution.

Advantages of Liquid Orals:

1. Liquids oral preparations are pourable and have faster absorption and rapid action.
2. They are more flexible to achieve the proper dosage of the medication.
3. These are commonly used by young children or elders who have trouble swallowing.
4. Products like adsorbents and antacids are more effective in liquid dosage forms.
5. They can be measured with ease using the measuring device provided with the package.
6. They can be easily flavoured, coloured or sweetened.
7. They are the only alternatives for certain drugs such as castor oil.

Disadvantages of Liquid Orals:

1. Oral liquid dosage forms usually have a shorter shelf life.
2. These have special storage requirements.
3. They have less dosage accuracy.
4. Problem occurs in the preservation of liquids oral preparations.
5. Being bulky, its transportation is difficult.
6. They are difficult to recover once lost due to spillage or breakage of the container.

SYRUP:

Syrups are sweetened, viscous, concentrated or nearly saturated aqueous solutions of sucrose containing 66.7% w/w of sugar, having specific gravity 1.31.

Classification of Syrups:

1. **Simple syrup:** In this, only water is used as a solvent. It contains sucrose in purified water and a combination of glycerin or sorbitol.
2. **Medicated syrup:** It contains some added medicinal substances in the syrups. e.g. Ephedrine sulphate syrup.
3. **Flavoured syrups:** It contains various aromatic or pleasantly flavoured substances and generally used as a vehicle or as a flavouring agent or for preservation.
4. **Invert syrup:** It is prepared by hydrolysing sucrose with hydrochloric acid and neutralising the solution with calcium or sodium carbonate.
5. **Artificial syrup:** It is prepared using an artificial sweetening agent i.e. aspartame or saccharin thickening agents such as methylcellulose, hydroxy methylcellulose, glycerin and propylene

6. **Dry syrup:** The syrup that is manufactured in dry powder form, that requires the addition of freshly boiled and cooled water at the time of dispensing is called dry syrup.

Advantages of Syrup:

1. Syrups can mask the bitter taste of drugs to administer easily to children.
2. Thick character of syrup has a soothing effect on irritated tissues of the throat.
3. Most syrup is inherently resistant to microbial growth.
4. Syrups are attractive and popular amongst children.
5. These are widely accepted due to the wide variety of flavours used.

Disadvantages of Syrup:

1. Patients who must consume food having low calories should be aware of the amount of the sugar present in syrup.
2. Patients taking syrups regularly are at the risk of dental caries.
3. It is not suitable for diabetic and paediatric patients due to the presence of sugar.
4. Crystallization of sugar takes place if the container is left open.

Formulation of Syrup:

1. **Vehicle**: Purified water.
2. **Adjuvants/Excipients:** added to improve safety efficacy and palatability.
   a. **Preservatives**: Generally, syrups are self-preservative. If required benzoic acid, sodium benzoate, methyl paraben is added.
   b. **Flavouring agents**: Orange oil, raspberry juice, peppermint oil, etc.
   c. **Colouring agents**: Amaranth, iron oxide, tartrazine, etc.
   d. **Stabilizers**: To prevent crystallization like glycerin, sorbitol, propylene glycol, etc.
   e. **Buffers**: To resist change in pH. e.g. Sodium citrate, sodium acetate etc.
   f. **Density modifier**: To modify the density like dextrose.

Storage of Syrup:

Syrups are preserved in tight, light-resistant containers, avoiding exposure to excessive heat and moisture until it is opened, and then it must be stored in a refrigerator till its complete consumption. Overall, syrups containing stable drugs are stored at 25-27°C and those containing thermolabile drugs are stored at 4-5°C in a refrigerator.

ELIXIR

Elixirs are clear, sweetened and flavoured hydroalcoholic liquid preparation intended for oral use.

Types of Elixirs:

1. **Flavoured elixirs:** They are used purely as diluting agents or solvents for drugs containing approximately 23% alcohol, e.g. Simple Elixir.
2. **Medicated elixir:** Elixirs containing therapeutically active compounds are known as medicated elixirs. e.g. Phenobarbital Elixir USP, Dexamethasone, Elixir USP, etc.
3. **Aromatic elixir USP:** An aromatic elixir is a pharmaceutical preparation containing a volatile active ingredient that is dissolved in a solution that contains some percentage (usually 40-60%) of ethyl alcohol and is designed to be taken orally.

Formulation Ingredients of Elixirs:

1. **Vehicles**: The elixirs are prepared using water, alcohol, syrup, glycerin, sorbitol, propylene glycol as vehicle

2. **Adjuvants/Excipients:**
   a. **Stabilizers**: Stabilizers are added to prepare stable elixirs. e.g. Citric acid, disodium EDTA.
   b. **Colouring agents**: Coal tar dyes like amaranth, compound tartrazine, tartrazine green, etc.
   c. **Flavouring agents**: Sweetening agents and fruit flavours like black currant syrup, raspberry juice, inverted syrup etc.
   d. **Preservatives**: Mostly not required when the alcohol content is above 20%, otherwise double strength chloroform, benzoic acid etc. are used as preservatives.

Advantages of Elixirs:

- Drugs having poor water solubility can be formulated.
- Hydroalcoholic preparation maintains both water soluble and alcohol soluble drugs in solutions. Hence, they are the stable dosage forms compared to syrups.
- Elixirs containing more than 20% alcohol usually act as self-preservative and do not require additional preservatives.
- Elixirs are less viscous than syrups and thus do not create difficulty in filtration.

Disadvantages of Elixirs:

- Elixirs are less sweet and less viscous.
- Elixirs are less effective in masking the bitter taste of drugs.
- Elixirs having a high percentage of alcohol require a sweetening agent other than sucrose since sucrose is slightly soluble. Saccharine can be used in such cases.
- Elixirs are more expensive than syrups.

Storage of Elixirs:

Elixirs are stored in tightly closed, light-resistant containers. Elixir preparation under use must be properly closed after withdrawal of dose and stored at places that prevent environmental effects, away from children.

SOLUTION:

Solution is a homogenous mixture of two or more substances in a solvent.

The component of a solution present in larger quantities is referred to as solvent while one present in smaller amounts is solute.

The various excipients used in dosage form for its stability as well as to improve patient compliance are:

1. Solubilising agent.
2. Viscosity controlling agent.
3. Buffers.
4. Antioxidants.
5. Colours.
6. Flavours.
7. Preservatives, etc.

Different techniques for solubility enhancement:

1. Solubilization using surfactant
2. Cosolvency
3. pH modification
4. Complexation
5. Hydrotrophy
6. Chemical modification of the drug

1. **Solubilization using surfactant:** Solubilization may be defined as the dissolution of poorly soluble solute molecules in water in presence of surfactant forming the thermodynamically stable solution. Surfactants are molecules with well-defined polar and non-polar region that allow to aggregate in solution to form micelles. Solubilization occurs by solute dissolving in or being absorbed into the micelles e.g. cresol with soap solution.
2. **Cosolvency:** Cosolvency is the process of enhancing the solubility of a very poorly soluble drug in water by adding water miscible solvent in which the drug is very soluble. The solvent employed in achieving this goal are called cosolvents. Enhanced solubility through cosolvency is however regarded as the result of independent solubility of the substance in each of the cosolvents. e.g. of cosolvents ethanol, sorbitol, glycerin, propylene glycol etc.
3. **pH modification:** Solubility of weak acid and weak bases can be markedly affected by pH. Hence solubilities of drugs, which are either weak acid or weak bases, may be influenced by variation in pH. e.g. Strong solution of ammonium acetate.
4. **Complexation:** Complexation is the association between two or more molecules to form a non-covalent based complex that has higher solubility than the drug itself. Organic compounds tend to associate with each other. Example: Complexation of iodine and potassium iodide in Iodine solutions.

   Main considerations involved in employing complexation technique are:
   - The amount of drug, which can be dissolved by specific complexing agents.
   - Whether the resulting complex is safe, stable & therapeutically effective.
5. **Hydrotrophy:** The term hydrotrophy designate the increase in solubility of a drug in water owing to the presence of large number of additives. e.g. Increased solubility of caffeine in presence of sodium benzoate and theophylline in presence of sodium salicylate. The possible mechanism of hydrotrophy is solubilization, complexation, and cosolvency.
6. **Chemical modification of the drug:** The method is based on preparing the water-soluble derivatives of poorly soluble drugs. eg. Alkaloids are poorly soluble, their derivatives with acids (alkaloidal salts) are soluble. Example drugs like corticosteroids have been esterified to produce water-soluble derivatives.

Advantages of solutions:

1. Onset of action of drug in solution form is faster than the solid dosage forms such as tablet and capsule.
2. It is convenient for oral route in case swallowing tablets or capsules is difficult.
3. Certain drugs which cause gastric irritation, such drugs can be formulated in solution form e.g. potassium chloride, aspirin etc.
4. It is the most convenient and more acceptable dosage form to the patients.
5. It is easy for adjusting the dose by simple dilution particularly in case of children.

Disadvantages of solutions

1. Solutions are excellent growth media for bacteria and microbial contamination.
2. In the case of a solution for internal use, dose has to be measured at every time.
3. Handling and transportation of solutions is difficult as it occupies more volume.
4. It is not economical as it is multi dose preparation.

Storage: Store in a plain or amber-coloured tightly closed container at a cool place.

Experiment No. 03

Preparation and Evaluation of Simple Syrup IP

1. Aim

To prepare, evaluate and submit 20 ml Simple Syrup I.P.

2. Practical Significance

Simple syrup is a multipurpose used liquid oral formulation, like sweetening agent, vehicle, antioxidant, preservative, etc. Through this practical student will be able to learn about definition, advantages, types, composition, method of preparation, evaluation, storage, use and labelling requirements of syrup.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of simple syrup I.P.	CO1-4	BTL3
2	Prepare and evaluate simple syrup I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Syrup I.P. is a sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7%w/w of sugar having specific gravity 1.31. It imparts high osmotic pressure. This osmotic pressure prevents the growth of bacteria, fungus and molds. The syrup is further classified into Simple flavored syrup and Medicated syrup. Simple flavored syrup does not contain any medicament but contains flavored substances whereas Medicated syrup contains medicinal substances. Simple syrup IP is prepared by hot method while simple syrup USP is prepared by cold method.

5. Requirements

a. Apparatus: 100 ml beaker, Glass rod, 100 ml measuring cylinder, narrow mouth glass bottle.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Sucrose I.P., Purified water.

6. Factor Calculation

Factor = Required Quantity/ Given Quantity

7. Formulation Table

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Sucrose	667 gm		
2	Purified water (q.s)	1000 ml		

8. Procedure

a. Weigh the required quantity of sucrose and mix with purified water.
b. Heat in a water bath until it dissolves with occasional stirring.

c. Add sufficient purified water to make up the weight.
d. Filter if necessary and adjust the weight to 20 ml.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer into the container, attach a prepared label and submit.

9. Use of Preparation: Pharmaceutical Aid

10. Direction: Use as directed

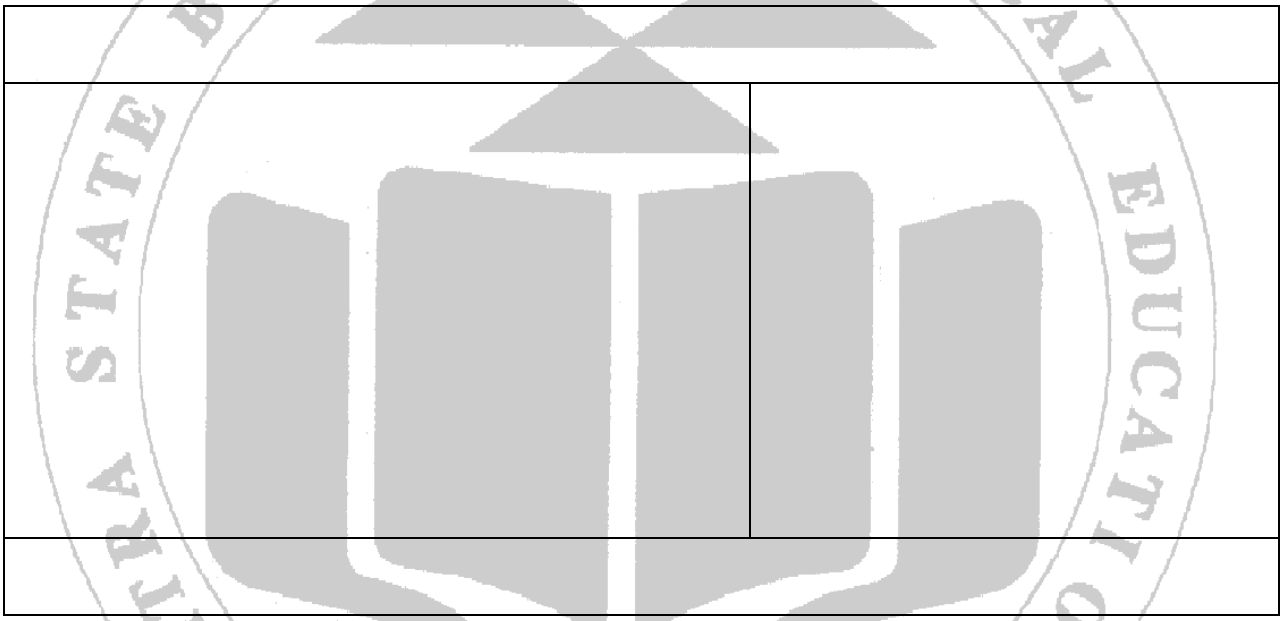
11. Precautions

a. Avoid overheating otherwise sucrose will be charred and become black.
b. Cool the preparation before transferring to the container.

12. Storage

It should be stored in a well closed container and kept in a cool place preferably below 25^0C.

13. Label



14. Evaluation Table

Name of preparation	Test	Specification	Observation
Simple Syrup IP	Description	Clear viscous liquid	
	Colour	Colourless	
	Odour	Odourless	
	Taste	Sweet	
	Viscosity	Viscous	
	Clarity	Clear	
	Volume	20 ml	

15. Result

_____ml of Simple syrup IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia 1955.
b. https://thepharmapedia.com.

18. Practical Related Questions

a. Define syrup.
b. What are the two types of syrups?
c. What are the advantages of using syrup as a dosage form?
d. Why is there no need to add preservatives in syrup?
e. What are the methods of preparation of syrup?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 04

Preparation and Evaluation of Piperazine Citrate Elixir IP

1. Aim

To prepare, evaluate and submit 30 ml of Piperazine Citrate Elixir I.P.

2. Practical Significance

Piperazine citrate elixir is primarily used to treat roundworm and pinworm infections in humans. Its practical significance lies in its effectiveness in eliminating these parasitic infections, which can cause discomfort and health issues if left untreated. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage, use, direction and evaluation of Piperazine citrate elixir I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Piperazine citrate elixir I.P.	CO1-4	BTL3
2	Prepare and evaluate Piperazine citrate elixir I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Elixirs are clear, sweetened and flavoured hydroalcoholic liquid preparation intended for oral use. The elixir is further classified into flavoured elixir and Medicated elixir. Flavored elixir does not contain any medicament but contains flavoured substances whereas Medicated elixir contains medicinal substances. Piperazine citrate elixir is primarily used as an anthelmintic to treat roundworm and pinworm infections in humans. It paralyzes the worms and makes them pass in the stool. In this preparation chloroform spirit acts as preservative, glycerin as a co-solvent, orange oil as flavouring agent and syrup as sweetening agent.

5. Requirements

a. Apparatus: 100 ml beaker, Glass rod, 100 ml measuring cylinder, narrow mouth glass bottle.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Piperazine citrate, chloroform spirit, glycerin, orange oil, syrup Purified water.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Piperazine citrate	18 gm		
2.	Chloroform spirit	0.5 ml		
3.	Glycerin	10 ml		
4.	Orange oil	0.025 ml		
5.	Syrup	50 ml		
6.	Purified water (q.s.)	100 ml		

8. Procedure

a. Weigh the required quantity of piperazine citrate and mix with a part of purified water.
b. Add the required quantity of chloroform spirit, glycerin, orange oil and syrup and make up the volume by adding purified water.
c. Evaluate formulation as per evaluation parameters and note the observations.
d. Transfer into the container, attach a prepared label and submit.

9. Use of Preparation:

Anthelmintic

10. Direction:

As directed by physician

11. Dose:

4-15 ml daily in a divided dose.

12. Storage:

It should be stored in a well closed container in a cool and dry place and protected from light.

13. Label:

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Piperazine citrate elixir IP	Description	Clear liquid	
	Colour	Colourless	
	Odour	Orange	
	Taste	Sweet	
	Viscosity	Clear	
	Clarity	30 ml	
	Volume	Clear liquid	

15. Result

_____ml of Piperazine citrate elixir IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia 1966
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

18. Practical Related Questions

a. Define Elixir.
b. What are the two types of Elixir?
c. Explain the formulation of elixir.
d. Name the preservatives added in piperazine citrate elixir I.P.
e. Name the co-solvent used in piperazine citrate elixir I.P.
f. Write the mechanism of action of piperazine citrate elixir I.P.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 05

Preparation and Evaluation of Aqueous Iodine Solution IP

1. Aim

To prepare, evaluate and submit 15 ml of Aqueous Iodine Solution I.P. (Synonym - Lugol's solution)

2. Practical Significance

Aqueous Iodine solution (Lugol's solution) is used as a source of iodine in hyperthyroidism and helps to prepare the thyroid gland for surgery. Through this experiment, the students will be able to learn about the composition, preparation through complexation, evaluation, storage, use, direction and labelling requirements of Aqueous iodine solution I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of aqueous iodine solution I.P.	CO1-4	BTL3
2	Prepare and evaluate aqueous iodine solution I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Aqueous iodine solution I.P. can be used along with antithyroid medications for the patients suffering with Graves' disease. Iodide has been shown to lower thyroid hormone levels and reduce blood supply within the thyroid gland. Iodine can also be used to sterilize wounds as it kills bacteria which cause infections. Lack of iodine causes the thyroid gland to enlarge leading to conditions like cretinism, hypothyroidism, and goitre.

Aqueous iodine solution contains 5% w/v of iodine and 10% w/v of potassium iodide. Iodine is practically insoluble in water. Thus, potassium iodide is used which acts as a solubilizing agent and increases its solubility. Potassium iodide reacts with iodine and forms soluble complexes known as polyiodide complexes like KI. I_2, KI.21_2, K1.31_2, Kl.nl_2, that are soluble in water.

5. Requirements

a. Apparatus: Conical flask (150 ml), glass beaker (200 ml), glass rod, glass volumetric cylinder (100 ml), spatula, glass mortar and pestle.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Iodine, potassium iodide.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Iodine	50 gm		
2	Potassium iodide	100 gm		
3	Purified water (q.s.)	1000 ml		

8. Procedure

a. Weigh accurately the required quantity of iodine and potassium iodide and triturate in a glass mortar to make a fine powder.
b. Add the required quantity of purified water to it and stir it continuously until iodine is completely dissolved.
c. Adjust the final volume with the remaining quantity of purified water.
d. Evaluate formulation as per evaluation parameters and note the observations.
e. Transfer into the container, attach a prepared label and submit.

9. Use of Preparation: As a source of iodine in hyperthyroidism.

10. Direction: As directed by the physician

11. Storage: Store in a well closed light and iodine resistant container in a cool place.

12. Dose: 0.3 to 1 ml

13. Label:

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Aqueous Iodine Solution IP	Description	Brown liquid	
	Colour	Deep brown	
	Odour	Pungent	

Name of preparation	Test	Specification	Observation
	Insoluble particles	Absent	
	Volume	15 ml	

15. Result

_____ml of Aqueous Iodine solution IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia 1966.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

18. Practical Related Questions

a. Define solutions.
b. How is solubility of iodine enhanced in aqueous iodine solution?
c. Why are glass mortar and pestle used for trituration of iodine and potassium iodide?
d. Which diseases are caused by deficiency of iodine?
e. Classify solutions based on the method of preparation.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Introduction to Biphasic Liquid Dosage forms: Emulsions

Emulsion:

An emulsion is a heterogeneous system, consisting of at least one immiscible liquid dispersed in the form of droplets (diameter 0.1 μm to 100 μm) in another liquid phase. The globules form the dispersed phase and the liquid in which the globules are dispersed is called continuous phase. Two immiscible liquids cannot be dispersed for a long period, so an emulsifying agent having a peculiar structure in which one end is hydrophilic and other is lipophilic is used. Because of that it is possible for an emulsifying agent to form a thin film at the interface and reduce the interfacial tension.

Types of Emulsion:

1. Oil in water (o /w)
2. Water in oil (w /o)

Identification tests: To decide the type of Emulsion.

a. Dye test
b. Dilution test
c. Conductivity test
d. Fluorescence test
e. Cobalt chloride test

Classification of emulsifying agents:

1. **Natural**:
   a. Vegetable source: Gum acacia, tragacanth, agar, starch, pectin, Irish moss.
   b. Animal source: wool fat, egg yolk, gelatin.
2. **Semi synthetic**: Methyl cellulose, Sodium carboxymethyl cellulose
3. **Synthetic**:
   a. Anionic: Sodium lauryl sulphate (SLS).
   b. Cationic: Cetrimide, benzalkonium chloride.
   c. Non-ionic: Glyceryl ester, glyceryl monoesters etc.
4. **Inorganic**: Milk of magnesia, Magnesium oxide, Magnesium trisilicate, Bentonite, etc.
5. **Alcohols (polyols):** Carbowax, cholesterol and lecithin.

Emulsions for oral mixtures are made with naturally occurring gums as they are inert with receptive therapeutic agents. Acacia is the best emulsifying agent for extemporaneous preparations for oral emulsion and are stable over a wide pH range 2 – 10 but they are too sticky for external use. Tragacanth increases viscosity; however, it is not a good emulsifying agent. Monovalent soaps which form o/w type of emulsion are not useful for oral mixture as they cause haemolysis.

Preparation of emulsions:

The following methods are commonly used for the preparation of emulsions on a small scale:

1. Dry gum method
2. Wet gum method
3. Bottle method
4. Other methods.

1. Dry gum method:

- Measure the required quantity of oil in a dry measure and transfer it into a dry mortar.
- Add the calculated quantity of gum acacia into it and triturate to form a uniform mixture.

- Add the required quantity of water and triturate vigorously till a clicking sound is produced and the product becomes white or nearly white due to the total internal reflection of light. The emulsion produced at this stage is known as primary emulsion.
- Add more water with trituration to produce the required volume.
- The following table shows the proportion of oil, water and gum acacia required for different types of oils.

2. Wet gum method:

In this method, the proportion of Oil:Water:Gum for preparing the primary emulsion is the same as given in the table.

- Calculate the quantity of oil, water and gum required for preparing the primary emulsion.
- Powder the gum acacia in a mortar. Add water and triturate it with gum to farm mucilage.
- Add the required quantity of oil in a small portion with rapid trituration until a clicking sound is produced and the produce becomes white or nearly white. At this stage the emulsion is known as primary emulsion.
- Add more water in small portions to the primary emulsion with trituration to produce the required volume of uniform emulsion.
- Transfer the emulsion to a bottle, cork it, label and submit.

Sr. No.	Type of oil	Example	Ratio of Oil:Water:Gum (O:W:G)
1	Fixed oil	Castor oil	4:2:1
		Almond oil	
		Arachis oil	
		Cod liver oil	
2	Volatile oil	Turpentine oil	2:2:1
		Peppermint oil	
		Cinnamon oil	
3	Mineral oil	Liquid paraffin	3:2:1

3. Bottle method:

Bottle method is used for preparation of emulsions of volatile and other non-viscous oils. The proportion of Oil:Water:Gum is 2: 2: 1.

- Measure the required quantity of the oil and transfer into a large bottle. Add the required quantity of powdered gum acacia.
- Shake the bottle vigorously, until the oil and gum are mixed thoroughly.
- Add the calculated amount of water all at once.
- Shake the mixture vigorously to form a primary emulsion.
- Add more water in small portions with constant agitation to produce required volume.

Recommended Containers: Screw capped plain bottles.

Special Labelling instructions: Shake well before use.

Stability of emulsions: Emulsion may break due to cracking, creaming, flocculation, coalescence and phase inversion.

Evaluation of emulsions: Emulsions should be evaluated for phase separation, globule size, rheology and stability.

Storage: Store in a tightly closed container at a cool place.

Experiment No. 06
Preparation and Evaluation of Cod Liver Oil Emulsion

1. Aim

To prepare, evaluate and submit 30 ml of Cod liver oil emulsion.

2. Practical Significance

Cod liver oil emulsion is used as a source of vitamin A, vitamin D andiron. Vitamin A is crucial for vision, immune function, and skin health, while vitamin D is important for bone health, immune function, and overall well-being. Through this experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction and labelling requirements of cod liver emulsion.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of cod liver emulsion	CO1-4	BTL3
2	Prepare and evaluate cod liver emulsion	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Cod liver oil is a fixed oil that requires the addition of acacia gum as an emulsifying agent. The proportions of 4:2:1 (oil: water: gum) will be used to prepare the primary emulsion. Cinnamon water (1 part of cinnamon in 39 parts of water) acts as a flavouring agent and vehicle. Cod liver oil is a pale-yellow tasteless liquid obtained from the liver of cod fish (Gaddus callarias) and contains omega-3-fatty acids and vitamin A and D. Gum acacia is used as an emulsifying agent which forms a protective barrier and reduces the interfacial tension. Ferric ammonium citrate acts as a source of iron.

5. Requirements

a. Apparatus: Mortar and pestle, Spatula, 100 ml Glass beaker, Pipette, Glass rod, 50 ml Measuring cylinder, 30 ml capacity Amber coloured bottle, etc
b. Equipment: Calibrated weighing balance.
c. Chemicals: Cod liver oil, gum acacia, syrup, ferric ammonium citrate, cinnamon water (1 part of cinnamon in 39 parts of water).

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Cod liver oil	30 ml		
2	Syrup	12 ml		
3	Ferric ammonium citrate	4 gm		
4	Cinnamon water (q.s)	90 ml		
Formula for primary emulsion: Cod liver oil is a fixed oil therefore the ratio of Oil: Water: Gum (i.e. O: W: G) will be 4:2:1 for primary emulsion				
	Cod liver oil	30 ml		
	Cinnamon water	15 ml		
	Gum Acacia	7.5 gm		

8. Procedure

a. Calculate quantities of oil, gum acacia, and water required for primary emulsion. Follow the dry gum method.
b. Measure the required quantity of cod liver oil in the dry measuring cylinder and transfer it to a dry mortar.
c. Weigh out gum acacia and transfer it to the above mortar and triturate rapidly so as to form a homogenous mixture.
d. Add measured quantities of cinnamon water in small quantities at a time into the mortar and triturate well after each addition.
e. Continue trituration until a clicking sound is produced and the product becomes white or nearly white. At this stage, the emulsion is known as the primary emulsion.
f. Mix syrup with 4 ml of cinnamon water and dissolve ferric ammonium citrate.
g. Add the above solution to the primary emulsion while stirring.
h. Add remaining water in small quantities at a time with constant trituration to get a homogeneous product.
i. Transfer the emulsion to a measuring cylinder and add more vehicles to make up the final volume. Stir thoroughly to form a uniform emulsion.
j. Evaluate formulation as per evaluation parameters and note the observations.
k. Transfer into the glass container, attach a prepared label and submit.

9. Use of Preparation: Source of vitamin A, vitamin D and iron.

10. Special Labelling Instructions: Shake well before use.

11. Direction: One tablespoonful to be taken twice a day.

12. Storage

Store in an airtight container away from light.

13. Dose

15-20 ml.

14. Label:

15. Evaluation Table

Name of preparation	Test	Specification	Observation
Cod liver oil emulsion	Description	Semi viscous	
	Colour	Light brown colour	
	Odour	Pungent, fish odour	
	Dilution test	O/W emulsion	
	Volume	30 ml	

16. Result

_____ml of Cod oil emulsion is prepared, evaluated and submitted in a _____ container with special instructions as_____.

17. Conclusion

_____

_____

18. References

a. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

19. Practical Related Questions

a. Enlist tests to detect type of emulsion.
b. What are necessary precautions for electrolytes (ferric ammonium citrate) before addition to primary emulsion?
c. Describe dry gum method for the preparation of emulsion.
d. What is the category of cod liver oil emulsion?
e. What is the use of cinnamon water?

(Space for Answers)

20. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 07
Preparation and Evaluation of Castor Oil Emulsion

1. Aim

To prepare, evaluate and submit 30 ml of Castor Oil Emulsion.

2. Practical Significance

Castor oil emulsion is used as a gentle laxative to relieve constipation. It works by stimulating the muscles in the intestines, aiding in bowel movements. Through this experiment, the students will be able to learn about the composition, preparation, evaluation, storage, use, direction, lab requirements or castor oil emulsion.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Castor oil emulsion.	CO1-4	BTL3
2	Prepare and evaluate Castor oil emulsion	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Castor oil emulsion is prepared by wet gum method, in which a primary emulsion is prepared in the ratio of 4:2:1 (fixed oil: water: gum). Gum acacia is to be used as an emulsifying agent which reduces the interfacial tension between oil and water. Castor oil can be used as an irritant/stimulant laxative. The castor oil in the emulsion works directly on the small intestine to promote bowel movement. Castor oil emulsion should not be used for longer than directed by your doctor or healthcare professional. This medicine can be habit-forming. Long-term use can lead your body to become dependent on the laxative for regular bowel movements, damage the intestines, malnutrition, and water and salt balance issues.

5. Requirements

a. Apparatus: 100 ml beaker, 50 ml measuring cylinder, pipette, mortar and pestle, amber coloured glass bottle.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Castor oil, gum acacia.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Castor oil	30 ml		
2	Purified water (q.s)	90 ml		
Formula for primary emulsion: Castor oil is a fixed oil, therefore the ratio of Oil: Water: Gum (O:W:G) will be 4:2:1 for primary emulsion.				
	Castor oil	30 ml		
	Purified water	15 ml		
	Gum Acacia	7.5 gm		

8. Procedure

a. Calculate quantities of oil, gum acacia, and water for primary emulsion. Follow the wet gum method.
b. Weigh out gum acacia and transfer it to the mortar.
c. Measure the quantity of water required for primary emulsion and triturate it with gum to form mucilage.
d. To this add castor oil in small quantities at a time with thorough trituration after each addition.
e. Triturate briskly without ceasing until a clicking sound is produced and the product becomes white or nearly white.
f. At this stage, the emulsion is known as the primary emulsion.
g. Add remaining water in small quantities at a time with constant triturating to get a homogeneous product.
h. Transfer the emulsion to a measuring cylinder and add more water to produce the final volume. Stir thoroughly to form a uniform emulsion.
i. Evaluate formulation as per evaluation parameters and note the observations.
j. Transfer into a well-closed container, attach a prepared label and submit.

9. Use of Preparation

As a purgative.

10. Direction

One tablespoonful to be taken before going to bed.

11. Instructions

Shake well before use

12. Storage

Store in an airtight container away from light.

13. Dose

15 – 30 ml

14. Label

15. Evaluation Table

Name of preparation	Test	Specification	Observation
Castor oil emulsion	Description	Viscous	
	Colour	Milky white	
	Odour	Odourless	
	Dye test	Emulsion type O/W	
	Volume	30ml	

16. Result

_____ml of Castor oil emulsion is prepared, evaluated and submitted in a _____ container with special instructions as_____.

17. Conclusion

_____

_____

18. References

a. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

19. Practical Related Questions

a. Define emulsions. Enlist the methods of preparation of emulsion.
b. Describe wet gum method.
c. Classify emulsifying agents.
d. Write the advantages of emulsions.
e. Enlist the identification tests for emulsions.

(Space for Answers)

20. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 08
Identification and Quality Control Tests for Emulsion

1. Aim

To perform the identification tests and quality control tests for emulsion.

2. Practical Significance

Quality control tests for emulsions play a vital role in ensuring product stability, consistency, compliance with regulations, and customer satisfaction. Through this experiment, students understand the different identification tests and stability of emulsion.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Identify the type of emulsion	CO4	BTL3
2	Explain the various quality control tests for emulsion.	CO4	BTL2
3	Determine the globular size of emulsion by performing QC test.	CO4	BTL3
4	Follow the cleanliness, safety and ethical practice in laboratory	CO 1-4	BTL5
5	Collaborate and communicate with fellow students	CO 1-4	BTL5

4. Relevant Theoretical Background

Quality control tests for emulsions are crucial for ensuring product consistency, stability, and efficacy. By conducting these tests, manufacturers can:

A. **Ensure Stability:** Emulsions can separate over time, leading to ineffective products. Quality control tests help identify potential stability issues, allowing adjustments to be made to the formulation or packaging to prevent separation.

B. **Verify Shelf Life:** Understanding the stability of emulsions aids in determining their shelf life. Quality control tests can assess how long the product remains stable under various conditions, helping manufacturers establish expiration dates and storage recommendations.

C. **Maintain Product Quality:** Consistent quality is essential for consumer satisfaction and brand reputation. Quality control tests help maintain product uniformity by monitoring factors such as viscosity, pH, particle size distribution, and appearance.

D. **Comply with Regulations:** Many industries have regulations governing product quality and safety. Quality control tests ensure that emulsions meet regulatory standards, minimizing the risk of recalls, fines, or legal issues.

E. **Optimize Manufacturing Processes:** Identifying and addressing quality issues during production can lead to process improvements and cost savings. Quality control tests provide valuable data for refining manufacturing processes and optimizing resource utilization.

Identification test for emulsion:

The identification testing is performed to verify the type of emulsion.

A. **Dilution test:** The emulsion will remain stable with the addition of an external phase (dispersion medium). When water is added to a test tube containing emulsion, if separation of oil globules

does not occur, the emulsion is of the o/w type. If the same is true with oil, the separation of oil globules takes place, leading to phase separation of the emulsion.

B. Conductivity test: Water is a good conductor of electricity, and oil is a bad conductor of electricity. Electrodes are dipped into an emulsion and connected to an electric bulb. A glowing electric bulb occurs when the emulsion contains water as a dispersing medium; hence, the emulsion will be o/w.

C. Dye test: The water-soluble dye (amaranth) is mixed with an emulsion and observed under a microscope. If the dispersed globules appear colorless and the background is red, this is an o/w type of emulsion. If we use an oil-soluble dye like Scarlet Red C or Sudan III and observe it under a microscope, the dispersed globules appear red, and the background is colorless. This is an o/w type of emulsion.

D. Cobalt chloride test: Anhydrous cobalt is blue in color, and hydrous cobalt is red or pink in color. When cobalt chloride paper dips in an emulsion, if a color change occurs, from blue to red or pink, the preparation contains water as an external (dispersed) phase, so the emulsion is o/w type.

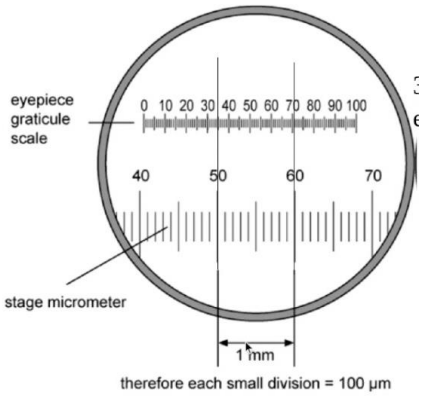
E. Fluorescence test: There are many oils that glow in the presence of UV light. Therefore, when emulsion is observed under a microscope, if globules show fluroscence, it is concluded that the preparation is O/W type.

Quality Control Tests for Emulsions:

Quality control testing is an important stage in the development of any formulation since it helps the research scientist to identify whether his product has the intended properties or not. The stability of the physical structure is critical in biphasic products such as emulsions. Some of the essential quality control tests are listed below.

A. Determination of globule size and size distribution:

The change in average particle size or droplet size distribution is an important parameter for evaluating emulsions. Optical microscopy, the Andresen apparatus, and the Coulter counter apparatus are routinely employed to determine the average globule size and distribution. The stage micrometer and eyepiece micrometer are the two most important components for determining globule size using microscopy. The standard stage micrometer is used to calibrate the eyepiece micrometer. The stage micrometer is a glass slide with a scale etched onto it. The scale is normally one millimeter long and divided into 100 sections. The stage micrometer's smallest division (least count) is 0.01 mm (10 µm) in length. An eyepiece micrometer is a small glass disc with a linear scale of 10 mm (divided into 1 mm and 0.1 mm parts) which is permanently fixed in the eye piece.



B. Determination of viscosity:

Viscosity determination is done to investigate potential changes caused by aging. Emulsions exhibit non-Newtonian flow behaviour. Therefore, cone and plate viscometers should be used to determine the viscosity of emulsions, but capillary and falling sphere viscometers should be avoided. A penetrometer is recommended for viscous emulsions since it helps to assess viscosity with age. The flocculation of globules causes an immediate increase in viscosity in oil/water emulsions.

C. Determination of phase separation:

This is another parameter that influences the formulation's stability. The separation of phases can be visually viewed or measured by determining the volume of the separated phases. Coalescence is an obvious indicator of instability in unstable formulations, and it often emerges within a month. Centrifugation at low or moderate rates speeds up the phase separation test. The strength of interfacial layers can be determined using high-speed centrifugation. Poor emulsions will entirely break at such speeds, whereas those with strong interfacial layers will remain stable.

D. Thermal test:

It is common practice to test an emulsion's stability by subjecting it to severe temperatures in alternate cycles. Thermal stresses are rigorous treatment methods, and emulsions that can tolerate them are termed stable. It should be emphasized that these thermal stresses have no direct correlation with the product's actual shelf life. Extreme temperatures, on the other hand, may influence emulgent partitioning between the two phases, providing an indirect indicator of emulsion stability.

E. Determination of electrophoretic zeta potential properties:

Because electrical charges on particles influence flocculation rate, electrophoretic metrics like zeta potential can be utilized to evaluate flocculation. O/W emulsions with fine globule size will have low resistance; however, high resistance suggests an increase in globule size due to oil droplet aggregation and instability.

5. Procedure

A. Dilution test:

a. Take a 5 ml emulsion in a clean and dry test tube.
b. Add equal volume of water and shake the test tube. Observe the test tube and note your observation.
c. Take another 5 ml emulsion in another dry test tube.
d. Add equal volume of oil and shake the test tube.
e. Observe the test tube and note your observation.

B. Dye test:

a. The water-soluble dye (amaranth) is mixed with a drop of an emulsion on a slide and observed under the microscope.

C. Determination of pH:

a. Measure the pH of emulsion at room temperature using a pH meter.
b. Repeat measurement thrice and determine the mean pH.

D. Determination of globular size by optical microscopy:

a. Thoroughly clean the stage, light reflecting mirror, microscope eyepiece, standard stage micrometer, and slide.

b. Increase the intensity of the light and place a standard stage micrometer on the stage,
c. Align the stage micrometer scale to the center of the 10X objective.
d. Adjust the coarse and fine adjustment knobs of the microscope so that the scale of the stage micrometer is visible (100 divisions).
e. Replace the eyepiece with the eyepiece micrometer. Now, the ruling of the eyepiece micrometer is visible over the stage micrometer scale. If necessary, rotate the eyepiece in such a manner to bring two scales parallel to each other.
f. Manually coincide one division of stage micrometer scale with one division of eyepiece micrometer (Point 1). Thereafter, check the further division of stage micrometer scale which coincides with another division of eyepiece micrometer (Point 2).
g. In between point 1 and point 2, count how many eyepiece micrometer divisions (x) correspond to stage micrometer divisions (y). Make a note of them and calibrate the eyepiece micrometer.
h. Remove the stage micrometer scale from the stage of the microscope,
i. Mount a drop of emulsion on the slide and cover it with a cover slip.
j. Place the slide on the stage of the microscope.
k. Observe and note a minimum of 100 globules for their size using a tally table.
l. Using the observation table and formula, calculate the arithmetic mean globule diameter.

E. Determination of thermal stability:

a. Weigh 100 g emulsion in a 250 ml glass beaker.
b. Using a hot plate and a magnetic stirrer, increase the temperature gradually to 70°C.
c. Observe if there is a change in the appearance of the emulsion.

(Note: Teachers can demonstrate the determination of viscosity and zeta potential of emulsion using official reference books or with the help of YouTube videos.)

6. Observations:

A. Dilution test:

Sr. No.	Test No.	Observation	Inference
1			
2			

B. Dye test:

Sr. No	Observation	Inferences

C. pH of Emulsion:

Reading No.	pH observed
1	
2	
3	

D. Average globular size:

a. One division on standard stage micrometer scale = 10 µm

b. Number of divisions of eyepiece micrometer coinciding (x) = _____

c. Number of divisions of standard stage micrometers coinciding (y) = _____

7. Calculation of Least count for calibration:

If _____ (X) divisions of eyepiece micrometer = _____ (Y) divisions of stage micrometer.

Then,

1 division of eyepiece micrometer $= \frac{X}{Y} \times 10$ = _____ (Z) µm (Least Count).

(Note: if particle cover one division of eyepiece means its size is Zµm)

Observation table for microscopic determination of globular size:

Sr. No.	Size range in µm	Mean size range in µm	No of globule (n)	n X d
1	00 - 50	25		
2	50 -100	75		
3	100 -150	125		
4	150 - 200	175		
5	200 - 250	225		
			∑ n =	**∑ n X d=**

A. Calculation of arithmetic mean globular size:

Arithmetic means globular size = ∑ n X d / ∑ n =

Thermal stress test:

Temperature	Observation	Inference
70^0 C		

8. Result

Identification tests and quality control tests for emulsion were demonstrated successfully.

9. Conclusion

_____

_____

10. References

a. https://youtu.be/QVNpTiFsGvw.

b. Subrahmanyam CVS and Shetty JT, Laboratory manual of Physical Pharmaceutics, 1st edition, Vallabh Prakashan, Delhi

11. Practical Related Questions

a. List the identification test for emulsion.
b. Name the different techniques of determination of globular size.
c. Write the formula to determine arithmetic mean globular size.
d. Write the procedure of determining the least count.
e. Why are quality control tests performed for emulsion?

(Space for Answers)

12. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO SUSPENSIONS

Suspension:

Suspension is a biphasic system consisting of an undissolved or immiscible solid material dispersed in a vehicle. It is a thermodynamically unstable system in which the solids (dispersed phase) are dispersed in a suitable liquid (dispersion medium) with the help of a suspending agent.

Advantages of suspensions

- The chemical stability of certain drugs is improved by formulating into a suspension. e.g.,Procaine penicillin G.
- Suspensions show greater bioavailability than solid dosage forms.
- Onset of action and duration of action can be controlled e.g. Protamine Zinc-Insulin suspension.
- Suspension helps to mask the unpleasant/ bitter taste of a drug e.g., Chloramphenicol.
- Large dose of insoluble drug is easier to swallow e.g. Antacid.
- Suspensions have ease of production and packing.

Disadvantages of suspensions

- Physical stability, sedimentation and compaction can cause problems.
- Due to the bulkiness of suspensions, sufficient care must be taken during handling and transport.
- The rate of absorption from suspensions is slower than solutions.
- Difficult to achieve uniform and accurate dose.
- Difficulty in re-dispersion of sediment.

Classification of suspensions

A. Based on route of administration:

a. Oral suspensions. These suspensions are taken by the oral route. e.g., Paracetamol suspension, Antacid suspension, etc.
b. Parenteral suspensions: These suspensions are sterile and administered by parenteral route. e.g., Procaine penicillin G, Insulin zinc suspension, etc.
c. Ophthalmic suspensions. These suspensions are sterile, isotonic with desired viscosity and instilled into the eye. e.g., Prednisolone acetate ophthalmic suspension.
d. Suspensions for external use: e.g., Calamine lotion.

B. Based on the Nature and behaviour of Solids:

a. Flocculated suspension: Example: Cefuroxime Axetil Oral Suspension.
b. Deflocculated suspension: Example: Paracetamol Oral Suspension Drops (Parald)

Formulation components

A. Suspending agents: These are classified as

a. **Polysaccharides**
   i. Natural Gum Acacia, gum tragacanth, starch, sodium alginate, gelatin, guar gum, etc.
   ii. Semisynthetic methyl cellulose, hydroxyethyl cellulose, sodium carboxymethyl cellulose.
b. **Inorganic clays:** Bentonite, veegum, hectorite.
c. **Synthetic:** Carbopol, colloidal silicon dioxide.
d. **Semi synthetic:** Microcrystalline cellulose, methyl cellulose, sodium carboxymethyl cellulose.

B. Wetting agents: Alcohol, Tween, Span, etc.

C. Flocculating agents: Sodium lauryl sulphate, Tween, Span, etc.

D. Preservatives: Sodium benzoate, chloroform, methyl paraben, propyl paraben, liquefied phenol, etc.

E. Solvents: Purified water, rose water, etc

F. Organoleptic additives: Sweetening agent, flavouring agent, colouring agent, etc.

Storage: Store in a well closed container. Do not keep it in a cold place.

Direction: Shake well before use. For external use only.

LOTION:

Lotions are suspensions or emulsions of dispersed solid or liquid materials in an aqueous vehicle intended for external application to the body.

- They are applied without friction and can be applied to broken skin also.
- These preparations can be applied directly to the skin or through cotton wool, cloth or cotton gauze.
- The insoluble material should be finely divided as particles as they are more soothing to inflamed areas.

Storage: Store in a well closed container. Do not keep it in a cold place.

Direction: Shake well before use. For external use only.

Experiment No. 09

Preparation and Evaluation of Calamine Lotion IP

1. Aim

To prepare, evaluate and submit 30 ml of Calamine lotion I.P.

2. Practical Significance

Calamine lotion I.P. is used as protective and astringent and is used in minor skin irritations that cause pain, itching and discomfort. Through this experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction and labelling requirements of Calamine lotion I.P.

3. Practical Outcomes (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Calamine lotion I.P.	CO1-4	BTL3
2	Prepare and evaluate Calamine lotion I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Calamine and zinc oxide are two indiffusible substances in the suspension which provide an astringent and protective effect to the skin. The lotion leaves a thin layer of calamine and zinc oxide on the skin when applied. It relieves itching, the pain of sunburn, insect bites, and other minor skin irritations.

Calamine is a mixture of 98% zinc oxide and a small proportion of ferric oxide. Ferric oxide gives a pink colour to calamine. Bentonite is colloidal hydrated aluminium silicate and acts as a suspending agent which swells in the presence of water and increases viscosity of the preparation to make these indiffusible solids diffusible. Sodium citrate acts as a chelating agent which forms a complex with free iron of ferric oxide. The sodium citrate causes partial deflocculation of the calamine and transforms the bentonite from a gel to a solution. In its absence, the suspension is much thicker and is not easy to pour from the bottle. Liquefied phenol acts as an antiseptic, preservative, and local anaesthetic. Glycerin acts as a humectant and gives a soothing effect to the skin. Rose water is used as a vehicle. Calamine lotion should be stored in a well-closed container because zinc oxide gradually converts to zinc carbonate due to atmospheric carbon dioxide.

5. Requirements

a. Apparatus: 100 ml beaker, 50 ml measuring cylinder, pipette, mortar and pestle, pipette, transparent bottle.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Calamine, Bentonite, zinc oxide, sodium citrate, liquefied phenol, glycerin, rose water.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Calamine	150 gm		
2	Zinc oxide	50 gm		
3	Bentonite	30 gm		
4	Sodium citrate	5 gm		
5	Liquefied phenol	5 ml		
6	Glycerin	50 ml		
7	Rose water (q.s.)	1000 ml		

8. Procedure

a. Dissolve sodium citrate in about 15 ml of rose water.
b. Triturate calamine, zinc oxide and bentonite with the solution of sodium citrate in a mortar to make a smooth paste.
c. Add liquefied phenol and glycerin to the above mixture.
d. Mix well and make up the volume with rose water.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer into a well-closed container, attach a prepared label and submit.

9. Use of Preparation: As a protective and astringent.

10. Direction: Apply to affected part without rubbing whenever necessary as directed by the physician.

11. Instructions

a. Shake well before use.
b. For external use only.

12. Storage: Store in an airtight container away from light.

13. Label

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14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Calamine lotion IP	Description	Viscous suspension	
	Colour	Pink	
	Odour	Perfumed	
	Grittiness	Free from grittiness	
	Spreadability	Spreads easily	
	Volume	30 ml	

15. Result

_____ml of Calamine lotion IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia 1966.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

18. Practical Related Questions

a. Define lotions.
b. What is the use of bentonite and sodium citrate in calamine lotion?

c. Define protective and astringent.
d. What are the special labelling instructions written on the label of lotions?
e. Why is calamine lotion stored in a well-closed container?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 10
Preparation and Evaluation of Magnesium Hydroxide Mixture BP

1. Aim

To prepare, evaluate and submit 30 ml of Magnesium Hydroxide Mixture B.P. (Synonym: milk of magnesia, cream of magnesia)

2. Practical Significance

Magnesium Hydroxide Mixture B.P. is used to treat as antacid and laxative to relieve acidity and constipation. Through this experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction and labelling requirements of magnesium hydroxide mixture B.P.

3. Practical Outcomes (PrOs)

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Magnesium Hydroxide Mixture B.P.	CO1-4	BTL3
2	Prepare and evaluate Magnesium Hydroxide Mixture B.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Magnesium hydroxide mixture is an aqueous oral suspension of hydrated magnesium oxide. It can be prepared from a suitable grade of light magnesium oxide. This preparation is not prepared by directly suspending magnesium hydroxide in water because magnesium hydroxide absorbs carbon dioxide from the surroundings. It is therefore prepared during preparation (in situ) through two reactions: precipitation reaction in between magnesium sulphate and sodium hydroxide, and hydration of light magnesium oxide with water. One can use either precipitation mechanism for preparation of magnesium hydroxide, but if magnesium hydroxide is prepared only by precipitation reaction between magnesium sulphate and sodium hydroxide then this precipitate may settle down immediately and will not distribute uniformly in the preparation. Also, if magnesium hydroxide is prepared only by hydration of light magnesium oxide with water, then preparation becomes viscous during storage and may cause difficulty during pouring. Hence in this preparation, magnesium hydroxide is prepared by both precipitation and hydration mechanism for uniform distribution of prepared magnesium hydroxide in the suspension.

The reactions of both these mechanisms are as follows:

a) Preparation of magnesium hydroxide by precipitation:

$$\underset{\text{Magnesium sulphate}}{MgSO_4} + \underset{\text{Sodium hydroxide}}{2NaOH} \rightarrow \underset{\text{Magnesium hydroxide}}{Mg(OH)_2} + \underset{\text{Sodium sulphate}}{Na_2SO_4}$$

b) Preparation of magnesium hydroxide by hydration:

$$\underset{\text{Light magnesium oxide}}{MgO} + \underset{\text{Water}}{2H_2O} \rightarrow \underset{\text{Magnesium hydroxide}}{Mg(OH)_2}$$

The precipitate of magnesium hydroxide once settled is washed with a large amount of water to remove sulphate ions of sodium sulphate formed during precipitation reaction from the preparation

because it may give purgative action. The sulphate test using barium chloride solutions can be used for confirmation of removal of sulphate ions. Chloroform and liquefied phenol act as preservative. This preparation should be stored in a well closed glass or plastic container because magnesium hydroxide reacts with carbon dioxide and forms magnesium carbonate which is indiffusible in nature. If a glass container is used, 0.1% citric acid is added to mask bitter taste of alkali leached from the glass container. Citric acid also gives its sour taste to the preparation and improves the palatability of preparation. Citric acid need not be added in case of plastic containers. This preparation should not be stored in the refrigerator at cold temperature because aggregation of dispersed particles may take place.

5. Requirements

a. Apparatus: 100 ml Glass beaker, mortar and pestle, Spatula, Pipette, Glass rod, 50 ml Measuring cylinder, 30 ml capacity Transparent bottle, etc.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Magnesium sulphate, Sodium hydroxide, Light magnesium oxide, Chloroform, liquefied phenol, citric acid.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Magnesium sulphate	47.5 gm		
2	Sodium hydroxide	15 gm		
3	Light magnesium oxide	52.5 gm		
4	Chloroform	2.5 ml		
5	Liquefied phenol	5 ml		
6	Citric acid	0.01 gm		
7	Purified water (q.s.)	1000 ml		

8. Procedure

a. Dissolve required quantity of magnesium sulphate in 200 ml of water in a beaker.
b. Take the required quantity of sodium hydroxide in mortar and add little water to it. Add light magnesium oxide to this solution and triturate to get smooth cream.
c. Pour this dispersion of sodium hydroxide and light magnesium oxide with continuous stirring to the initially prepared magnesium sulphate solution to form magnesium hydroxide. Allow the precipitate of magnesium hydroxide to settle.
d. Once magnesium hydroxide is settled, remove clear supernatant liquid and wash precipitate of magnesium hydroxide repeatedly with water to remove sulphate.
e. The removal of sulphate can be confirmed by carrying out sulphate test with barium chloride solution. (For this, the test solution is acidified using a few drops of hydrochloric acid, and then

a few drops of barium chloride solution are added. White precipitate of barium sulphate is formed if sulphate ions are present).

f. Once filtrate is free from sulphate ions, mix washed precipitate with purified water and add required quantity of chloroform, liquefied phenol and citric acid and pour this dispersion in the measuring cylinder.
g. Make up the volume up to 30 ml using purified water.
h. Evaluate formulation as per evaluation parameters and notet he observations.
i. Transfer into a well-closed container, attach a prepared label and submit.

9. Use of Preparation

As an antacid and laxative.

10. Dose

1-4 ml as antacid and 8-16 ml as laxative.

11. Direction

As directed by the physician.

12. Instructions

Shake well before use.

13. Storage

Store in a well closed container in a cool place

14. Label:

15. Evaluation Table:

Name of preparation	Test	Specification	Observation
Magnesium Hydroxide Mixture BP	Description	Viscous suspension	
	Colour	White	
	Odour	Aromatic	
	pH	10	
	Redispersibility	Easily dispersed	
	Volume	30 ml	

16. Result

_____ml of Simple syrup IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

17. Conclusion

_____

_____

18. References

a. British Pharmacopoeia 1993.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.
c. www.webmad.com.

19. Practical Related Questions

a. Define antacid and laxative.
b. What is the test to confirm the removal of sulphate ions during the preparation of magnesium hydroxide mixture?
c. Explain the formation of magnesium hydroxide precipitate during preparation of Magnesium Hydroxide Mixture B.P.
d. Why is magnesium oxide added in the preparation?
e. What is the role of citric acid in magnesium hydroxide mixture?

(Space for Answers)

20. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO OINTMENTS

Ointment:

Ointments are semisolid preparations meant for external application to the skin or mucous membrane. They usually contain a medicament dissolved, suspended or emulsified in an ointment base. These should spread easily and have a smooth, non-gritty feel.

Ointments are typically used as

- Emollients to make the skin more pliable
- Protective barriers to prevent harmful substances from coming in contact with the skin
- Vehicles for hydrophobic drugs.

Advantages of Ointments:

- The bioavailability of the drug is high due to bypass of hepatic metabolism.
- Chemically more stable.
- Increase in the contact time due to high viscosity of the product.

Disadvantages of Ointments:

- Greasy or oily in nature.
- Patient non-compliance.
- Accurate quantity cannot be applied.

Classification of Ointments:

A. On the Basis of Penetration:

a. **Epidermic ointments**: These ointments are intended to produce their action on the surface of the skin and produce local effect.

b. **Endodermic ointments**: These ointments are intended to release the medicaments that penetrate into the skin.

c. **Diadermic ointments**: These ointments are intended to release the medicaments that pass through the skin and produce systemic effects.

B. On the Basis of Therapeutic Use:

a. **Antibiotic ointments**: These ointments are used to kill microorganisms. Examples: Bacitracin ointment, Chlortetracycline ointment, Neomycin ointment, etc.

b. **Antifungal ointments**: These ointments are used to inhibit or kill fungi. Examples: Benzoic acid ointment, Salicylic acid ointment, Nystatin ointment, etc.

c. **Anti-inflammatory ointments**: These ointments are used to get relief from inflammatory allergic and pruritic conditions. Examples: Betamethasone valerate ointment, Fluocinolone acetonide ointment.

d. **Antipruritic ointments**: These ointments are used to relieve itching. Examples: Benzocaine ointment, Coal tar ointment, etc.

e. **Astringent ointments**: These ointments are used to cause skin cells or mucus membranes to shrink, by precipitating proteins from their surface. Examples: Zinc oxide ointment, Acetic acid ointment, Tannic acid ointment, etc.

f. **Anti Eczematous ointments**: These ointments are used to prevent oozing and excretion from vesicles on the skin. Examples: Ichthamol ointment, Salicylic acid ointment, Sulphur ointment, etc.

g. **Keratolytic ointments**: These are used to remove or soften the horny layer of skin. Examples: Resorcinol ointment, Salicylic acid ointment, Sulphur ointment, etc.

h. **Counter-irritant ointments**: These ointments are applied locally to irritate the skin, reducing or relieving another irritation or deep cited pain. Examples: Capsicum ointment, Methyl salicylate ointment, lodine ointment, etc.

i. **Anti-Dandruff ointments**: These ointments are used to treat dandruff. Examples: Salicylic acid ointment, Cetrimide ointment, etc.

j. **Parasiticide ointments**: These ointments are used to destroy or inhibit living infestation ticks and lice. Examples: Benzyl benzoate ointment, Hexachloride ointment, Sulphur ointment, etc.

k. **Protectant ointments**: These ointments are used to protect skin from moisture, air, sunrays other substances like soap and chemicals. Examples: Calamine ointment, Zinc oxide ointment.

Ointment base:

It is a component of an ointment that acts as a carrier or vehicle for the medicament.

Factors Affecting the Selection of a Suitable Base:

A. Dermatological Factors:

- Absorption and penetration into skin.
- Effect on the function of skin.
- Miscibility and compatibility with the secretions of the skin.
- It should not irritate the skin.
- It should keep the skin moist.
- It should be easy to apply and remove from the skin.

B. Pharmaceutical Factors:

- Stability.
- Consistency.
- Solvent properties.
- Emulsifying properties.

Classification of ointment bases:

A. Oleaginous bases: Soft paraffin, hard paraffin, liquid paraffin.

B. Absorption bases:

  a. Non emulsified bases: Wool fat, wool alcohol, beeswax, cholesterol.

  b. Water in oil emulsion: Hydrous wool fat.

C. Emulsion bases: w/o emulsion

D. Water soluble bases: Carbowaxes (polyethylene glycol).

Additives:

Apart from drug/drugs and ointment base, the following additives are added to make a stable ointment:

a. **Preservatives**: They prevent microbial growth. Example: Methyl paraben, propyl paraben, benzoic acid.

b. **Humectants**: They reduce loss of moisture or prevent drying of preparation. Example: Glycerin, propyl glycol, sorbitol.

c. **Antioxidants**: They prevent oxidative degradation. Example: BHT, BHA, tocopherol, propyl or methyl gallates.

d. **Chelating agents**: They prevent the catalytic oxidative degradation of trace elements. Example: EDTA

Methods of Preparation of Ointments:

A. **Trituration or levigation method**: e.g. Sulphur ointment.

B. **Emulsification method**: e.g. Vanishing cream.

C. **Fusion method:** e.g. Simple ointment USP.

D. **Chemical reaction method**: e.g. Non-staining iodine ointment.

Storage:

Ointments are dispensed in glass or plastic bottles having screw caps with impermeable liners. Nowadays, ointments are generally supplied in plastic or metallic collapsible tubes. They should be stored in a well closed container in a cool place.

Labelling:

A. Store in a cool place.
B. For external use only.

Experiment No. 11

Preparation and Evaluation of Simple Ointment IP

1. Aim

To prepare, evaluate and submit 20 gm of Simple ointment I.P.

2. Practical Significance

Simple ointment IP. is used as an emollient or an ointment base. Through this experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction, and labelling requirements of Simple ointment LP.

3. Practical Outcomes (PrOs)

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Simple ointment I.P.	CO1-4	BTL3
2	Prepare and evaluate Simple ointment I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Simple ointment is prepared by fusion method. It is an absorption base consisting of wool fat, hard paraffin, cetostearyl alcohol and yellow or white soft paraffin. Wool fat acts as an emulsifying agent. Hard paraffin acts as a stiffening agent which stiffens the base. Cetostearyl alcohol has an emollient effect and also enhances stability of ointment. Yellow or white soft paraffin exerts an emollient effect.

5. Requirements

a. Apparatus: Spatula, glass rod, evaporating dish and water bath
b. Equipment: Calibrated weighing balance.
c. Chemicals: Wool fat, cetostearyl alcohol, hard paraffin, yellow or white soft paraffin.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Wool fat	50 gm		
2	Cetostearyl alcohol	50 gm		
3	Hard paraffin	50 gm		
4	Yellow or white soft paraffin	850 gm		

8. Procedure

a. Grate hard paraffin and weigh all the ingredients accurately.
b. Melt hard paraffin and cetostearyl alcohol in a porcelain dish kept on a water bath.
c. To above molten mixtures add wool fat and soft paraffin and stir it well to help melting of all ingredients.
d. After melting, remove porcelain dish from water bath and stir it continuously until semisolid base is obtained.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer into a wide-mouth container, attach a prepared label and submit.

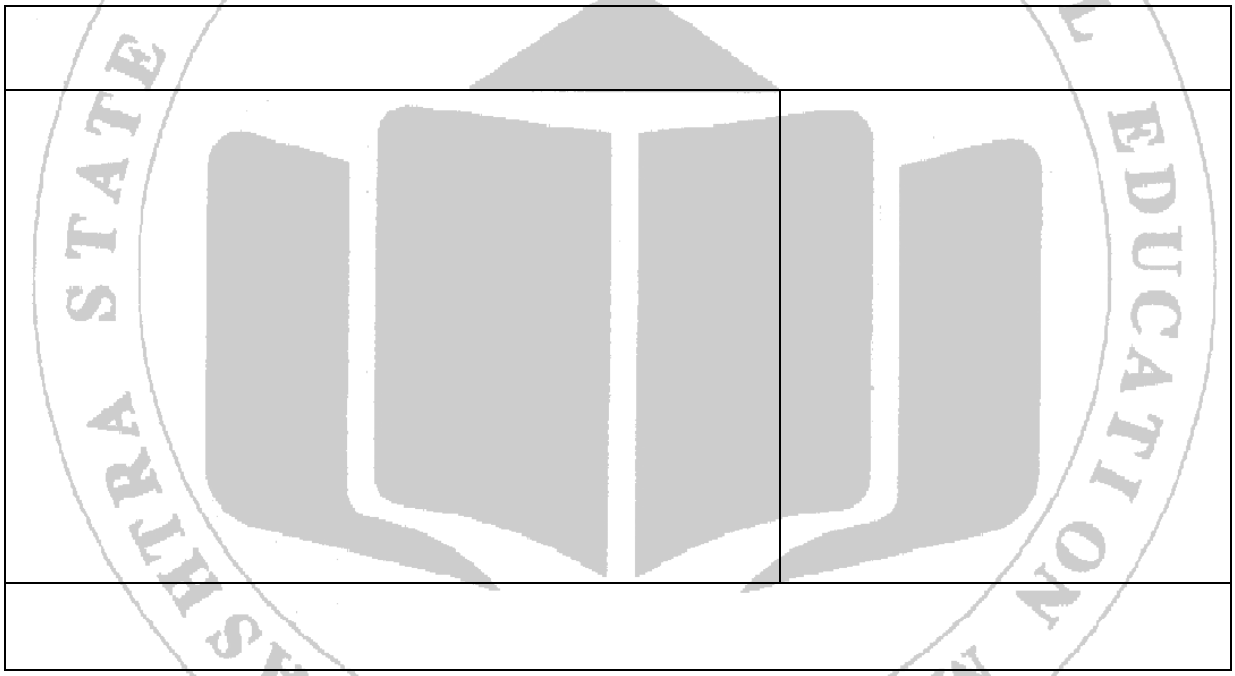
9. Use of Preparation: As an emollient and ointment base

10. Direction: As directed by the physician.

11. Instructions: For external use only.

12. Storage
Store in a well-closed container away from light.

13. Label



14. Evaluation Table

Name of preparation	Test	Specification	Observation
Simple ointment IP	Description	Smooth ointment	
	Colour	White or yellow	
	Odour	Odourless	
	Consistency	Semisolid	
	Spreadability	Spreads easily	
	Weight	20 gm	

15. Result

_____ml of Simple ointment IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia 1966.
b. Laboratory Manual of Pharmaceutics-II, published by Maharashtra State Board of Technical Education, Mumbai.

18. Practical Related Questions

a. Define ointments.
b. Give the classification of ointments.
c. Classify ointment bases with one example of each class.
d. Enlist the factors which govern the selection of an ideal base for ointments.
e. Enlist the methods used for the preparation of ointments.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 12

Preparation and Evaluation of Sulphur Ointment IP

1. Aim

To prepare, evaluate and submit 10 gm of Sulphur Ointment I.P.

2. Practical Significance

Sulphur ointment I.P. is used to treat acne, scabies and seborrheic dermatitis. Through this experiment, students will learn about the composition, method of preparation, labelling aspects, storage, use, direction and evaluation of Sulphur ointment I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Sulphur ointment I.P.	CO1-4	BTL3
2	Prepare and evaluate Sulphur ointment I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Sulphur is used for several skin conditions and available in the form of ointment, cream and lotion. Sulphur has antiseptic, parasitic cand scabicide activity and is used in treatment of scabies and acne. Finely divided precipitated sulphur is amorphous in nature and forms a smooth ointment as compared to sublimed one.

Sulphur ointments are intended to treat wide variety of skin conditions like acne, eczema, dermatitis, blackheads, blemishes and rosacea. Sulphur ointment kills the invasive mite and eliminates skin irritation & soreness owing to scabies. The concentrations of sulphur in the ointment may vary from 0.5 to 10% depending on the product and its application.

5. Requirements

a. Apparatus: Spatula and ointment slab.
b. Equipment: Calibrated weighing balance.
c. Chemicals: Simple ointment I.P. and sulphur.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Sulphur	100 gm		
2	Simple ointment I P.	900 gm		

8. Procedure

a. Weigh the required quantity of sulphur (sieved through sieve No 85) and simple ointment accurately.
b. Place sulphur on one part of the clean ointment slab and simple ointment on the other part of the ointment slab.
c. Take a small quantity of sulphur and levigate with about three times its weight of simple ointment at the centre of the ointment slab using an ointment spatula until sulphur is mixed (geometric mixing) thoroughly.
d. Continue this process until all quantity of sulphur is mixed with simple ointment so as to get homogenous and smooth ointment.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer required quantity of sulphur ointment in a wide mouth light resistant container or collapsible tube, attach a label and submit.

9. Use of Preparation:

Treatment of acne, scabies and seborrheic dermatitis.

10. Direction:

Apply on the affected area as directed by the physician.

11. Instruction

For external use only.

12. Storage:

Store in a cool place and protect from light.

13. Label

14. Evaluation Table

Name of preparation	Test	Specification	Observation
Sulphur Ointment IP	Texture	Smooth	
	Colour	Light yellow	
	Consistency	Semisolid	
	Grittiness	Free from grittiness	
	Spreadability	Easily spreads	
	Weight	20 gm	

15. Result

_____ml of Sulphur ointment IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia 1966.

18. Practical Related Questions

a. Describe levigation method for preparation of ointments.
b. Which type of sulphur is used in this experiment and why?
c. What is geometric mixing?
d. Which ointment base is used to prepare sulphur ointment I.P.?
e. Name the excipients used in the preparation of ointments with examples.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO CREAMS

Creams

Creams are homogenous, semisolid or viscous emulsion preparations that are intended for application to the skin or mucous membranes for protective, therapeutic and prophylactic purposes. Creams are less greasy and easier to apply as compared to ointments.

Classification of creams

A. **Oily creams (w/o emulsions)**

These are hydrophobic w/o emulsions that are usually anhydrous and absorb only small amounts of water. They contain w/o emulsifying agents such as wool fat, sorbitan esters, and monoglycerides.
Example: Fluocinolone acetonide cream, Cold cream.

B. **Aqueous creams (o/w emulsions)**

These are hydrophilic o/w emulsions that contain water miscible bases. They contain o/w emulsifying agents such as sodium or triethanolamine soaps, sulphated fatty alcohols, and polysorbates combined, if necessary, with w/o emulsifying agents.
Examples: Moisturizing cream, Vanishing cream.

Advantages of Creams:

- Creams are used to deliver drugs that exhibit a low aqueous solubility.
- They provide prolonged contact at their site of application.
- Creams are simple to apply as they spread more easily.
- Creams are usually non-irritating when applied to the skin.
- Creams are water washable, less greasy and easy to wipe away.

Disadvantages of Creams:

- Pharmaceutical creams being emulsions are thermodynamically unstable.
- They are less hydrophobic, so risk of contamination is high.
- Some of the creams can cause irritation on exposure to sunlight.
- Application of exact quantity of creams is difficult.

Uses of creams:

- Helps to protect the skin.
- Act as sunscreens.
- Helps in moisturizing the skin.
- Gives cleansing and emollient effect
- Acts as a vehicle for drug substances such as local anaesthetics, anti-inflammatory agents,
- hormones, antibiotics, antifungals or counter-irritants.

Formulation of creams: Following additives are used in the formulation of creams -

- **Vehicles**: Very commonly used aqueous vehicle is water.
- **Bases**: These act as a medium for incorporating the active medicaments. e.g. Oils, fats, waxes like liquid paraffin, lanolin, etc.
- **Emollients**: These help to soften or soothe the skin. e.g. Lanolin, mineral oil.
- **Preservatives**: These are added to prevent the microbial degradation of the product. e.g. Methylparaben, propyl paraben.

- **Antioxidants**: These are added to prevent the oxidative degradation of the preparation. e.g. Sodium metabisulphite.
- **Humectants**: These help to retain the moisture in the preparation and prevent drying out.e.g. Glycerin, propylene glycol.
- **Colouring agents**: To give a pleasing appearance. e.g. Saffron, indigo, etc.

Storage:

Store at temperatures below 25°C unless otherwise directed. Do not freeze.

Labelling:

For external use only.

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Experiment No. 13

Preparation and Evaluation of Cetrimide Cream BP

1. Aim

To prepare, evaluate and submit 20 gm of Cetrimide Cream B.P.

2. Practical Significance

Cetrimide is an antimicrobial surfactant and is particularly beneficial for treating minor burns. It helps to soothe the affected area, reduce pain, and prevent infection, promoting faster healing. Through the experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction and labelling requirements.

3. Practical Outcomes (PrOs)

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Cetrimide cream B.P.	CO1-4	BTL3
2	Prepare and evaluate Cetrimide cream B P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Cetrimide is a cationic hydrophilic surfactant; chemically it is a quaternary ammonium compound. It is used as an antiseptic in the treatment of superficial wounds, burns and minor skin infections. Cetostearyl alcohol is a non-ionic hydrophobic surfactant which acts as an emulsifying agent. It increases viscosity of the preparation. Liquid paraffin helps to increase emollient properties. Purified water acts as a vehicle.

5. Requirements

a. **Apparatus**: 100 ml beaker, glass rod, spatula, porcelain dish and water bath.
b. **Equipment:** Calibrated weighing balance.
c. **Chemicals:** Cetrimide, cetostearyl alcohol, liquid paraffin and purified water.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Cetrimide	0.5 gm		
2	Cetostearyl alcohol	5.0 gm		
3	Liquid paraffin	50 gm		
4	Purified water (q.s.)	100 gm		

8. Procedure

a. Dissolve cetrimide in freshly boiled and cooled water (aqueous phase).
b. Dissolve the cetostearyl alcohol in the liquid paraffin with the aid of gentle heat in a porcelain dish (oily phase) on a water bath.
c. Add the warm aqueous phase to the warm oily phase and stir until cold. The cream can be homogenized in a mortar.
d. Fill the cream in a suitable wide mouth container taking precautions not to touch the sides.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer into a well-closed container, tap the bottle lightly to form a uniform layer at the bottom, attach a label and submit.

9. Use of Preparation:

As an antiseptic.

10. Direction:

Use as directed.

11. Instructions:

For external use only.

12. Storage:

Store in a well-closed container in a cool place.

13. Label:

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Cetrimide Cream BP	Description	White cream	
	Odour	Odourless	
	Consistency	Semisolid	
	Grittiness	Free from grittiness	
	Spreadability	Easily spreadable	
	Weight	20 gm	

15. Result

_____ml of Cetrimide Cream BP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. Reference:

a. British Pharmacopoeia 2004.

18. Practical Related Questions

a. Define and classify creams.
b. Write any four uses of creams.
c. Write advantages and disadvantages of creams.
d. Describe the formulation of creams.
e. What is the use of Cetrimide cream B.P.?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO GELS

Gels:

Gels are homogenous, clear, translucent semisolid preparations that are applied externally to the skin or mucous membrane.

Classification of gels

- **Hydrophilic gel:** This consists of water, glycerol, or propylene glycol with suitable gelling agents such as tragacanth, starch, cellulose polymers, etc. Example: Active gel™
- **Non-aqueous gel:** This exhibits physical cross-linked three-dimensional gel networks with suitable mechanical characteristics for use as a vehicle for topical drug delivery. e.g. Diclozor gel
- **Organogel**: This is prepared by dissolving/dispersing the organ regulator in hot solvent to produce an organic solution/dispersion which, on cooling, sets to form a gel. e.g. Diltigesicorganogel
- **Xerogel**: It is a gel in which the vehicle is removed leaving a polymer network as film. e.g. Silica xerogel
- **Amphiphilic gel**: This is prepared by mixing the solid gelator like sorbitan monostearate or sorbitan monopalmitate and the liquid sorbitan esters or polysorbate and heating them at 60^0C to form a clear isotropic sol phase and cooling the sol phase to form an opaque semisolid at room temperature. e.g. L-ascorbic acid 20% topical serum gel
- **Supramolecular gel**: This consists of 3-D networks of molecular self-assembly. e.g. Diclofenac gel
- **Hydrogel**: This consists of water and an insoluble hydrophilic polymer. When exposed to water, the dry polymer swells and absorbs liquid to form cross-linked strands either by chemical or by physical forces to immobilize the polymer. e.g. Oxalgin gel

Advantages of gel:

- Gels are easy to formulate as compared to other semisolid dosage forms.
- They have a cooling effect due to solvent evaporation.
- Viscosity of the gel does not change significantly during storage.
- They are elegant and non-greasy.
- They are easy to apply and remove.
- Gels can be applied over the skin for slow and prolonged drug absorption.

Disadvantages of gels

- Not suitable for drugs that are prone to hydrolysis.
- Gels, being aqueous, are prone to microbial growth.
- The formulation ingredients may cause irritation.
- The gelling agents may precipitate and result in salting out.

Formulation of gels: The major components of a gel are:

a. **Drug/s**: Generally local anaesthetics, spermicide, antiseptic, antiallergic, analgesic, anti-inflammatory, antipruritic, etc are formulated as gels.

b. **Solvent/vehicle:** Normally purified water is used as a solvent. Cosolvents like alcohol, glycerol, propylene glycol, PEG 400, etc may be added to enhance the solubility of the drug in the formulation.

c. **Gelling agent:** These are added to convert a liquid phase into a semisolid. Some gelling agents form a cross-linked network whereas others form a gel by physical entanglement or macromolecular chains.

Classification of gelling agents: -

a. **Natural polymers** - Proteins (gelatin, collagen), Polysaccharides (pectin, tragacanth, agar, alginic acid).

b. **Semisynthetic polymers** - Cellulose derivatives such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, carboxymethyl cellulose and hydroxypropyl methyl cellulose.

c. **Synthetic polymers** - Carbomer 934, carbomer 940, polyacrylamide, poloxamer, polyvinyl alcohol, polyethylene and its co-polymers.

d. **Inorganic substances** - Bentonite, aluminum hydroxide.

Additives:

a. **Buffers** - These may be added to aqueous and hydroalcoholic based gels to control the pH of the formulation. e.g. phosphate, citrate, etc.

b. **Humectant** - These are substances that retain water or prevent moisture loss in a product or application site. e.g. glycerin, propylene glycol.

c. **Preservative** - These are added to prevent microbial growth and degradation of formulation ingredients. E.g. methyl paraben, propylparaben, chlorhexidine gluconate.

d. **Antioxidant and chelating agents** - In gels, antioxidants and chelating agents are used to prevent or reduce oxidative degradation of formulation components. e.g. sodium metabisulphite, disodium edetate.

Uses of gels

- Topical drug delivery (medicated).
- Sustained delivery of drug when injected intramuscularly or implanted into the body.
- In cosmetic preparations.
- Lubricant for catheters.
- Bases for patch testing.
- In electrocardiography.
- For dental care.

Storage

Store in a cool place. Do not freeze.

Labelling

- For external use only
- Replace the cap after use

Experiment No. 14

Preparation and Evaluation of Sodium Alginate Gel

1. Aim

To prepare, evaluate and submit 20 gm of Sodium Alginate Gel.

2. Practical Significance

Sodium alginate gel is commonly used in wound dressings due to its ability to absorb exudate (fluid from wounds), in the treatment of burns to soothe pain, and promote the healing. Through this experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction and labelling requirements of sodium alginate gel.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of sodium alginate gel	CO1-4	BTL3
2	Prepare and evaluate sodium alginate gel.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Sodium alginate gel acts as a protective barrier over the wound, soothe pain, and promote healing. It can be used as lubricants for catheters and other medical devices. It can also be used as a vehicle for topical delivery of certain medicaments.

Sodium alginate is a naturally occurring anionic polymer obtained from brown seaweed. It consists of mannuronic (M) and guluronic (G) acids organized in various combinations. Calcium gluconate acts as a gelling agent. Calcium ions from calcium gluconate cross-link the guluronic acids from alginate polymer chains through ionic bonds, forming a three-dimensional gel network. As the cross-linking reaction progresses, the alginate solution undergoes a phase transition from a liquid to a gel. Glycerin acts as a dispersing agent which is mixed with sodium alginate to prevent lump formation. As sodium alginate is susceptible to microbial growth, methyl hydroxy benzoate is added as a preservative.

5. Requirements

a. **Apparatus**: Beakers, measuring cylinder (50 ml.), spatula, pipette, water bath and glass rod.

b. **Equipment:** Calibrated weighing balance.

c. **Chemicals:** Sodium alginate, glycerol, methyl hydroxybenzoate, calcium gluconate.

6. Factor Calculation

Factor = Required Quantity/ Given Quantity =

7. Formulation Table

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1	Sodium alginate	10 gm		
2	Glycerol	10 gm		
3	Methyl hydroxybenzoate	0.2 gm		
4	Calcium gluconate	0.5 gm		
5	Purified water (q.s.)	100 ml		

8. Procedure

a. Wet the sodium alginate with the glycerol in a glass beaker.
b. Dissolve the preservative and calcium gluconate in about 80% of water with the aid of heat. Cool to about 60°C and stir rapidly with a high-speed stirrer.
c. Add sodium alginate-glycerol mixture to the vortex in small amounts and continue stirring until the dispersion is homogeneous.
d. Evaluate formulation as per evaluation parameters and write the observations.
e. Pack in a well-closed container, attach a label and submit.

9. Use of Preparation: As a protective, absorbent, lubricant and dermatological vehicle.

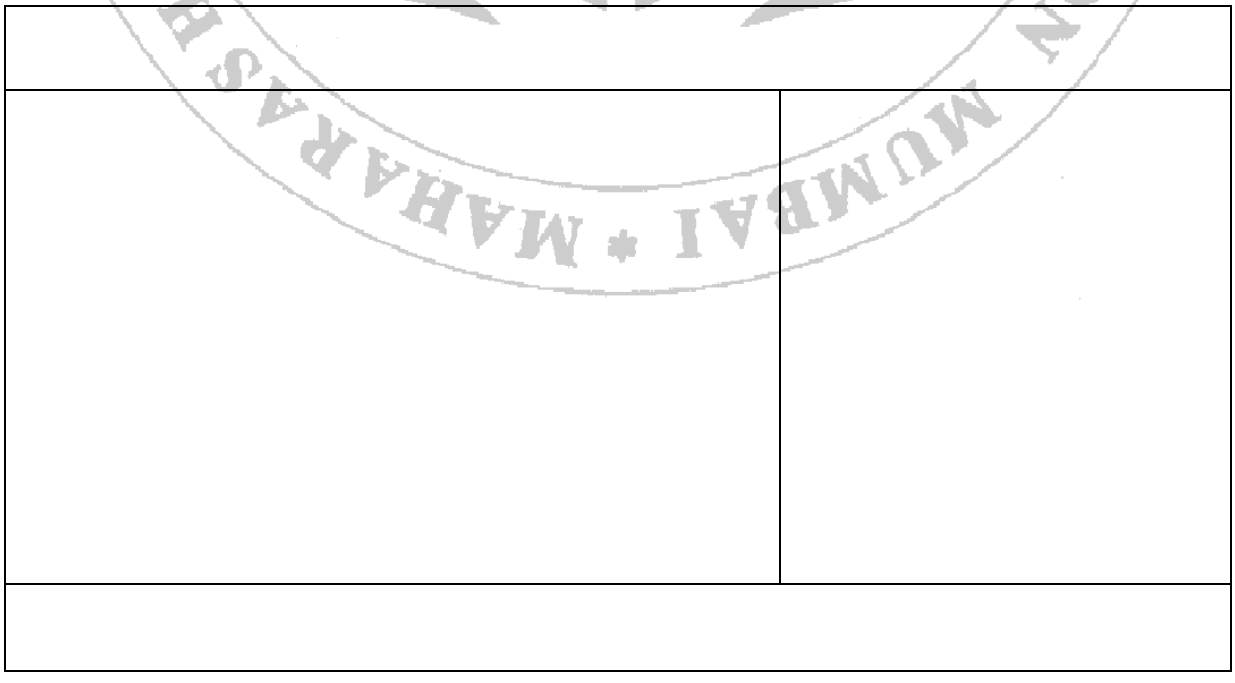
10. Instructions:

a. For external use only
b. Replace the cap after use

11. Storage:

Store in a cool place. Do not freeze.

12. Label:



13. Evaluation Table:

Name of preparation	Test	Specification	Observation
Sodium alginate gel	Description	Clear gel	
	Odour	Odourless	
	Consistency	Semisolid	
	Grittiness	Free from grittiness	
	Texture /Spreadability	Smooth/ Easily spreadable	
	Weight	20 gm	

14. Result

_____ml of Sodium alginate gel is prepared, evaluated and submitted in a _____ container with special instructions as_____.

15. Conclusion

_____

_____

16. References

a. Ansel H.C., Pharmaceutical Dosage Forms and Drug Delivery, 10th edition, Lippincott Williams & Wilkins.
b. Laboratory Manual of Pharmaceutics-II, published by Maharashtra State Board of Technical Education, Mumbai.

17. Practical Related Questions

a. What are gels?
b. Give four examples of natural gelling agents.
c. What is the role of calcium gluconate in the formation of sodium alginate gel?
d. Classify gels.
e. What is the use of sodium alginate gel?

(Space for Answers)

18. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO LINIMENTS

Liniments

Liniments are topical semi liquid preparations intended for application to the skin with rubbing onto the affected area. They are not to be applied to broken skin as they can cause skin irritation. The oil or soap base provides ease of application and massage. They produce a feeling of warmth in the area where they are applied and act as rubefacients and counter-irritants.

Classification of liniments:

A. Based on the nature of dispersion medium:

a. **Oil-based liniments** - These contain fatty oils (sunflower, linseed, castor oil) or fat-like substances (lanolin) as dispersion medium.
b. **Alcohol-based liniments** - These contain alcohol as well as various medicinal substances.
c. **Soap-based liniments** - These contain alcoholic solutions of soap as a dispersion medium.

B. Based on therapeutic category:

a. **Antipruritic liniments** - used to relieve itching. e.g. Sanhuang liniment.
b. **Astringent liniments** - Cause tissues to contract and protect them. e.g. Kloss liniment.
c. **Emollient liniments** - Used to soften skin or treat dry skin. e.g. Bast liniment.
d. **Rubefacient liniments** - Cause redness to the skin. e.g. Capsicum liniment.
e. **Analgesic liniments** - Used for muscle pain or for arthritis pain. e.g. Sloan's liniment Camphor liniment.
f. **Counter-irritant liniments** - These liniments contain agents applied locally to produce superficial irritation to reduce pain and inflammation in deeper skin. e.g. Methyl salicylate liniment.
g. **Anti-inflammatory liniments** - Reduces inflammation or swelling. e.g. Dhanwantharam liniment
h. **Fungicidal liniments** - These contain drugs to destroy fungi and inhibit their growth.e.g. Toenail fungus liniment, Himalaya Rumalaya liniment.

Advantages of liniments:

- Liniments are well absorbed through the skin and show high bioavailability.
- Evaporation of alcoholic solvent from liniments provides a cooling effect.
- They are usually non-staining.
- They are less viscous as compared to ointments and gels.

Disadvantages of liniments:

- Liniments cannot be applied on broken skin.
- To become effective, liniments need to be applied with friction by rubbing.
- They have to be stored in coloured fluted bottles.
- Avoid exposure to the eyes while applying liniments.

Storage:

The liniments should be packaged in tightly closed coloured fluted bottles or amber coloured bottles. They should be stored in cool and dry place away from sunlight. They should be stored away from children.

Labelling:

- For external use only
- Shake well before use.
- Not to be applied to open wounds or broken skin.

Experiment No. 15

Preparation and Evaluation of Turpentine Liniment IP

1. Aim

To prepare, evaluate and submit 20 ml of Turpentine liniment IP.

2. Practical Significance

Turpentine liniment I.P. has been traditionally used topically for its analgesic properties to treat the inflammatory pain caused by rheumatoid arthritis and osteoarthritis. Through this experiment, the students will be able to learn about the composition, preparation, evaluation, storage, use, direction and labelling requirements of Turpentine liniment I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Turpentine liniment I.P.	CO1-4	BTL3
2	Prepare and evaluate Turpentine liniment I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Turpentine liniment helps in reducing the pain and swelling due to muscle strains, sprains, and backache. Turpentine oil (turpentine spirit, or wood turpentine) is a liquid derived by distilling resin from certain pine trees. It acts as a rubefacient and counter-irritant in this preparation. Camphor acts as a rubefacient and moderate analgesic. It is an o/w emulsion where turpentine oil is dispersed in purified water. Soft soap is used as an emulsifying agent because turpentine oil lacks the free fatty acids that react with alkali to form soap, Camphor is not water soluble, however, it is soluble in turpentine oil, and therefore it is solubilized in turpentine oil before adding the oily phase to the aqueous phase.

5. Requirements

i. **Apparatus**: Mortar and pestle, measuring cylinder (50 ml.), pipette, and beaker

j. **Equipment:** Calibrated weighing balance.

k. **Chemicals:** Soft soap, camphor, turpentine oil.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Soft soap	90 gm		
2.	Camphor	50 gm		
3.	Turpentine oil	690 ml		
4.	Purified water (q.s.)	1000 ml		

8. Procedure

a. Weigh the required quantity of camphor and dissolve in a measured quantity of turpentine oil in a beaker.
b. Mix the required quantity of soft soap in mortar with purified water and triturate to form a soapy solution.
c. To the soap solution, add camphor-turpentine oil solution drop wise with trituration until a thick emulsion is formed.
d. Then add a little purified water and transfer contents to the measuring cylinder and make up the volume using purified water.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer the liniment into a narrow mouth, tightly closed amber glass bottle, attach the label and submit.

9. Use of Preparation: As a counter irritant and rubefacient.

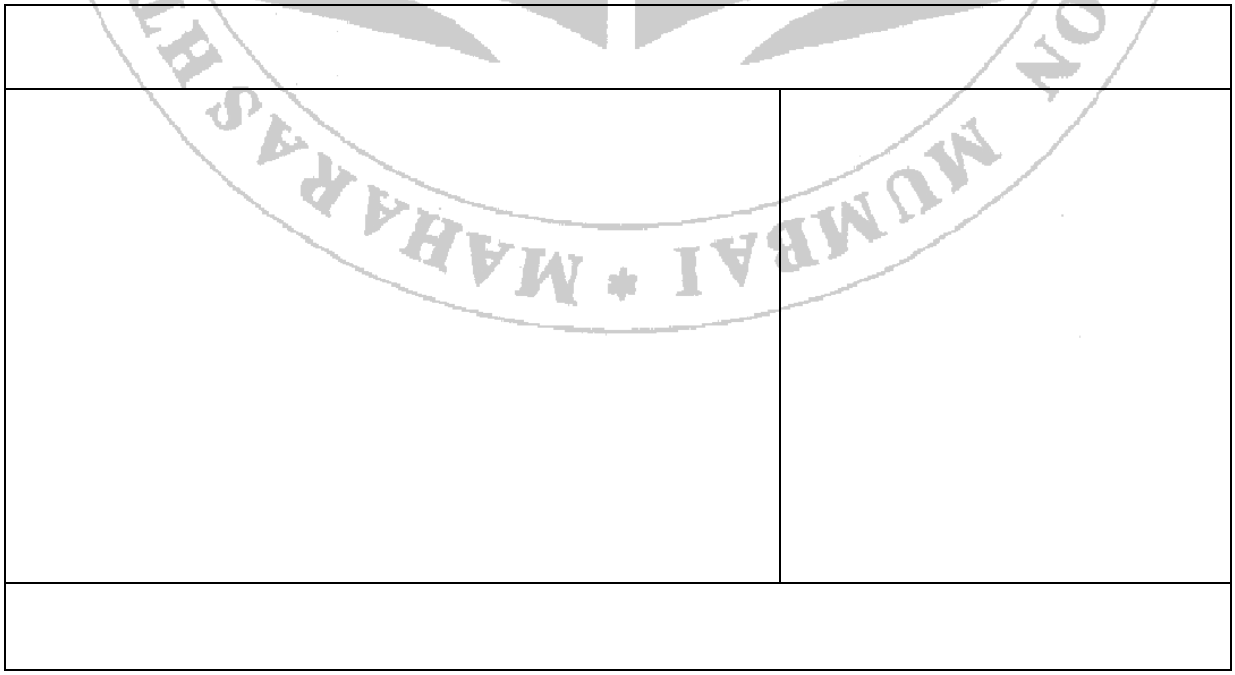
10. Direction: To be rubbed on the affected parts of the body as directed by the physician.

11. Instructions:

- For external use only.
- Shake well before use.
- Not to be applied to open wounds or broken skin.

12. Storage: Store in an airtight container in a cool and dry place away from light.

13. Label:



14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Turpentine Liniment IP	Description	Semi-liquid	
	Colour	White	
	Odour	Pleasant	
	Volume	20 ml	

15. Result

_____ml of Turpentine Liniment IP is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Laboratory Manual of Pharmaceutics-II, published by Maharashtra State Board of Technical Education, Mumbai.
b. Indian Pharmacopoeia 1966.

18. Practical Related Questions

a. What are liniments?
b. What is the composition of soft soap?
c. Define rubefacient and counter-irritant.
d. What are the special labeling instructions written on the label of liniments?
e. What is the role of soft soap in Turpentine liniment I.P.?

(Space for Answers)

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19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 16

Preparation and Evaluation of White Liniment BP

1. Aim

To prepare, evaluate and submit 20 ml of White liniment B.P

2. Practical Significance

White liniment B.P. is often used as a topical analgesic to alleviate minor aches and pains, such as those caused by muscle strains, sprains, or arthritis. It can provide a warming or cooling sensation when applied to the skin, which may help soothe discomfort. Through this experiment, the students will be able to learn about the composition, preparation, evaluation, storage, use, direction, labelling requirements of White liniment B.P

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of White liniment B.P.	CO1-4	BTL3
2	Prepare and evaluate White liniment B.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

White liniment is an emulsion which contains 25% turpentine oil by volume. Turpentine oil acts as a rubefacient and counter irritant. The w/o emulsions have poor physical stability. Their stability can be improved by phase inversion technique. Dilute ammonia solution and oleic acid react to form a monovalent soap (ammonium oleate) that is ionizable. The hydrophilic property of monovalent soap leads to the formation of o/w emulsion. Addition of ammonium chloride increases the rate of forward reaction and minimizes the ionization due to the common ion effect. As a result, non-ionizable soap precipitates out in excess, making the surfactant-oil interface more lipophilic and resulting in phase inversion i.e., formation of w/o emulsion.

$R\text{-}COOH + NH_4 \rightarrow R\text{-}COONH_4$ (Ionizable o/w emulsion)

$R\text{-}COOH + NH_4 \rightarrow R\text{-}COONH_4$ (Excess Ionizable w/o emulsion)

5. Requirements

f. **Apparatus**: Measuring cylinder (50 ml.), pipette, beakers and bottle.
g. **Equipment:** Calibrated weighing balance.
h. **Chemicals:** Ammonium chloride, dilute ammonia solution, oleic acid, turpentine oil.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Ammonium chloride	12.5 ml		
2.	Dilute ammonia solution	45 ml		
3.	Oleic acid	85 ml		
4.	Turpentine oil	250 ml		
5.	Purified water (q.s.)	1000 ml		

8. Procedure

a. Mix oleic acid with a measured quantity of turpentine oil in a tared bottle.
b. Mix dilute ammonia solution with equal volume of previously warmed water (50°C).
c. Add the diluted ammonia solution into the bottle and shake it to produce a milky white emulsion.
d. Dissolve ammonium chloride in the remaining amount of water.
e. Add this solution drop by drop in the emulsion and shake after each addition.
f. Adjust the final volume.
g. Evaluate formulation as per evaluation parameters and write the observations.
h. Transfer the liniment into a narrow mouth, tightly closed amber glass bottle, attach the label and submit.

9. Use of Preparation: As a counter irritant and rubefacient

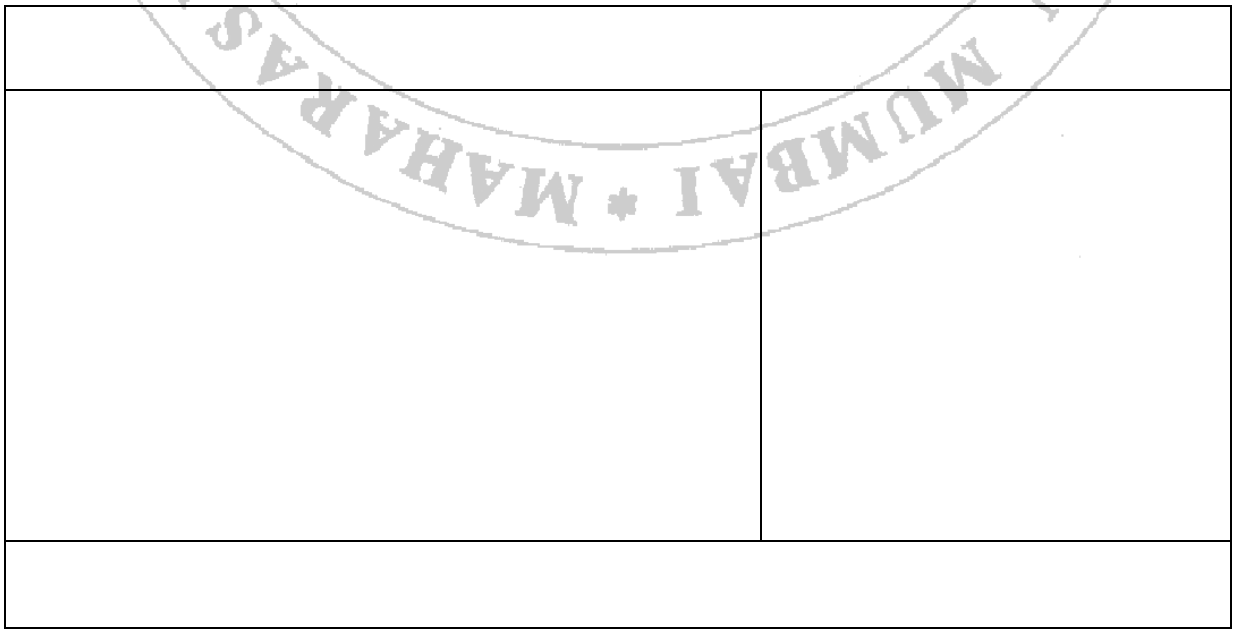
10. Direction: To be rubbed on the affected parts of the body as directed by the physician.

11. Instructions:

- For external use only
- Shake well before use
- Not to be applied to open wounds or broken skin.

12. Storage: Store in a well closed container, in a cool place away from light.

13. Label:



14. Evaluation Table:

Name of preparation	Test	Specification	Observation
White liniment B.P	Description	Semi-liquid	
	Colour	White	
	Odour	Pleasant	
	Volume	20 ml	

15. Result

_____ml of White liniment B.P is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. British Pharmacopoeia 1973.
b. Laboratory Manual of Pharmaceutics-II, published by Maharashtra State Board of Technical Education, Mumbai.

18. Practical Related Questions

a. What is the role of oleic acid and ammonia solution in White liniment B.P.?
b. Write the differences between Turpentine liniment I.P. and White liniment B.P.
c. How does the phase inversion take place in this liniment?
d. What is the use of White liniment B.P.?
e. Differentiate between lotions and liniments.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO DRY POWDERS

Powders:

Powders are solid dosage forms which contain a mixture of finely divided drug(s) and excipients in a dry form meant for internal or external use. Finely divided powders are obtained by unit processes like milling, crushing, grinding with the help of different equipment such as hammer mill, ball mill, etc.

Classification of powders:

A. Oral powders in unit dose sachets e.g. Electoral powder sachet (ORS).
B. Bulk powders for oral administration e.g.Triphala powder (Laxative).
C. Topical powders:
    a. Dusting powders: e.g. Candid dusting powder (antifungal).
    b. Insufflations: e.g Steroids (local effect) and anti-asthma drugs.
D. Effervescent powders e.g Eno effervescent powder (antacid).
E. Powders for oral solution or suspension e.g., Augmentin powder, cholestyramine powder for suspension (for reduction of elevated LDL).

Advantages:

- They are more stable than liquid dosage forms.
- Powders are suitable to administer drugs having higher doses. e.g. the dose of methylcellulose oral powder as laxative is 1g to 4g.
- Rapid dissolution of powder facilitates rapid absorption.
- Manufacturing of powder is simple and economic; hence product cost is quite low.
- Powders can be used internally as well as externally.
- They are easier to carry than liquid dosage forms.

Disadvantages:

- Bulk powders are not suitable for the administration of potent drugs with low dose.
- The masking of unpleasant taste may be a problem with powders.
- Powders are not a suitable form for administration of drugs that are unstable in or cause damage to the stomach.
- Volatile, deliquescent or hygroscopic drugs are difficult to dispense in powder form.
- Powders are bulky and inconvenient to carry.

Mixing of powders

Mixing of powders is usually done by various methods like spatulation, trituration, geometric dilution, sifting and tumbling.

Granules and effervescent granules

Granules are solid dosage forms composed of dry aggregates of powder particles that may contain one or more drug substances with or without excipients. They are intended to be swallowed or dissolved in liquid prior to administration.

Effervescent powders/granules are solid dosage forms of medicament which produce effervescence in presence of water and are meant for internal use. They contain drug/drugs mixed with citric acid, tartaric acid and sodium bicarbonate. Saccharin may be added as a sweetening agent. Before administration, the desired quantity of the powder/granules is dissolved in water. In the presence of water, the acid and bicarbonate react together producing effervescence. The released CO_2 masks undesirable taste of drugs. Effervescent granules are prepared by heat method or wet method.

Storage: Store in a tightly closed container in a dry place.

Labelling: Not to be swallowed directly

Experiment No. 17

Preparation and Evaluation of Sodium phosphate Effervescent Granules USP

1. Aim

To prepare, evaluate and submit 20 gm of Sodium phosphate effervescent granules U.S.P.

2. Practical Significance

Sodium phosphate effervescent granules USP is used to relieve occasional constipation. Through this experiment the students will be able to learn about the composition, preparation, evaluation, storage, use, direction, labelling requirements of Sodium phosphate effervescent granules U.S.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Sodium phosphate effervescent granules U.S.P.	CO1-4	BTL3
2	Prepare and evaluate Sodium phosphate effervescent granules U.S.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Sodium phosphate is employed as a cathartic/ purgative which promotes bowel movement in constipation. The unpleasant saline taste of sodium phosphate is masked by the effervescence produced by sodium bicarbonate, citric acid, and tartaric acid when they come into contact with water. The combination of citric and tartaric acid produces good granules. When tartaric acid is used alone, the resulting granules lose their hardness rapidly due to which they break and become powder. Similarly, citric acid alone produces a sticky mass which is difficult to granulate.

In this experiment, the effervescent granules are prepared by dry/fusion method where the granules are prepared by the one molecule of water of crystallization liberated by citric acid during heating.

Chemical reactions:

$$3NaHCO_3 + C_6H_8O_7.H_2O \rightarrow C_6H_5NaO_7 + 3CO_2 + 3H_2O$$

$$2NaHCO_3 + C_4H_6O_6 \rightarrow C_4H_4NaO_6 + 2CO_2 + 2H_2O$$

5. Requirements

a. **Apparatus**: Mortar and pestle, spatula, porcelain dish and sieves.
b. **Equipment:** Calibrated weighing balance.
c. **Chemicals:** Sodium phosphate, sodium bicarbonate, citric acid and tartaric acid.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Sodium phosphate	200 gm		
2.	Sodium bicarbonate	477 gm		
3.	Citric acid	162 gm		
4.	Tartaric acid	252 gm		
Note: To compensate the loss of material due to liberated carbon dioxide and evaporated water of crystallization, the total weight of powder material is to be taken 1091 gm instead of 1000 gm. Weight of powder to be taken 21.82 gm instead of 20 gm for compensating the loss)				

8. Procedure

a. Weigh all ingredients accurately and mix in ascending order of their weights by trituration.
b. Place a porcelain dish in a boiling water bath.
c. Then place the powder mixture in the hot porcelain dish and mix it thoroughly to form a damp mass of powder.
d. Pass this coherent mass of powder through sieve no 08 superimposed on sieve 20. The fines will be below the sieve no 20.
e. Collect the uniform wet granules retained on sieve 20, spread on a butter paper and dry at a temperature not exceeding 60°C.
f. Evaluate formulation as per evaluation parameters and note the observations.
g. Fill dry granules in an airtight wide mouth container, attach a label and submit.

9. Use of Preparation: As a Cathartic

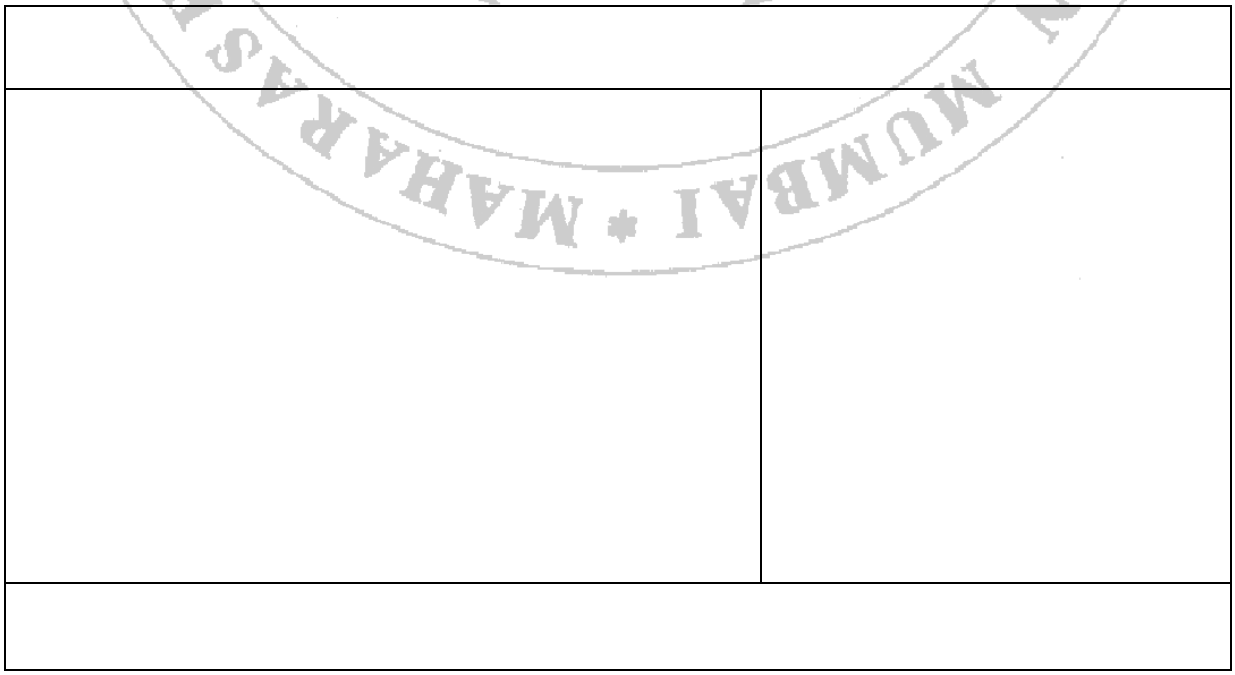
10. Direction: As directed by the physician

11. Instructions: Drink the solution with effervescence.

12. Storage: Store in an airtight container at a dry place.

13. Dose: One or two teaspoonfuls of granules in water.

14. Label:



15. Evaluation Table:

Name of preparation	Test	Specification	Observation
Sodium phosphate effervescent granules U.S.P.	Description	Granules	
	Colour	White	
	Odour	Odourless	
	Check effervescence	Effervescent	
	Weight	20 gm	

16. Result

_____ml of White liniment B.P is prepared, evaluated and submitted in a _____ container with special instructions as_____.

17. Conclusion

_____

_____

18. References

a. United State Pharmacopoeia 2024.

19. Practical Related Questions

a. What are effervescent granules?
b. How citric acid and tartaric acid react with sodium bicarbonate to produce effervescence?
c. What would happen if tartaric acid is used alone in the preparation of effervescent granules?
d. Describe the fusion method to prepare effervescent granules.
e. Why is sodium phosphate formulated as effervescent granules?

(Space for Answers)

20. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 18

Preparation and Evaluation of Zinc Oxide Salicylic Acid Dusting Powder

1. Aim

To prepare, evaluate and submit 10 gm of Zinc Oxide-Salicylic acid Dusting Powder.

2. Practical Significance

Zinc Oxide-Salicylic Acid Dusting Powder is used in the treatment of minor non-weeping wounds. Both zinc oxide and salicylic acid exhibit anti-inflammatory properties, making the dusting powder effective in soothing irritated skin and reducing redness and swelling associated with various dermatological conditions like eczema or psoriasis. Through this experiment, the students will be able to learn the composition, preparation, evaluation, storage, use, direction and labelling requirements of Zinc Oxide-Salicylic acid Dusting Powder.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Zinc Oxide-Salicylic acid Dusting Powder	CO1-4	BTL3
2	Prepare and evaluate Zinc Oxide-Salicylic acid Dusting Powder	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Dusting powders are bulk powders that are used externally for local applications and are not intended to have a systemic effect. They are very fine free flowing powders containing antiseptics, antipruritic, astringents, antiperspirants, absorbents, lubricants, etc. Two types of dusting powders are Surgical dusting powder &Medical dusting powder.

Medical dusting powder is used for superficial skin problems whereas surgical dusting powder is used in body cavities and on serious wounds, burns and umbilical cords of neonates. Medical dusting powders must be free of pathogens, whereas surgical dusting powders must be sterilized before use.

The majority of dusting powders contain starch, talc or kaolin. As these substances can be infected with harmful germs, they must be sterilized using the dry heat method (at 160°C for 2 hours).
Sifter-top containers or aerosol containers are used to dispense the dusting powders. Powder puffs or sterile gauze pads can also be used to apply dusting powders.

Zinc oxide-Salicylic acid dusting powder is a medical dusting powder. This powder contains zinc oxide, which acts as an astringent, and salicylic acid, which acts as a local antiseptic. Starch is used as absorbent. As small particles are less likely to irritate the affected area, the dusting powder is sieved through sieve 80.

5. Requirements

a. **Apparatus**: Sieve (80#), mortar and pestle
b. **Equipment:** Calibrated weighing balance.
c. **Chemicals:** Zinc oxide, salicylic acid and starch powder.

6. Factor Calculation

Factor = Required Quantity/ Given Quantity =

7. Formulation Table

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Zinc oxide	20 gm		
2.	Salicylic acid	2 gm		
3.	Starch powder	78 gm		

8. Procedure

a. Weigh all the ingredients accurately.
b. Mix salicylic acid with zinc oxide followed by starch powder by light trituration in mortar.
c. Then pass the powder mixture through sieve 80.
d. Sterilize in a hot air oven at 160°C for two hours.
e. Evaluate formulation as per evaluation parameters and note the observations.
f. Transfer into the wide mouth container, attach the label, and submit.

9. Use of Preparation: As an astringent and local antiseptic

10. Direction:

Use as directed.

11. Storage:

Store in a well closed container.

12. Instruction:

FOR EXTERNAL USE ONLY

13. Label:

<table>
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<tr><td colspan="2"></td></tr>
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14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Zinc Oxide-Salicylic acid Dusting Powder	Description	Fine powder	
	Colour	White	
	Grittiness	No Grittiness	
	Weight	10 gm	

15. Result

_____ml of White liniment B.P is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Laboratory Manual of Pharmaceutics-II, published by Maharashtra State Board of Technical Education, Mumbai.
b. Ansel H.C., Pharmaceutical Dosage Forms and Drug Delivery, 10th edition, Lippincott Williams & Wilkins.

18. Practical Related Questions

a. What are dusting powders? Mention their types.
b. What types of containers are used for storage of dusting powders?
c. What is the use of starch powder?
d. What is the use of zinc oxide salicylic acid dusting powder?
e. How are dusting powders sterilized?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

INTRODUCTION TO INJECTABLES/PARENTERAL

Parenteral/injectable dosage forms are sterile products intended for administration by injection, infusion or implantation into the body. These are administered by injection under or through one or more layers of the skin or mucous membrane

Advantages:

- Quick onset of action.
- The drug which cannot be administered by oral route, can be administered by this route.
- It can be administered to unconscious patients.
- Drug action can be prolonged by modifying the formulation.
- Transfusion fluids containing nutritive like glucose electrolytes such as sodium chloride can be given by this route.

Disadvantages:

- Injection causes pain at the site of injection.
- The trained persons are required to administer.
- The administration of drugs through the wrong route of injection may prove to be fatal.
- It is difficult to save a patient when an overdose is given.
- There are chances of sensitivity reaction or allergic reaction.

Parenteral/Injectable dosage form must possess the following characteristics:

- Injectable products must be sterile.
- Injectable products must be free from pyrogenic (endotoxin) contamination.
- Injectable solutions must be free from visible particulate matter.
- Injectable products should be isotonic.
- Injectable products must be stable.
- Injectable products must be neutral in pH.

Types of Parenteral/Injectable:

- Solutions
- Sterile solids
- Sterile suspensions
- Emulsion
- Transfusion fluids
- Implants
- Types of parenteral based on volume:
    a. Small volume: 100 ml or less
    b. Large volume: single dose and more than 100 ml

Formulation of Parenteral/Injectable

- **Vehicles**:
    - Aqueous vehicles: Water for injection, Sterile water for injection, Bacteriostatic water for injection.
    - Water miscible vehicles: Polyethylene glycol, Ethyl alcohol, Propylene glycol, Glycerin.
    - Non-aqueous vehicles: Fixed oils (Corn oil, cotton seed oil, sesame oil), Ethyl oleate.

- Additives:
    - **Antibacterial Agent**: Benzalkonium chloride (0.01%), Phenol (0.5%), Cresol (0.3%) Phenyl mercuric acid (0.002%) Benzyl alcohol (1%), Chlorobutanol (0.5%) & Chlorocresol (0.2%).
    - **Antioxidant Agents**: Thiourea, ascorbic acid (0.1%), sodium bisulfite (0.15%), sodium metabisulfite (0.15%).
    - **Buffer**: Acetic acid (0.22%), citric acid (0.5%) lactic acid (0.1%), potassium phosphate (0.1%), sodium citrate (4.0%).
    - **Tonicity contributors**: Sodium chloride & dextrose are the commonly used tonicity contributors.
    - **Chelating Agent**: Citric acid, calcium edetate and tartaric acid, which chelate the metal ions.
    - **Solubilizing Agents**: Polysorbate 80, Polysorbate 20, alcohol, glycerin etc.
    - **Wetting agent**: Tween 80, sorbitan trioleate.
    - **Suspending agent**: Acacia, Polyvinyl pyrrolidone, etc.
    - **Emulsifying agents**: Lecithin.
    - **Viscosity contributor**: Glycerin.

Containers:

Injections are supplied in single dose containers i.e. ampoules and multiple dose containers i.e. vials. Single dose containers may be useful for all injections preparation, administration at one time with volume 1 ml or more. Multiple dose containers permit the withdrawal of a single dose by sterile syringes without affecting the quality of the remaining solution.

Ideal properties of container:

- It should be sufficiently transparent.
- It should maintain quality and quantity during storage.
- It should be non-permeable and yield no foreign substance into preparation.

Sealing of Ampoules: Ampoules are sealed by melting a portion of the glass neck.

Two types of seals are employed normally:

a. Tip seal (bead seal).
b. Pull seal.

a. Tip seal (bead seal):

Tip seals are made by melting enough glass at the tip of the neck of an ampoule to form a bead and close the opening. These can be done rapidly at a high temperature in gas-oxygen flame. To produce a uniform bead, the ampoule's neck must be heated evenly on all sides by rotating the ampoules in a single flame.

b. Pull seal:

Pull seals are made by heating the neck of the ampoule below the tip, leaving enough of the tip for grasping with forceps or other mechanical devices.

Closures:

- Vials or bottles are fitted with suitable closures, which ensure a good seal, prevent entry of microorganisms and other contaminants and usually permits the withdrawal of a part, or the whole of the content of the container.
- Rubber is the material of choice for closure for multiple dose vials, intravenous fluid bottles.
- Rubber closure permits the introduction of needle from a hypodermic syringe into a multiple dose vial and provides for resealing of the vial after the needle is withdrawn.

- Rubber closure is held in position by an aluminum seal.

Sterilization Process:

Parenteral/ Injectables are sterilized by following process:

- Moist heat sterilization: Autoclaving.
- Dry heat sterilization: Hot air oven.
- Chemical method of sterilization: Using a bactericidal solution or heating with bactericidal solution.
- Filtration method of sterilization: Passing the solution thorough bacteria proof filter. (Membrane filter/sintered glass filter of 0.45 micron).

Quality control test for Parenteral/ Injectables:

- Sterility test
- Clarity test
- Leakage test
- Pyrogen test
- Extractable volume
- Uniformity of content
- Assay

Storage:

Storage in a cool place and dry place.

Labelling: Label of preparation states:

- The name of preparation.
- The percentage of content of a drug of a liquid preparation.
- The amount of active ingredients in a dry preparation (reconstituted).
- The volume of liquid to be added to prepare an injection or suspension from a dry preparation (reconstituted).
- The route of administration.
- A statement of storage condition and expiry date.
- The name and proportions of all substances added to increase stability or usefulness.

Experiment No. 19
Preparation and Evaluation of Sodium Chloride Injection IP

1. Aim

To prepare, evaluate and submit 100 ml Sodium Chloride Injection I.P.

2. Practical Significance

Sodium chloride injection is essential in medical, pharmaceutical, and laboratory settings for various practical applications related to hydration, medication administration, and tissue maintenance. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Sodium Chloride Injection I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Sodium Chloride Injection I.P.	CO1-4	BTL3
2	Prepare and evaluate Sodium Chloride Injection I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

The term parenteral in medical terminology means beyond the intestine (par = beyond, enteral = intestines). Thus, parenteral in medicine means the input of drugs or medications into the human body in a way not involving the intestines or the digestive tract. Parenteral dosage forms are sterile products intended for administration by injection, infusion or implantation into the body.

Sodium chloride injection serves as a saline irrigant, a priming fluid for hemodialysis treatments, a vehicle or diluent for suitable medications for parenteral administration. Sodium chloride injection is a sterile, pyrogen free, foreign particle free, isotonic preparation. It contains 0.9%w/v of sodium chloride.

5. Requirements

a. **Apparatus**: 100 ml beaker, Glass rod, 100 ml measuring cylinder, Sintered glass filter or membrane filter of 0.45 micron.
b. **Equipment:** Calibrated weighing balance, vacuum filtration assembly.
c. **Chemicals:** Sodium chloride, Sterile water for injection.

6. Factor Calculation

Factor = Required Quantity/ Given Quantity =

7. Formulation Table

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Sodium chloride	9 gm		
2.	Sterile water for injection (q.s)	1000 ml		

8. Procedure

a. Weigh the required quantity of sodium chloride and mix with a part of Sterile water for injection in a beaker.
b. Filter the solution through a bacteria proof filter.
c. Transfer to an infusion container close with rubber closure and keep in autoclave for sterilization at 121^0C for 30 min maintaining 15 psi pressure.
d. Evaluate the formulation and note the observations.
e. Attach a prepared label and submit.

9. Use of Preparation: An electrolyte replenisher

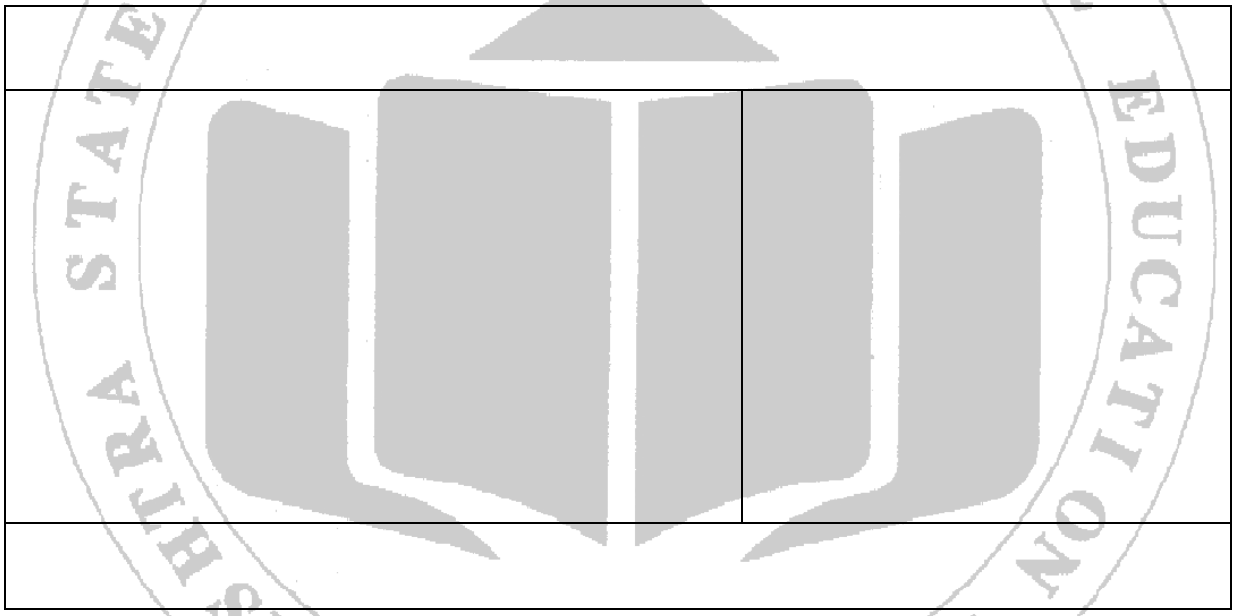
10. Direction: As directed by physician

11. Dose: 2-10 ml/kg through IV route.

12. Storage

It should be stored in a cool and dry place and protected from light.

13. Label



14. Evaluation Table

Name of preparation	Test	Specification	Observation
Sodium Chloride Injection I.P.	Description	Clear liquid	
	Particulate matter	No particle seen	
	Leakage	No leakage	
	Taste	Saline	
	pH	4.5 to 7	
	Volume	100 ml	

15. Result

_____ml of White liniment B.P is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopeia2007.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.
c. Subrahmanyam CVS, Shetty JT, Mutta KS and Swami SMV., "Laboratory manual of Industrial Pharmacy" Vallabh Publications, 2020.

18. Practical Related Questions

a. Define parenterals.
b. What are the types of Parenterals?
c. What are the types of sealing processes of ampoules?
d. List the formulation ingredients of Parenterals.
e. Name the preservatives added in injectables.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 20

Preparation and Evaluation of Calcium Gluconate Injection IP

1. Aim

To prepare, evaluate and submit two ampoules of 10 ml each of Calcium Gluconate Injection I.P.

2. Practical Significance

Calcium gluconate injections play a crucial role in managing various medical emergencies and conditions related to calcium and electrolyte imbalances. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Calcium Gluconate Injection I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Calcium Gluconate Injection I.P.	CO1-4	BTL3
2	Prepare and evaluate Calcium Gluconate Injection I.P.	CO1-4	BTL5
3	Design the label for product and choose suitable container	CO1-4	BTL5
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

The most common cation in the human body is calcium. The permeability of cell membranes and capillaries, as well as the healthy functions of the neurological, muscular, and skeletal systems, all depend on calcium. This cation is necessary for many physiological activities, such as blood coagulation, respiration, cardiac, smooth, and skeletal muscle contraction, renal function, and neural transmission. It is also a crucial activator in a wide range of enzymatic reactions. In addition, calcium controls the release and storage of hormones and neurotransmitters, the absorption of cyanocobalamin (vitamin B12), the binding and uptake of amino acids, and the secretion of gastrin.

This injection is a saturated solution of calcium gluconate, which serves as an electrolyte and calcium source. About thirty parts of cold and five parts of boiling water will gradually dissolve it. 10% w/v calcium gluconate is included. Calcium D-saccharate stops calcium gluconate from precipitating.

5. Requirements

a. **Apparatus**: 100 ml beaker, Glass rod, 100 ml measuring cylinder, ampoules, Sintered glass filter or membrane filter of 0.45 micron.
b. **Equipment:** Calibrated weighing balance, jet burner.
c. **Chemicals:** Calcium gluconate, calcium D-saccharate, water for injection.

6. Factor Calculation:

Factor = Required Quantity/ Given Quantity =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Calcium gluconate,	9.65 gm		
2.	Calcium D-saccharate	0.35 gm		
3.	Water for injection (q.s)	100 ml		

8. Procedure

a. A weighed quantity of calcium gluconate is dissolved in water for injection with the aid of heat.
b. Add calcium D-saccharate in the above solution.
c. Filter it by using Whatman filter paper or 0.45 µm membrane filter.
d. Fill the solution in clean and pre-sterilized ampoules and seal it.
e. Sterilize filled ampoules by using autoclave at 121°C, 15 psi pressure for 30 minutes.
f. Evaluate the formulation and note the observations.
g. Attach a prepared label and submit.

9. Use of Preparation:

To manage hypocalcemia, in deficiency of calcium.

10. Direction:

As directed by physician

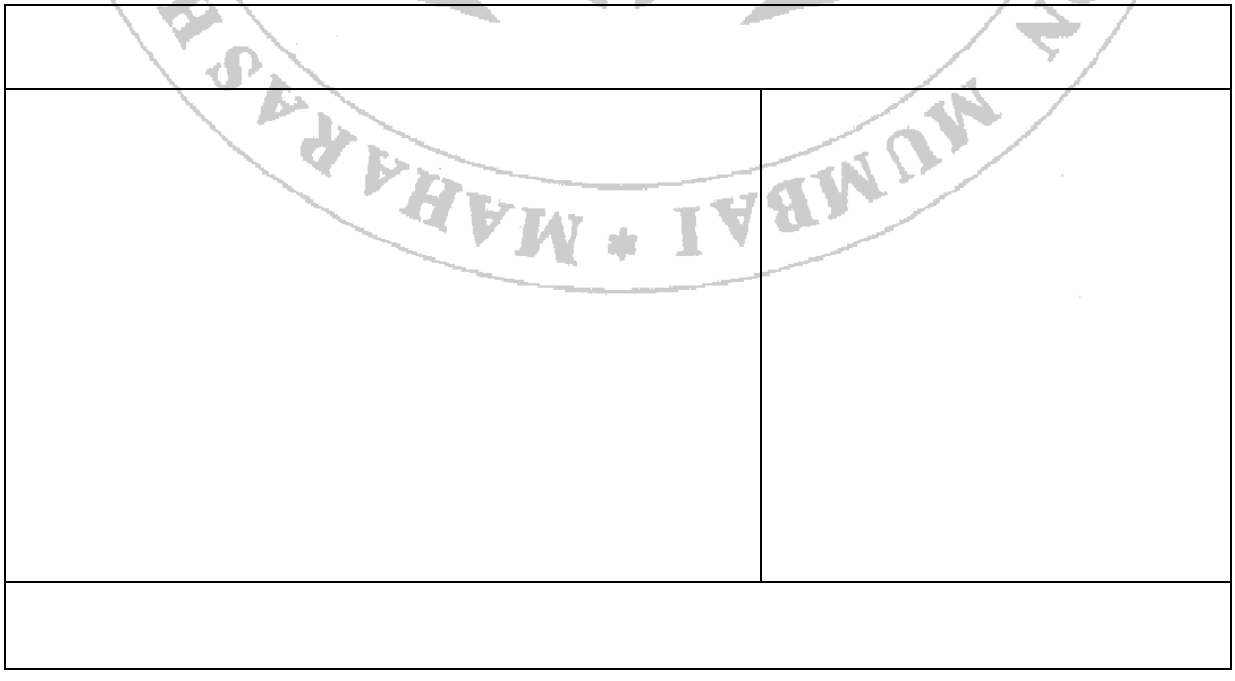
11. Dose:

0.5 ml/kg/hour through IV route.

12. Storage:

It should be stored in a cool and dry place and temperature not exceeding 40^0C.

13. Label:



14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Calcium Gluconate Injection I.P.	Description	Clear liquid	
	Particulate matter	No particle seen	
	Leakage test	No leakage	
	pH	6.0 to 8.2	
	Tip of ampoule	Round/Sharp	
	Volume	10 ml	

15. Result

_____ml of Calcium Gluconate Injection I.P. is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopeia2007.
b. Cooper and Gunn "Dispensing Pharmacy".

18. Practical Related Questions

a. State the use of Calcium Gluconate Injection I.P.
b. What is the role of Calcium D-saccharate?
c. What precaution should be taken while filling preparation in the ampoule?
d. State the labelling requirement for injectables.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 21

Demonstration of Quality Control Tests for Injection

1. Aim

To demonstrate the quality control tests for single dose parenteral formulation (injection)

2. Practical significance

The production of sterile, apyrogenic and particulate-free parenteral products becomes a big challenge to the pharmaceutical manufacturers. Quality control tests help ensure that injections are free from contaminants, impurities, or microorganisms that could potentially harm patients. These tests also evaluate the potency and efficacy of injections. Through the demonstration of the quality control tests for sterile injections, the students will be able to learn about the procedure and standards of various tests in the evaluation of the single dose parenteral solutions.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Explain various quality control tests for injections.	CO4	BTL2
2	Identify the presence or absence of leakage, particulate matter, microorganisms and pyrogens in the injections.	CO4	BTL3
3	Describe the procedure for various evaluation tests.	CO4	BTL2
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

The quality control tests for the evaluation of the parenteral preparations include:

A. Sterility test
B. Pyrogen test
C. Clarity test
D. Leakage test
E. Assay
F. Uniformity of content
G. Extractable volume
H. pH

A. **Sterility test**

Sterility testing attempts to reveal the presence or absence of viable microorganisms in a sample number of containers taken from a batch of product. The product to be tested is transferred aseptically in sterile nutrient media and incubated for a specific period of time at an optimum temperature. The nutrient medium must be sterile and must be able to produce microbial growth. The culture media used for sterility testing are:

a. **Fluid thioglycolate medium (FTM)**: Primarily intended for the culture of anaerobic bacteria, incubation of the media: 14 days at 30 -35°C

b. **Soyabean casein digest medium (SCDM):** Primarily intended for the culture of both fungi and aerobic bacteria, incubation of the media: 14 days at 20 -25°C

Sterility testing is carried out by two methods

a. Direct inoculation method

In this method, the specified quantity of sample under test is drawn aseptically from the container and transferred into two test tubes containing FTM and SCDM culture media. These test tubes are incubated in an incubator for not less than 14 days and observed for growth of microorganisms

b. **Membrane filtration method**

This method involves filtration of the sample under test through a membrane filter having a porosity of 0.45 microns. After the filtration, the membrane is divided into two halves and each half is transferred into 100 ml of both culture media. They are then incubated for not less than 14 days and observed for growth of microorganisms.

If there is no visual indication of microbial growth in the culture media, the sample under the test is assumed to be free of microbial contamination.

B. Pyrogen test

Pyrogens are metabolic products of living or dead microorganisms, with Gram -ve bacteria producing the most potent pyrogens. Chemically, they are lipopolysaccharides, water soluble, heat stable, and can pass through bacteria-proof filters. On injection into the body, they cause increase in body temperature, body aches, and vasoconstriction within 1 hour. Rabbit pyrogen test and LAL test are performed to detect the presence or absence of pyrogens in sterile parenteral preparations.

a. Rabbit Test

This test involves measurement of the rise in body temperature of rabbits following the intravenous injection of a sterile solution of the substance under examination. Rabbits are sensitive to pyrogens/endotoxins. For this test, 3 healthy rabbits of either sex are selected weighing not less than 1.5 kg. All glassware, syringes and needles must be thoroughly washed with water for injection and heated in a hot air oven at 250°C for 30 minutes or at 200°C for 1 hour. A clinical thermometer is used for recording the temperature of the rabbit and it is inserted into the rectum of rabbits to the depth of 5 cm.

Preliminary Test (Sham Test)

If animals are used for the first time in a pyrogen test, inject intravenously 10 ml of Pyrogen-free saline solution warmed to about 38.5°C. Record the temperatures of the animals, beginning at least 90 minutes before injection and continuing for 3 hours after injection of the solution being examined. Any animal showing a temperature variation of 0.6 °C or more must not be used in the main test.

Main Test:

This test is carried out using a group of three rabbits. The solution to be tested is warmed to 38.5°C before injection. The solution is injected slowly into the marginal vein of the ear of each rabbit over a period not exceeding 4 minutes. The volume of injection is not less than 0.5 ml per kg and not more than 10 ml per kg of body weight. The temperature of each animal is recorded at half-hourly intervals for 3 hours after the injection. The difference between the "initial temperature" and the "maximum temperature" which is the highest temperature recorded for a rabbit is taken to be its response.

Interpretation of results:

If the sum of the responses of the group of three rabbits does not exceed 1.4°C and if the response of any individual rabbit is less than 0.6°C, the preparation under examination passes the test. If the response of any rabbit is 0.6°C or more, or if the sum of the response of the three rabbits exceeds 1.4°C, continue the test using five other rabbits. If not more than three of the eight rabbits show individual responses of 0.6°C or more, and if the sum of responses of the group of eight rabbits does not exceed 3.7°C, the preparation under examination passes the test.

b. **Bacterial Endotoxin Test: LAL Test.**

Limulus Amoebocyte Lysate (LAL) Assay is an in vitro assay that detects the presence of bacterial endotoxins pyrogen in parenteral products and also determines their concentration. This test is based on the gelling property of limulus amebocyte lysate enzyme, which is isolated from the horseshoe crab (limulus polyphemus). In the presence of bacterial endotoxin, the enzyme gels, and the degree of gelling is proportional to the amount of endotoxin present. The test can measure the amount of bacterial endotoxin present.

C. Clarity test

Clarity testing is used to determine the particulate matter in the parenteral preparation as particulate matter can be a major problem in parenteral products especially in intravenous solutions. Hence all parenteral products should be free from particulate matter. The visual inspection against black and white background can detect particles up to 50 microns. Transparent or white particles/fibres can be detected against a black background, while black or dark particles can be observed against a white background in this test. Equipment such as coulter counter, electronic particle counter, etc., based on the concepts of light scattering, light absorption, and electrical resistance can also be used to detect the particles.

D. Leakage test

The leaker test is used to ensure the package integrity. The leakage arises when there are incompletely sealed ampoules. A dye bath test (generally 1% methylene blue solution) can be used to detect leakage. The ampoules are submerged in a dye bath followed by the application of vacuum and pressure. The ampoules are washed after being removed from the dye bath. The ampoules are then examined visually or by using UV spectroscopy to detect the presence of dye. The dye used can be green, yellowish-green or blue. To accelerate the migration of dye through the pores, a surfactant or a low viscosity fluid can be added to the dye solution to get better results. The dye test is widely used in the pharmaceutical industry and is approved for use in development of parenteral preparations.

E. Assay

The assay is performed as per the procedure given in the monograph.

F. Uniformity of content

The suspensions for injection that are presented in single dose containers and that contain less than 10 mg or less than 10 percent of active ingredient must comply with this test.

The content of active ingredient(s) of each of 10 containers taken at random is determined using the method given in the monograph or by any other suitable analytical method of equivalent accuracy and precision. The preparation under examination complies with the test if the individual values thus obtained are all between 85 and 115 per cent of the average value.

G. Extractable volume

Single-dose containers, such as ampoules, cartridges, or prefilled syringes must be filled with enough injection to allow administration of the nominal volume indicated on the label. Filling

with a volume somewhat greater than the nominal volume to be withdrawn ensures compliance with the standards for extractable volume. If the volume of injection in the single-dose container is same as that of volume mentioned on the label, it may not give the required dose.

H. pH

The pH can be tested by the pH paper and pH meter and compared with the pH of the preparation given in the monograph.

5. Requirements

a. **Apparatus**: Beakers, measuring cylinder (50 ml), syringe, needles, pipette, conical flask, test tubes, test tube stand, and glass rod.
b. **Equipment**: Digital pH meter, clarity test apparatus, leak test apparatus, incubator, hot air oven.
c. **Chemicals**: Marketed single dose parenteral preparation (30×5 mL ampoules).

6. Procedure

A. Sterility test by direct inoculation

a. Prepare FTM and SCDM using official books.
b. Take a specific amount of FTM and SCDM in separate flasks which have been sterilized previously.
c. Break-open an ampoule at the neck.
d. Using a sterile pipette or syringe, remove the solution from the ampoule.
e. Aseptically inoculate a small portion of the sample to the medium flask.
f. Without excessive aeration, mix the sample with the medium.
g. Allow the medium to incubate for not less than 14 days.
h. During the incubation period, regularly check the medium for microbial growth.

B. Clarity test

a. Remove any labels from the outside of the container, then wash and dry it.
b. Switch on the lamp of the clarity test apparatus.
c. Gently invert or spin the container, making sure there are no air bubbles.
d. Examine for about 5 seconds in front of the white panel of clarity test apparatus.
e. Repeat the procedure in front of black panel of the clarity test apparatus.
f. Take note of any particles that may be present.

C. Leakage test:

a. Take a suitable amount of 1% methylene blue solution in the vacuum desiccator of the leak test apparatus.
b. Immerse all the ampoules in the dye solution and close the lid.
c. Turn on the vacuum valve of desiccator and vacuum regulator valve.
d. Close the vacuum release valve of the desiccator.
e. Using the regulating valve, adjust the vacuum to 25 inches of Hg (85 kPa) and maintain it for 15 minutes.
f. Close the vacuum valve and fully open the vacuum regulator in order to release the vacuum.
g. Turn off the vacuum pump.
h. Wait for one minute to allow the dye to enter the leaking ampoules.
i. Take out the ampoules and wash with water to remove the dye adhered to the outer surface of ampoules.

j. Inspect the ampoules visually for the presence of dye within the solution.

D. Determination of extractable volume

a. Use six ampoules (Five for test and one for rinsing the syringe).
b. Take a syringe and rinse it with the liquid in one ampoule reserved for rinsing.
c. Break-open the ampoule reserved for the test at the neck.With the help of a syringe, withdraw the injection solution as much as possible and transfer it to a dry graduated cylinder.
d. Repeat the procedure until the solution from 5 containers has been transferred to the cylinder
e. Measure the total volume and calculate the average content. (Specification as per I.P.: The average content of the 5 containers should not be less than the nominal volume and not be more than 115% of the nominal volume)

E. Determination of pH

a. Determine the pH of injection using pH paper and pH meter.

7. Observations:

Sr. No	Test	Observation	Inference
1	Sterility test		
2	**Clarity test:** Against white panel:		
	Against black panel:		
3	Leakage test		
4	Extractable volume		
5	**pH Test:** pH observed:		
	pH specified in official book:		
	Official book used:		

8. Result

The quality control tests on injections were demonstrated successfully.

9. Conclusion

_____

_____

10. References

a. Indian Pharmacopeia2022.

11. Practical Related Questions

a. Enlist quality control tests for parenteral.

b. What are pyrogens and what are their properties?
c. Why are rabbits used in pyrogen testing?
d. Name the culture media used for sterility testing.
e. What is LAL?

(Space for Answers)

12. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**04**	**02**	**02**	**02**	**10**	

Introduction to Capsules

Capsules are solid unit dosage forms in which the drug substances are enclosed in a water-soluble shell or an envelope.

Types of Capsules:

There are mainly two types of capsules.

1. **Hard Gelatin Shelled Capsules: -**

   Hard gelatin shelled capsules are types of capsules which contain almost dry, powdered ingredients or miniature pellets. Generally, hard Shelled Capsules are made in two halves: a smaller-diameter "body" that is filled and then sealed using a larger-diameter "cap".

   Capacity of capsule with capsule size to fill the material:

Capsule No	000	00	0	1	2	3	4	5
Capacity in mg	950	600	450	300	250	200	150	100

2. **Soft Gelatin shelled capsules:**

   Soft gelatin shelled capsules are primarily used for oils and other active ingredients that can dissolve or be suspended in oil.

   Both hard and soft gelatin shelled capsules are made from aqueous solutions. The aqueous solution is prepared from gelling agents such as animal protein, mainly gelatin, plant polysaccharides, and the derivatives of both plants and animals. Apart from this, several other ingredients were added to the gelling agent solution, including plasticizers such as glycerin or sorbitol to decrease the capsule's hardness. Other agents are added like coloring agents, preservatives.

Advantages:

- Drugs with unpleasant taste and odour can be administered.
- Very smooth and slippery.
- Economical.
- Easy to handle.
- Release medicament in GIT.
- Made of gelatin, hence inert.
- Attractive in appearance.
- Available in various sizes.
- Micro-encapsulation provides SR dosage form.

Disadvantages:

- Hygroscopic drugs cannot be filled.
- Concentrated preparation which needs dilution cannot be given.
- They become sticky in damp weather.
- Material filled in the capsule must not react with gelatin.

Formulation of capsule:

1. **Diluents**: To increase bulk quantity, e.g. lactose, sorbitol, starch etc.
2. **Disintegrants**: To break the capsule, e.g. starch, sodium starch glycolate, etc.
3. **Absorbents**: Eutectic or hygroscopic drugs need absorbent. e.g. oxides and carbonates of magnesium and calcium.
4. **Glidants**: To ensure a regular flow of powder, e.g. talc and magnesium stearate.

5. **Anti dusting agents**: During filling of the capsule in an automatic filling machine a lot of dust comes out. To avoid this anti dusting agent is added e.g. inert oils.

Capsule filling machines:

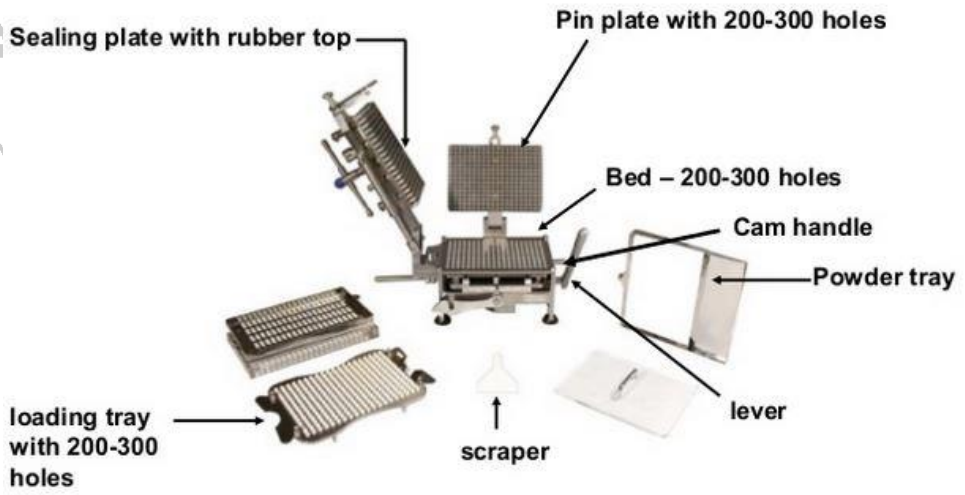
a. Hand/manually operated capsule filling machine.
b. Semi- automatic capsule filling machine.
c. Automatic capsule filling machine.

Components of a Hand/manually operated capsule filling machine:

a. Bed
b. Loading tray
c. Powder tray
d. Pin plate
e. Sealing Plate
f. Lever
g. Cam handle

Steps involved in filling of hard gelatin capsule using hand operated capsule filling machine:

a. The empty capsules are filled in loading tray & placed over bed.
b. The caps are separated from bodies by cam handle.
c. Fill the powder from the powder tray in the body of the capsule using a scraper (Excess powder removed).
d. The pin plate is lowered and the powder pressed for tight filling.
e. Powder tray is removed.
f. Cap holding tray is placed and the rubber top plate is pressed.
g. The lever is operated to lock the caps and bodies and the capsules are removed.



Experiment No. 22

Preparation and Evaluation of Tetracycline Hydrochloride Capsules

1. Aim

To prepare, evaluate and submit 10 capsules of 250 mg Tetracycline Hydrochloride.

2. Practical Significance

Tetracycline capsules contain antibiotics used to treat various bacterial infections, including respiratory tract infections, urinary tract infections, acne, and certain sexually transmitted diseases. Their practical significance lies in their effectiveness against a wide range of bacterial pathogens, making them valuable in both medical and veterinary settings. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Tetracycline Hydrochloride capsule.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Tetracycline Hydrochloride capsule.	CO1-4	BTL3
2	Prepare and evaluate Tetracycline Hydrochloride capsule.	CO1-4	BTL5
3	Operate hand operated capsule filling machine and disintegration apparatus	CO1-4	BTL3
4	Design the label for product and choose suitable container	CO1-4	BTL5
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

Tetracycline is used to treat infections caused by bacteria including pneumonia and other respiratory tract infections; certain infections of skin, eye, lymphatic, intestinal, genital and urinary systems; and certain other infections that are spread by ticks, lice, mites, and infected animals. It is also used along with other medications to treat acne. Tetracycline is also used to treat plague. It can also be used in patients who cannot be treated with penicillin to treat certain types of food poisoning, and anthrax.

Dried talc serves as a glidant and dried starch acts as a disintegrating agent in this formulation. It is common to take tetracycline capsules twice or four times a day. Tetracycline needs to be taken at least an hour before or after meals or snacks, preferably without food. Tetracycline shouldn't be used with food, especially if it contains dairy products like ice cream, milk, yoghurt, or cheese.

5. Requirements

a. **Apparatus**: Empty capsule shells, Mortar and pestle, sieve,

b. **Equipment:** Calibrated weighing balance, hand operated capsule filling machine, disintegration test apparatus.

c. **Chemicals:** Tetracycline hydrochloride, dried starch and dried talc.

6. Factor Calculation

Required Quantity = Quantity given X Number of capsule

7. Formulation Table *(Note: Calculate quantity for one extra capsule)*

Sr. No.	Ingredients	Quantity Given	Quantity Required (Qty given x Factor)	Uses
1.	Tetracycline hydrochloride	250 mg		
2.	Dried starch	25 mg		
3.	Dried talc	25 mg		

8. Procedure

a. Clean all glassware and dry them properly.
b. Weigh all ingredients as per calculated quantity, calculate one extra capsule quantity.
c. Pass dry starch and talcum powder through Sieve No. #100.
d. Mix all the ingredients with ascending order by their weights in mortar and pestle to form a uniform blend.
e. Select an empty capsule shell of size of appropriate capacity and fill the content in the capsule shell using a hand operated capsule.
f. Clean the capsules by de-dusting and polish it by clean cloth.
g. Evaluate formulation as per evaluation parameters and note the observations.
h. Transfer into an air-tight container, attach a prepared label and submit.

9. Use of Preparation

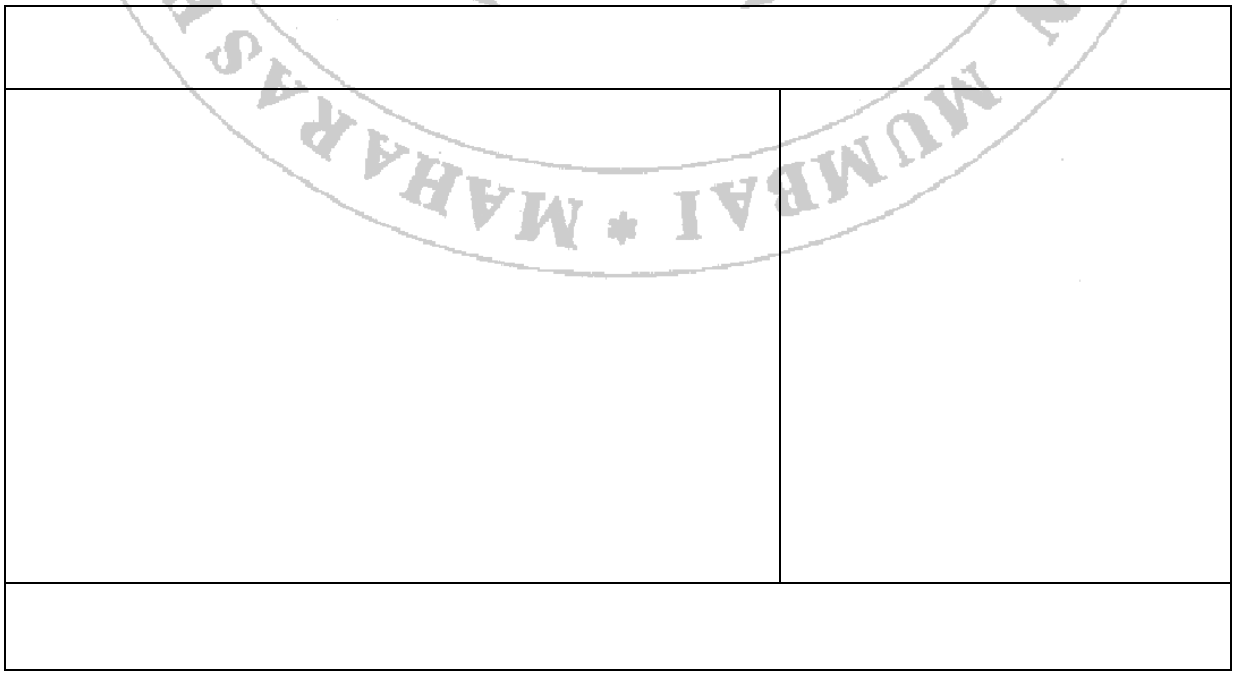
As an antibiotic to treat various bacterial infections, including respiratory tract infections, urinary tract infections, acne, and certain sexually transmitted diseases.

10. Direction: As directed by physician.

11. Dose: 250 mg orally every 6 hrs for 7 to 14 days.

12. Storage: It should be stored in an airtight container in a cool and dry place.

13. Label



14. Evaluation Table

Name of preparation	Test	Specification	Observation
Tetracycline Hydrochloride capsules	Description	Smooth and intact	
	Weight variation	As per I.P.	
	Disintegration time	Maximum 15 min	

15. Result

_____ capsules of Tetracycline Hydrochloride capsules is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. Indian Pharmacopoeia2007.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

18. Practical Related Questions

a. Define capsule.
b. What are the types of capsules?
c. Differentiate between hard and soft gelatin capsules.
d. Why milk should be avoided while taking the tetracycline?
e. Enlist the parts of a hand operated capsule filling machine.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 23
Demonstration of Quality Control Tests for Capsules

1. Aim

To demonstrate the quality control tests for marketed hard gelatin capsules.

2. Practical significance

Evaluation tests for capsules play a vital role in ensuring the quality, safety, and effectiveness of products, as well as in enhancing consumer confidence and regulatory compliance. Quality control testing means checking the dosage forms during and after the production process to make sure that they are of expected standard. Demonstrating quality control tests for capsules is essential to increase the understanding about the quality control tests used for the evaluation of the capsules.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Explain types of quality control tests for hard gelatin capsules.	CO4	BTL2
2	State the standard specifications for various Q.C. tests for capsule as per I.P.	CO4	BTL1
3	Describe the procedure for various evaluation tests.	CO4	BTL2
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

The manufacturing personnel in the production department perform in-process quality control tests for capsules at predetermined intervals during product manufacturing and the results are noted on the batch record. Negative results in these tests are used to make changes in manufacturing process parameters. Various tests are performed on capsules to ensure that they meet all the compendial and regulatory criteria standards.

Quality control tests for capsules are:

A. Appearance (unofficial):

The capsules should be smooth and intact. Physical instability is indicated by significant changes in the shell's appearance such as hardening or softening, cracking, swelling, mottling, or discoloration.

B. Weight variation (official):

20 intact hard gelatin capsules are weighed individually and the average weight per capsule is determined. The capsule passes the test if each of the individual weights is within 90-110% of the average weight. If the capsule does not come in this range, then the weight of the content of each individual capsule is determined and compared with the average weight of the contents. As per the I.P., not more than two of the individual weights may deviate from the average by more than the percentage deviation shown in the table and none may deviate by more than twice that percentage. Specifications for weight variation test as per I.P.

Average weight of capsule contents	Percentage deviation
Less than 300 mg	±10
300 mg or more	±7.5

If the average net weight of 2 to 6 capsules deviates by the percentage deviation in the table and twice that percentage, determine the contents of additional 40 capsules and the average content of 60 capsules. In a total of 60 capsules, not more than 6 of the 60 capsules should deviate from the average by more than the percentage deviation in the table and none more than twice that percentage.

C. Uniformity of content (official):

The content of active ingredient in each of randomly selected 10 capsules is determined by the method given in the monograph of that capsule or by any other suitable analytical method. The capsules pass the test if not more than one capsule is having the drug content outside the limits of 85 to 115% of the average drug content and none of the capsules is having the drug content outside the limits of 75 to 125% of the average content.

If two or three capsules are having the drug content outside the limits of 85 to 115 percent of the average content but within the limits of 75 to 125 per cent, the test is repeated using another 20 capsules. The capsules pass the test if not more than three individual capsules of the total 30 capsules are having the drug content outside the limits of 85 to 115% of the average content and none of the capsules are having the drug content outside the limits of 75 to 125% of the average content.

D. **Disintegration test (official):**

The disintegration of hard and soft gelatin capsules is evaluated to ensure that the drug is fully dissolved and absorbed from the gastrointestinal tract after disintegration. The procedure and apparatus for the disintegration test for hard and soft gelatin capsules are the same as those for tablets.

E. **Dissolution test (official):**

A dissolution test determines the rate and amount of drug dissolved from the capsule dosage form. The dissolution test uses the same apparatus, dissolution media, and procedure that are used in the dissolution test for tablets.

1000 ml of water which should be free from dissolved air having a temperature of 36.5ºC to 37.5ºC is placed into the vessel. The specified number of capsules is placed in the basket. The apparatus is set, the motor is started and the rotation speed is adjusted to 100 rpm or as directed in the monograph. The stated volume of solution is withdrawn from the vessel after 45 minutes or after the time specified in the monograph. It is filtered and the amount of active ingredient present in it is determined by the method given in the monograph.

5. Procedure

a. Appearance: Examine the capsules using a biconvex lens for cracks, swelling, mottling and color.

b. Weight variation

i. Weigh 20 capsules individually (WF1, WF2, WF20) and calculate the average weight.
ii. The capsule passes the test if each of the individual weights is within 90-110% of the average weight.
iii. If the capsule does not come in this range, open the capsules and remove the contents.
iv. Weigh the empty shells of capsules individually and record weight (WE1, WE WE20)
v. Calculate the weight of the filled material by subtracting the weight of empty shells from the weight of filled capsules (WF1-WEI, WF2-WE2....WF20-WE20)

vi. Determine the average of the weight of the filled material.
vii. Calculate % deviation allowed as per the table No.01 and calculate upper limit and lower limit.
viii. Calculate % deviation of individual capsules from the average weight.
ix. Compare weights of filled material of individual capsules to ensure whether they are within permissible limits or not.

c. Disintegration

i. Remove the basket rack assembly from the apparatus.
ii. Place the required quantity of water (800 to 900 ml) into the beaker provided with apparatus.
iii. Place the beaker at its position and switch on the temperature knob to attain the temperature of medium to 37ºC.
iv. Place one capsule in each of the 6 tubes of the basket and suspend the assembly in water maintained at 37ºC+ 2ºC.
v. Do not use the discs for hard capsules except when the capsules float.
vi. Operate the apparatus for 30 minutes in the case of hard capsules.
vii. At the end of 30 minutes, remove basket assembly and observe each tube for any residue of the capsule (except fragments of gelatin shell).
viii. The capsule passes the test if no residue is left on the screen of the apparatus.
ix. If one or two capsules fail to disintegrate, repeat the test on 12 additional capsules. The sample passes the test if not less than 16 out of the total 18 capsules disintegrate.

6. Observations

A. Appearance

Sr. No	Test	Observation	Inference
1	Cracks		
2	Swelling		
3	Mottling		
4	Colour		

B. Weight variation

Capsule No.	Weight of filled capsule W_F (mg)	Weight of empty shell W_E (mg)	Weight of contents of capsule (mg) $W_c = W_F - W_E$	Difference (mg) between $W_{avg} - W_c$	Percent deviation ($W_{avg} - W_c / W_{avg}$ X 100)	More/Less than official limit
1.						
2.						
3.						
4.						
5.						
6.						

Capsule No.	Weight of filled capsule W_F (mg)	Weight of empty shell W_E (mg)	Weight of contents of capsule (mg) $W_c = W_F - W_E$	Difference (mg) between $W_{avg} - W_c$	Percent deviation ($W_{avg} - W_c / W_{avg} \times 100$)	More/Less than official limit
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						
Average weight of filled material (mg) = _____ /20 = _____ mg						
No. of capsules falling beyond the official limit = _____						
Inference:						

C. Disintegration:

Sr. No	Capsule No	Disintegration time (min)	Residue on screen	Passes/Does not pass
A.	I			
B.	II			
C.	III			
D.	IV			
E.	V			

7. Result

_____

_____

8. Conclusion

_____

_____

9. References

a. Indian Pharmacopoeia2022.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai.

10. Practical Related Questions

a. Enlist the tests that are performed under quality control of capsules.
b. Write the specification table weight variation test for capsules as per I.P.
c. What should be done if one of the six capsules fails the disintegration test?
d. What is the limit for disintegration time of the capsules as per I.P.?
e. Describe the disintegration test for hard gelatin capsules.

(Space for Answers)

11. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**04**	**02**	**02**	**02**	**10**	

Introduction to Tablets

A tablet is a combination of powdered excipients and active ingredients that have been compressed or pressed into a solid state.

Types of tablets:

- **Tablet ingested orally:**
  - Compressed, multiple compressed tablet and Multilayer tablet
  - SR tablet
  - Enteric coated tablet and Sugar-coated tablet
  - Film coated tablet
  - Chewable Tablet
- **Tablet used in oral cavity:**
  - Buccal tablet
  - Sublingual tablet
  - Dental cone.
- **Tablet administered by other routes:**
  - Implantation tablet
  - Vaginal tablet
- **Tablet used for preparation of solution:**
  - Effervescent tablet
  - Dispensing tablet
  - Hypodermic tablet
  - Tablet triturate

Advantages:

- Easy to administer.
- Easy to dispense.
- More stable.
- Accuracy in dose.
- Bitter and nauseous substances can be easily dispensed.
- Light and compact.
- Economical.

Disadvantages:

- Problem with compression to crystalline drug.
- Taste masking is a problem.
- Slow dissolution.
- Includes several processing steps.
- Application of heat might degrade the thermolabile therapeutic agents

Formulation:

a. **Drug substance:** Analgesic, Antipyretics, Antibiotics, NSAID, etc
b. **Diluents**: To increase the bulk of formulation e.g. Lactose, microcrystalline cellulose.
c. **Disintegrants**: These help to break the tablet e.g. Starch, guar gum, sodium alginate.
d. **Binders**: To make a cohesive mass e.g Starch paste 10%, gelatin 10%,

e. **Glidants**: To improve the flow property of granules which facilitate smooth flow of granules from hopper to die cavity, e.g magnesium carbonate, Talc
f. **Lubricants**: To reduce the friction of the tablet with a die cavity. e.g. Magnesium stearate.
g. **Organoleptic agents**: colour, flavour, sweetener can be added as per requirement of formulation.

Method of preparation:

- **Wet granulation**: wet granulation done for those drugs which are stable to heat and moisture.
  Drug + Excipients → Blending → Formation of cohesive mass → Screening → Drying → Screening → Blending → Compression.
- **Dry granulation** (**Slugging**): Dry granulation done for those drugs which are stable to heat and but not to moisture.
  Drug + Excipients → Blending → Slugging (formation of big size tablet) → Screening → Blending → Compression.
- **Direct Compression**: Direct compression done for those drugs which are sensitive to both heat and moisture.
  Drug + Excipients → Blending → Compression.

Tablet compression machine:

Compression machine:

a. Single punch:
b. Multiple punch:
c. Rotary tablet:
d. Dry cota tablet.

Parts of Single punch hand operated tablet punching machine:

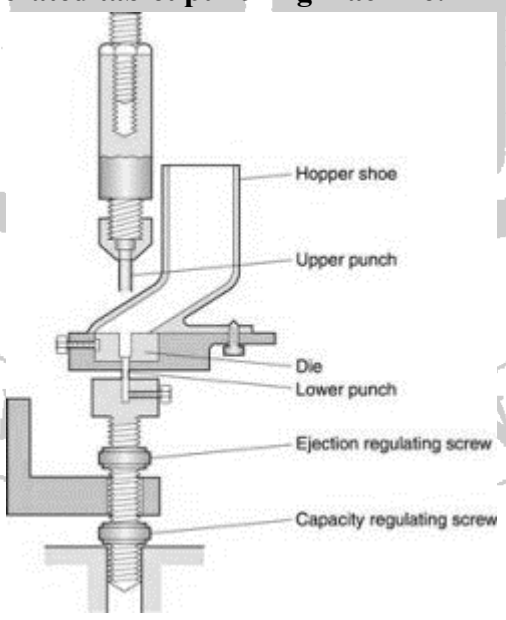


Fig: Single Punch Hand Operated Tablet Punching machine

- Hopper.
- Lower punch.
- Upper punch.
- Die cavity.
- Ejection regulating screw.
- Capacity regulation screw.

One die and one set of punches are included with a single-punch press. A hopper that is fastened to a hopper shoe on the die table holds the powder. The hopper shoe traverses the die back and forth in a translational or rotating action. After the hopper shoe is placed above the die, powder is fed into the die by gravity powder flow. The amount of powder poured into the die is determined by the location of the lower punch. The powder is squeezed when the hopper shoe is positioned next to the die and the upper punch lowers into the die chamber. Since the lower punch stays fixed during compression, the top punch applies pressure and the lower punch regulates it.

Tablet coating:

Tablet coating is the process where coating material is applied to the surface of the tablet to achieve the desired properties of dosage form over the uncoated variety.

Types of coating:

a. Sugar coating.
b. Film coating.
c. Enteric coating.

Purpose/advantages/significance of tablet coating:

a. To mask the taste.
b. To improve the appearance of the tablet.
c. To prevent the medicament from atmospheric effect.
d. To control the site of action.
e. To produce SR products.

Quality control of tablets:

a. Shape of tablet.
b. Appearance.
c. Content of active ingredients.
d. Hardness test.
e. Uniformity of weight.
f. Friability test.
g. Disintegration.
h. Dissolution.

Experiment No. 24
Formulation and Evaluation of Paracetamol Tablets IP

1. Aim

To prepare, evaluate and submit 10 Paracetamol Tablets I.P. of 500 mg each.

2. Practical Significance

The practical significance of Paracetamol tablet manufacturing lies in its widespread use as a common over-the-counter pain reliever and fever reducer. Efficient manufacturing ensures consistent availability and quality of this medication, contributing to public health by providing a reliable treatment option for various ailments. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Paracetamol Tablets I.P.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Paracetamol Tablets I.P.	CO1-4	BTL3
2	Prepare and evaluate Paracetamol Tablets I.P.	CO1-4	BTL5
3	Operate hand operated tablet punching machine, hardness tester, friability tester and disintegration test apparatus.	CO1-4	BTL3
4	Design the label for product and choose suitable container	CO1-4	BTL5
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

Paracetamol is a medicine used as analgesic and antipyretic. It is dangerous to take more than the recommended dose of Paracetamol. Its overdose can damage your liver and cause death. In the formulation of Paracetamol tablets, lactose is added as a diluent, which increases the bulk quantity; dried starch acts as a disintegrant, which helps break the tablet into gastric medium; starch paste acts as a binder, which makes the preparation a cohesive mass; magnesium stearate reduces the friction of the tablet with the die cavity; and talc is used as a glidant to improve the flow property of granules.

5. Requirements

a. **Apparatus**: Mortar and pestle, sieve (#10, #22 and #44, #60), beaker, spatula.

b. **Equipment:** Calibrated weighing balance, hand operated tablet punching machine, Monsanto hardness tester, Friability test apparatus, and disintegration test apparatus.

c. **Chemicals:** Paracetamol I.P., Lactose, starch, magnesium stearate and dried talc.

6. Factor Calculation:

Required Quantity = Quantity given X Number of tablets =

7. Formulation Table *(Note: calculate one or two tablet extra to compensate for wastages.)*

Sr. No.	Ingredients	Quantity Given per tablet	Quantity Required for _____+tablets	Uses
1.	Paracetamol I.P.	500 mg		
2.	Lactose	75 mg		
3.	Dried starch	20 mg		
4.	Starch paste (10%)	Q.S.		
Post granulation			Weight of granules: _____	
5.	Fines	10%		
6.	Dried Starch	5%		
7.	Talc	1%		
8.	Magnesium stearate	1%		

8. Procedure

A. Preparation of Paracetamol Granules:

a. Weigh all ingredients as per calculated quantity.
b. Separately pass Paracetamol, Lactose and Starch through Sieve No. 60.
c. Add Paracetamol, Lactose and Starch by ascending order in mortar pestle and triturate to produce uniform blend.
d. Add starch paste in the above blend and mix well to produce coherent mass.
e. Pass coherent mass through Sieve No. 10 and dry the granules at 60°C for 1 hour.
f. Then place butter paper at bottom and arrange Sieve No. 22 and 44 by ascending order.
g. Then pass the dried granules through Sieve No. 22 below which Sieve No. 44 is kept.
h. The granules retained on Sieve No. 44 are the desired granules and powder which pass through Sieve No. 44 are fines retained on butter paper.
i. Weigh the granules, store in a well closed container and make it ready for compression.

B. Preparation of Tablets from Granules:

a. Calculate and weigh granules equivalent to 10 tablets of Paracetamol Tablet I.P. 500 mg.
b. Calculate and add 10% fines, 5% starch, 1% talc, 1% magnesium stearate.
c. Mix the granules and above powders uniformly with the help of spatula.
d. Make a ready machine available in your laboratory with all necessary settings.
e. Compress the granules into tablets with optimum hardness and friability.
f. Evaluate formulation as per evaluation parameters and note the observations.
g. Transfer into an air-tight container, attach a prepared label and submit.

9. Use of Preparation: As an antipyretic and analgesic

10. Direction: As directed by physician

11. Dose: 500 mg orally every 6 hrs SOS

12. Storage: It should be stored in an airtight container in a cool and dry place.

13. Calculation

a.	Weight of Paracetamol drug (A)	=	gm
b.	Weight of watch glass + Starch paste before granulation	=	gm
c.	Weight of watch glass + Starch paste after granulation	=	gm
d.	Weight of starch paste used (b-c)	=	gm
e.	Mixture (drug + lactose + dried starch + starch paste used (d) i.e. Total mixture (X gm, dough mass)	=	gm
f.	Weight of dry granules	=	gm
g.	Weight of 10% fine	=	gm
	Weight of dry granules (f) + weight of fines (g) =_____ g (Y gm of mass)	=	gm
	X grams of dough mass contains: _____ (a grams) of drug	=	gm
	Y grams of mass contains (Y/X) = _____ (b grams) of drug.	=	gm
	Total Weight of tablets = b/0.500 =	=	gm
h.	Weight of 5% dried Starch	=	gm
i.	Weight of 1% magnesium stearate	=	gm
j.	Weight of 1% Talc	=	gm
	Total Weight = (f+g+h+i+j) = _____ (Z gm)	=	gm
	Weight of each tablet = Z/total no of tablets =_____gm		

14. Label:

15. Evaluation Table:

Name of preparation	Test	Specification	Observation
Paracetamol Tablets I.P.	Hardness	4-10 kg/cm^2	
	Disintegration time	Maximum 15 min	

16. Result

_____ tablets of Paracetamol IP are prepared, evaluated and submitted in a _____ container with special instructions as _____.

17. Conclusion

_____

_____

18. References

a. Indian Pharmacopoeia2007.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai

19. Practical Related Questions

a. Define a tablet.
b. What are the types of tablets ingested orally?
c. Name the binder used in the formulation of Paracetamol Tablets I.P.
d. List the parts of a hand operated punching machine.
e. State the reasons for tablet coating.

(Space for Answers)

20. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 25

Demonstration of Tablet Manufacturing Process

1. Aim

To demonstrate various steps and equipment used in the tablet manufacturing process.

2. Practical Significance

A demonstration of the tablet manufacturing process helps students comprehend the numerous steps involved in the tablet granulation process, as well as the various equipment utilized in the tablet manufacturing process.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Describe various steps of the tablet manufacturing process.	CO2	BTL2
2	Enlist the various equipment/machines employed in the tablet manufacturing process.	CO2	BTL1
3	Explain the compression technique.	CO2	BTL2
4	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

A tablet is a combination of powdered excipients and active ingredients that have been compressed or pressed into a solid state.

Steps of tablet manufacturing process:

A. Dispensing of the Material: It is the most crucial phase in the tablet formulation process. In this initial phase, each substance is precisely weighed by the dosage formula.
Following balances are used in weighing of material.

- Digital balance.
- Electronic weighing balance.
- Single pan dispensing balance.

B. Sizing of the Material: The composition of the formulation material should be finely divided; yet size reduction is necessary for easy mixing.
Following equipment are used in sizing:

- Hammer mill.
- Roller mill.
- Ball mill.
- Fluidized energy mill.
- Cutter mill.
- Vibration mill.

C. Powder Mixing (blending): Blending a powder in a blender according to needs to get a uniform mixture. Medication ingredients and excipients are combined in a geometric dilution.
Following equipment are used in blending:

- V-type blender.
- The double Cone blender.
- The ribbon blender.

- The octagonal blender.
- The bin blender.
- Vibration mill.

D. Granulation of Material

The process of particle enlargement using the agglomeration technique is one of the most important unit processes in the manufacture of pharmaceutical dosage forms, primarily tablets and capsules. The granulation process converts fine powders into free-flowing, dust-free granules that are easy to compress.

Wet Granulation

Wet granulation is the most common approach, and the granules are generated by wet massing the excipients and API with granulation liquid with or without binder.

The steps for a wet granulation tablet manufacturing process

- Weigh, mill, and mix active pharmaceutical ingredients APIs with powdered excipients.
- Prepare the binder solution.
- Mix binder solution with powders to create a damp mass.
- Wet screen the dampened powder into pellets or granules using a mesh screen.
- Dry the moist granules.
- Use dry screening to size granulation.
- Mix the dried granules with lubricant and disintegrants.
- Compress the granules into tablets.

Dry granulation

Dry granulation facilitates the aggregation of dry powder particles through mechanical compression (slugs) or compaction (roller compaction).

The steps for a dry granulation tablet manufacturing process

- Weigh and mill formulation ingredients like drug substances and excipients.
- Mix the milled powders.
- Compress the mixed powders into slugs.
- Mill and sieve the slugs.
- Mix the granules with lubricant and disintegrants.
- Compress them into tablets.

Direct compression

The direct compression methods have the advantages of a fast process that only requires mixing and compressing. It also avoids a wide range of wet and dry granulation problems. All active ingredients directly compressed by adding filler-binders.

The steps for a direct compression tablet manufacturing process

- Weigh and mill therapeutic agents and excipients.
- Mix the milled powders, disintegrants, and lubricants.
- Compress the tablets.

Following equipment are used for granulation

- Double roller extrusion granulator (for dry granulation).
- Rapid mixer granulator.

- Rotating shape granulator.
- Mechanical agitator granulator.
- Fluidized bed spray granulator.
- Integrated High Shear granulator.

E. Drying of Granules

The wet granules must be dried for the designated amount of time in a fluidised bed dryer or tray dryer set at 60^0C.

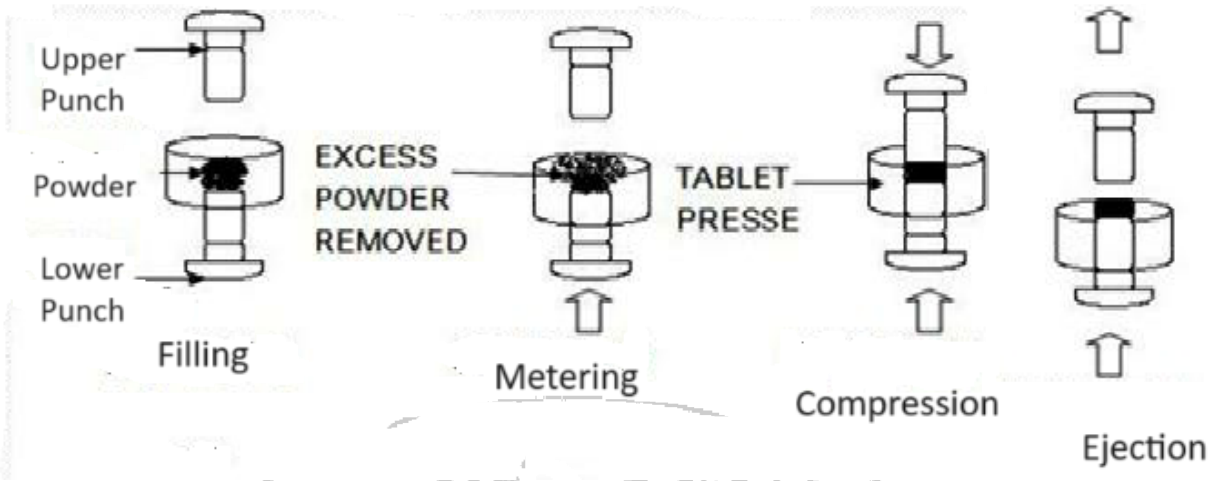
Following dryers are used in drying of granules

- Spray dryer.
- Rotary dryer.
- Fluidized bed dryer.

F. Compression of Tablets

Granules are pressed into a variety of shapes in this process, including round, oval, rectangular, and other shapes using a tablet compression machine. Any additional symbol or code number may be entered into the tablet. The compression machines utilized are single punch or multi station rotary.

- **Filling**: This procedure of the tablet compression machine involves the transfer of the granules into position for tablet compression. The mixture flows from hopper to the die cavity.
- **Metering**: The metering procedure for the tablet compression procedure involves removal of excess granules from the compression machine. At this stage, the required weight (volume) of granules to be compressed into tablets is controlled by the height of the lower punch in the die. The height of the lower punch is controlled by the metering cam.
- **Compression**: During the compression stage, the top and bottom punch come together by pressure within the die to form the tablet. As the punches enter the compression stage, the top and bottom punches move between two large wheels called compression rolls. These compression rolls push the punches towards the die to form the product. So, the distance between the top and bottom punches determines the thickness and the hardness of the tablets.
- **Ejection**: The ejection procedure for the tablet compression process involves removal of the tablet from the lower punch-die station. In this stage, the upper punch retracts from the die cavity and rises above. Then the lower punch rises in the die, which in turn pushes the tablet upward to the top of the die cavity. Then by a scrapper, tablets are collected in the container.



G. Coating of Tablet:

Coating the tablets is necessary to eliminate their disagreeable taste, to protect against environmental effects and to release them at target site. The tablet is made colourful and aesthetically pleasing by coating it.

Types of coating:

- Film coating.
- Enteric coating.
- Sugar coating.

Following equipment are used for coating:

- Pan coating.
- Fluidized bed coating system.
- Rotary dryer coater.

5. Procedure

Different tablet manufacturing steps demonstrated as listed below and observation are noted.

6. Observation Table

Sr. No.	Tablet manufacturing steps	Equipment/process demonstrated
1	Dispensing	
2	Sizing (size reduction)	
3	Mixing (blending)	
4	Granulation	
5	Drying	
6	Compression	
7	Coating	
8	Packaging	

7. Result

Tablet manufacturing steps were demonstrated successfully.

8. Conclusion

_____

_____

9. References

a. Mehta R. M., "Dispensing pharmacy" Nirali Prakshan Delhi.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai

10. Practical Related Questions

a. Define granulation.
b. List the steps of the tablet manufacturing process.
c. Write the method of preparation of granules by the slugging method.
d. List the coating equipment.
e. Enlist the steps of compression of the tablet.

(Space for Answers)

11. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**04**	**02**	**02**	**02**	**10**	

Experiment No. 26
Demonstration of Quality Control Tests for Tablets

1. Aim

To demonstrate the quality control tests for marketed tablets.

2. Practical significance

Evaluation tests for tablets play a vital role in ensuring the quality, safety, and effectiveness of products, as well as in enhancing consumer confidence and regulatory compliance. Quality control testing means checking the dosage forms during and after the production process to make sure that they are of expected standard. Demonstrating quality control tests for tablets is essential to increase the understanding about the official and unofficial control tests used for the evaluation of the manufactured tablets.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcomes	Mapped CO	BTL
1	Explain types of official and unofficial quality control tests for tablets.	CO4	BTL2
2	State the standard specifications for various Q.C. tests for tablets as per I.P.	CO4	BTL1
3	Describe the procedure for various Q.C. tests.	CO4	BTL3
4	Develop skills for measurement, weighing and mixing of ingredients	CO1-4	BTL3
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5

4. Relevant Theoretical Background

Many tests are performed in order to ensure the quality of the manufactured tablets and these tests are known as quality control tests. Quality control tests can be classified into two types:

- In-process quality control (IPQC) tests
- Final product quality control (FPQC) tests

In process quality control tests are carried out during the manufacturing process at regular intervals. The objective of IPQC is to monitor and, if necessary, adjust the manufacturing process in order to achieve the required standards. The IPQC tests for tablets include unofficial tests like general appearance, size and shape, mechanical strength/hardness and friability and official tests like weight variation, disintegration time and dissolution test. FPQC tests are performed after the completion of the manufacturing process according to the pharmacopoeia specifications, to determine whether the quality parameters are within acceptable limits. FPQC tests include assay (determination of drug content in tablet), content uniformity, in- vitro dissolution and some of the IPQC tests for confirmation purposes.

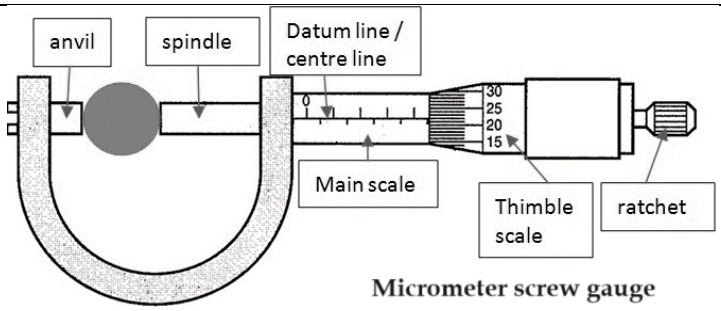
Unofficial tests:

a) General appearance:

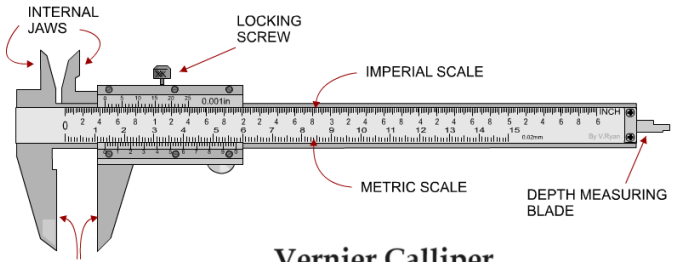
The appearance of tablets including its shape, color, size, and identification mark plays an important role in easy identification by both healthcare professionals and patients.

b) Dimensions:

The tablet's diameter and thickness are measured with the help of a micrometer screw gauge and a Vernier calliper.



Micrometer screw gauge



Vernier Calliper

c) Hardness:

Tablet hardness is indicative of the tablet's mechanical strength and resistance to chipping, breakage or crumbling during handling, transportation, and consumption. The crushing strength/mechanical strength of a tablet is measured through hardness testing. The Pharmacopoeia has not fixed any standard for hardness or mechanical strength of tablets. Normally, tablet hardness ranges from 4 to 10 kg/cm². The most common hardness testing equipment include Monsanto tester, Pfizer hardness tester.

Monsanto hardness tester

Pfizer Hardness tester

d) Friability:

This test is performed to evaluate the ability of tablets to withstand wear and tear in packing, handling and transportation. The apparatus used to perform this test is called friabilator. The Roche Friabilator is the most popular friability testing equipment. The apparatus consists of a plastic chamber which is divided into two parts, and it revolves at a speed of 25 rpm. Twenty tablets are weighed and placed in the plastic chamber. The chamber is rotated for 4 minutes or 100 revolutions. During each revolution, the tablets fall from 6 inches. The tablets are removed from the chamber after 100 revolutions and weighed. Loss in weight indicates friability. The percent friability is determined using the following formula:

Percent friability = $[(W_1-W_2)/W_1]x100$

Where, W_1 - is the weight of the tablets before test.

W_2- is the weight of the tablets after the test.

The tablets are considered to be of good quality if the loss in weight is less than 1%.

Official tests:

a) Weight variation test:

It is desirable that every individual tablet in a batch should be uniform in weight but a small variation in the weight is liable to occur. Therefore, a little variation is allowed in the weight of the tablet by the pharmacopoeia.

Specifications for weight variation test as per I.P.

Sr. No	Average weight of tablet	Percentage deviation (±)
1	80 mg or less	10
2	More than 80 mg & less than 250 mg	7.5
3	250 mg or more	5

b) Disintegration test:

Disintegration of a tablet means to break the tablet into smaller particles after swallowing. The time required for disintegration of a tablet is called disintegration time. In general, Pharmacopoeia has prescribed a limit of 15 minutes for most of the uncoated tablets.

Disintegration test apparatus (as per IP specifications): The apparatus consists of a rigid basket-rack assembly supporting 6 cylindrical glass tubes. These tubes are held vertically by 2 superimposed transparent plastic plates with six holes having the same diameter as the tubes. Woven wire gauze of stainless steel is attached to the underside of the lower plate. The assembly is raised and lowered between 28 and 32 times per minute in the liquid at 37ºC. The tablets are kept immersed in the liquid within the tubes by means of cylindrical guided discs. The assembly is suspended in the liquid medium in a 1000 ml beaker.

Disintegration test apparatus

c) Dissolution test:

The test is done for measuring the amount of time required for a given percentage of the drug in a tablet to go into solution under specified conditions in I.P. The apparatus consists of a cylindrical vessel made of glass or other transparent material having 1000 ml capacity. The vessel is fitted with a lid having 4 holes, one for the shaft of the stirrer, second for placing the thermometer and remaining two for removing the sample. A cylindrical stainless-steel basket made of woven wire cloth having an aperture size of 425 μm. An electric motor for rotating the basket in the vessel in speeds between 25 to 150 rpm. The vessel is equipped with a suitable device for withdrawal of the sample of the dissolution medium. The vessel should be securely clamped in a water bath maintained at 37ºC $\pm$ 0.5ºC.

Dissolution test apparatus

5. Procedure

a) Appearance

Examine the tablets using a biconvex lens for surface roughness, cracks, depression, pinholes, color and polish.

b) Dimensions

Step 1. Determine the diameter of the tablet using the Vernier calliper as shown below.

i. Initially determine the least count and zero error of the Vernier calliper. Close the outer measuring jaws and check whether the O^{th} mark on the Vernier scale is aligned with the O^{th} mark on the main scale as shown in the figure.
Also check whether the 10^{th} mark on the Vernier scale coincides with the 9^{th} mark on the main scale. If they coincide, then zero error will be nil. In such a case, calculate only the least count (LC). If they do not coincide, then calculate the LC and zero error.

LC = 1MSD - IVSD

where MSD= Main scale division and VSD=Vernier scale division.

Zero error = MSR_0+ (VSR_0 x LC)

where, MSR_0 = Main scale reading when jaws are closed, and VSR_0 Vernier scale reading i.e. number of the Vernier scale division which coincides with the division of the main scale when jaws are closed.

ii. Place the tablet laterally between the two jaws of the Vernier calliper and adjust the movable jaw so that it softly holds the tablet without exerting excessive pressure. After that, tighten the screw on the Vernier scale.

iii. From the position of the zero mark of the Vernier scale on the main scale, note the main scale reading (MSR)

iv. Note the number (n) of the Vernier scale division which coincides with the division of the main scale.

v. Determine the diameter of the tablet using the formula given below

Diameter (cm) = [MSR+(n x LC)] - Zero error

Repeat the procedure for two more tablets

Step 2. Determine the thickness of the tablet using a micrometer screw gauge as shown below.

i. Determine the pitch of the micrometer screw gauge by rotating the screw for 4 times and noting the distance covered by the edge of the screw on the pitch scale. (The distance moved by the tip of the screw on the pitch scale during one complete rotation is called the pitch of the screw. For a screw gauge of 100 circular division, the pitch is 1 mm i.e. for one rotation of screw, distance travelled by tip of screw on the pitch scale in 1 mm)

ii. Determine the LC of the screw gauge using the following formula.

LC = Pitch of screw/Number of divisions on circular scale

(LC of screw gauge is the distance moved by the tip of the screw when the screw is turned through 1 division of the head scale/pitch scale).

iii. Find the zero error by bringing the anvil and the screw into contact with each other. (Note the division number on the circular scale that coincides with the pitch scale line. The product of division number that coincides with the pitch scale line and LC is equal to zero error)

iv. Move the screw away from the anvil, place the tablet axially in between anvil and screw, and then use the ratchet head to move the screw back towards the anvil. When the ratchet slips and the screw does not move, stop moving the ratchet.

v. Take note of how many divisions on the pitch scale are visible and uncovered by the edge of the screw. This is referred to as the pitch scale reading (PSR)

vi. Take note of the division number (n) of the circular scale that lies over the reference line.

vii. Determine the thickness of the tablet using the formula given below:

Thickness (mm) = [PSR+(n x LC)] - Zero error

viii. Repeat the procedure for two more tablets.

c) Weight variation

a. Take 20 tablets.
b. Weigh the tablets individually and record weight.
c. Take the weight of 20 tablets collectively.
d. From collective weight, calculate average weight of tablet.
e. Consider the % variation from the weight of individual tablets by referring to Table (26.1).
f. Calculate % variation from average value.
g. Calculate upper limit and lower limit.
h. Compare weights of individual tablets to ascertain whether they are within permissible limits or not.

d) Hardness

a. Place the tablet diametrically on a fixed anvil of the Monsanto hardness tester.
b. Rotate the top screw of the tester to hold the tablet between the fixed and moving anvil of the tester.
c. Adjust the scale suitably to zero.
d. Rotate the top screw of the tester again to exert pressure on the tablet.
e. Continue the rotation of the screw till the tablet breaks.

f. At this stage, record the reading on scale.
g. Repeat the procedure for four more tablets.

e) Friability

a. Take 20 tablets, check their weight collectively (W_1).
b. Place these tablets in the plastic chamber of the friabilator.
c. Operate the friabilator for 100 revolutions at 25 rpm.
d. Once again remove the drum and weigh them (W_2)
e. Calculate the percent friability using the formula.

Percent friability $[(W_1-W_2)/W_1]x100$

Where, W_1 - is the weight of the tablets before test.
W_2 - is the weight of the tablets after the test.

f) Disintegration

a. Remove the basket rack assembly from the apparatus.
b. Place the required quantity of water (800 to 900 ml) into the beaker provided with the apparatus.
c. Place the beaker at its position and switch on the temperature knob to attain the temperature of medium to 37°C.
d. Add one tablet in each tube of the basket rack assembly and put in discs, if necessary,
e. Suspend assembly in medium and operate the apparatus for 15 minutes.
f. Observe continuously each tablet until it disintegrates.
g. Record disintegration time for all tablets.
h. At the end of 15 minutes, remove the basket assembly and observe each tube for any residue of the tablet.

6. Observations

a) Appearance

Sr. No	Test	Observation	Inference
1	Surface roughness		
2	Cracks		
3	Depression		
4	Pinholes		
5	Colour		
6	Polish		

b) Dimensions:

Step 1. Diameter

1 M.S.D. = 1 mm

10 V.S.D. = 9 M.S.D.

1 V.S.D. = 9/10 M.S.D. = 0.9 mm

Least count (LC) = 1 M.S.D. - 1 V.S.D. = (1 - 0.9) mm = 0.1 mm = 0.01 cm

Zero error = _____ cm

n= no. of vernier scale division which coincides with the division of main scale when jaws are closed.

Sr. No	Tablet No.	MSR	n	Zero error (x cm)	Diameter (cm) = [MSR + (n x LC)] - x
1	I				
2	II				
3	III				
Average tablet diameter (cm)					

Step 2. Thickness:

Pitch Scale Reading PSD = 1 mm

Number of full rotations given to screw = 4

Distance moved by the screw = _____ mm

Therefore, Pitch =

Number of divisions on circular scale = 100

Least count LC = Pitch of screw/Number of divisions on circular scale

LC = _____.

Zero error (x) = _____mm

Sr. No	Tablet No.	PSR	n	Zero error (x cm)	Thickness (cm) = [PSR + (n x LC)] - x
1	I				
2	II				
3	III				
Average tablet thickness (cm)					

c) Hardness

Tablet No.	Hardness (kg/cm^2)	Tablet No.	Hardness (kg/cm^2)
I		IV	
II		V	
III			
Average tablet diameter **(kg/cm^2)**			

d) Weight variation

Tablet No.	Individual Tablet weight (mg)	Average weight (mg)	Difference	Percent deviation Wavg -Wtab/Wavg X 100	More/Less than official limit
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Average Percent Deviation = _____

No. of tablets falling beyond the official limit = _____

Inference: _____

_____

e) Friability

Weight of 20 tablets (gm)		Difference W_1-W_2	Percent friability $[(W_1-W_2)/W_1] \times 100$
Before test W_1	After test W_2		

Inference: _____

_____

f) Disintegration

Sr. No	Tablet No	Disintegration time (min)	Residue on screen	Passes/Does not pass
1	I			
2	II			
3	III			
4	IV			
5	V			
6	VI			

7. Result

Various in-process quality control tests for the tablets were demonstrated successfully.

8. Conclusion

_____

_____

9. References

a. Mehta R. M., "Dispensing pharmacy" Nirali Prakashan Delhi.
b. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai

10. Practical Related Questions

a. Name the official and unofficial tests for the evaluation of tablets.
b. Write the specification table for weight variation test as per I.P.
c. Name three hardness testers that can be used to determine the hardness of the tablet.
d. Name the instruments used to determine the diameter and thickness of tablet?
e. What is the limit for disintegration time of the uncoated tablets as per I.P.?

(Space for Answers)

11. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**04**	**02**	**02**	**02**	**10**	

INTRODUCTION TO COSMETICS

According to D&C Act 1940, cosmetics are defined as the articles intended to be rubbed, poured, sprinkled or sprayed or introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance.

Functions of Cosmetics:

- Maintain body health and hygiene.
- Avoid premature ageing of skin.
- Give a sense of well-being.
- Improve overall looks and personality.

Classification of cosmetics:

1. According to their functions:

a. Curative functions: e.g., antiperspirants and hair preparations, etc.
b. Protective functions: e.g., Sunscreen, Moisturizers, etc.
c. Corrective functions: e.g., face powders. Foundation, etc.
d. Decorative functions: e.g., lipsticks, nail polishes, mascara etc.

2. According to body parts:

a. For skin: e.g. Creams, Lotions, Powders, Deodorants, Antiperspirants, etc.
b. For nails: e.g. Nail polish, Nail polish removers, Manicure preparations, etc.
c. For oral cavity: e.g., Dentifrices and Mouthwashes, etc.
d. For eye: e.g., Eye creams, eye lashes, eye line, etc.
e. For hair: e.g. shampoo, hair remover, hair dyes, hair tonics & hair sprays, etc.

CREAMS

Cream formulation is a semisolid emulsion dosage form used externally on the skin.

Classification of skin care creams:

a. According to function: Cleansing creams, foundation cream, massage cream, etc.
b. According to characteristic properties: Cold creams, vanishing cream, etc.
c. According to the nature or type of emulsion: o/w emulsion, w/o emulsion, etc
d. According to the therapeutic value: Insect repellent creams, topical creams, etc

Foundation cream:

These are designed to be applied to the face after cleansing to provide a smooth emollient base for application of facial makeup.

Moisturizing creams:

These creams are applied at night, their application during daytime is not very useful. The occlusive layer of these creams slows the rate of transepidermal water loss, thus having a moisturizing effect.

Cleansing cream:

Cleansing creams are used to remove facial makeup. They are also used to improve the healthy and good appearance of skin which requires frequent cleansing to remove grime, sebum and other secretions, dead cells and applied makeup.

Cold cream:

Cold creams are water in oil emulsion, which when applied on the skin, a cooling effect is produced due to slow evaporation of water present in the emulsion. It is mostly used in the winter season.

Vanishing creams:

These are oil in water type emulsion which when applied to the skin leave an almost invisible layer on it. Hence, they are called vanishing cream.

Container: Wide mouth plastic container.

Storage: Unless otherwise noted, store at a temperature below 25^0 C. Avoid freezing

Labelling:

Name of product	Qty
Composition: Direction for use: Use of preparation: Storage: Special instructions (if any):	Mfg licence no: Mfg Batch no.: Mfg date: Expiry date: MRP in Rs: **FOR EXTERNAL USE ONLY**
Mfg by: (Roll No) and Name of Institute	

SHAMPOO:

These are the solution or suspension containing surface active agents which are used to remove dirt, grease, and debris from the hair, scalp and other parts of the body without affecting the natural gloss of hair.

Shampoo helps to keep hair fragrance, lustrous, soft and manageable.

Types of shampoo:

- Medicated shampoo
- Clear shampoo
- Gel shampoo
- Soap shampoo
- Cream shampoo
- Baby shampoo
- Aerosol shampoo
- Powder shampoo

Qualities of an ideal shampoo:

a. It should be capable of removing dirt, grease from hair.
b. It should be nontoxic.
c. It should be non-irritant.
d. It should provide sufficient fragrance to the hair.
e. It should be effective in small amounts.
f. It should be easily removed.
g. It should produce sufficient foam.
h. It should reduce fluffiness and smoothens the hair shaft.

Formulation of Shampoo:

1. Conditioning agent:

- These are used in lubricating the hair and improving the texture of the hair.
- It reduces the fluffiness and smoothens the hair shaft.

- Ex. Lanolin, glycerin, and propylene glycol.

2. Thickening agent:

- These increase viscosity and provide desired consistency.
- Ex. Polyvinyl alcohol, methyl cellulose, sodium alginate.

3. Solubilizing agent:

- These are used to dissolve poorly soluble substances so as to get clear shampoo.
- Ex. Ethyl alcohol, glycerol, propylene glycol. And mono ethyl ether.

4. Opacifying agent:

- Opacifying agent added to make shampoo opaque.
- Ex. Glycol, glyceryl stearate, cetyl alcohol.

5. Preservative:

- Preservatives are added to prevent microbial growth.
- Ex. Methyl paraben, propyl paraben etc.

Container:
Narrow mouth plastic container, wide mouth plastic, pouches and plastic collapsible tubes.

Storage:
Store in a cool place protected from direct sunlight and replace the cap tightly.

Labelling:

1. For external use only.
2. Keep away from the reach of the children.
3. Mention that preparation is Medicated or non-medicated.

LOTIONS:
Lotions are liquid or viscous preparations intended for external application to the skin surface without friction. Lotions can be emulsions or solutions. On application to the skin, the water evaporates, leaving a residue of the medicament on the skin surface. The evaporation causes cooling, and therefore lotions can be applied to the acute area. The cooling effect may be enhanced by the inclusion of alcohol. Even though lotions are usually applied without friction, the insoluble matter should be divided very finely. A variety of ingredients are added to the preparation to produce better dispersions or to improve its cooling, soothing, drying, or protective properties.

Basic ingredients in body lotion:

- **Emollients**: help maintain soft, smooth skin.e.g. cetyl esters, glyceryl dilaurate, lanolin.
- **Emulsifiers**: it helps ingredients that naturally repel one another (e.g. oil and water) stay together and maintain their consistency. E.g. cetearyl alcohol, cetyl alcohol, ceteareth-20.
- **Fragrances**: It provides the pleasant smell common in many products.
- **Humectants**: It helps to attract and retain moisture to the surface of the skin. E.g. glycerin
- **Occlusives**: It helps for slow moisture evaporation from our skin's surface (typically oil-based). E.g. lanolin oil, dimethicone.
- **pH Adjusters**: It helps to regulate the pH of a product keeping it safe to use on the skin. E.g. sodium hydroxide.
- **Preservatives**: it helps to prevent unwanted bacteria and fungi from growing in the product. E.g. alcohol denat., chlorphenesin, benzyl alcohol.

- **Solvents**: It helps to dissolve the ingredients. E.g. water, alcohol denat., benzyl alcohol.

Container:

Wide mouth plastic container with screw cap, fluted jars, etc.

Storage:

Store in a cool place protected from direct sunlight and replace the cap tightly.

Labelling:

- For external use only
- Shake well before use.

TOOTHPASTE:

Toothpastes are semisolid dosage forms applied on the tooth surface externally with the help of a toothbrush for cleaning the surface of the teeth. It helps in removal of food particles, reduction of superficial plaque and teeth stains, polishing the teeth surfaces and freshening mouth breath. The pastes are generally very thick and stiff due to high solid content.

Qualities of toothpaste:

- It should be Economical.
- It should be non-toxic and non-irritant.
- It should be sweetened and flavoured
- It should have a good abrasive effect.
- It should give a fresh and clean sensation.
- It should be efficient in removing food substances, plaque and other foreign particles.

Formulation of toothpaste:

a. **Abrasives**: Helps to remove plaque and stains while causing only negligible damage to tooth structures or gums e.g. Calcium carbonate, sodium metaphosphate, magnesium carbonate, sodium carbonate and sodium chloride
b. **Binders**: Utilised to give toothpaste the right amount of viscoelasticity and form while preventing the separation of powdered and liquid constituents. E.g. cellulose, methyl cellulose, polyvinyl pyrrolidone, PEG Solution, etc.
c. **Detergents**: Detergents lower the surface tension of the liquid environment in the oral cavity so that they penetrate and dissolve plaque. This makes it easier to clean the teeth. E.g. deoxycholic acid and sodium lauryl sulphate.
d. **Flavouring agents**: Offer a delicious flavour, guaranteeing a pleasurable experience for the consumer. E.g. clove, lemon, spearmint, rose, and peppermint, etc.
e. **Humectants**: These prevent the quick drying of preparation. E.g. glycerin.
f. **Preservatives**: To prevent the growth of harmful bacteria and mould. E.g. Parabens and formaldehyde.
g. **Sweetening agents**: It improves the taste of toothpastes and gives them a mild and sweet taste.e.g., sucrose, aspartame, cyclamate, etc.

Labelling:

- FOR EXTERNAL USE ONLY
- REPLACE THE CAP TIGHTLY AFTER USE.

Experiment No. 27
Formulation and Evaluation of Cold Cream

1. Aim

To prepare, evaluate and submit 10 gm of Cold cream.

2. Practical Significance

Cold cream, traditionally made from water, oil, and wax, is a practical skincare product with multiple benefits, especially for those with dry or sensitive skin. Through this experiment, students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Cold cream.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcome	Mapped CO	BTL
PrO1	Calculate the factor for determining the working formula of Cold cream.	CO1-4	BTL3
PrO2	Prepare and evaluate Cold cream.	CO1-4	BTL5
PrO3	Explain the method of preparation and role of various agents.	CO1-4	BTL2
PrO4	Design the label for product and choose suitable container	CO1-4	BTL5
PrO5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
PrO6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

Creams are viscous semi-solid emulsions intended for external application to the skin or certain mucous membranes where occlusive action is not required. Creams are classified into two categories

a. Aqueous cream (o/w type)
b. Oily cream (w/o type).

This cold cream is an oily cream which spreads like a thin film over the skin surface. The main principle of cold cream involves slow evaporation of water which leads to cooling sensation. The name cold cream is derived from the cool feeling that the cream leaves on the skin.

In earlier days cold creams were prepared from animal fats and vegetable oils but such vegetable oils become rancid. That is why such vegetable oils are replaced by mineral oils which give a more stable product and emollient action. The cold creams are o/w type of emulsion but after application on the skin, sufficient water evaporates to cause the phase inversion and produce w/o type of emulsion. This cold cream contains 16% white beeswax as the base of the cream. The borax is used as an emulsifying agent and methyl paraben and propyl paraben present in the formulation acts as preservatives. To improve the stability of the product the liquid paraffin is used to find a way around the rancidity issue.

Owing to the presence of purified water, the cream leaves a cooling sensation on the skin. Generally, from the palatability point of view perfume may be used. Overall, the cream is used to clean, moisturise and soften the skin.

5. Requirements

a. **Apparatus**: Beaker, Measuring cylinder, Pipette, Glass rod, Spatula.

b. **Equipment:** Calibrated weighing balance, Electric water batch.

c. **Chemicals:** White beeswax, Liquid paraffin, borax, Methyl paraben, Propyl paraben, Perfume.

6. Factor Calculation:

Required Quantity = Quantity required/Quantity given =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given/ tablets	Quantity Required (Qty Given X Factor)	Uses
1	White beeswax	16 gm		
2	Liquid paraffin	50 gm		
3	Purified water	33 gm		
4	Borax	0.8 gm		
5	Methyl paraben	0.18 gm		
6	Propyl paraben	0.02 gm		
7	Perfume	q.s		

8. Procedure

a. White beeswax (MP 62-64°C) was taken to a beaker and melted on a water bath at 70°C.
b. To this melted wax liquid paraffin and propyl paraben was added and mixed properly to produce the oily phase.
c. In another beaker borax and methyl paraben was dissolved in water and the solution was heated at 70°C to produce the aqueous phase.
d. When both the aqueous and oily phase attained 70°C, then the aqueous phase was added to oily phase with agitation.
e. Add the perfume at room temperature.
f. Evaluate the preparation as per evaluation parameter and note the observations.
g. The cream was then packed in a wide mouthed screw capped amber jar or in a collapsible tube.
h. It was then labelled and submitted.

9. Use of Preparation

As an emollient and protective.

10. Direction

Use as directed.

11. Storage

It should be stored in a wide mouthed screw capped amber jar or in a collapsible tube in a cool and dry place.

12. Special Instruction

FOR EXTERNAL USE ONLY

13. Label:

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Cold cream	Appearance	White	
	Fragrance	Perfumed	
	pH	5-8	
	Consistency	Smooth	
	Washability	Not easily washable	
	Weight	10 gm	

15. Result

_____gm of Cold cream is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. B.M. Mithal, R.N. Shah, A Handbook of cosmetics, 1st ed Delhi, Vallabh Prakashan, 2000.
b. Mehta R. M., "Dispensing pharmacy" Nirali Prakshan Delhi.
c. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai

18. Practical Related Questions

a. Define cream.
b. What are the preservatives used in formulation of cold cream?
c. Mention the use of beeswax.
d. Write the precaution to take while mixing oily phase with aqueous phase.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 28
Formulation and Evaluation of Vanishing Cream

1. Aim

To prepare, evaluate and submit 10 gm of Vanishing cream.

2. Practical Significance

Vanishing cream, often used as a moisturiser, is suitable for various skin types and makeup applications. It can provide a smooth base for makeup. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Vanishing cream.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcome	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Vanishing cream.	CO1-4	BTL3
2	Prepare and evaluate Vanishing cream.	CO1-4	BTL5
3	Explain the method of preparation and role of various agents.	CO1-4	BTL2
4	Design the label for product and choose suitable container	CO1-4	BTL5
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

Vanishing creams are oil in water type emulsion which when applied to the skin leave an almost invisible layer on it. Hence, they are called vanishing cream. These creams can quickly be washed off with water due to the presence of o/w emulsifiers. It is frequently used as a moisturizer because of its quick absorption into the skin, which make it perfect for regular usage without leaving a greasy residue. It is appropriate for a range of skin types and cosmetic applications because it helps hydrate the skin without clogging pores. Vanishing cream is prepared by emulsification of stearic acid by means of alkalis such as potassium hydroxide. The main ingredient in vanishing cream is stearic acid which gives a pearly white shining appearance to the cream, which on application gives a thin white film of free stearic acid. To maintain consistency and spreadability, glycerin is added.

5. Requirements

1. **Apparatus**: Beaker, Measuring cylinder, Pipette, Glass rod, evaporating dish, Spatula.
2. **Equipment:** Calibrated weighing balance, Electric water batch.
3. **Chemicals:** Stearic acid, Potassium hydroxide, Glycerin, Methyl paraben, Propyl paraben, Perfume.

6. Factor Calculation:

Required Quantity = Quantity required/Quantity given =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given/ tablets	Quantity Required (Qty Given X Factor)	Uses
1	Stearic acid	15 gm		
2	Potassium hydroxide	0.7 gm		
3	Purified water	76 gm		
4	Glycerin	8 gm		
5	Methyl paraben	0.2 gm		
6	Propyl paraben	0.02 gm		
7	Perfume	q.s		

8. Procedure

a. Stearic acid (mp 69.3°C) was taken in an evaporating dish and melted on a water bath at 70°C to produce the oily phase.
b. Potassium hydroxide was dissolved in freshly boiled and cooled purified water in a beaker.
c. Then glycerin was added in the potassium hydroxide solution with stirring and the mixture was heated to 70°C to form the aqueous phase.
d. When both the aqueous and oily phase attained 70°C, then the oily phase was added to the aqueous phase with agitation.
e. Then the calculated amounts of methyl & propyl paraben followed by the perfume were added into the cream and stirred until cold enough to assist packing.
f. Evaluate the preparation for evaluation parameter and note the observations.
g. Then pack the cream in a wide mouthed container, label and submit.

9. Use of Preparation:

As a moisturizer.

10. Direction:

Use as directed.

11. Storage:

It should be stored in a wide mouthed well closed container in a cool and dry place.

12. Special Instruction:

FOR EXTERNAL USE ONLY

13. Label:

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14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Vanishing cream	Appearance	White	
	Fragrance	Perfumed	
	Consistency	Smooth	
	Washability	Easily washable	
	pH	5 to 8	
	Weight	10 gm	

15. Result

_____gm of Vanishing cream is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. B.M. Mithal, R.N. Shah, A Handbook of cosmetics, 1st ed Delhi, Vallabh Prakashan, 2000.
b. Mehta R. M., "Dispensing pharmacy" Vallabh Prakshan Delhi.

18. Practical Related Questions

a. Define vanishing cream.
b. State the role of potassium hydrochloride in vanishing cream.
c. How does this preparation become pearl white?
d. Why is glycerin added in this preparation?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 29
Formulation and Evaluation of Clear Shampoo

1. Aim

To prepare, evaluate and submit 10 ml clear shampoo.

2. Practical Significance

Shampoo is essential for maintaining clean, healthy hair. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of clear shampoo.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcome	Mapped CO	BTL
1	Calculate the factor for determining the working formula of clear shampoo.	CO1-4	BTL3
2	Prepare and evaluate clear shampoo.	CO1-4	BTL5
3	Explain the method of preparation and role of various agents.	CO1-4	BTL2
4	Design the label for product and choose suitable container	CO1-4	BTL5
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

Shampoo, a cosmetic preparation serves several purposes beyond just cleaning hair. It helps remove dirt, excess oil, and product buildup, promotes scalp health, prevents dandruff, and can even improve the appearance and manageability of hair. Additionally, many shampoos contain conditioning agents to hydrate and strengthen hair strands. Surfactant that is utilized as a cleaning and foaming agent is sodium lauryl sulphate. Sodium citrate is incorporated as a viscosity modifier. In order to condition the formulation and keep it from drying out, glycerin is added. HPMC-K100 is employed as a thickening agent. Avoid using too much clear shampoo since the surfactants can cause the scalp to become dry and stimulate the production of more oil by the underlying cells.

5. Requirements

a. **Apparatus**: Beaker, Measuring cylinder, Pipette, Glass rod, Spatula.

b. **Equipment:** Calibrated weighing balance, Electric water batch.

c. **Chemicals:** Sodium lauryl sulphate, Sodium citrate, HPMC K100, Glycerin, Methyl paraben, Propyl paraben, Perfume and colour.

6. Factor Calculation:

Required Quantity = Quantity required/Quantity given =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given/ tablets	Quantity Required (Qty Given X Factor)	Uses
1	Sodium lauryl sulphate	10 gm		
2	Sodium citrate	1 gm		
3	HPMC K100	3 gm		
4	Glycerin	5 gm		
5	Methyl paraben	0.18 gm		
6	Propyl paraben	0.02 gm		
7	Perfume	q.s		
8	Colour	q.s		
9	Purified water (q.s)	100 ml		

8. Procedure

a. Dissolve sodium lauryl sulphate and sodium citrate in 75% of purified water.
b. Add methyl paraben, propyl paraben and glycerin to the above prepared solution.
c. Add colour and perfume to the preparation.
d. Disperse HPMC K100 in the above solution with continuous stirring for 20 minutes at 60°C
e. Cool the preparation.
f. Add the water up to required volume.
g. Evaluate the preparation as per parameters given and note the observations.
h. Lastly transfer the solution to the container, label and submit.

9. Use of Preparation: As a hair cleaning product.

10. Direction: Use as directed.

11. Storage: It should be stored in a narrow mouthed, well closed container in a cool and dry place.

12. Special Instruction: FOR EXTERNAL USE ONLY

13. Label:

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Clear shampoo	Appearance	Clear with no grittiness	
	Fragrance	Perfumed	
	Consistency	Semi solid, Smooth	
	Washability	Easily washable	
	pH	5 to 8	
	Volume	10 ml	

15. Result

_____ ml of clear shampoo is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. B.M. Mithal, R.N. Shah, A Handbook of cosmetics, 1st ed Delhi, Vallabh Prakashan, 2000.
b. Mehta R. M., "Dispensing pharmacy" Vallabh Prakashan Delhi.
c. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai

18. Practical Related Questions

a. Define Shampoo.
b. State the role of sodium citrate in clear shampoo.
c. Why is HPMC K100 included in this preparation?
d. Mention the types of shampoo.
e. Write the brand name and manufacturer's name of any one marketed medicated shampoo.

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 30
Formulation and Evaluation of Body Lotion

1. Aim

To prepare, evaluate and submit 10 gm of Body lotion.

2. Practical Significance

Body lotion maintains skin's hydration levels by locking in the moisture, keeping the skin healthy, soft, and supple. Maximum sold lotion in the market is body lotion. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of body lotion.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcome	Mapped CO	BTL
1	Calculate the factor for determining the working formula of body lotion.	CO1-4	BTL3
2	Prepare and evaluate body lotion.	CO1-4	BTL5
3	Explain the role of various agents.	CO1-4	BTL2
4	Design the label for product and choose suitable container	CO1-4	BTL5
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Backgrounds:

Body lotion helps to moisturize and hydrate the skin, preventing dryness and flakiness, especially in harsh weather conditions or after bathing. Secondly, it can improve the skin's texture and appearance by smoothing rough areas and softening the skin. Additionally, body lotion often contains ingredients that can soothe irritation and reduce redness, making it beneficial for those with sensitive skin or conditions like eczema.

The most common moisturizing ingredients are occlusive agents, which create a barrier that keeps water from escaping the skin. Dimethicone, mineral oil, and petrolatum are examples of occlusive agents. Glycerin is the humectant that is most typically utilized. The lotion's feeling on the skin is then enhanced by the addition of emollients which includes silicones, coconut oil, and cetyl esters. Body lotions need to contain emulsifiers as well as moisturizers since they help blend the oil and water together. Glyceryl stearate and stearic acid are frequently used as emulsifiers. The mixture is kept stable and given a pleasing appearance with the use of thickeners and other ingredients, like colorants, perfume, and preservatives are added to the mixture to make it well-rounded.

5. Requirements

a. **Apparatus**: Beaker, Measuring cylinder, Pipette, Glass rod, Spatula.

b. **Equipment:** Calibrated weighing balance, Electric water batch.

c. **Chemicals:** Sodium lauryl sulphate, Sodium citrate, HPMC K100, Glycerin, Methyl paraben, Propyl paraben, Perfume and colour.

6. Factor Calculation:

Required Quantity = Quantity required/Quantity given =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given/ tablets	Quantity Required (Qty Given X Factor)	Uses
1	Cetyl alcohol	2 gm		
2	Stearic acid	0.8 gm		
3	Glyceryl monostearate	1.5 gm		
4	Glycerin	3 gm		
5	Liquid paraffin (mineral oil)	5.25 gm		
6	Methyl paraben	0.1gm		
7	Propylparaben	0.05 gm		
8	Isopropyl myristate	1.5 gm		
9	Carbopol 934P	5 gm		
10	Triethanolamine	0.9 gm		
11	Perfume	q.s.		
12	Purified water (q.s)	79.9 gm		

8. Procedure

a. Accurately weigh all the solid ingredients and measure all liquid ingredients.
b. Clean all the glassware and dry it properly.
c. Take purified water in a beaker and carbopol 934P, glycerin, methyl paraben and triethanolamine to it (aqueous phase).
d. Heat aqueous phase up to 70°C with continuous agitation until all the solid ingredients are completely dissolved.
e. In another beaker take mineral oil and cetyl alcohol, stearic acid, glyceryl monostearate, propyl paraben and isopropyl myristate to it (oily phase).
f. Slowly add oily phase to aqueous phase (maintained at 70°C) with continuous stirring to obtain uniform emulsion.
g. Stir this mixture for 30 minutes and allow it to cool.
h. At a temperature below 40°C, add perfume.
i. Evaluate formulation as per evaluation parameters and note the observations.
j. Fill the lotion in a suitable wide mouth container followed by labelling and submission.

9. Use of Preparation:

As a moisturizer.

10. Direction:

Use as directed.

11. Storage:

It should be stored in a well closed container in a cool and dry place.

12. Special Instruction:

FOR EXTERNAL USE ONLY

13. Label:

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Body lotion	Appearance	Clear with no grittiness	
	Fragrance	Perfumed	
	Colour	White	
	Consistency	Semi solid, Smooth	
	Washability	Easily washable	
	pH	5 to 5.5	
	Weight	10 gm	

15. Result

_____gm of body lotion is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. B.M. Mithal, R.N. Shah, A Handbook of cosmetics, 1st ed Delhi, Vallabh Prakashan, 2000.
b. Mehta R. M., "Dispensing pharmacy" Vallabh Prakashan, Delhi.
c. Laboratory Manual of Pharmaceutics-I, published by Maharashtra State Board of Technical Education, Mumbai

18. Practical Related Questions

a. Define body lotion.
b. State the uses of body lotion.
c. Why is mineral oil included in this preparation?
d. Mention the use of isopropyl myristate.
e. Write the brand name and manufacturer's name of any one marketed body lotion.
f. Can body lotion be applied to the face? Yes or no and why?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 31
Formulation and Evaluation of Toothpaste

1. Aim

To prepare, evaluate and submit 10 gm of Toothpaste.

2. Practical Significance

Toothpaste serves several practical purposes: it cleans teeth by removing plaque and food particles, freshens breath, prevents tooth decay and gum disease, and can contain ingredients to address specific dental concerns like sensitivity or whitening. Through this experiment students will learn about formulation, method of preparation, labelling aspects, storage conditions, uses, directions and evaluation of Toothpaste.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcome	Mapped CO	BTL
1	Calculate the factor for determining the working formula of Toothpaste.	CO1-4	BTL3
2	Prepare and evaluate Toothpaste.	CO1-4	BTL5
3	Explain the role of various agents.	CO1-4	BTL2
4	Design the label for product and choose suitable container	CO1-4	BTL5
5	Apply cleanliness, safety and ethical practice in laboratory	CO1-4	BTL3
6	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Backgrounds:

Toothpaste is used to promote oral hygiene: it helps to strengthen the enamel that has been attacked by acids. It contains an abrasive that aids in removing dental plaque and food from the teeth, assists in suppressing halitosis (bad smelling breath), and delivers active ingredients (most commonly fluoride) to help prevent tooth decay (dental caries) and gum disease (gingivitis).

An ideal formulation of toothpaste must contain an abrasive agent, surfactant, humectant, gelling agent, sweetener, flavoring agent, preservative and a vehicle. This toothpaste contains 55% calcium carbonate, an abrasive agent which cleans the teeth. Sodium carboxymethyl cellulose is used here as a gelling agent to bind all the particles together to render consistency to the paste. Sodium lauryl sulphate is a surfactant and it reduces down the surface tension between the teeth adhered to dirty materials and water, this facilitates the filthy materials expulsion from the oral cavity.

Glycerin being a humectant retains the moisture in the paste during its use and when stored. It preserves the consistency and gloss of the product. Sodium saccharin is used to impart sweetness to the paste. Pastes are susceptible to microbial growth and that is why preservatives are used. Sodium benzoate is used here as a preservative and menthol contributes flavor to the paste. Menthol assists to deodorize the buccal cavity. Purified water is used here as a vehicle.

5. Requirements

a. **Apparatus**: Mortar and pestle, Measuring cylinder, Pipette, Glass rod, Spatula.

b. **Equipment:** Calibrated weighing balance.

c. **Chemicals:** Precipitated calcium carbonate, Sodium lauryl sulphate, Sodium saccharine, Sodium carboxymethyl cellulose, Glycerin, Sodium benzoate, Menthol.

6. Factor Calculation:

Required Quantity = Quantity required/Quantity given =

7. Formulation Table:

Sr. No.	Ingredients	Quantity Given/ tablets	Quantity Required (Qty Given X Factor)	Uses
1	Precipitated calcium carbonate	55 gm		
2	Sodium carboxymethyl cellulose	1 gm		
3	Sodium lauryl sulphate	1 gm		
4	Glycerin	22 gm		
5	Sodium saccharine	0.5 gm		
6	Menthol	1gm		
7	Sodium benzoate	0.5 gm		
8	Purified water	19 gm		

8. Procedure

a. First, precipitated calcium carbonate was triturated in a mortar to reduce its size.
b. It was then passed through sieve no. 120 to obtain uniform sized powder.
c. The sieved calcium carbonate powder was weighed precisely using an electronic balance.
d. Sodium carboxymethyl cellulose was taken in a separate mortar and triturated with water to form smooth mucilage.
e. Then glycerin, sodium saccharine, sodium lauryl sulphate, followed by calcium carbonate were added one after one to the second mortar with continuous trituration to make a smooth paste.
f. Then sodium benzoate and menthol were finally incorporated in the paste.
g. Evaluate formulation as per evaluation parameters and note the observations.
h. Fill the paste in an aluminium collapsible tube followed by labelling and submission.

9. Use of Preparation

As a dentifrice, to clean the teeth and to deodorize the buccal cavity.

10. Direction

Use as directed.

11. Storage

It should be stored in a well closed aluminium collapsible tube in a cool and dry place.

12. Special Instruction

- FOR EXTERNAL USE ONLY
- REPLACE THE CAP TIGHTLY AFTER USE.

13. Label

14. Evaluation Table:

Name of preparation	Test	Specification	Observation
Toothpaste	Appearance	Free from grittiness	
	Fragrance	Perfumed	
	Consistency	Smooth	
	Weight	10 gm	

15. Result

_____gm of toothpaste is prepared, evaluated and submitted in a _____ container with special instructions as_____.

16. Conclusion

_____

_____

17. References

a. B.M. Mithal, R.N. Shah, A Handbook of cosmetics, 1st ed Delhi, Vallabh Prakashan, 2000.

18. Practical Related Questions

a. Define dentifrices.
b. State the uses of toothpaste.
c. Why is glycerin added in this preparation?
d. Mention the use of calcium carbonate.
e. Write the brand name and manufacturer's name of any two marketed toothpastes.

f. Why should strong abrasive agents not be used in the preparation of toothpaste?

(Space for Answers)

19. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Packaging in appropriate container & labelling	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained							
Max Marks	**02**	**02**	**02**	**02**	**02**	**10**	

Experiment No. 32
Demonstration of Use of Special Dosage Forms

1. Aim

To demonstrate the technique of use and storage of special dosage forms.

2. Practical Significance

For the improvement of drug effects, some special dosage forms have been designed, such as insulin pens, inhalers, and spacers. Insulin pens are incredibly useful for people with diabetes. Inhalers are essential for people with respiratory tract infection and spacers are crucial accessories for inhaler users, especially for those who have difficulty coordinating their inhaler technique. Through this experiment, students will learn about the technique of use, which will help them in counselling patients for correct technique of uses and storage of these dosage forms.

3. Practical Outcome (PrOs)

After completion of this practical, the students will be able to:

PrO	Practical Outcome	Mapped CO	BTL
1	Recognize insulin pens, inhalers, and spacers	CO2	BTL1
2	List the various parts of special dosage form	CO2	BTL1
3	Demonstrate technique of use of insulin pens, inhalers, and spacers	CO2	BTL3
4	Follow the cleanliness, safety and ethical practice in laboratory	CO1-4	BTL5
5	Collaborate and communicate with fellow students	CO1-4	BTL5

4. Relevant Theoretical Background

Inhalers:

Inhalers are essential for people with respiratory conditions such as asthma or chronic obstructive pulmonary disease (COPD). They deliver medication directly to the lungs, providing quick relief during asthma attacks or helping to manage symptoms over the long term. Inhalers are portable and easy to use, allowing individuals to carry them wherever they go for immediate access to medication when needed. They significantly improve the quality of life for those with respiratory conditions by providing effective symptom relief and helping to prevent exacerbations.

Spacers:

Spacers are crucial accessories for inhaler users, especially for those who have difficulty coordinating their inhaler technique. They improve the delivery of medication to the lungs by slowing down the speed of the medication particles, making it easier to inhale effectively. Spacers also reduce the risk of side effects such as oral thrush by minimizing the amount of medication deposited in the mouth and throat. Overall, spacers enhance the effectiveness and safety of inhaler use, making them essential tools for managing respiratory conditions like asthma and COPD.

Insulin pens:

Insulin pens are incredibly practical for people with diabetes because they provide a convenient and discreet way to administer insulin. They're portable, easy to use, and offer precise dosing, which is crucial for managing blood sugar levels effectively throughout the day. Additionally, their design makes them suitable for use in various settings, including at home, work, or while traveling.

5. Procedure

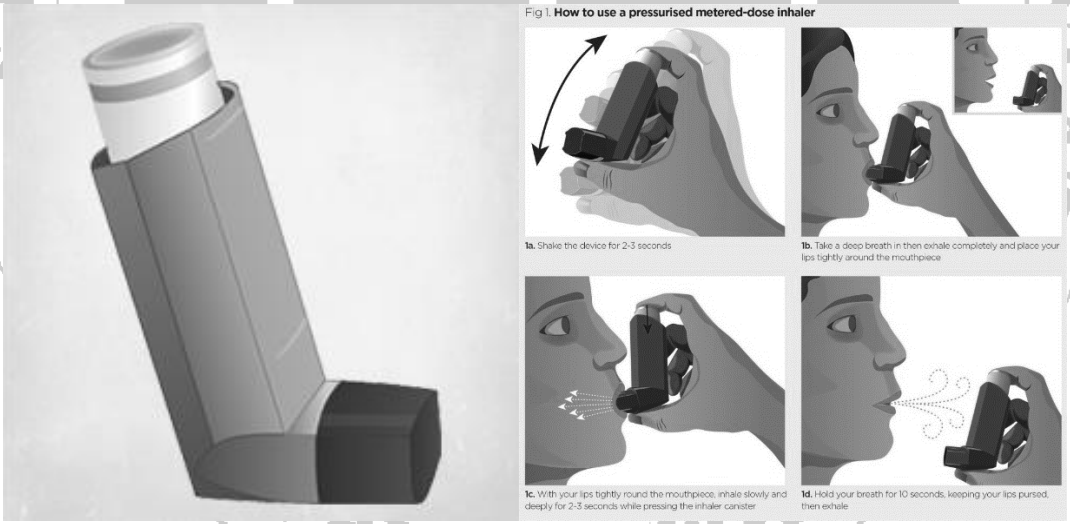
A. Demonstration of technique of uses of special dosage form:

I. Metered dose inhaler:

A metered-dose inhaler is a small, hand-held device filled with medicine to treat breathing problems. It helps deliver a certain amount of medicine through your mouth and into your lungs. It is commonly used to treat breathing difficulties related to asthma, chronic obstructive pulmonary disease (COPD), and other respiratory problems.

Method of use:

a. Remove the cap and hold the inhaler upright.
b. If your doctor recommends, use a spacer (a hollow, plastic chamber) to filter the medicine between the inhaler and your mouth. The chamber protects your throat from irritation from the medicine.
c. Stand or sit up straight.
d. Shake the inhaler.
e. Tilt your head back slightly and breathe out all the way.
f. Put the inhaler in your mouth.
g. Press down on the inhaler quickly to release the medicine as you start to breathe in slowly.
h. Breathe slowly for 3 to 5 seconds.
i. Hold your breath for 10 seconds to allow medicine to go deeply into your lungs.
j. Breathe out slowly.
k. Repeat puffs as directed by your doctor. Wait 1 minute before taking the second puff.



Cleaning and maintenance of Inhaler:

a. Unscrew the top of the inhaler. Always keep the top section dry.
b. Remove the metal canister and store it away from water.
c. Rinse the inhaler's plastic housing with warm water.
d. If feasible, allow the casing to dry overnight, and keep a backup inhaler on hand in case it is needed.
e. Once dry, replace the canister in the bottom of the inhaler, attach the cap, and screw the top back on.

Storage:

a. Keep the lid on your inhaler. This keeps dust and debris out, so you won't breathe it in.

b. Keep your inhaler at the appropriate temperature. Extreme temperatures and high altitudes can have an effect on the medication in your inhaler. Don't keep your inhaler where it could get too hot or cold, such as in your car or on a sunny windowsill.
c. Store your inhaler somewhere dry. Keeping your inhaler in the bathroom may cause the drug to become moist.
d. All medications should be stored safely, out of the reach of children.

II. Spacers:

Getting Ready

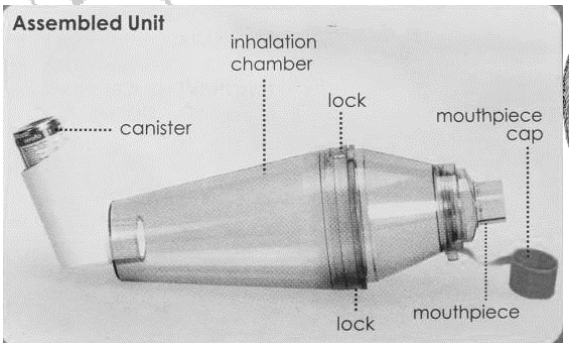
a. If you have not used the inhaler in a while, you may need to prime it.
b. Take the cap off the inhaler and spacer.
c. Shake the inhaler hard 10 to 15 times before each use.
d. Attach the spacer to the inhaler.
e. Breathe out gently to empty your lungs. Try to push out as much air as you can.

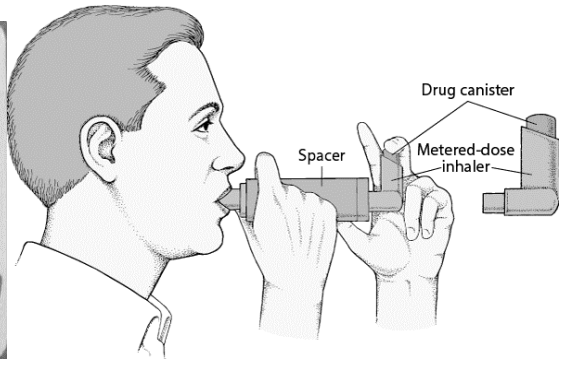
Breathe in Slowly

a. Put the spacer between your teeth and close your lips tightly around it.
b. Keep your chin up.
c. Start breathing in slowly through your mouth.
d. Spray one puff into the spacer by pressing down on the inhaler.
e. Keep breathing in slowly. Breathe as deeply as you can.

Hold Your Breath

a. Take the spacer out of your mouth.
b. Hold your breath as you count to 10, if you can. This lets the medicine reach deep into your lungs.
c. Pucker your lips and slowly breathe out through your mouth.
d. If you are using inhaled, quick-relief medicine (beta-agonists), wait about 1 to 2 minutes before you take your next puff. You do not need to wait between puffs for other medicines.
e. Put the caps back on the inhaler and spacer.
f. After using your inhaler, rinse your mouth with water, gargle, and spit. Do not swallow the water. This helps reduce side effects from your medicine.





Cleaning and maintenance of spacers:

a. Dismantle your spacer
b. Wash all parts in clean, warm water with liquid dishwashing detergent.
c. Allow the pieces to air dry without rinsing; drying with a cloth or paper towel can result in static building up on the inside of the spacer, causing the medication to adhere to the sides.
d. Clean the mouthpiece with detergent.
e. When thoroughly dry and reassemble as needed.

Storage of spacer:

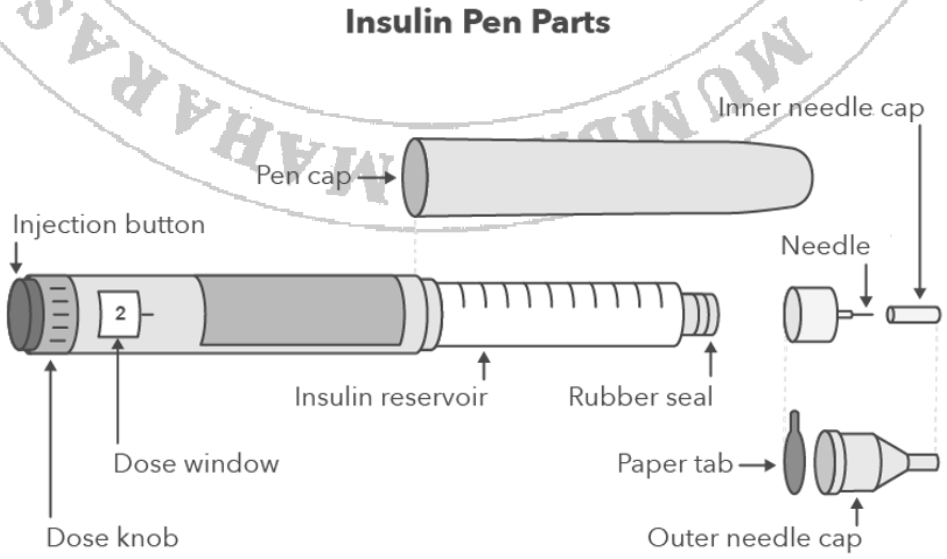
a. Keep your spacer away from dust and liquids so that you don't breathe them in.
b. If you carry your spacer in your bag, keep it in a plastic-free sealed purse or small bag so it doesn't get scratched, and so small objects don't get stuck inside it.

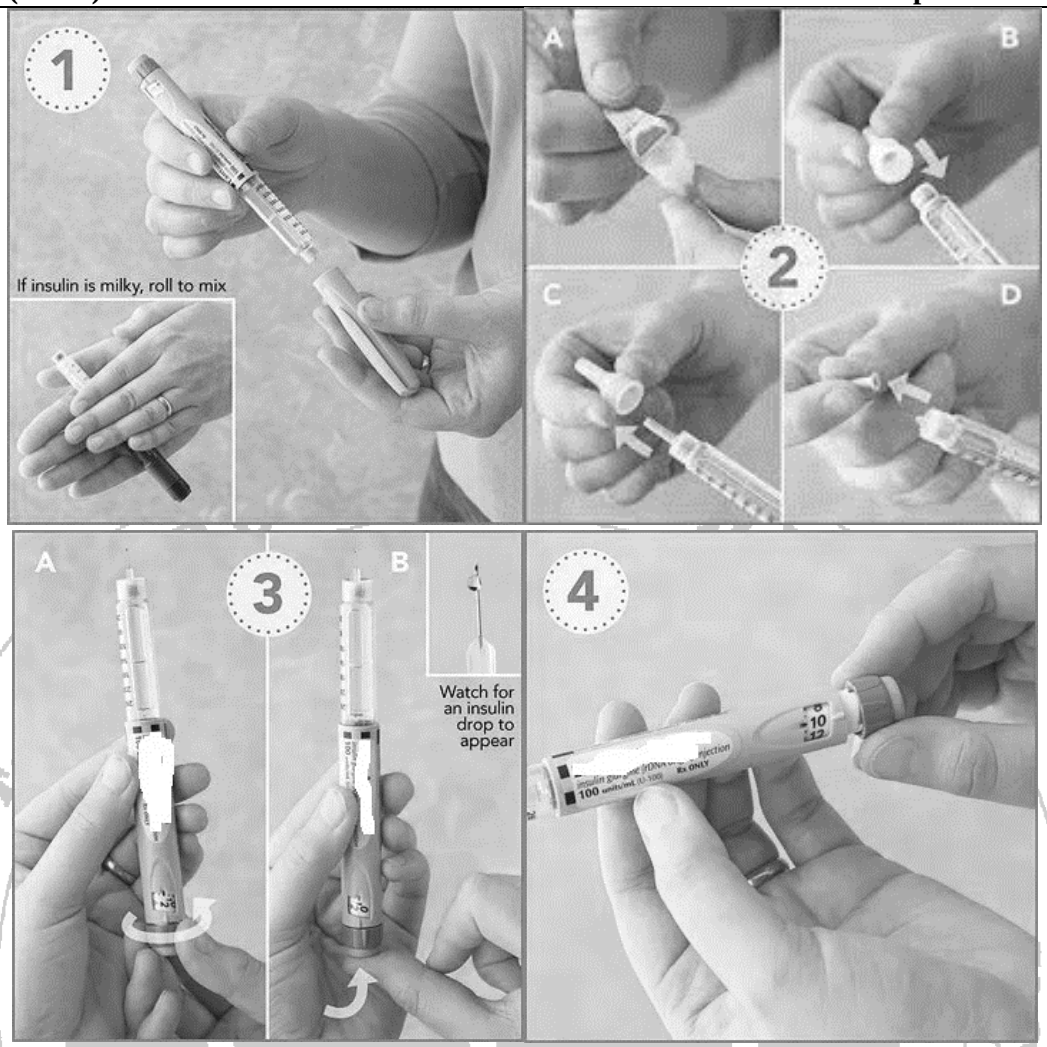
III. Insulin pen:

An insulin pen is an injection device that you can use to deliver preloaded insulin into your subcutaneous tissue — the innermost layer of skin in your body. These pens are one form of insulin therapy for people with diabetes. They're a type of multiple daily injection (MDI).

Parts of an insulin pen

- **Insulin reservoir**: This is a clear plastic container that holds the insulin in the pen. You can see the "quality" of the insulin (like if it's cloudy or clear) and how much insulin is left in the pen. Some pens have insulin cartridges (reservoirs) that you can replace. Other pens are disposable, you throw them away once the insulin reservoir runs out.
- **Pen cap**: The cap protects the insulin reservoir from damage when you're not using the pen.
- **Rubber seal**: The rubber seal is where you connect a single-use needle for an injection.
- **Needle**: Needles for insulin pens are single-use, which means you only use them for one injection and then throw them away. Each needle comes in a sterile protective container. You remove the needle from the container and attach it to the pen before an injection. Pen needles come in different sizes. Talk to your healthcare provider to choose the pen needle that's best for you.
- **Dosage knob**: This is a knob you turn to select the insulin dose you need.
- **Dosage window**: This shows the number of units of insulin you select using the knob.
- **Injection button**: Once you inject the pen needle, you press the injection button to give the insulin dose.
- **Label**: The label tells you the type and brand of insulin in the pen and its expiration date.





Demonstration of use of insulin pen

6. Observation Table

Sr. No.	Special dosage form	Brand name of marketed product	Name of manufacturer
1	Inhaler		
2	Spacer		
3	Insulin pen		

7. Result

The technique of use of special dosage form _____ were demonstrated successfully.

8. Conclusion

_____

_____

9. References

a. Pharmaceutical services division, Ministry of Health Malaysia, Handbook of inhaler devices: A Practical Guide for Pharmacists: 1-15, 57-71.

b. Pearson TL, Practical aspects of insulin pen devices, J. Diabetes Sci Technol, 2010:4(3):522-531.

10. Practical Related Questions

a. What do you mean by metered dose inhaler?
b. List the parts of the inhaler.
c. Write the conditions for maintenance of the inhaler.
d. List the parts of the insulin pen.
e. Write the use of an insulin pen.
f. How is spacer useful for kids?

(Space for Answers)

11. Assessment Scheme:

Particular	Performance – Preparation (Motor skill)	Manual completion	Discipline (Affective domain)	Viva-voce	Total	Signature of teacher
Marks Obtained						
Max Marks	**04**	**02**	**02**	**02**	**10**	

GUIDELINES FOR CONDUCTION OF SESSIONAL PRACTICAL EXAMINATION

Class: F.Y. D. Pharm **Subject: Pharmaceutics (20051)**

Max marks: 80 **Time: 3 hours**

Q. 1 Write synopsis on the following: **(10)**

Definition, classification, differences in dosage form, theoretical background, Specific methods, Uses of preparation, Quality control tests, Uses/role of ingredients, Specific storage and labelling instructions,

(Question = 5 question of 2 marks each is to be asked)

Q. 2 Major Experiment:

Prepare, evaluate and submit following preparation with proper labelling. **(30)**

Emulsions, Suspension (Mixture), Tablet, Ointments, Creams, Cosmetics, Effervescent granules, Injectable (Ampoules).

Q. 3 Minor Experiment:

Prepare and submit following preparation with proper labelling. **(20)**

Syrup, Elixir, Solution, Lotion, Liniments, dry powder, capsule.

Q. 4 Practical record marks **(10)**

Average marks of experiments (First sessional experiments no 01 to 10, Second sessional experiments no 11 to 21, Third sessional experiments no 22 to 32)

Q. 5 Viva voce **(10)**

Questions Pertaining to the practical curriculum

GUIDELINES FOR CONDUCTION OF ANNUAL PRACTICAL EXAMINATION

Class: F.Y. D. Pharm **Subject: Pharmaceutics (20051)**

Max marks: 80 **Time: 3 hours**

Q. 1 Write synopsis on the following: **(10)**

Definition, classification, differences in dosage form, theoretical background, Specific methods, Uses of preparation, Quality control tests, Uses/role of ingredients, Specific storage and labelling instructions, Special instructions.

Question = 5 question of 2 marks each is to be asked.

Q. 2 Major Experiment: **(35)**

Prepare, evaluate and submit following preparation with proper labelling:

Emulsions, Suspension (Mixture), Tablet, Ointments, Creams, Cosmetics, Effervescent granules, Injectable (Ampoules).

Q. 3 Minor Experiment: **(25)**

Prepare and submit following preparation with proper labelling.

Syrup, Elixir, Solution, Lotion, Liniments, dry powder, capsule.

Q. 4 Viva voce **(10)**

Questions Pertaining to the practical curriculum