FIRST YEAR DIPLOMA IN PHARMACY

PH

A LABORATORY MANUAL FOR PHARMACEUTICS I

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 changing technological and environmental challenges.

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MSBTE believes in the followings:

- Education industry produces live products.
- Market requirements do not wait for curriculum changes.
- Question paper is the reflector of academic standards of educational organization.
- Well designed curriculum needs effective implementation too.
- Competency based curriculum is the backbone of need based program.
- Technical skills do need support of life skills.
- Best teachers are the national assets.
- Effective teaching learning process is impossible without learning resources.

A Laboratory Manual for

Pharmaceutics – I

(0805)

(Industrial Pharmacy)

Maharashtra State

Board of Technical Education, Mumbai

(Autonomous) (ISO-9001-2015) (ISO/IEC 27001:2013)

Maharashtra State Board of Technical Education,
(Autonomous) (ISO 9001 :2015) (ISO/IEC 27001 : 2013)
4th Floor, Government Polytechnic Building, 49, Kherwadi,
Bandra (East), Mumbai - 400051.
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MAHARASHTRA STATE BOARD OF TECHNICAL EDUCATION

Certificate

This is to certify that, Mr. / Ms. _____

roll no. _____ of First Year Diploma in Pharmacy has completed the term work satisfactorily in **Pharmaceutics – I (0805)** for the academic year 20_____ to 20_____ as prescribed in the curriculum.

Place : _____ Enrolment No.: _____

Date : _____ Exam. Seat No.: _____

Subject Teacher

Seal of Institution

Principal

External Examiner

LEARNING OVERVIEW

OBJECTIVE OF STUDYING PHARMACEUTICS – I (INDUSTRIAL PHARMACY)

"The desire to make medicine perhaps the greatest feature which distinguishes man from the animal". Initially drug existing in nature was used in raw state like root, bark and leaves to maintain health of human being. Due to development in science and technology, different dosage forms were designed and consumed by living being to maintain good health.

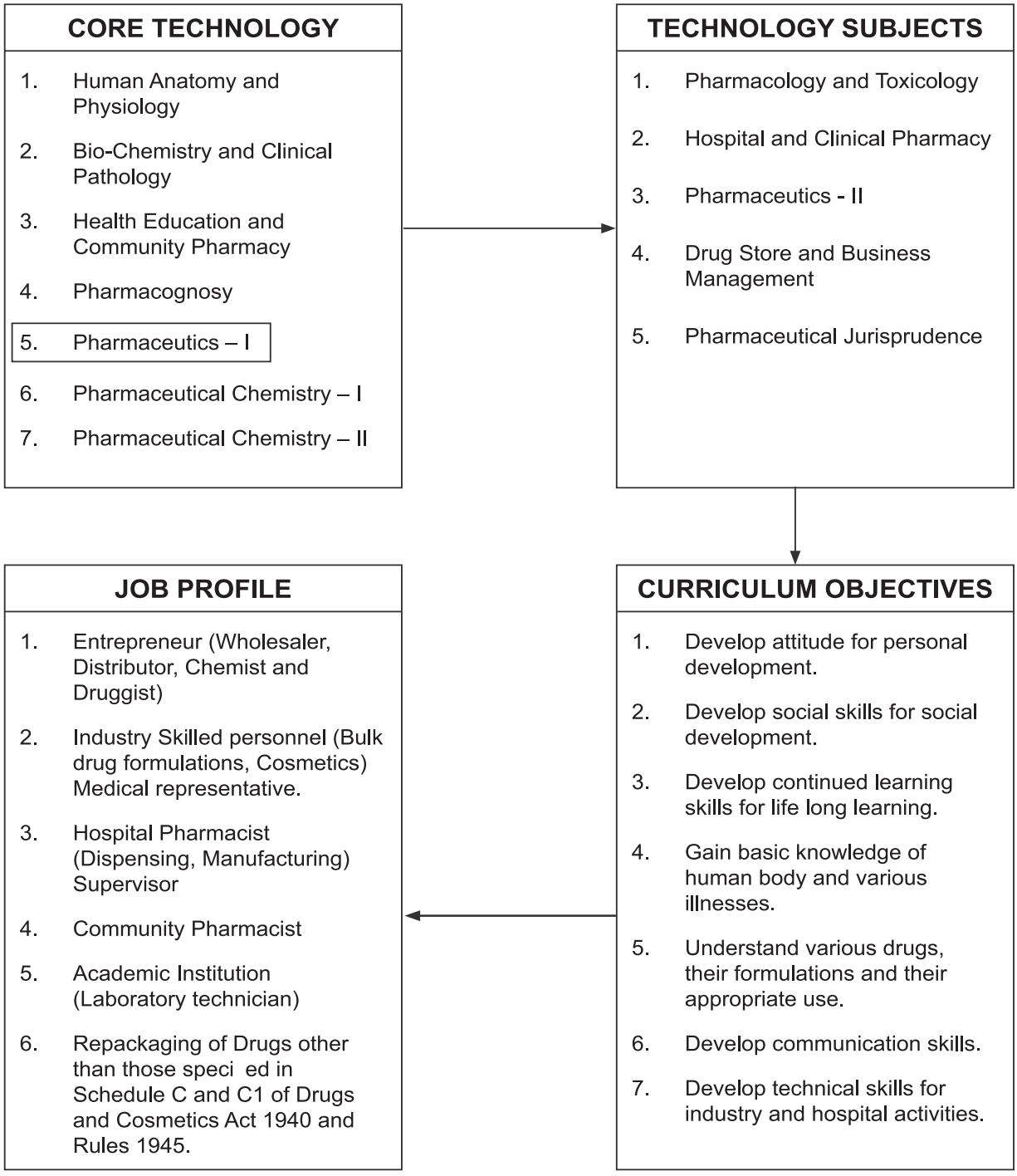
OBJECTIVE OF STUDYING PHARMACEUTICS – I

1. To study different types of dosage forms and their bio-availability in different dosage forms.
2. Development of improved dosage form with greater bio-availability, improved stability, Novel drug delivery system like Implants, Prodrugs, Controlled Drug Delivery systems, Nanoparticles which will reduce frequency of administration and having good onset of action.
3. Development of formulation using excellent and economic excipients.
4. Studying techniques and unit processes used in manufacturing of dosage form like size reduction, size separation, mixing, ltration, and extraction.
5. Studying problems faced in manufacturing and method to rectify those problems.
6. To identify imperfections or defects in nal marketed products and methods to rectify defects. e.g. capping, lamination in tablet, phase separation in emulsion, pH change, precipitation, colour change in solution.
7. To select packing system eg. container, closure for solution, strip packing for tablet, aerosol packing etc.
8. The labeling of different dosage form according to Drug and Cosmetic act.

Scope of learning Pharmaceutics - I

1. The Pharmacist is only expert in drug. He is having legally granted responsibility to handle drug. It is his professional responsibility to know all about those drugs. The pharmacist & pharmacist alone is in that unique position of embracing complete drug expertise.
2. Pharmaceutical industry with by broad de nition includes the makers of prescription, veterinary and proprietary drugs, cosmetics and toiletries and offer many career opportunities in various above scienti c discipline.
3. Pharmaceutically trained scientist can serve in various industries in different capacities, Research and development, Pharmaceutical production, Analytical research, Quality control and assurance, Scienti c information and regulatory affairs, Clinical testing, Professional relation, Sales and marketing, Management and more.

LINK / BLOCK DIAGRAM SHOWING INTER RELATIONSHIP OF SUBJECT AREAS, CURRICULUM OBJECTIVES AND JOB PROFILE.



GRAPHICAL STRUCTURE OF SUBJECT AREA

First Year Diploma in Pharmacy

Pharmaceutics - I (Industrial Pharmacy)

Applications/ Problems:

To manufacture and evaluate different type of dosage forms, novel drug delivery systems to encounter the frequency and bioavailability problems of drugs.

Applied different techniques for the solution of unit process problems faced during manufacturing, selection of packaging material and labeling according to drug and cosmetic act and rules.

Procedures:

Procedures for percentage calculation, size reduction, Size separation, Mixing and homogenization, heat process.

Process of lling capsule, production of tablet, tablet coating and micro encapsulation of tablet.

Method for drying, distillation, sterilization of the formulation of various drugs.

Principles:

Principles of metrology, alligation method, milling, size separation, Darcy's law, extraction, distillation, sterilization.

Concept:

Weighing, volumetric measurement, ltration, packaging, size separation, mixing, homogenization, viscosity, extraction, desiccation, distillation, sterilization, friability test, capsule lling.

Facts:

Balance, spatula, measuring cylinder, pipette, funnel, strip and blister package, wide /narrow mouth bottles, mortar and pestle, ball mill, sieve shaker, propeller mixer, silverson homogenizer, ostwald viscometer, percolator, soxhlet apparatus, desiccator, round bottom ask, condensor, hot air oven, autoclave, sintered glass funnel, tablet press, coating pan, disintegration test apparatus, dissolution test apparatus, friabilator, capsule lling machine.

DEVELOPMENT OF SKILLS

In design of experiments, students will learn speci c knowledge such as concepts, principles, procedures, labeling skill and evaluation of various dosage form. In addition, students are also expected to make efforts to develop desired intellectual and motor skills.

A broad perspective of acquisition of skills and content speci c knowledge is given below:

A. Intellectual skills:

1. Requirements for labeling (I_1).
2. Concept of solubility (I_2).
3. Role of distributive agents (I_3).
4. Principle of co-solvency (I_4).
5. Concept of saponi cation and micellar formation (I_5).
6. Concept of colour change at different pH using indicators (I_6).
7. Concept of complexation for enhancement of solubility (I_7).
8. Concept of size reduction (I_8).
9. Concept of drug to solvent ratio (I_9).
10. Concept of extraction for organised and unorganised drugs (I_{10}).
11. Concept of reserved percolation (I_{11}).
12. Role of suspending / thickening agent (I_{12}).
13. Concept of unit and bulk dosage form (I_{13}).
14. Concept of uniformity of weight (I_{14}).
15. Concept of disintegration test (I_{15}).
16. Concept of dissolution test (I_{16}).
17. Concept of size separation by sieving (I_{17}).
18. Concept of sterilization and its techniques (I_{18}).
19. Concept of design of aseptic area (I_{19}).
20. Concept of aseptic techniques (I_{20}).
21. Concept of encapsulation (I_{21})

B. Motor skill

1. Labeling of different dosage forms (M_1).
2. Skill for measurement of volume, weighing (M_2).
3. Skill for ltration and clari cation (M_3).
4. Skill for calculation of alcohol by alligation method (M_4).
5. Adjustment of pH (M_5).
6. Skill for distillation (M_6).
7. Skill for maceration (M_7).
8. Skill for percolation (M_8).
9. Skill for soxhelation (M_9).
10. Skill for formation of different emulsions (M_{10}).
11. Skill for uniform mixing (M_{11}).
12. Skill for moulding (M_{12}).
13. Skill for aming (M_{13}).
14. Skill for calculating the amount of diluents (M_{14}).
15. Skill for polishing the capsules (M_{15}).
16. Skill for performing disintegration test (M_{16}).
17. Skill for performing friability test (M_{17}).
18. Skill for measuring dimensions (M_{18}).
19. Skill for granulation (M_{19}).
20. Skill for sieving (M_{20}).
21. Skill for autoclaving (M_{21}).
22. Skill for sealing the ampoules (M_{22}).
23. Skill for performing leakage and clarity test (M_{23}).
24. Skill for microscopic examination (M_{24}).

GRID TABLE

Following table gives grid of the experiments and related intellectual and motor skills.

- Teacher shall ensure for development of generic skills during the practicals.
- Students are expected to focus on acquiring speci c skills mentioned therein.

Sr. No.	Name of the Experiments	Intellectual skills	Motor skills
1.	To know your Pharmaceutics -I (Industrial Pharmacy) Laboratory.	I_1	M_1
2.	To understand concept of Labeling.	I_1	M_1
3.	**Introductions to Aromatic Waters** To prepare, evaluate and submit Chloroform Water I.P.	I_1, I_2	M_1, M_2
4.	To prepare, evaluate and submit Camphor Water I.P.	I_1, I_2	M_1, M_2, M_3
5.	To prepare, evaluate and submit Concentrated Cinnamon Water B.P.C.	I_1, I_2, I_3	M_1, M_2, M_3, M_4
6.	To prepare, evaluate and submit Concentrated Peppermint Water B.P.C.	I_1, I_2, I_3	M_1, M_2, M_3, M_4
7.	To prepare, evaluate and submit Concentrated Dill Water I.P.	I_1, I_2, I_3	M_1, M_2, M_3, M_4
8.	**Introduction to Solutions** To prepare, evaluate and submit Benzoic Acid Solution B.P.C.	I_1, I_2, I_4	M_1, M_2
9.	To prepare, evaluate and submit Cresol with Soap Solution I.P.	I_1, I_2, I_5	M_1, M_2
10.	To prepare, evaluate and submit Strong Ammonium Acetate Solution B.P.C.	I_1, I_2, I_6	M_1, M_2, M_4
11.	To prepare, evaluate and submit Aqueous Iodine Solution I.P.	I_1, I_2, I_7	M_1, M_2
12.	To prepare, evaluate and submit Weak Iodine Solution I.P.	I_1, I_2, I_7	M_1, M_2
13	To prepare, evaluate and submit Compound Sodium Chloride Solution I.P.	I_1, I_2,	M_1, M_2,
14.	To prepare, evaluate and submit Surgical Chlorinated Soda Solution B.P.	I_1, I_2,	M_1, M_2 , M_5
15.	**Introductions to Spirits** To prepare, evaluate and submit Peppermint Spirit B.P.	I_1, I_2	M_1, M_2, M_4

Sr. No.	Name of the Experiments	Intellectual skills	Motor skills
16.	To prepare, evaluate and submit Aromatic Spirit of Ammonia I.P.	I_1, I_2, I_3	M_1, M_2, M_4, M_5
17.	To prepare, evaluate and submit Compound Orange Spirit B.P.	I_1, I_2	M_1, M_2, M_4
18.	**Introduction to Tincture** To study the effect of Drug to Solvent Ratio on Preparation of Orange Tincture I.P.	I_1, I_2, I_8, I_9, I_{10}	M_1, M_2, M_3, M_4, M_7
19.	To study the effect of size reduction on preparation of Strong Ginger Tincture I.P.	I_1, I_2, I_8, I_9	M_1, M_2, M_3, M_4, M_8
20.	To prepare, evaluate and submit Catechu Tincture B.P.	I_1, I_2, I_8, I_9	M_1, M_2, M_3, M_4, M_7
21.	To prepare, evaluate and submit Compound Benzoin Tincture I.P.	I_1, I_2, I_8, I_9, I_{10}	M_1, M_2, M_3, M_4, M_7
22.	**Introduction to Extracts** To prepare, evaluate and submit Liquorice Liquid Extract	I_1, I_2, I_8, I_9, I_{10}	M_1, M_2, M_7
23.	To prepare, evaluate and submit Vasaka Liquid Extract I.P.	I_1, I_2, I_8, I_9, I_{10}, I_{11}	M_1, M_2, M_8
24.	To nd the total alkaloidal content in Cinchona powder by continuous hot extraction process.	I_2, I_8	M_1, M_2, M_9
25.	**Introduction to Creams** To prepare, evaluate and submit Vanishing Cream.	I_1, I_5	M_1, M_2, M_{10}, M_{11}
26.	To prepare, evaluate and submit Cold Cream	I_1, I_5	M_1, M_2, M_{10}, M_{11}
27.	To prepare, evaluate and submit Buffered Cream B.P.	I_1, I_5	M_1, M_2, M_{10}, M_{11}
28.	**Introduction to Cosmetics** To prepare, evaluate and submit Calamine Lotion I.P.	I_1, I_{12}	M_1, M_2, M_{11}
29.	To prepare, evaluate and submit Clear Shampoo.	I_1, I_5	M_1, M_2
30.	To prepare, evaluate and submit Tooth Paste.	I_1, I_8, I_{12}	M_1, M_2, M_{10}
31.	To prepare, evaluate and submit Hair Grooming Gel.	I_1, I_{12}	M_1, M_2, M_{11}
32.	To prepare, evaluate and submit Lipstick.	I_1	M_1, M_2

Sr. No.	Name of the Experiments	Intellectual skills	Motor skills
33.	**Introduction to Capsules** To prepare, evaluate and submit Chloramphenicol Capsules I.P.	I_1, I_{13}, I_{14} I_{15}, I_{16}	M_1, M_2, M_{11}, M_{14}, M_{15}, M_{16}
34.	To prepare Liquid Paraf n Microencapsules	I_2, I_{21}	M_{24}
35.	To prepare, evaluate and submit Magnesium Oxide Capsules U.S.P.	I_1, I_{13}, I_{14} I_{15}, I_{16}	M_1, M_2, M_{11}, M_{14}, M_{15}, M_{16}
36.	**Introduction to Tablets** To prepare, evaluate and submit Granules Ready for Compression of Compound Sodium Bicarbonate Tablets I.P.	I_1, I_8, I_{13} I_{17}	M_1, M_2, M_{11}, M_{14}, M_{19}, M_{20}
37.	To prepare, evaluate and submit Granules Ready for Compression of Calcium Lactate Tablets I.P.	I_1, I_8, I_{13} I_{17}	M_1, M_2, M_{11}, M_{14}, M_{19}, M_{20}
38.	To prepare, evaluate and submit Granules Ready for Compression of Paracetamol Tablets I.P.	I_1, I_8, I_{13} I_{17}	M_1, M_2, M_{11}, M_{14}, M_{19}, M_{20}
39.	Evaluation of Tablets as per I.P.	I_1, I_{13}, I_{14} I_{15}, I_{16}	M_1, M_2, M_{16}, M_{17}, M_{18}
40.	**Introduction to Preparation involving sterilization** To prepare, evaluate and submit Sterile Water For Injection I.P.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
41.	To prepare, evaluate and submit Sodium Chloride Injection I.P.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
42.	To prepare, evaluate and submit Dextrose injection I.P.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
43.	**Introduction to Ophthalmic Preparations** To prepare, evaluate and submit Atropine Sulphate Eye Drops I.P.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
44.	To prepare, evaluate and submit Boric Acid Eye Lotion.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
45.	To prepare, evaluate and submit Atropine Sulphate Eye Ointment I.P.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
46.	To prepare, evaluate and submit Zinc Sulphate Eye Drops I.P.	I_1, I_{13}, I_{18} I_{19}, I_{20}	M_1, M_2, M_3, M_{21}, M_{22}, M_{23}
47.	Report of visit to Pharmaceutical Industry	I_8, I_{14}, I_{15}, I_{16}	M_{16}, M_{17}, M_{19}, $M_{20,}$ M_{21}

GUIDELINES FOR TEACHERS

Teachers shall discuss the following points with students before start of practicals of the subject.

1. **Learning Overview:** To develop better understanding and importance of the subject. To know related skills to be developed such as Intellectual skills and Motor Skills.
2. **Link / Block Diagram:** Context of the subject in the form of link diagram showing interrelationship of various subject areas, curriculum objectives and job pro le.
3. **Graphical structure:** In this topics and sub topics 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.
4. **Know your Laboratory work:** To understand the layout of laboratory, speci cations of Equipments/ Instruments/ Materials, procedure, working in groups, planning time etc. Also to know total amount of work to be done in the laboratory.
5. Teacher shall ensure that required equipments are in working condition before start of experiment, also keep operating instruction manual available.
6. Explain prior concepts to the students before starting of each experiment.
7. Involve students activity at the time of conduct of each experiment.
8. While preparing, labeling, evaluation; each student (from batch of 20 students) shall be given a chance to perform/observe the experiment.
9. About two-three experiments will be performed in each practical turn.
10. List of questions is given at the end of each experiment. Teacher shall instruct the students to attempt particular questions from that list. Teacher shall ensure that each student writes the answers to the allotted questions in the laboratory manual after performance is over.
11. If the experimental setup has variations in the speci cations of the equipments, the teachers are advised to make the necessary changes, wherever needed.
12. Teacher should ensure that the respective skills and competencies are developed in the students after the completion of the practical exercise.
13. Teacher is expected to share the skills and competencies to be developed in the students.
14. Teacher may provide additional knowledge and skills to the students even though not covered in the manual but are expected from the students after they pass out.
15. Teacher shall ensure that visits recommended in the manual are covered.
16. Teacher may suggest the students to refer additional related Of cial books/Technical papers/ Reference books/Seminar Proceedings, etc.
17. Teacher is expected to ask questions to the students to tap their achievements regarding related knowledge and skills so that students can prepare while submitting record of the practicals. Focus should be given on development of enlisted skills rather than theoretical / codi ed knowledge.
18. Teacher should organize Group discussions / Brain storming sessions / Seminars to facilitate the exchange of knowledge amongst the students.
19. Teacher should ensure that received CIAAN-2004 norms are followed simultaneously and progressively, while assessing the performance of students.
20. Teacher shall also refer to the Circular No. MSBTE/D-50/ Pharm Lab Manual/2006/3160 dated 4thMay 2006 for additional guidelines.

INSTRUCTIONS FOR STUDENTS

Students shall read the points given below for understanding the theoretical concepts and practical application.

1. Listen carefully to the lecture given by teacher about importance of subject, curriculum philosophy, graphical structure, skills to be developed, information about equipments, instruments, procedure, method of continuous assessment, tentative plan of work in laboratory and total amount of work to be done in a year.
2. Students shall undergo study visit to the laboratory for types of chemicals, equipments, instruments before performing experiments.
3. Read the write up of each experiment to be performed, a day in advance.
4. Organize the work in the group whenever suggested and make a record of suggestions made by teacher wherever possible.
5. Understand the purpose of experiment and its practical implications.
6. Write the answers of the questions allotted by the teacher during practical hours if possible or afterwards, but immediately.
7. Students should not hesitate to ask any dif culty faced during conduct of practical exercise.
8. The student shall study all the questions given in the laboratory manual and practice to write the answers to these questions.
9. Student shall visit the recommended industry or hospital or retail pharmacy and should study the know how of the shop oor practices and the operations of machines.
10. Student shall develop maintenances skills as expected by the industries.
11. Student shall develop the habit of group discussion related to the experiments / exercises so that exchange of knowledge / skills should take place.
12. Student shall attempt to develop related hands-on-skills and gain con dence.
13. Student shall focus on development of skills rather than theoretical or codi ed knowledge.
14. Student shall visit the nearby medical stores, industries, laboratories, technical exhibitions; trade fair even if not included in the Lab Manual. In short, students should have exposure to the area of work right in the student hood.
15. Student shall insist for the completion of recommended laboratory work, visits, answers to the given questions, etc.
16. Student shall develop the habit of evolving more ideas, innovations, skills, etc. than included in the scope of the manual.
17. Student shall refer technical magazines, proceedings of the Seminars, refer websites related to the scope of the subject and update their knowledge and skills.
18. Student should develop the habit of not to depend totally on teachers but to develop self-learning techniques.
19. Student should develop the habit to communicate with the teacher without hesitation with respect to the academics involved.
20. Student should develop habit to submit the practicals exercise continuously and progressively on the scheduled dates and should get the assessment done.

List of Experiments and Record of Progressive Assessment

Sr. No.	Name of the Experiments	Page No.	Date of perfor-mance	Date of submis-sion	Assess-ment Max. Marks 10	Sign. of Teacher and Remarks
1.	To know your Pharmaceutics -I (Industrial Pharmacy) Laboratory.	1				
2.	To understand concept of Labeling.	6				
. 3.	**Introductions to Aromatic Waters** To prepare, evaluate and submit Chloroform Water I.P.	10				
4.	To prepare, evaluate and submit Camphor Water I.P.	15				
5.	To prepare, evaluate and submit Concentrated Cinnamon Water B.P.C.	18				
6.	To prepare, evaluate and submit Concentrated Peppermint Water B.P.C.	21				
7.	To prepare, evaluate and submit Concentrated Dill Water I.P.	24				
8.	Introduction to Solutions To prepare, evaluate and submit Benzoic Acid Solution B.P.C.	30				
9.	To prepare, evaluate and submit Cresol with Soap Solution I.P.	33				
10.	To prepare, evaluate and submit Strong Ammonium Acetate Solution B.P.C.	36				
11.	To prepare, evaluate and submit Aqueous Iodine Solution I.P.	39				
12.	To prepare, evaluate and submit Weak Iodine Solution I.P.	42				
13	To prepare, evaluate and submit Compound Sodium Chloride Solution I.P.	46				
14.	To prepare, evaluate and submit Surgical Chlorinated Soda Solution B.P.	49				
15.	Introductions to Spirits To prepare, evaluate and submit Peppermint Spirit B.P.	52				
16.	To prepare, evaluate and submit Aromatic Spirit of Ammonia I.P.	56				
17.	To prepare, evaluate and submit Compound Orange Spirit B.P.	60				
18.	Introduction to Tincture To study the effect of Drug to Solvent Ratio on Preparation of Orange Tincture I.P.	63				

Sr. No.	Name of the Experiments	Page No.	Date of performance	Date of submission	Assessment Max. Marks 10	Sign. of Teacher and Remarks
19.	To study the effect of size reduction on preparation of Strong Ginger Tincture I.P.	68				
20.	To prepare, evaluate and submit Catechu Tincture B.P.	71				
21.	To prepare, evaluate and submit Compound Benzoin Tincture I.P.	74				
22.	**Introduction to Extracts** To prepare, evaluate and submit Liquorice Liquid Extract	77				
23.	To prepare, evaluate and submit Vasaka Liquid Extract I.P.	82				
24.	To nd the total alkaloidal content in Cinchona powder by continuous hot extraction process.	85				
25.	**Introduction to Creams** To prepare, evaluate and submit Vanishing Cream.	88				
26.	To prepare, evaluate and submit Cold Cream	92				
27.	To prepare, evaluate and submit Buffered Cream B.P.	95				
28.	**Introduction to Cosmetics** To prepare, evaluate and submit Calamine Lotion I.P.	98				
29.	To prepare, evaluate and submit Clear Shampoo.	103				
30.	To prepare, evaluate and submit Tooth Paste.	107				
31.	To prepare, evaluate and submit Hair Grooming Gel.	111				
32.	To prepare, evaluate and submit Lipstick.	115				
33.	**Introduction to Capsules** To prepare, evaluate and submit Chloramphenicol Capsules I.P.	119				
34.	To prepare Liquid Paraf n Microencapsules	124				
35.	To prepare, evaluate and submit Magnesium Oxide Capsules U.S.P.	128				

Sr. No.	Name of the Experiments	Page No.	Date of perfor-mance	Date of submis-sion	Assess-ment Max. Marks 10	Sign. of Teacher and Re-marks
36.	**Introduction to Tablets** To prepare, evaluate and submit Granules Ready for Compression of Compound Sodium Bicarbonate Tablets I.P.	131				
37.	To prepare, evaluate and submit Granules Ready for Compression of Calcium Lactate Tablets I.P.	139				
38.	To prepare, evaluate and submit Granules Ready for Compression of Paracetamol Tablets I.P.	142				
39.	Evaluation of Tablets as per I.P.	145				
40.	**Introduction to Preparation involving sterilization** To prepare, evaluate and submit Sterile Water For Injection I.P.	150				
41.	To prepare, evaluate and submit Sodium Chloride Injection I.P.	159				
42.	To prepare, evaluate and submit Dextrose injection I.P.	162				
43.	**Introduction to Ophthalmic Preparations** To prepare, evaluate and submit Atropine Sulphate Eye Drops I.P.	165				
44.	To prepare, evaluate and submit Boric Acid Eye Lotion.	170				
45.	To prepare, evaluate and submit Atropine Sulphate Eye Ointment I.P.	173				
46.	To prepare, evaluate and submit Zinc Sulphate Eye Drops I.P.	176				
47.	Report of visit to Pharmaceutical Industry	179				
					Total Marks	
					***Aver-age marks out of 10**	

*** To be transferred to Proforma I1 of CIAAN – 2004.**

Note: The Guidelines for the conduct of annual practical examination are enclosed in the end.

Experiment No. 1

1.0 Title:

To Know your Pharmaceutics - I (Industrial Pharmacy) Laboratory

2.0 Prior Concepts:

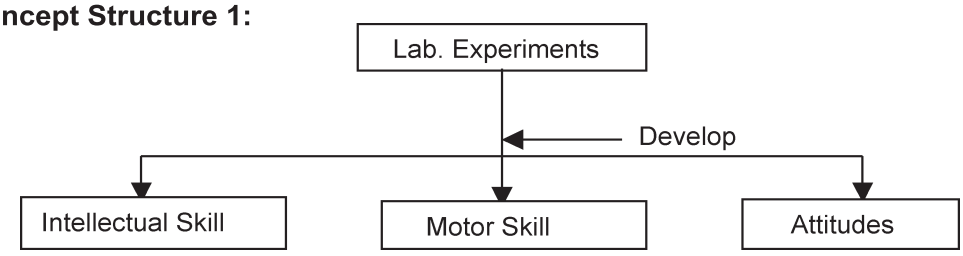
Curriculum of the subject, Basic mathematical concepts.

3.0 New concepts:

Proposition 1: Laboratory Experiments

Laboratory experiments are expected to develop intellectual skills, motor skills and attitudes in students.

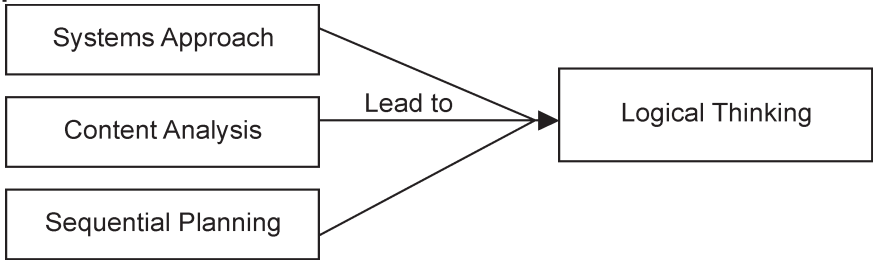
Concept Structure 1:



Proposition 2: Logical thinking

Logical thinking is developed in students through systems approach, content analysis and sequential planning of laboratory work.

Concept structure 2:



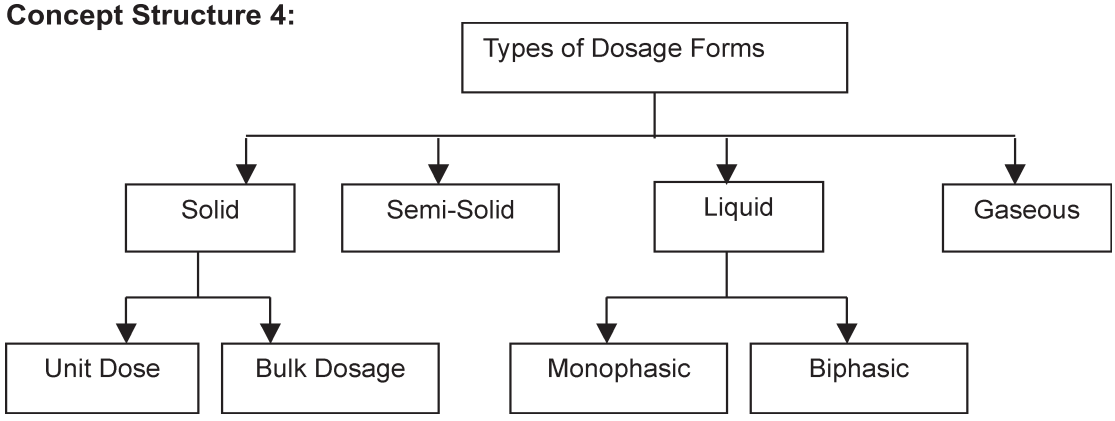
Proposition 3: Dressing

Clean Apron/ Laboratory coat, white head cover is necessary. Full mask and gloves are required during handling of toxic and irritant drugs.

Proposition 4: Dosage Forms

Suitable formulations for administration of drugs.

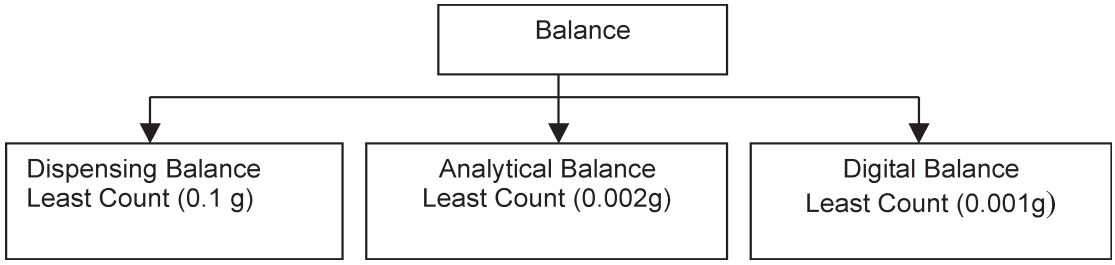
Concept Structure 4:



Proposition 5: Balance

It is defined as an instrument for determining the relative weights of substances. It should be selected correctly for the specific task at hand, used skillfully, protected from damage, and checked periodically.

Concept Structure 5:



Proposition 6: Weighing Procedure

Avoid direct contact with the drug and excipients. Weigh solid drugs and excipients only on butter paper using spatula. Fold the edges of butter paper to avoid spillage. Liquid Measurement is done by using properly clean, dried pipette or measuring cylinder.

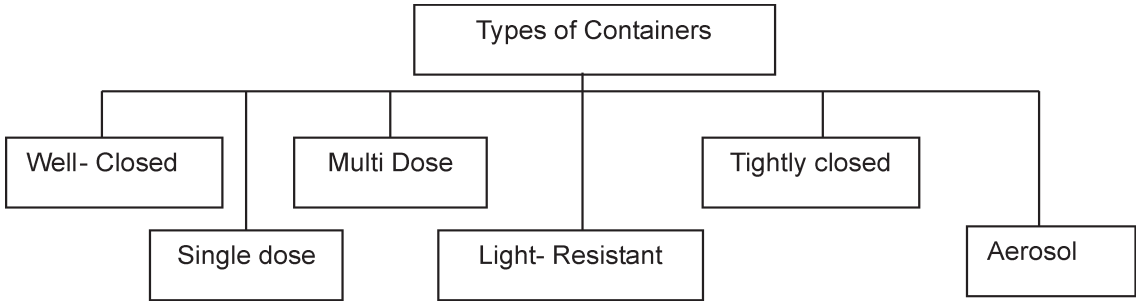
Proposition 7: Packaging

Packaging is an operation involved in preparing articles for transport, storage, display and use. In all aspects of pharmaceutical packaging it must be borne in mind that it is necessary to combine commercial sales appeal with appropriate professional restraint.

Proposition 8: Containers

Device that holds the drug and it may or may not be in direct contact with the pharmaceutical preparation.

Concept Structure 8:



Proposition 9:

Storage:

To ensure the stability of a pharmaceutical preparation for the period of its intended shelf life, the product must be stored under proper storage conditions. The labeling of each product includes the desired conditions of storage.

Cold – Any temperature not exceeding 8^0C and usually between 2^0C and 8^0C.

Cool – Any temperature between 8^0 and 25^0C.

Ambient/ Room Temperature – Temperature prevailing in a working area.

Warm – Any temperature between 30^0C and 40^0C.

Protection from freezing – Where in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or destructive alteration of the dosage form, the container label bears an appropriate instruction to protect the product from freezing. (Examples- Creams, emulsions)

Proposition 10: Shelf life; Expiration Dating Period

The time interval that a drug product is expected to remain with in the approved shelf life specification provided that it is stored under the conditions defined on the label in the proposed containers and closure. Shelf life is mainly defined as time required for 10% of the drug to be inactive. (Patient will not get the prescribed/required dose of the active drug).

Proposition 11: Current Good Manufacturing Practices (cGMP)

The cGMP are the requirements that drugs, and the methods used in, or the facilities or controls in their manufacture, processing, packing, or holding conform with those practices that will assure that such drugs meet the requirements of the act as to safety, and have the identity, strength, quality, and purity characteristics that they purport or are represented to possess. If they do not, they are adulterated.

GMP regulations were introduced in the form of amended SCHEDULE M in 1988 and again been amended in a major way by the Drugs and cosmetics rules, 2001.

4.0 Learning objectives:

Intellectual skills:

To understand application of excipients, formulation design and development.

Motor Skills:

Ability in calculations, weighing, compounding, evaluation and dispensing of formulation.

5.0 Diagram:

Dispensing Balance (0.1- 100 grams)

Bulb Pipette (1,2,5,10,25,50,100 ml)

Double pan Balance (1- 5000grams)

Electronic Balance (1mg- 200 grams)

Autoclave (1210C, 15 psi, 20 min).

Mortar and pestle (Porcelain, Glass)

6.0 Stepwise procedure:

Read the learning overview carefully

1. Listen to the lecture given by teacher about importance of subject, curriculum philosophy,
2. Graphical structure, skills to be developed, information about equipment, instrument, procedure method of continuous assessment and tentative plan of work in laboratory.
3. Observe the laboratory for types of equipment, instruments, and material to be used. There will be used for performing experiment in the laboratory.

7.0 Observation table: (Student to write observations)

Types of Pipette:	1. ……..., 2. ……. , 3. ……..
Apparatus used for weighing:	1. ……..., 2. ……. , 3. ……..
2 parts of Autoclave:	1. ……..., 2. …….
Least count of Digital balance:	1. ……...,

8.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... Q. ..…... Q. ..…. Q. ..…. (Question numbers to be allotted by the teacher.)

1. State the important of graphical structure in understanding the scope of the subject.
2. What is the importance of link diagram of the curriculum of the subject?
3. State two motor skills to developed through this subject.
4. Classify the curriculum and different groups of subject.
5. State the importance of job description in designing the curriculum.
6. Give importance of self-life?
7. Mention the precautions to be taken during weighing?
8. Give two applications of mortar and pestle?
9. Write any five good laboratory practices (GLP).
10. Explain the meaning of ambient temperature.
11. Define the meaning of least count.
12. Mention the names of different types of pipettes.
13. Name the four different parts of the autoclave.
14. Write the materials used for construction of mortar and pestle.
15. Give the precaution to be taken during reading of liquid meniscus.

(Space for answers)

(Space for answers)

Experiment No. 2

1.0 Title:

To understand concept of Labeling.

2.0 Prior Concepts:

Types of dosage preparations, containers, storage conditions, Shelf life/Expiry date.

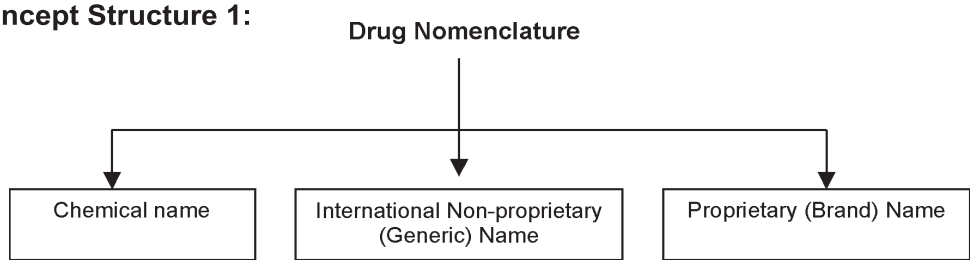
3.0 New concepts:

Proposition 1: Drug Nomenclature.

A drug generally has three categories of names:

1. **Chemical name:** It is the IUPAC name of the drug that describes the substance chemically. Example: Acetyl salicylic acid.
2. **International Non-proprietary name (INN) / Generic names:** It is the name accepted and approved by the World Health Organization. It has been preferred for the main title of a new drug substance over other names. Examples: Aspirin is generic name for Acetyl salicylic acid.
3. **Proprietary (Brand) name:** It is the name assigned by the manufactures and is his property or Trademark. One drug may have multiple proprietary names, example: Dispirin or Ecospirin for aspirin from different manufacturers.

Concept Structure 1:



Proposition 2: Label

It means a display of written, printed or graphic matter upon the immediate container of any article. The objective of labeling is to ensure the appropriate and safe use of the medication. The Foods and Drug Administration approve labeling requirements for each product. Label gives the patient clear and complete instructions on how to take or use the preparations.

Proposition 3: Schedules

Schedule G: List of substances that should be required to be used under medical supervision and which are required to be labeled accordingly.

Schedule H: List of substances should be sold by retailer only on prescription of registered medical practitioner.

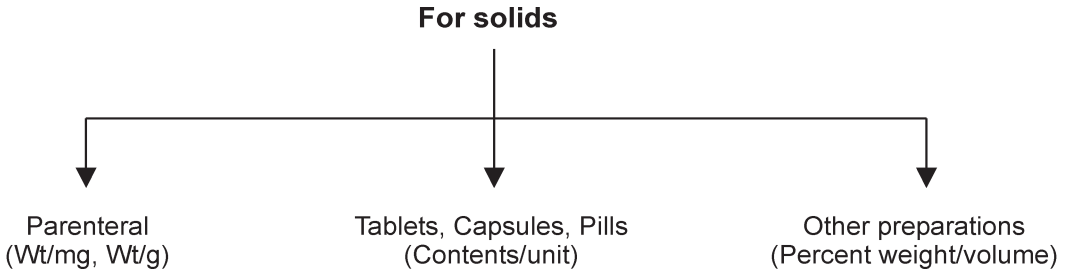
Schedule F: Standards of ophthalmic preparations.

Schedule X: List of drugs for sale of which special license is necessary.

Proposition 4: General Labeling requirements:

1. **Name of the drug:** For drugs included in the official pharmacopoeia i.e. Indian pharmacopoeia, the letters 'I.P.' should follow the name. For drugs included in the National formulary of India the name should followed letters N.F.I.
2. **Net contents:** In terms of weight, measure, volume, numbers of units of contents, number of units of activity it should be expressed in metric system.

For oral liquids: Content / 5ml (single dose)
Content /ml (dose is below 5ml)



3. Name of the manufactures and address of the premises of the manufacturer where the drug has been manufactured.
4. **Batch No:** It is a reference number from which details of the manufacturer of the particular batch from which the substance in the container is taken are recorded and are available for inspection. It is preceded by the words: 'Batch No.' or 'B. No.' or 'Batch' or 'Lot No' or 'Lot'.
5. **License Number:** It is preceded by the words 'Mfg. Lic. No.' or 'M.L. No.'
6. Date of manufacturing.
7. Date of Expiry/shelf life.
8. **Alcohol content:** If more than 3% by volume. It is expressed in term of average percentage by volume of absolute alcohol.
9. For Drugs under schedule 'G', 'H', and 'X', Narcotics, analgesics, hypnotics, sedatives, antiepileptics, hypoglycemics, a conspicuous red vehicle line on the left side running throughout the body of the label required to be printed.
10. **For schedule G drugs:**

    Caution: It is dangerous to take this preparation except under medical supervision, surrounded by a line within which these shall be no other words.

    For schedule H drugs:

    Warning: 'To be sold by retail on the prescription of a registered medical practitioners only'.
11. If it contains a substance specified in schedule H be labeled with the symbol R_x and conspicuously displayed on the left top corner of the label.
12. If medicines meant for external application, shall be labeled with the words in capital **'FOR EXTERNAL USE ONLY'**
13. For ophthalmic preparation: Additional specifications shall be shown on label of container.

    The statement "Use within one month after opening".

    Name and concentration of preservative.

    The words " Not for Ingestion"
14. Indication/use.
15. Directions for use: For example for lotions "Shake Well Before Use" or for solutions " Dilute 1 tablespoon with glass of water" etc.
16. Storage: For Example for Spirits, Tinctures

" Stored in air-tight Container protected from excessive heat, light and freezing".

4.0 Learning objectives:

Intellectual Skills:
To understand the different requirement of labeling.

Motor Skills:
Preparation of labels for different dosage forms.

Sample label:

GENERIC NAME (OFFICIAL PHARMACOEPIA, IF ANY) VOLUME/AMOUNT/QUANTITY.		
Composition: ALCOHOL CONTENT	Category/ Indication: Directions for use: Dose: Storage : Special precautions: FOR EXTERNAL USE ONLY.	Schedule Mfg. Lic. No. Batch No. Mfg. Date Exp. Date Retail Price.
Mfg. By: Roll No, Batch, Name of College /Institute, Place.		

	MAX GLOW LIPSTICKS	**Net Wt. 3.5 g**
Contains: Shea butter to nourish Vitamin E to protect FDC approved colors and Flavors. 	For protective and moisturizing action. **Directions for use:** Rub gently without pressure. **Storage:** Keep Away from Heat and Light FOR EXTERNAL USE ONLY.	**Mfg. Lic. No.** 00200345 **Batch No.** 23/4-05 **Mfg. Date** April 2006 **Exp. Date:** 2 Years after date of Mfg. **Retail Price.** Rs.45 including all taxes
Mfg. By: Roll No 32, Batch B, METs Institute of Pharmacy, Bandra, Mumbai		

R_x	**PROTAMINE ZINC INSULIN INJECTION**	**40 units per ml**
Schedule H To be sold by retail on the prescription of a registered medical practitioners only **Direction:** Shake gently before dose is withdrawn.	**Category:** Hypoglycemic **Route of Administration:** S.C. **Storage:** Store at a temperature between 2^0C and 8^0C. Do not Freeze. **NOT FOR INGESTION**	Reject the ampoule if any visible particle is present **Mfg. Lic. No. 234** **Batch No. 23-6-7** **Mfg. Date May 06** **Exp. Date- Feb 08** **MRP: Rs: Rs 90.0** **(Including all Taxes)**
Mfg. By: Roll No 6, Batch A, N.S.S. College of Pharmacy, Tardeo, Mumbai		

Note: Students using information given in a sample label, can adopt different style of labeling, provided that particulars should appear in a conspicuous manner.

5.0 Questions :

Answer Q..... Q….. Q..... Q 8 (compulsory)(Question numbers to be allotted by the teacher.)

1. Explain the significance of shelf life.
2. With the example of any two drugs explain the drug nomenclature.
3. Name any five active pharmaceuticals ingredients that come under schedule G and H.
4. Explain the significance of batch number on the label.
5. Write the labeling requirements of Opthalmic products.
6. Write the requirement for labeling alcohol content.
7. Write the different storage temperatures for different formulations.
8. Draw one label for practice in the space provided below.

(Space for answers)

INTRODUCTION TO AROMATIC WATERS

Aromatic waters are clear aqueous solution saturated with volatile Oils (e.g. rose oil, Peppermint oil, or other aromatic or volatile substances eg. camphor. Their odours and taste are of those of the drugs or volatile substances from which they are prepared.

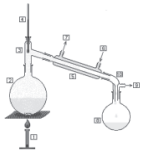
Aromatic waters may be used for perfuming, flavoring or for special purposes for eg.

1. Camphor water has been used as the vehicle in ophthalmic solutions owning to its ability to contribute refreshing, stimulating effect to the preparation.
2. Hamamelis water known as witch hazel is employed as a rub, perfume and as an astringent in various cosmetic preparations, particularly in after-shave lotions.

Aromatic waters
- Simple Aromatic water
- Concentrated Aromatic water

Method of Aromatic water preparation
- Distillation method
- Solution method
- Alternate solution method

1. Distillation Method:



The distillation method involves the placing of the coarsely ground odoriferous portion of the plant or drug from which the aromatic water is to be prepared in a suitable still, with sufficient purified water. Most of the volume of water is then distilled. The excess oils collected with the distillate rises to the top of the aqueous product and are removed. The remaining aqueous solutions, saturated with volatile material require clarification by filtration.

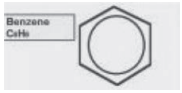
2. Solution Method:

Aromatic water is prepared by intermittently shaking 2ml (if liquid) or 2gm (if solid) of the volatile substance with 1000ml of purified water in suitable container for period of 15 minutes. After the period of agitation the mixture is set aside for 12 hours or longer to permit the excess oil and the solid substance to settle. Without further agitation the mixture is passed through a wetted filter paper and purified water added as needed to bring the volume of the filtrate upto the prescribed quantity.

3. Alternative solution Method:

By this method the volatile oil or suitably comminuted aromatic solid is thoroughly incorporated with 15gms of talc and to this mixture is added 1000ml of purified water. The resulting slurry is thoroughly agitated several times for the period of 30 minutes and then filtered.

Preparation of concentrated Aromatic water:



These products are alcoholic non aqueous preparations containing 2% of volatile oils They are forty times stronger than the ordinary aromatic waters. Many volatile oils contain aromatic part and non-aromatic part. The aromatic portion is much more soluble in a weak alcohol than the non-aromatic portion.

Hence when a solution of the oil in 90% alcohol is diluted with a limited amount of water the aromatic portion of the oil remains in solution while the non-aromatic portion is precipitated off, separating as an oily layer. Therefore 50gms of talc is added for 1000ml of preparation which acts as a distributing agent, and will absorbs the non-aromatic part. The solution is agitated and set aside for a few hours and filtered.

Storage: Aromatic water deteoriate with time and it should be made in small quantities and protected from intense light and excessive heat and stored in airtight, light resistance container.

Note for teacher: Any other official aromatic water can be done beside the preparation given in the manual for these experiments

Experiment No. 3

1.0 Title:

To prepare, evaluate and submit 100ml of Chloroform Water I.P. by Simple Solution Method. (Read the Introduction of Aromatic Waters.)

2.0 Prior Concepts:

Different types of solutions, volumetric measurement

3.0 New concepts:

Proposition 1: Pharmaceutical Aid

Preparation used as an excipient or base or vehicle for formulation of other pharmaceutical preparations.

Proposition 2:

Types of aromatic water
- Simple Aromatic water
- Concentrated Aromatic water

Proposition 3:

Storage: Aromatic waters are stored in air tight, light resistant container.

4.0 Learning objectives:

Intellectual Skills:

To understand the concept of solubility.

Motor Skills:

Skill for measurement of volume.

5.0 Apparatus:

Glass Beaker (250 ml), Volumetric Cylinder (100 ml), Volumetric Pipette (1ml).

6.0 Formulation Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Chloroform I.P.	2.5 ml		
2. Purified water I.P. (q.s.)	1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Step wise procedure:

It is saturated solution of chloroform in purified water .The solubility of chloroform is 1 in 800 parts of water.

1. Measure the required quantity of chloroform.

2. Add sufficient quantity of purified water to make the required volume with constant stirring so that chloroform gets uniformly mixed.

Dose: 15 to 30 ml

Category: Pharmaceutical Aid.

Storage: store in airtight container in cool place away from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the Preparation	Test	Specification	Observations
Chloroform water I.P.	Description	Clear	
	Colour	Colourless	
	Volume	100 ml.	
	Odour	Aromatic	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..…... (Question numbers to be allotted by the teacher.)

1. What are Aromatic waters?
2. Classify Aromatic waters on the basis of there strength.
3. State the solubility of Chloroform in water.
4. Define Pharmaceutical Aids.
5. Write storage conditions for chloroform water with their significance?
6. What is the concentration of chloroform in chloroform water?
7. State expiry date that you will mention for chloroform water?

(Space for answers)

Experiment No. 4

1.0 Title:

To prepare, evaluate and submit 100ml of Camphor Water I.P. by Simple Solution Method.

2.0 Prior Concepts:

Different types of solutions, volumetric measurement, weight measurement.

3.0 New concepts:

Proposition 1:

Camphor water I. P is aromatic water.

Proposition 2:

Types of aromatic water
- Simple Aromatic water
- Concentrated Aromatic water

Proposition 3:

Storage: Aromatic waters are stored in air tight, light resistant container.

4.0 Learning objectives:

Intellectual Skills:

To understand concept of solubility.

Motor Skills:

Skill for weighing and measuring volume.

5.0 Apparatus:

Glass Beaker (250 ml), Volumetric Cylinder (100 ml), Volumetric Pipette (1ml), Electronic Balance.

6.0 Formulation Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Camphor	1g		
2. Alcohol (90%)	2ml		
3. Purified water q.s.	1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Step wise procedure:

Camphor is soluble 1 in 7,000 parts of water and the strength of camphor is 1 in 10,000 that is near to saturation. Camphor is very soluble in alcohol than in water therefore it is prepared by dissolving the camphor in alcohol and adding this solution in small portion to the water.

1. Weigh required quantity of camphor.
2. Dissolve camphor in 90% alcohol.
3. Add this mixture in successive portions to the purified water in small proportions.
4. Shake well after each addition.
5. Set aside for 1 hr.
6. Filter & adjust the volume.

Dose: 15 to 30ml.

Category: Pharmaceutical Aid, Carminative.

Storage: Store in airtight container, in a cool place away from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Camphor water I.P.	Description Colour Odour Volume	Clear Colourless Aromatic 100ml.	

10.0 Result:

……ml of …….. preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. Q. ..….. (Question numbers to be allotted by the teacher.)

1. Write meaning of carminative?
2. State the purpose of 90 % alcohol in preparation of camphor water?
3. Write preparations in which camphor water can be used.
4. What is the concentration of camphor in camphor water?
5. What care has to be taken while diluting the camphor water and why?
6. State the normal dose for camphor water?
7. Calculate the amount of camphor in 5 ml of preparation.
8. Give two examples of volatile oil.
9. State the apparatus in which particle size reduction of camphor is carried out.
10. State the process use for size reduction of camphor.

(Space for answers)

Experiment No. 5

1.0 Title:

To prepare, evaluate and submit 30ml of Concentrated Cinnamon Water B.P.C. by Simple Solution Method.

2.0 Prior Concepts:

Different solutions, volumetric measurement, weight measurement.

3.0 New concepts:

Use of Talc as Distributive Agent.

Proposition 1:

Cinnamon water is concentrated Aromatic water.

Proposition 2:

Types of aromatic water — Simple Aromatic water; Concentrated Aromatic water

Proposition 3:

Storage: Store in airtight, light resistant container.

4.0 Learning objectives:

Intellectual Skills:

1. To understand concept of solubility.
2. To understand the use of talc as distributive agent.

Motor Skills:

1. Skill for weighing and measurement of volume.
2. Skill for clarification and filtration.

5.0 Apparatus:

Glass Beaker (250 ml), Volumetric Cylinder (100 ml), Volumetric Pipette (1ml), Volumetric Flask, Funnel, Dispensing Balance.

6.0 Formulation Table (As per B.P.C.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Cinnamon Oil	20 ml		
2. Alcohol (90%)	600ml		
3. Purified talc	50g		
4. Purified Water q.s.	1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

This preparation is made by solution method. The whole of the oil is dissolved in 90% alcohol. Upon addition of the water, the non-aromatic terpenes present in the oil get precipitated. Vigorous shaking during addition of the water is necessary to dissolves any of the aromatic portion of the oil. The talc absorbs the precipitated terpenes and thus makes it possible to obtain a clear bright filtrate.

1. Measure the required quantity of cinnamon oil.
2. Add the required quantity of alcohol.
3. Than add purified water in small portion with constant stirring.
4. Add the calculated amount of talc, stir for 15 minutes.
5. Keep aside for 30 minutes and filter.
6. Make the required volume with water.

Dose: 0.3 to 1ml.

Category: Carminative and Pharmaceutical Aid.

Storage: Store in airtight container in a cool place away from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Cinnamon water B.P.C.	Description	Clear	
	Colour	Colourless	
	Odour	Odour of cinnamon	
	Volume	30ml.	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. State the strength of concentrated cinnamon water?
2. Why should the preparation stored in amber colour bottle?
3. Calculate the concentration of alcohol by allegation method in terms of absolute alcohol.
4. State the purpose of talc in preparation of concentrated cinnamon water?
5. Cinnamon water will come under which category of aromatic water.
6. Calculate concentration of cinnamon oil per ml of preparation.
7. In what proportion is talc added to the preparations.
8. What care has to be taken while pipetting the cinnamon oil?

(Space for answers)

Experiment No. 6

1.0 Title:

To prepare, evaluate and submit 30ml of Concentrated Peppermint Water B.P.C. by Simple Solution Method.

2.0 Prior Concepts:

Different types of solution, volumetric measurement.

3.0 New concepts:

Proposition 1:

Concentrated peppermint water is aromatic water.

Proposition 2:

Types of aromatic water
- Simple Aromatic water
- Concentrated Aromatic water

Proposition 3:

Storage: Store in airtight, light resistant container.

4.0 Learning objectives:

Intellectual Skills:

1. To understand concept of solubility.
2. To understand the use of talc as distributive agent.

Motor Skills:

1. Skill for weighing and measurement of volume
2. Skill for clarification and filtration.

5.0 Apparatus:

Glass beaker (250 ml), Volumetric cylinder (100 ml), Volumetric pipette (1ml), Funnel.

6.0 Formulation Table (As per B.P.C.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Peppermint Oil.	20 ml		
2. Alcohol (90 %)	600ml		
3. Purified Water (q.s.)	1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Peppermint oil is the volatile oil distilled with steam from the fresh over ground parts of the flowering plants of mentha piperita linn. (Family labiate)

7.0 Stepwise procedure

Peppermint oil is the volatile oil distilled with steam from the fresh over ground parts of the flowering plants of mentha piperita linn. (Family labiate)

1. Measure the required quantity of peppermint oil and dissolved in 90 % alcohol.
2. Add successive quantity of purified water with constant stirring to make the required volume.
3. Clarify if necessary and make the required volume.
4. Transfer to container and label it.

Note: If preparation is turbid than method for preparation of concentrated aromatic water can be used.

Dose: 0.25 to 1ml.

Category: As flavoring agent and carminative.

Storage: Store in airtight container, in a cool place away from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Peppermint water B.P.C.	Description	Clear	
	Colour	Colourless	
	Odour	Odour of peppermint oil	
	Volume	30ml.	

10.0 Result:

……ml of …….. preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q. ..…... Q. …..... Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. State the use of peppermint water?
2. How can you prepare dilute peppermint water from concentrated peppermint water?
3. What is the difference between clarification and filtration?
4. Why does the solution become turbid on diluting the preparation with water?
5. What does B.P.C. stands for?
6. Calculate the alcohol percentage in terms of absolute alcohol in the preparation.
7. State the precaution to be taken while storing aromatic water.
8. State the strength of absolute alcohol as per I.P.

Note: Student can be taught to prepare dilute peppermint water from concentrated peppermint water by diluting the concentrated peppermint water 40 times.

(Space for answers)

Experiment No. 7

1.0 Title:

To prepare, evaluate and submit 30 ml of Concentrated Dill Water I.P. by Simple Solution Method.

2.0 Prior Concepts:

Different types of solutions, volumetric measurement.

3.0 New concepts:

Proposition 1:

Concentrated Dill water is aromatic water.

Proposition 2:

Types of aromatic water —— Simple Aromatic water
—— Concentrated Aromatic water

Proposition 3:

Storage: Store in airtight, light resistance container.

4.0 Learning objectives:

Intellectual Skills:

1. To understand concept of solubility.
2. To understand the use of talc as distributive agent.

Motor Skills:

1. Skill for weighing and measurement
2. Skill for clarification and filtration.

5.0 Apparatus:

Glass Beaker (250 ml), Volumetric Cylinder (100 ml), Volumetric Pipette (1ml), Volumetric Flask, Funnel, Dispensing Balance.

6.0 Formula Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Dill Oil	20 ml		
2. Alcohol (90 %)	600ml		
3. Purified Talc	50 g		
4. Purified Water (q.s.)	1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Dill consists of dried ripe fruits of Anethum graveolens family (umbelliferae). Dill oil is obtained by distillation; it contains not less than 45% w/w and not more than 63% w/w of carvone.

1. Pipette out the required quantity of Dill oil in a beaker
2. Dissolve the oil in the stated amount of 90% Alcohol.
3. Add the required quantity of purified water, with constant stirring, the non-aromatic parts tends to precipitates out, so add calculated quantity of talc, which act as distributive agent.
4. Stir constantly and set aside for 30 minutes.
5. Filter the solution and make up the volume with purified water.

Dose: 0.3 ml to 1 ml.

Category: Carminative and flavouring agent.

Storage: Store in airtight container, in a cool place away from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Dill Water I.P.	Description	Clear	
	Colour	Colourless	
	Odour	Odour of dill oil	
	Volume	30ml.	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ……. Q..….. (Question numbers to be allotted by the teacher.)

1. Calculate the percentage of Alcohol in terms of absolute alcohol in Dill water by alligation method.
2. What are carminatives?
3. Give the name of official preparation of concentrated Dill water.

4. State the function of talc in preparation of Dill water.
5. Why should Dill water be stored in tightly closed containers?
6. Write the complete reference of Dill Water monograph.
7. State the concentration of volatile oil in concentrated Aromatic water?
8. Give biological source of Dill.
9. Name the volatile part of Dill oil and what's its concentration?

(Space for answers)

INTRODUCTION TO SOLUTIONS

A solution is physically and chemically homogenous mixture of two or more substances. Main consideration in the formulation of solution is solubility of medicament in solvent.

Solutions:

The component of a solution present in larger quantity is referred to as **solvent** while one present in smaller amount is **solute.** In true solutions, the solute is present in the molecular or the ionic form & hence true solutions are referred to as **molecular dispersions.**

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. Anti Oxidants,
5. Colours,
6. Flavours,
7. Preservatives, etc.

Descriptive terms for solubility:

Descriptive term	Parts of solvent for 1 part of solute
Very soluble	Less than 1part
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10000
Insoluble or practically insoluble	More than 10000

Different techniques for solubility enhancement:

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

1. Solublization using surfactant:

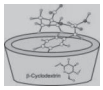
Solublization may be defined as the dissolution of poorly soluble solute molecules in water in presence of surfactant forming the thermodynamically stable solution. Surfactants are molecules with well defined polar and non-polar region that allow to aggregate in solution to form micelles. Solublization occurs by solute dissolving in or being adsorbed into the micelles e.g. cresol with soap solution.

2. Cosolvency: 

1. Cosolvency is 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.
2. The solvent employed in achieving this goal are called cosolvents.
3. Enhance solubility through cosolvency is however regarded as the result of independent solubility of the substance in each of cosolvents. e.g. of cosolvents ethanol, sorbitol, glycerin, propylene glycol etc.

3. pH modification: 

1. Solubility of weak acid and weak bases can be markedly affected by pH.
2. 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 drug itself. Organic compounds have a tendency to associate with each other. Example: Complexation of iodine and potassium iodide in Iodine solutions.

Main considerations involved in employing complexation technique are:

1. The amount of drug, which can be dissolved by specific complexing agent.
2. Whether the resulting complex is safe, stable & therapeutically effective.

5. Hydrotrophy: 

1. The term hydrotrophy designate the increase in solubility of a drug in water owing to the presence of large amount of additives. eg. Increased solubility of caffeine in presence of sodium benzoate and theophylline in presence of sodium salicylate.
2. The possible mechanism of hydrotrophy is considered to be solublization, complexation, and cosolvency.

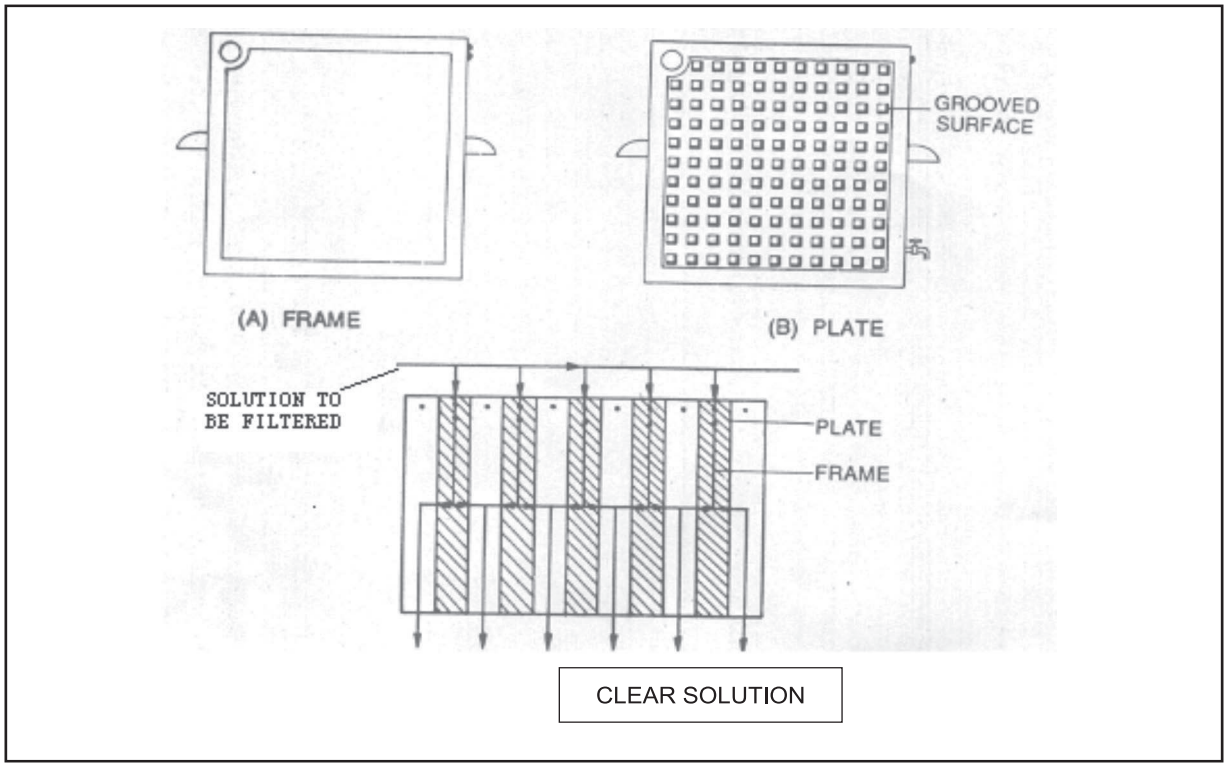
6. Chemical modification of the drug: 

The method is based on preparing the water-soluble derivatives of poorly soluble drugs. eg. Alkaloids are poorly soluble, their derivative with acids (alkaloidal salts) are fairly soluble. Example drugs like corticosteroids have been esterified to produce water-soluble derivatives.

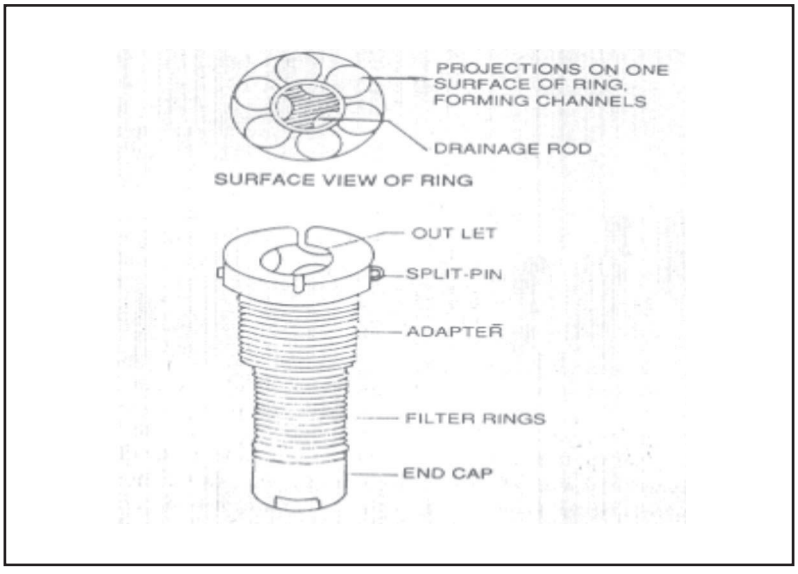
Other important problems involved in the development of formulation for liquid preparations are:

1. Stability,
2. Sterility,
3. Organoleptic qualities,
4. Viscosity,
5. Tonicity,
6. Specific gravity.

DIFFERENT FILTERS USED IN INDUSTRY FOR NON-STERILE FILTRATION OF SOLUTION



FILTER PRESS



META FILTER

Experiment No. 8

1.0 Title:

To prepare, evaluate and submit 25 ml Benzoic Acid Solution B.P.C. (Synonym Liquior acidi benzoici) using Cosolvency Method.

2.0 Prior Concepts:

Different solubility enhancement techniques, volumetric measurement, weight measurement.

3.0 New concepts:

Proposition 1: Benzoic acid solution B.P.C.

Solubility enhancement by cosolvency method.

Proposition 2:

Formation of clear homogeneous solution.

4.0 Learning objectives:

Intellectual Skills:

To understand concept of solubility enhancement of Benzoic acid by using cosolvent.

Motor Skills:

1. Skill for measurement.
2. Skill for dissolution.

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (250 ml), Glass rod, Volumetric Cylinder (100 ml), Dispensing Balance, Spatula.

6.0 Formulation Table (As per B.P.C.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Benzoic Acid	50 g		
2. Propylene glycol	750 ml		
3. Purified water q.s.	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Benzoic acid is organic acid, which is insoluble in water; therefore propylene glycol is used as cosolvent. Benzoic acid is soluble in propylene glycol, which is miscible with water.

Procedure:

1. Dissolve Benzoic acid in propylene glycol.
2. Add sufficient water in small proportion in beaker to produce required quantity with vigorous shaking.
3. Filter, if any foreign particles are present.

Category: Antibacterial and antifungal.
Storage: Well closed airtight container away from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Benzoic Acid solution B.P.C.	Description Colour Odour Volume	Clear Colourless Odourless 25 ml	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. State the mechanism by which Benzoic acid is dissolved in water?
2. Give some examples of cosolvents.
3. State the purpose of cosolvent in preparation of benzoic acid solution.
4. What are different techniques of solubility enhancement?
5. Draw a layout of liquid oral unit in industry.
6. Write any three filters used in industry for non-sterile filtrations of solutions?
7. Draw well labeled diagram of Meta filter.

(Space for answers)

(Space for answers)

Experiment No. 9

1.0 Title:

To prepare, evaluate and submit 25ml Cresol with Soap Solution I. P. (Synonym Lysol) by Micelle Formation.

2.0 Prior Concepts:

Solubility, volumetric measurement, weight measurement.

3.0 New concepts:

Proposition 1: Cresol with soap solution

Solubility enhancement by micelle formation.

Proposition 2:

Preparation of soft soap by saponification process.

4.0 Learning objectives:

Intellectual Skills:

1. To understand concept of solubility enhancement of cresol by micelle formation.
2. To understand saponification reaction.

Motor Skills:

1. Skill for making soaps
2. Skill for dissolution.

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (250 ml), Glass rod, Volumetric Cylinder (100 ml), Dispensing Balance, Spatula.

6.0 Formulation Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Cresol	500 ml		
2. Vegetable Oil	180 g		
3. Potassium Hydroxide	42 g		
4. Purified water q.s.	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Solution of cresol with soap solution contains 50 % of cresol. Solubility of cresol in water is only 2 %. The solubility of cresol in water is increased by using soap of fatty acid. They are prepared from vegetable oil such as cottonseed oil, linseed oil, soyabean oil and potassium hydroxide with water until saponification is complete. Soap forms charged aggregates as ionic micelles. These micelles contain linoleyl radical which solublise cresol giving clear solution. Then required volume is adjusted with purified water.

Procedure:

1. Dissolve potassium hydroxide in required quantity of purified water.
2. Add Vegetable oil to it.
3. Heat mixture on water bath till a small portion of mixture dissolves in water without the separation of oily drops.
4. Add cresol to above mixture and mix thoroughly to get clear solution.
5. Then add sufficient purified water to make up the volume.

Category: Disinfectant

Storage: Store in a well-closed container, protected from light.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Cresol with soap solution I.P.	Colour	Amber coloured to reddish brown	
	Odour	Phenolic	
	Solubility	Soluble in water	
	Volume	25ml.	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. ….... Q. ..…. Q. ..….. (Question numbers to be allotted by the teacher.)

1. Write any two precautions to be taken during performing this experiment with reasons.
2. State the saponification reaction?
3. State the category of cresol with soap solution I.P and explain it.
4. What is critical micelle concentration (CMC)?

5. State the solubility of cresol in water and how it is increase in preparation of Lysol solution.
6. State the problem you will face, if saponification reaction is not complete?
7. How will you check whether the saponification reaction is complete?
8. Write the test for alkalinity for cresol with soap solution; give reasons for doing this test.

(Space for answers)

Experiment No. 10

1.0 Title:

To prepare, evaluate and submit 25ml Strong Ammonium Acetate Solution B.P.C. by pH Adjustment Method. (Synonym: Liquor ammonium acetalise fortis)

2.0 Prior Concepts:

Different solubilization methods, volumetric measurement, weight measurement.

3.0 New Concepts:

Proposition 1: Strong Ammonium acetate solution.
Concept of pH adjustment using colour indicators.

Proposition 2:
Formation of active ingredient by chemical reaction.

4.0 Learning Objectives:

Intellectual Skills:

To understand concept of pH adjustment by using indicator solutions.

Motor Skills:

1. Skill for measurement.
2. Skill for dissolution.
3. Skill for pH adjustment.

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (200 ml), Glass rod, Volumetric Cylinder (100 ml), Dispensing Balance, Spatula.

6.0 Formulation Table (As per B. P.C.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Ammonium bicarbonate	470 g		
2. Glacial Acetic Acid	453 g		
3. Strong ammonia solution	Quantity sufficient		
4. Purified water (Freshly boiled & cooled) Quantity sufficient to produce)	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

The ammonium acetate is formed by chemical reaction between ammonium bicarbonate and Acetic acid.

$$NH_4\,HCO_3 + CH_3COOH \longrightarrow CH_3COONH_4 + H_2O + CO_2$$

Ammonium Bicarbonate   **Acetic Acid**   **Ammonium Acetate**

Carbon dioxide remains in solution giving it a good taste.

Ammonia should be used for neutralization of excess of acetic acid. If ammonium bicarbonate is used, then it forms a concentrated solution and reaction ceases. To push reaction in forward direction strong solution of ammonia is added. It also neutralises the excess acetic acid.

Weak solution of ammonium acetate is prepared by admixture of one volume of strong solution and seven volume of distilled water.

The solution is most effective and stable between pH 7.0 – 8.0

The pH is adjusted by using two indicators Bromothymol blue & thymol blue.

Bromothymol blue:

pH 6 (Yellow) → Green → pH 7.6 (Blue)

Thymol blue:

pH 6 (Yellow) → pH 9.6 (Blue)

The solution should be stored in lead free bottle because lead reacts to form lead acetate and thus pH of solution varies.

1. Mix glacial acetic acid with purified water.
2. Add ammonium bicarbonate in small quantity at a time until it dissolves.
3. Then add sufficient amount of ammonia solution until one drop of resulting solution diluted with 10 drops of water gives full blue colour with one drop of Bromothymol blue and full yellow colour with one drop of thymol blue solution.
4. Then add sufficient amount of purified water to produce required volume.

Category: Diaphoretic, diuretic.
Storage: Preserve in lead free container.
Dose: 1 to 4 ml

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Strong Ammonium Acetate solution B.P.C.	Description Colour Odour pH Volume	Clear Colourless vinegar 7.0 – 8.0 25 ml	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ……. Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. State the pH of strong ammonium acetate solution B.P.C.?
2. State the reactions involved in formulation of strong ammonium acetate solution B.P.C.?
3. What are indicators used for adjustment of pH in strong ammonium acetate solution B.P.C.?
4. State the category and storage conditions required for strong ammonium acetate solution B.P.C.?
5. Define diaphoretic and diuretic.
6. Why lead free container is use for storage of strong ammonium acetate solution B.P.C.?
7. Why it is necessary to adjust the pH of strong ammonium acetate solution B.P.C.?
8. State the difference between strong ammonia solutions and dilute ammonia solution.
9. Why is ammonia solution used in adjustment of the pH?

(Space for answers)

Experiment No. 11

1.0 Title:

To prepare, evaluate and submit 25 ml of Aqueous Iodine Solution I. P. by Complexation. (Synonym: Lugol's solution)

2.0 Prior Concepts:

Solubility, volumetric measurement, weight measurement.

3.0 New concepts:

Proposition 1:

Aqueous Iodine solution prepared by complexation.

Proposition 2:

Aqueous Iodine solution (5 % w/v): Source of Iodine for internal use.
Weak Iodine solution (2 % w/v): Antiseptic for external use.
Strong Iodine solution (10 % w/v): Antiseptic for external use.

4.0 Learning objectives:

Intellectual Skills:

1. To understand concept of solubility by complexation.
2. To understand colour difference due to different strengths of iodine
3. To understand difference between aqueous Iodine solution and alcoholic Iodine solution due to the difference in solvent used.

Motor Skills:

1. Skill for measurement.
2. Skill for dissolution.

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (200 ml), Glass rod, Volumetric Cylinder (100 ml), Dispensing Balance, Spatula, Glass mortar and pestle.

6.0 Formulation table (As per I. P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Iodine 2. Potassium Iodide 3. Purified water q.s.	50 g 100 g 1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Aqueous Iodine is a solution containing 5 % w/v of Iodine & 10 % w/v of potassium iodide. Iodine is powered in glass mortar. Iodine is insoluble in water. Therefore potassium iodide is used as solublising agent with which iodine forms polyiodide complex. These polyiodide complexes are soluble in water.

$$KI + I_2 \longrightarrow KI_2 + KI_3$$

Water insoluble **Water-soluble polyiodide complexes**

1. Triturate iodine and potassium iodide in glass mortar; add one-fourth quantity of vehicle.
2. Transfer in conical flask and shake well till it dissolves.
3. Then add sufficient purified water to make the required volume.

Category : Source of Iodine

Dose: 0.3 to 1 ml

Storage: Preserve aqueous solution of Iodine in well-closed container, the material of which is resistant to Iodine.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Aqueous Iodine solution.	Description	Clear	
	Colour	Reddish	
	Odour	Pungent	
	Volume	25ml.	

10.0 Result:

……ml of …….. preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q. ..... Q. ..... Q. ..... Q. ..... (Question numbers to be allotted by the teacher.)

1. How solubility of Iodine enhances in Aqueous Iodine solution.
2. Explain the category of Aqueous Iodine solution.
3. Give the synonym for 'Aqueous Iodine solution' I.P.
4. Why glass mortar and pestle used for trituration of iodine and potassium iodide?
5. Deficiency of iodine leads to which disease?
6. State the solubility of iodine in water.
7. If metallic closure is used for storing these preparation what will be outcome?

(Space for answers)

Experiment No. 12

1.0 Title:

To prepare, evaluate and submit 20ml of Weak Iodine Solution I.P. (Synonym: Tincture Iodine) by complexation.

2.0 Prior Concepts:

Different method of solubility enhancement, volumetric measurement, weight measurement.

3.0 New concepts:

Proposition 1:

Weak Iodine solution prepared by complexation.

Proposition 2:

Aqueous Iodine solution (5 % w/v): Source of Iodine for internal use.

Weak Iodine solution (2 % w/v): Antiseptic for external use.

Strong Iodine solution (10 % w/v): Antiseptic for external use.

4.0 Learning objectives:

Intellectual Skills:

1. To understand concept of solubility enhancement by complexation & by using alcohol as vehicle.
2. To understand concept of penetration enhancement by using alcohol as vehicle.
3. To understand difference between aqueous Iodine solution and weak Iodine solution.

Motor Skills:

1. Skill for measurement.
2. Skill for dissolution.

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (200 ml), Glass rod, Volumetric Cylinder (100 ml), Dispensing Balance, Glass mortar and pestle, Spatula.

6.0 Formulation table (As per I. P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Iodine 2. Potassium Iodide 3. Alcohol (50 %), sufficient produce	20 g 25 g 1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \text{...}$$

7.0 Stepwise procedure

Tincture of iodine or weak iodine solution I.P. contains 2 % w/v iodine and 2.5% w/v potassium iodide. The alcohol content is 45 to 48% w/v. Alcohol (50 %) is the vehicle used in the preparation of

weak Iodine solution. Solubility of Iodine is increased by addition of potassium Iodide. Potassium Iodide also prevent formation of ethyl Iodide which otherwise is formed in the reaction of Iodine with ethyl alcohol and the solution would not remain antiseptic. Alcohol evaporates from the skin leaving behind film of Iodine. It also dissolves cutaneous fat and therefore increases absorption of Iodine through the skin. This solution can also be given internally in case of Iodine deficiency.

1. Triturate Potassium Iodide and Iodine in glass mortar.
2. Add required quantity of alcohol (50 %) and make the volume.

Category: Antiseptic.

Storage: Preserve weak Iodine solution in well-closed container made up of Iodine resistant material.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Weak Iodine solution I.P.	Description	Clear	
	Colour	Reddish	
	Odour	Pungent	
	Volume	20ml.	

10.0 Result:

……ml of …….. preparation is submitted in …….. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. Q. ..…Q 9 (Compulsory)(Question numbers to be allotted by the teacher.)

1. Give the synonym for ‘weak Iodine solution I.P.’.
2. What is difference between Aqueous Iodine solution I.P. and weak Iodine solution I.P?
3. State the category of weak Iodine solution I.P?

4. State the use of alcohol in weak Iodine solution?
5. State the use of potassium iodide in iodine tincture?
6. Give official formula for iodine tincture.
7. Why alcohol is called universal solvent? Give reason.
8. State the solubility of iodine in alcohol.
9. Using alligation method, write the method of preparation of weak iodine solution from strong iodine solution.

(Space for answers)

(Space for answers)

Experiment No. 13

1.0 Title:

To prepare, evaluate and submit 100 ml Compound Sodium Chloride Solution I. P. (synonym: Ringer's solution)

2.0 Prior Concepts:

Different solubilization methods, volumetric measurement, weight measurement.

3.0 New concepts:

Proposition 1:

Compound sodium chloride solution I.P. is a mixture of three salts therefore word compound is used in the title of this solution.

4.0 Learning objectives:

Intellectual Skills:

To understand concept of dissolution.

Motor Skills:

1. Skill for measurement.
2. Skill for dissolution

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (200 ml), Glass rod, Volumetric Cylinder (100 ml), Electronic Balance, Spatula.

6.0 Formulation table (As per I. P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Sodium Chloride	8.6 g		
2. Potassium Chloride	0.3 g		
3. Calcium Chloride	0.33 g		
4. Purified water, q.s.	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Compound sodium chloride solution I.P. contains three electrolytes i.e. sodium chloride 0.86% w/v, potassium chloride 0.03%w/v and calcium chloride hydrated 0.033% w/v. It is used as fluid and electrolyte replenisher in case of excessive loss of water and salt from the body. It is also used as irrigation solution. It is to be taken in large quantities as required by the patients.

1. Dissolve three salts in a sufficient quantity of recently boiled purified water.
2. Make up volume up to 1000 ml.
3. Filter the solution, returning the filtrate, until free from suspended particles.

Category: Irrigation solution (For external use). / Electrolyte replenisher

Storage: Store in well close container in cool place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

The label states the strength as the percentages w/v of sodium chloride, potassium chloride and calcium chloride.

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Compound Sodium Chloride solution I.P.	Description Colour Odour Taste pH	Clear Colourless Odourless Mildly saline 5 - 7.5	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. Give the synonym of compound sodium chloride solution.
2. What is minimum weighable quantity on electronic balance?
3. Name different filtration units used in Industry for non-sterile filtration.
4. What are active ingredients of Ringer's solution?
5. Why word "compound" is used in the nomenclature of this formulation?
6. Under which medical condition there is excessive loss of body fluids?
7. What are isotonic solutions?
8. Write the routes of administration through which preparations given should be isotonic?

(Space for answers)

(Space for answers)

Experiment No. 14

1.0 Title:

To prepare, evaluate and submit 25 ml Surgical Chlorinated Soda Solution B. P. (Dakin's Solution).

2.0 Prior Concepts:

Different solubilization methods, volumetric measurement, weight measurement.

3.0 New Concepts:

Proposition 1:
Surgical chlorinated soda solution B. P.
Formation of active ingredient by chemical reaction.

4.0 Learning Objectives:

Intellectual Skills:
To understand chemical reactions involved in formation of chlorine.

Motor Skills:
1. Skill for measurement.
2. Skill for dissolution.

5.0 Apparatus:

Conical flask (150 ml), Glass Beaker (200 ml), Glass rod, Volumetric Cylinder (100 ml), Dispensing Balance, Spatula.

6.0 Formulation Table (As per B.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Boric Acid	4 gm		
2. Chlorinated lime	18.8 gm		
3. Sodium carbonate	37.6 gm		
4. Purified water	100 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Calcium chlrohypochlorite, principle constituent of bleaching power, decompose on addition of water.

$$\underset{\text{Calcium chloro hypochlorite}}{2\,Ca(OCl)Cl} \longrightarrow \underset{\text{Calcium hypochlorite}}{Ca(OCl)_2} + \underset{\text{Calcium chloride}}{CaCl}$$

It reacts with sodium carbonate,

$$\underset{\text{Calcium chloro hypochlorite}}{Ca(OCl)_2} + \underset{\text{Sodium Cabonate}}{Na_2CO_3} \longrightarrow \underset{\text{Sodium hypochlorite}}{2\,NaOCl} + \underset{\text{Calcium carbonate}}{CaCO_3}$$

$$\underset{\text{Calcium chloride}}{CaCl_2} + \underset{\text{Sodium carbonate}}{Na_2CO_3} \longrightarrow \underset{\text{Sodium chloride}}{2\,NaCl} + \underset{\text{Calcium carbonate}}{CaCO_3}$$

Bleaching power always contains some amount of calcium hydroxide. This reacts with sodium carbonate.

$$\underset{\text{Calcium hydroxide}}{Ca(OH)_2} + \underset{\text{Sodium carbonate}}{Na_2CO_3} \longrightarrow \underset{\text{Calcium carbonate}}{CaCO_3} + \underset{\text{Sodium hydroxide}}{2NaOH}$$

Sodium hypochlorite hydrolyses in solution to produce sodium hydroxide.

$$\underset{\text{Sodium hypochlorite}}{NaOCl} + H_2O \longrightarrow \underset{\text{Sodium hydroxide}}{NaOH} + \underset{\text{Hypochloric acid}}{HOCl}$$

Hence the filtrate is very alkaline and too caustic for wounds. The added boric acid reacts with sodium hydroxide and neutralize it. Hence the finished product is almost neutral and also buffered.

$$\underset{\text{Sodium hydroxide}}{2NaOH} + \underset{\text{Boric acid}}{4H_3BO_3} \longrightarrow \underset{\text{Sodium burate}}{Na_2B_4O_7} + 7H_2O$$

The pH of the solution is 9.5. Alkaline solution is stable. Too much alkalinity renders irritation to the tissue. Sodium borate formed acts as buffer and prevent further hydrolysis. Bleached filter paper guards the loss of chlorine and also colour change.

1. Dissolve Sodium carbonate in water.
2. Add this solution gradually with constant trituration to previously powdered chlorinated lime.
3. Shake it occasionally for 10 minutes.
4. Decant or filter it through bleached filter.
5. Dissolve boric acid in the filtrate.

Category: As a bactericide. For external use only.
Storage: It should be stored in cool place away from the light.
Content: Available chlorine content 0.50 to 0.55 percent w/v calculated as chlorine.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Surgical Chlorinated Soda Solution B.P.	Description Colour Odour	Clear Colourless Odourless	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..….. Q. ….... Q. ..….. (Question numbers to be allotted by the teacher.)

1. Why Boric acid is added in surgical chlorinated soda solution.
2. State the pH of surgical chlorinated soda solution?
3. State the active constituent and percentage of it in surgical chlorinated soda solution?
4. State the reactions involved in the preparation of surgical chlorinate soda solution B.P.

(Space for answers)

INTRODUCTION TO SPIRITS

Spirits are defined as alcoholic or hydroalcoholic solutions of medicinal substances as volatile substances. The alcohol concentration of spirit is high ranging from 60 – 85 %. Spirits are used as flavouring agent. They are popularly known as essence. These preparations must be stored in closed containers to avoid the loss of alcohol or volatile principles by evaporation. The container should also be light resistant. Light energy decomposes the volatile constituents with the loss of flavour. They should be kept in cool place at the temperature below 20°C. They should be protected from flame or fire.

Preparation of spirits:

Generally one of the following methods is used for the preparation of the spirits.

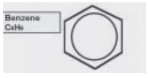
1. Simple solution:

Majority of the spirits are prepared by this method, which consists of dissolving the volatile substance in alcohol by agitation, eg. chloroform spirit, spirit of ether.

2. Solution with maceration:

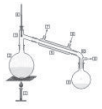
The method consists of macerating the leaves of drug in a suitable solvent to exclude undesirable constituents or to extract desired. Constituents of leaves of the drug are macerated by water to extract water-soluble constituents. It is expressed and to the marc, alcohol is added. This is mixed with filtered liquid example peppermint spirit.

3. Chemical reaction:



Official products are not prepared by this method. In preparation of ethyl nitrate spirit, this method is employed using sodium nitrate with mixture of alcohol and sulphuric acid in cold.

4. Distillation method:



Aromatic spirit of Ammonia is prepared by this method. Brandy and whisky are also made by distillation process.

Experiment No. 15

1.0 Title:

To prepare, evaluate and submit 20ml Peppermint Spirit B.P. by Simple Solution Method.

2.0 Prior Concepts:

Different solubilization methods, volumetric measurement.

3.0 New Concepts:

Proposition 1:

Peppermint spirit B.P. is spirit prepared by simple solution method.

Proposition 2:

Spirits are stored in air tight, light resistant container.

4.0 Learning Objectives:

Intellectual Skills:

To understand concept of solubility.

Motor Skills:

Skill for measurement

5.0 Apparatus:

Glass Beaker (250 ml), Volumetric Cylinder (100 ml), Volumetric Pipette (1ml)

6.0 Formula Table (As per B.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Peppermint oil 2. Alcohol (90 %) q.s.	100 ml 1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

1. Dissolve peppermint oil in 90 % alcohol and stir vigorously.
2. If the solution is not clear, shake it well with 50 g talc for 1000 ml of preparation.
3. Set it aside and filter to get clear liquid.

Alcohol content: 78 – 82 % v/v

Category: Aromatic, carminative and in dental preparation.

Storage: Store in a cool and dark place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Peppermint spirit B.P.C.	Description Colour Odour Volume	Clear Colourless Aromatic 20 ml	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... (Question numbers to be allotted by the teacher.)

1. Define spirits.
2. What are different methods for preparation of spirits?
3. What are storage conditions for spirits?
4. State the other name for spirit.
5. Calculate the strength of preparation in terms of absolute alcohol by alligation method.
6. What are carminatives? Give example of one aromatic water used as carminative.

(Space for answers)

(Space for answers)

Experiment No. 16

1.0 Title:

To prepare, evaluate and submit 100 ml Aromatic Spirit of Ammonia I.P. by Distillation Method. (Synonym: Spirit of Sal volatile)

2.0 Prior Concepts:

Different solubilization methods, volumetric measurement, Distillation.

3.0 New Concepts:

Proposition 1:
Aromatic spirit of ammonia I.P. is prepared by distillation method.

Proposition 2:
Spirits are stored in air tight, light resistant container.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the preparation of spirit by distillation method
2. To understand difference between aromatic waters and spirits.

Motor Skills:

Skill for measurement.

5.0 Apparatus:

Distillation assembly, Conical flask (150 ml), Volumetric Cylinder (100 ml), Dispensing balance, Spatula.

6.0 Formulation table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Ammonium Bicarbonate	25 g		
2. Strong ammonia solution	70 ml		
3. Lemon oil	5 ml		
4. Nutmeg oil	3 ml		
5. Alcohol (90 %)	750 ml		
6. Purified water, sufficient to produce	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Aromatic spirit of ammonia contains 1.185 % v/v of free ammonia (Limits 1.12 to 1.25) and 3 % w/v of ammonium bicarbonate (2.76 to 3.24). Aromatic spirit of ammonia or spirit of sal volatile is prepared by distillation.

The solution of spirit contains ammonium bicarbonate with ammonia in alcohol and flavoured with lemon oil and nutmeg oil. It also contains 3 % w/v of ammonium carbonate, which is formed by chemical reaction between ammonia and ammonium bicarbonate.

During distillation the first portion collected contains more amount of alcohol, while the second portion with more amount water. Hence this liquid is opalescent. Ammonia and ammonium bicarbonate when dissolved are converted into normal carbonate.

$$NH_4HCO_3 + NH_3 \longrightarrow (NH_4)_2CO_3$$

This conversion is essential before the admixture with alcohol portion of the distillate as ammonium bicarbonate is almost insoluble in alcohol and account for collection of distillate in two portions.

1. Place lemon oil, nutmeg oil and alcohol (90 %) with 375 ml of purified water in still.
2. Distillate first 875 ml of distillate and keep it aside.
3. Collect 35 ml of second portion of distillate.
4. Place the second portion of distillate with ammonium bicarbonate and ammonia solution in a bottle of more than 120 ml capacity.
5. Securely close the bottle and gently warm it in a water bath at 60°C, shaking from time to time until all the salt has been dissolved.
6. Cool and filter the resulting solution through cotton wool and gradually mix the filtrate with first portion of distillate.
7. Add sufficient purified water to produce required volume.

Storage: Stored in well-filled, well closed, container in a cool place, away from light.

Category: Used as reflex respiratory stimulant.

Dose: 1 to 5 ml

Label Content:

Free ammonia	1.12 % v/v
Ammonium carbonate	3 % w/v
Alcohol	64 – 70 % v/v

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Aromatic spirit of Ammonia I.P.	Description Colour Odour Volume Taste	Clear Colourless Ammonical 100 ml Pungent	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. ….... Q. ..….. Q. ..….. (Question numbers to be allotted by the teacher.)

1. What are active ingredients present in Aromatic spirit of ammonia?
2. State flavouring agents used in Aromatic spirit of ammonia?
3. Explain the category of aromatic spirit of ammonia?
4. State the method of preparation of Aromatic spirit of ammonia?
5. Why aromatic spirit of ammonia not prepared by simple solution method?
6. Why distillate is collected in two portions?
7. Calculate the strength of preparation in terms of absolute alcohol.
8. Write the storage conditions for aromatic spirit of ammonia. What can happen if container is not well filled?

(Space for answers)

(Space for answers)

Experiment No. 17

1.0 Title:

To prepare, evaluate and submit 20 ml Compound Orange Spirit B.P.

2.0 Prior Concepts:

Different solubilization techniques, volumetric measurement.

3.0 New Concepts:

Proposition 1:
Compound orange spirit prepared by simple solution method.

Proposition 2:
Spirits are stored in air tight, light resistant container.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of solubility.
2. To understand difference between aromatic waters and spirits.

Motor Skills:

Skill for measurement.

5.0 Apparatus:

Beaker (250ml), Measuring Cylinder (100ml), Funnel, Filter Paper.

6.0 Formulation Table (As per B.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Terpeneless orange oil	2.5 ml		
2. Terpeneless lemon oil	1.3 ml		
3. Anise oil	4.25 ml		
4. Coriander oil	6.25 ml		
5. Alcohol (90 %) q. s.	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Compound orange spirit contains terpeneless orange oil, terpeneless lemon oil, anise oil and coriander oil in alcohol. Terpeneless oils are used because they are stronger in flavour and they are more soluble.

1. Measure the required ingredients with the help of pipette and transfer in beaker
2. Add required volume of the alcohol
3. Mix uniformly. .
4. Filter if necessary.

Category: Flavouring agent.

Storage: Store in well-closed containers at temperature not exceeding 25°C, protected from light.

Alcohol content: 86 to 90 % v/v.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Compound Orange Spirit B.P.	Description Colour Odour Volume	Clear, volatile liquid Colourless Characteristic 20 ml.	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

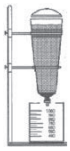
11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. (Question numbers to be allotted by the teacher.)

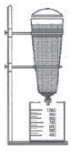
1. State the different methods of preparation of spirits?
2. Why terpeneless oils are used in preparation of compound orange spirit B.P.?
3. What can happen if spirits are stored in transparent containers?
4. State the type of container used for storage of spirits?
5. State the difference between aromatic water and spirit?

(Space for answers)

(Space for answers)



INTRODUCTION TO TINCTURES



Tinctures, according to the Pharmacopoeia of India, are defined as alcoholic or hydroalcoholic solutions usually containing, in comparatively dilute proportions, the active principles of vegetable or animal drugs. Thus solutions of chemical substances are not included in the IP definition of tinctures. However, in USP, solutions of chemical substances are included under tinctures.

Strong/ Weak Iodine solution I.P. – Iodine Tincture USP.

Application of Tinctures

1. **For Internal Use:**
   Cardiotonic – Digitalis Tincture I.P.
   Anticholinergics – Belladonna Tincture I.P.
   Parasympatholytics – Datura Tincture I.P.
   Emetic – Ipecacuanha Tincture I.P.
2. **As Flavoring Agent** – Orange Tincture I.P.

Benefits of Tinctures:

Tinctures are very stable preparations and can be stored for longer period without loss of potency, decomposition and degradation.

Reasons for fall in Popularity of Tinctures:

Increasing use of pure drugs isolated from animals, plants, or prepared by synthetic processes. However, tinctures are still in use where comparatively low potency and large dosages are recommended.

Production:

Tinctures are prepared by maceration, percolation or other suitable, validated methods, using alcohol of suitable concentration. Tinctures may also be obtained by dissolving or diluting extracts in alcohol of suitable concentration.

1. **Production by Percolation (Process P)**
   If necessary, reduce the matter to be extracted to pieces of suitable size. Mix thoroughly with a portion of the prescribed extraction solvent and allow to stand for an appropriate time. Transfer to a percolator and allow the percolate to flow slowly making sure that the matter to be extracted is always covered with the remaining extraction solvent. The residue may be pressed out and the expressed fluid combined with the percolate.
2. **Production by Maceration (Process M)**
   Unless otherwise prescribed, reduce the matter to be extracted to pieces of suitable size, mix thoroughly with the prescribed extraction solvent and allow to stand in a closed container for an appropriate time. The residue is separated from the extraction solvent and, if necessary, pressed out. In the latter case, the two liquids obtained are combined.
3. **Production From Extracts:**
   The tincture is prepared by dissolving and diluting an extract, using alcohol of appropriate concentration.

Evaluation Tests:

1. Organoleptic Characters
   1. Smell
   2. Taste
   3. Clarity on shaking
2. Relative Density (Where Applicable)
3. Dry Residue/Total solid content (Where applicable)

   In a flat-bottomed dish introduce 2.00 gm or 2.0ml of the tincture. Evaporate to dryness on a water-bath and dry in an oven at 100°C – 105°C for 3h. Allow to cool in a desiccator over diphosphorus pentoxide R and weigh. Calculate the result as a mass percentage or in grams per liter.
4. Alcohol content
   It includes determination of ethanol, methanol and 2-propanol content.
5. Active Drug content

Storage:

Store in cool and dark place, in tightly closed containers.

Labeling:

The label should states:

The vegetable or animal matter used

Where applicable, that fresh vegetable or animal matter was used.

The concentration of alcohol used for the preparation.

The concentration of alcohol in the final tincture.

Content of Active principle.

Dose

Experiment No. 18

1.0 Title:

To study the effect of Drug to Solvent Ratio on Preparation of Orange Tincture I.P. using Maceration

Process. 1. Drug: Solvent :: 1:1
2. Drug: Solvent :: 1:4

2.0 Prior Concepts:

Definitions of terms used in extraction (i.e. Marc, Menstrum…), processes of extraction, factors effecting efficiency of extraction.

3.0 New Concepts:

Proposition 1: Drug: Solvent ratio
It is the ratio of weight of drug to volume of solvent.

Proposition 2: Tincture evaluation
Evaluation of tinctures is done for organoleptic properties (smell, colour, taste, clarity on shaking), and total solid content.

Proposition 3: Maceration without adjustment
During simple maceration of organized drugs, final volume is not adjusted whereas in case of unorganized drugs it is always adjusted.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the parameters for optimization of drug to solvent ratio.
2. To understand the concept of batch and continuous process.

Motor Skills:

Skill for setting an extraction experiment.

5.0 Apparatus:

Electronic Digital weighing balance (Least Count = 0.01 gram), Measuring Cylinder, Well-stopper wide mouth bottle (1L), Filtration Unit, Glass/Plastic Funnel, Filter Paper, Cloth piece for pressing marc, Porcelain dish for evaporation of Menstrum.

6.0 Formulation Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
Fresh orange peel, in thin slices	250 g		
Alcohol (90%)	1000ml.		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

1. Weigh two equal amount of fresh orange peel 250 grams and place them in two separate bottles (1L) respectively.
2. To first bottle, add 250 ml of 90% alcohol (menstrum) and to second bottle add 1000 ml of 90% alcohol.

3. Keep the well-closed bottles for seven days, and shake them occasionally.
4. After seven days, add 750 ml of 90% alcohol to first bottle.
5. Filter the contents of both bottles separately and press the marc.
6. Evaluate the tinctures for organoleptic properties (smell, colour, taste, clarity on shaking), and total solid content as described in introduction.
7. Fill the formulation in narrow mouth bottle, label it and dispense.

Dose: 2 to 4 ml.
Total solid content: Not less than 4.2%.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Parameters	Dilution ratio	
	1:1	1:4
Total solid Content		

10.0 Result:

This concludes that on increase in dilution ratio, the extraction efficiency …….. .

11.0 Questions :

Answer Q. ..…... Q. …..... Q. ..…... (Question numbers to be allotted by the teacher.)

1. Why final volume is not adjusted?
2. Can the same results can be expected with other drugs also? Give reasons?
3. Can we use dried orange peels? Give reasons?
4. What you learned from this experiment?
5. State the unit used for expressing alcohol content?
6. Mention the factors responsible for fall in popularity of tinctures?

(Space for answers)

Experiment No. 19

1.0 Title:

To study the effect of size reduction on preparation of Strong Ginger Tincture I.P. (Essence of Ginger) using percolation process.

i. Coarse Powder (10/44)
ii. Moderately Coarse powder (22/60)

2.0 Prior Concepts:

Different types of percolation process.

3.0 New Concepts:

Proposition 1: Sieve no.
Sieve number indicates the number of meshes in a length of 1 inch (2.54 cm) in each transverse direction parallel to the wires.

Proposition 2: Categorization of Powders
Powders are categorized in to five grades depending upon their particle size. Particle size is expressed as a/b where a is the sieve number through which all particles must pass, and b is the sieve number through which not more than 40% of particles pass.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the advantages of percolation process over other processes.
2. To understand the principle behind imbibition and packing in a percolator.

Motor Skills:

Skill for setting an extraction experiment.

5.0 Apparatus:

Electronic Digital weighing balance (Least Count = 0.01 gram), Measuring Cylinder (100 ml), Percolator (1litre capacity), Glass/Plastic Funnel, Filter Paper, Cloth piece for pressing marc, Porcelain dish for evaporation of Menstrum.

6.0 Formulation Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Ginger in powder form	500 grams		
2. Alcohol (90%), sufficient to produce	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

1. Weigh two equal amount 500 grams of coarse powder and moderately coarse powder.
2. Imbibe the weighed drug with sufficient quantity of menstrum.
3. Arrange the drug in percolator.
4. Add menstrum to produce the total volume 1000 ml and macerate for 24 hrs.
5. Percolate the saturated solution formed by downward displacement. The rate of collection of percolate is generally 10-30 drops per minute.
6. After collecting the required quantity, the marc is taken out from the percolator. It is pressed to recover the costly solvent.

7. Expressed liquid is mixed with percolate and then the final volume is made by adding more of menstrum.
8. Evaluate the tinctures for organoleptic properties (smell, colour, taste, clarity on shaking), and total solid content as described in introduction.
9. Fill the formulation in narrow mouth bottle, label it and dispense.

Category: Carminative

Dose: 0.3 to 0.6 ml

Total solid content: Not less than 2.0% w/v

Weight per ml: At 20°C, 0.832 to 0.846

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

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9.0 Observation and evaluation:

Parameters	Particle Size	
	10/44	22/60
Total solid Content		

10.0 Result:

This concludes that on size reduction the extraction efficiency……

11.0 Questions :

Answer Q. ..…... Q. …..... Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. State advantages of percolation process over maceration process?
2. Give principle of imbibition?
3. State any two parameters for selection of solvent system?
4. State the different stages of percolation.
5. What would be the out come if water is used instead of alcohol?
6. What advantage does the tincture have over other formulation, like aromatic water and spirits?
7. State the advantage of using alcohol as menstrum.
8. What are the factors that influence the total solid content in preparation of Tinctures?

(Space for answers)

Experiment No. 20

1.0 Title:

To prepare, evaluate and submit 20 ml of Catechu Tincture B.P. using Maceration.

2.0 Prior Concepts:

Extraction procedures for organized and unorganized drugs.

3.0 New Concepts:

Proposition 1:

Catechu Tincture is prepared by maceration with adjustment.

4.0 Learning Objectives:

Intellectual Skills:

To understand the use of alcohol for extraction.

Motor Skills:

Skill for setting an extraction experiment.

5.0 Apparatus:

Dispensing weighing balance, Measuring Cylinder (100ml), Well-Stopper wide mouth bottle (1L), Glass/Plastic Funnel, Filter Paper, Cloth piece for pressing marc.

6.0 Formulation Table (As per B.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Catechu, crushed 2. Cinnamon, bruised 3. Alcohol(45%),sufficient to produce	200 g 50g 1000ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}}$$

7.0 Stepwise procedure

1. Weigh the calculated amount of crushed catechu and bruised cinnamon.
2. Transfer all the powdered ingredients into closed vessel (approx 1 L).
3. Macerate with 800 ml of alcohol (45%) in a closed vessel for not less than two days with occasional shaking.
4. Filter and pass sufficient alcohol (45%) through the filter to produce the required volume.

Alcohol content: 36 to 40 v/v.
Total solids: 12-17 % w/v.
Dose: 2.5 to 5 milliliters.
Category: Astringent

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Catechu Tincture B.P.	Description Odour	Brownish Yellow, clear liquid Pleasant	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. ….... Q. ..….. (Question numbers to be allotted by the teacher.)

1. Write the biological source of Catechu.
2. Define the category of Catechu Tincture B.P.
3. Write the procedure to find the total solid content.
4. Write the meaning of maceration with adjustment, and for which type of drugs it is applicable.
5. Are Extracts and Tinctures identical? If so give reasons?
6. How does spirits differ from tinctures in formulation and applications?

(Space for answers)

(Space for answers)

Experiment No. 21

1.0 Title:

To prepare, evaluate and submit 50 ml of Compound Benzoin Tincture I.P. (Friar's Balsam) using Maceration.

2.0 Prior Concepts:

Extraction procedures for organised and unorganised drugs.

3.0 New Concepts:

Proposition 1: Source
Benzoin is a balsamic resin obtained from Styrax benzoin, known in commerce as Sumatra Benzoin or from Styrax tonkinensis known in commerce as Siam Benzoin (form styraceae).

Proposition 2: Protective
Agents that protects / isolates the exposed surface (skin or other membranes) from harmful or annoying stimulate (U.V.light, heat, toxins, etc.)

4.0 Learning Objectives:

Intellectual Skills:

To understand the use of alcohol for extraction.

Motor Skills:

Skill for setting an extraction experiment.

5.0 Apparatus:

Dispensing balance (Least Count = 0.01 gram), Measuring Cylinder (100ml), Well-Stopper wide mouth bottle (1L), Glass/Plastic Funnel, Filter Paper, Cloth piece for pressing marc, Porcelain dish for evaporation of Menstrum.

6.0 Formulation Table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Benzoin, crushed	100 g		
2. Prepared Storax	75 g		
3. Balsam of Tolu	25 g		
4. Aloes	20 g		
5. Alcohol (90%), sufficient to produce	1000ml		

7.0 Stepwise procedure

Benzoin is an unorganised drug and its extraction is carried out by maceration with adjustment. Resins are practically insoluble in water; therefore alcohol is used for extraction.

1. Weigh the calculated amount of Benzoin, Prepared Storax, Balsam of Tolu and aloe.
2. Pulverized all the weighed solid ingredients.
3. Transfer all the powdered ingredients into closed vessel (approx 1 L).
4. Macerate with 800 ml of alcohol (90%) in a closed vessel for not less than two days with occasional shaking.
5. Filter and pass sufficient alcohol (90%) through the filter to produce the required volume.

Alcohol content: 70 to 77% v/v.
Total solids: Not less than 13.5%.
Category: Protective.
Labeling: Benzoin should be labeled to indicate whether it is Sumatra Benzoin or Siam Benzoin.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Compound Benzoin Tincture I.P.	Description	Brown colour, viscous liquid	
	Odour	Pleasant	
	Total solids	More than 13.5 %	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

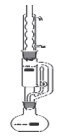
Answer Q. ..…... Q. …..... Q. ..…..(Question numbers to be allotted by the teacher.)

1. State the synonym of Compound Benzoin Tincture.
2. Define the category of Compound Benzoin Tincture.
3. State three differences between maceration of organised and unorganised drugs.
4. State the active constituent of Compound Benzoin Tincture.
5. Write the difference between batch and continuous extraction procedure.

(Space for answers)

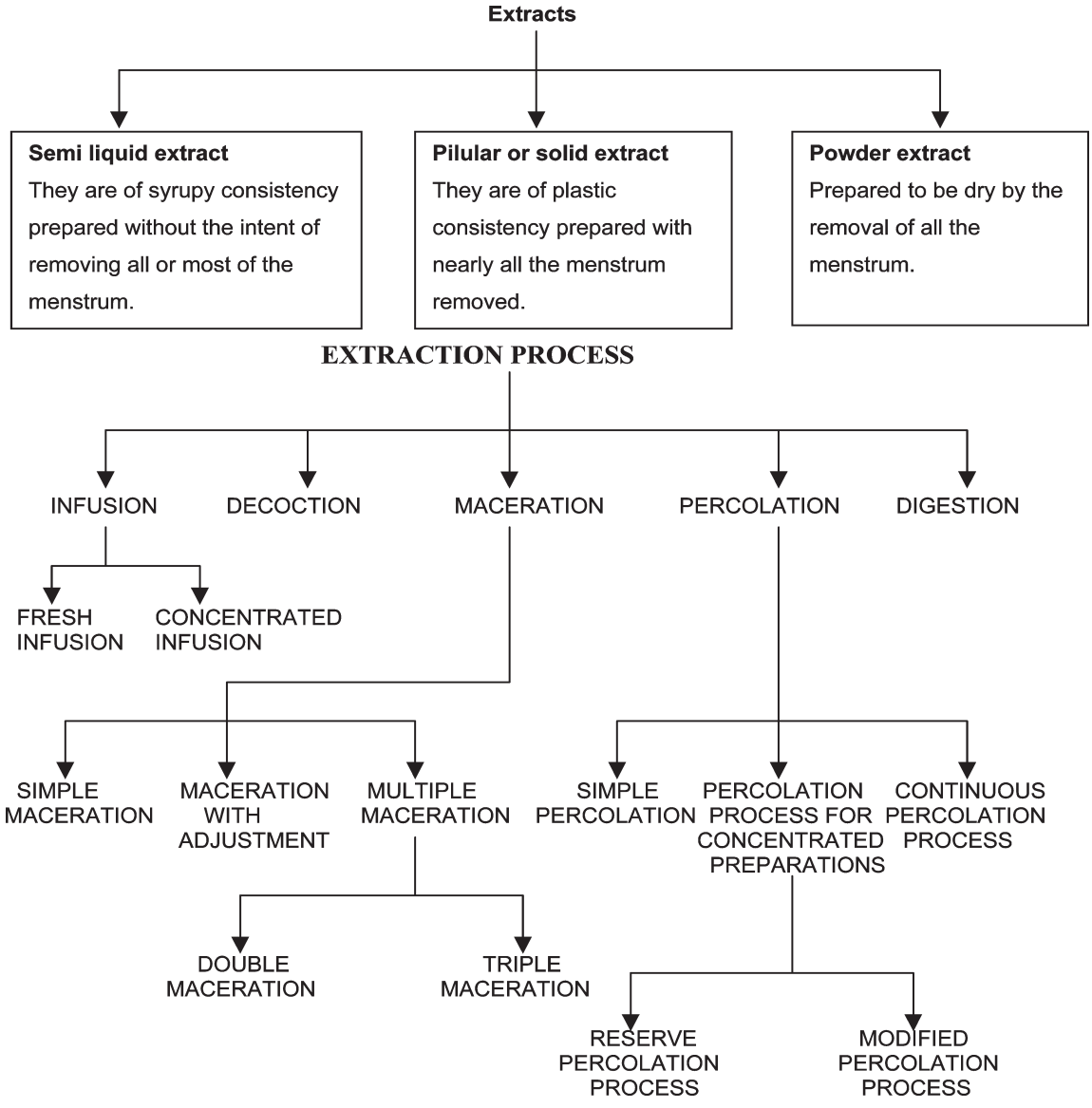
(Space for answers)

INTRODUCTION TO EXTRACTS



Extracts are concentrated preparation of vegetable or animal drugs obtained by removal of the active constituent of the respective drugs with suitable menstrum, evaporation of all or nearly all of the solvent and adjustment of the residual masses or powders to the prescribed standards.

Extracts are potent preparation usually between two and six times as potent, on a weight basis of the crude drug. They contain primarily the active constitutes of the crude drugs with a great portion of the inactive constitutes the structural component of the crude drug having been removed. Their function is to provide in small amount and in convenient, stable physical form the medicinal activity and character of the bulkier plant that they represent.



Normally a closed vessel is used for the maceration process and different types of percolators are used for extraction process. They are of three types

1. Conical percolators
2. Cylindrical percolators
3. Steam jacketed percolators

For industrial scale they are two main methods employed termed maceration and percolation. Both being operated on batch process. The choice of method depends upon the physical characteristic of the raw material and the economic consideration and as designated in the monographs of the official preparation.

Meceration : The general process on a small scale consist of placing the solid material to be extracted in a closed vessel with the whole of the menstrum or extraction solvent, and allowing them to stand for seven days shaking occasionally. The liquid is strained off and the marc or solid residue is pressed to remove as much solvent as possible, the liquid so obtained are mixed and clarified by filtration.

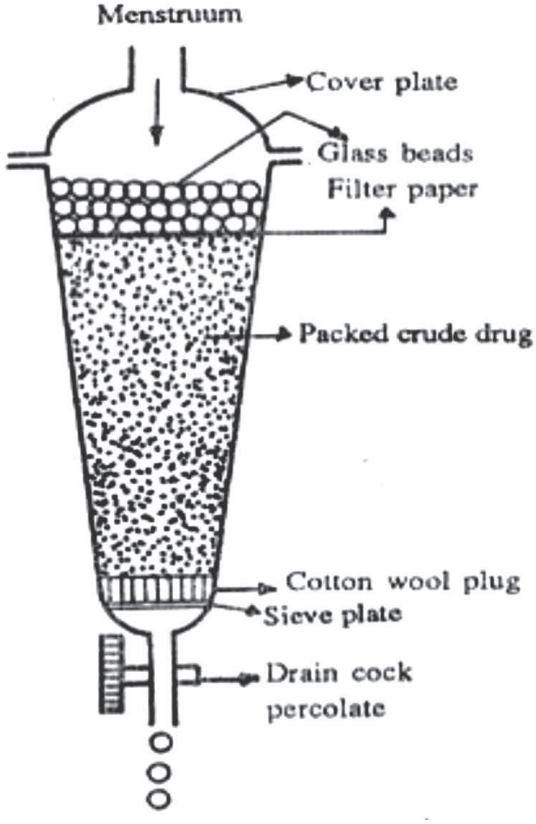
Percolation: In this process the raw material is packed into a column and the solvent is allowed to percolate through it. Although some material may be packed into the percolator in the dry state e.g. ginger. Most drugs require preliminary moistening. The solid material is mixed with sufficient solvent and the moist mass is allowed to stand for 4 hours in a well-closed vessel.

After the preliminary moistening subsequent packing into the percolator is also assigned since the solvent displaces occluded air and enables the material to be more evenly distributed. If the material is not packed evenly the percolating solvent will run mainly through the largest cannels resulting in inefficient extraction.

After packing the column sufficient menstrum is passed over it to saturate it and when liquid begin to drip from the bottom of the percolator the tap at its base is closed. Enough of the menstrum is then added to maintain a layer above the drug. The closed column is then allowed to stand for 4 hours.

After this preliminary maceration, the outlet is opened sufficiently to produce a controlled slow rate of percolation. The volume of percolates to be calculated for the given weight of raw material depends upon the nature of the final product.

Storage: Extracts are stored in cool-place in light resistant and well-closed container to protect the access of moisture.



Percolator

Experiment No. 22

1.0 Title:

To prepare evaluate and submit 100 ml of Liquorice Liquid Extract.

2.0 Prior Concepts:

Different types of extracts.
Different method of preparation of extracts.

3.0 New Concepts:

Proposition 1:
Liquorice liquid extract is a liquid extract prepared by triple maceration.

Proposition 2:
Extracts are normally stored in amber coloured glass bottle in a cool place.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand concept of extracts.
2. To understand the process of maceration.
3. To understand the different procedure used in preparation of extracts.

Motor Skills:

1. Skill for calculating the menstrum for triple maceration process.
2. Skill for carrying out the maceration process.
3. Skill for extracting the liquid extract and pressing the marc to recover the last traces of extracts.

5.0 Apparatus:

Dispensing Balance, A glass vessel, Filter cloth, Tincture press.

6.0 Formulation table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Liquorice, unpeeled in coarse powder	1000 g		
2. Chloroform water	Quantity sufficient		
3. Alcohol 90 %	Quantity sufficient		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Liquorice consists of the dried, peeled or unpeeled, root and stolon of Glycyrrhiza glabra family leguminosae and other species of Glycyrrhiza yielding a drug having sweet taste and almost free from bitterness.

1. The drug is macerated thrice by using the menstrum, which is divided in to three parts in such a manner that the same volume is used for each maceration.
   Note : Teacher should give volume of drug retained by 1 gm. of drug and let students calculate volume of menstrum require for first, second and third maceration.
2. The whole drug is macerated for one hour with a part of menstrum required for first maceration and strained.
3. Macerate again for one hour with a part of menstrum required for second maceration and strained.
4. Macerate again for one hour with a part of menstrum required for third maceration and strained.

5. Press the marc lightly.
6. Combine the liquids obtained from first, second and third maceration.
7. Set aside for 12 hours and decant the clear liquid and filter the remainder.
8. Evaporate until the weight /ml of the liquid is 1.198 gm/ml.
9. Add to this liquid, one fourth of its volume of alcohol (90%).
10. Allow to stand for not less than four weeks and filter.

Category: Demulcent.
Dose: 2 to 4 ml.

Volume of menstrum required for first maceration

$$= \frac{\text{Total vol. of menstrum} - \text{Vol. to be retained by drug}}{3} + \text{Vol. to be retained by the drug}$$

Volume of menstrum used for 2nd and 3rd maceration

$$= \frac{\text{Total Vol. Of menstrum} - \text{Vol. used in first maceration}}{2}$$

8.0 Labeling of formulation:

(Students shall write all aspect of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Liquid extract of Liquorice	Description Taste Wt/ml Total solids	Brown colour viscous liquid. Sweet 1.125 to 1.140 gm/ml 40 to 45 % w/v	

10.0 Result:

……ml of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..…... (Question numbers to be allotted by the teacher.)

1. Calculate the menstrum required for each stage of triple maceration.
2. What is the difference in maceration process of organised and unorganised drug?
3. What does the term expectorant and demulcent mean?
4. Explain the test for total solids.
5. Define extracts.
6. Why is imbibing stage necessary before percolation?
7. Give the names of different percolator used.
8. Give official preparation of liquorice liquid extract with their marketed name.

(Space for answers)

Experiment No. 23

1.0 Title:

To prepare and submit 100 ml of Vasaka Liquid Extract I. P.

2.0 Prior Concepts:

Different types of extracts.

Different method of preparation of extracts.

3.0 New Concepts:

Proposition 1:
Vasaka liquid extract is prepared by reserved percolation process.

Proposition 2:
Extracts are normally stored in amber coloured glass bottle in a cool place.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand concept of extracts.
2. To understand the process of percolation.
3. To understand reserve percolation.
4. To understand the different procedure used its preparation of extracts.

Motor Skills:

1. Skill for imbibition.
2. Skill for carrying out percolation.
3. Skill for carrying out the percolation process.

5.0 Apparatus:

Dispensing Balance, Percolator, Filter paper, Distillation unit, Measuring cylinder.

6.0 Formulation table (As per I.P.):

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Vasaka powder pass through 40 # 2. Alcohol 40 %v/v	1000 g quantity sufficient		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Vasaka consist of the fresh and dried leaves of Adhatoda vasica family Acanthaceae. The first portion which is alcoholic contains most of the active ingredients is reserved. The percolate is collected till all the drug is exhausted, and the percolate is distilled to syrupy consistency to which the reserved portion is added.

1. Exhaust the drug by percolation process, reserving the first 75 ml of the percolate.
2. Recover the alcohol from the remainder percolate by distillation process.
3. Evaporate the residue to consistency of soft extract.
4. Dissolve the soft extract in the reserved portion.
5. Add sufficient 40% alcohol to produce 100ml.

Category: Expectorant.
Dose: 1 to 2 ml.

8.0 Labeling of formulation:

(Students shall write all aspect of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of the preparation	Test	Specification	Observation
Liquid extract of Vasaka	Colour Description Odour	Brown colour Viscous liquid Pleasant	

10.0 Result:

……ml of …….. preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q. ..…... Q. …..... Q. ..…... Q. ..…... (Question numbers to be allotted by the teacher.)

1. Give the Biological source of vasaka.
2. What advantage does reserved percolation have over simple percolation?
3. What is the difference between the extracts and tincture?
4. Give the different stages of percolation.
5. State three ideal quality of the menstrum.
6. State the menstrum used in preparation of vasaka liquid extract.
7. How will you know that the drug in the percolator is exhausted?
8. State the other name for exhausted drug.
9. Draw a neat and well label diagram of percolator.

(Space for answers)

(Space for answers)

Experiment No. 24

1.0 Title:

To find the total alkaloidal content in 10 grams of Cinchona powder by continuous hot extraction process.

2.0 Prior Concepts:

Different types of extracts.

Different methods of preparation of extracts.

3.0 New Concepts:

Proposition 1:
The Cinchona alkaloids are poorly water-soluble and have good solubility in alcohol.

Proposition 2:
Cinchona alkaloids are thermostable and efficiently extracted by continuous hot extraction process using methanol as solvent.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of extracts.
2. To understand the concept of continuous extraction process (soxhelation).
3. To understand the advantages of soxhelation.

Motor Skills:

1. Skill for carrying out soxhelation.
2. Skill for calculating the total alkaloid content.

5.0 Apparatus:

Dispensing Balance, Thimble, Soxhlet apparatus, Heating mantle, condenser.

6.0 Formulation table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Cinchona Powder, moderately fine	10 g		
2. Methanol	quantity sufficient		
3. Calcium hydroxide (10%)	quantity sufficient		

Soxhelation Apparatus

7.0 Stepwise procedure

1. Weigh 10 gm of Cinchona powder, treat with Calcium hydroxide for 1 hour and filter.
2. Place the treated drug on filter paper and roll the filter paper and insert the filter paper in thimble.
3. Place the thimble in wide central tube of the extractor.
4. Place the solvent i.e. methanol in round bottle flask (previously weigh the flask).
5. Connect the flask to soxhlet apparatus and place the whole apparatus on a heating mantle.
6. Allow the extraction to continue for 2 hours.
7. Cool the apparatus and distill out the methanol.
8. Weight the flask.
9. Calculate the alkaloid content.
10. Perform the chemical test by dissolving the 0.1g extract in bromine water and dilute ammonia solution, emerald green colour is obtained.

Category: Antimalarial

Dose: 0.12 to 0.5 g.

8.0 Observation and evaluation:

Weight of Cinchona powder x gm

Weight of empty flask y gm

Weight of flask after soxhelation and distillation of methanol. z gm

$$\text{Percentage Content of alkaloidal content} = \frac{(z - y)\ 100}{x}$$

=…… %

9.0 Result:

The percentage of alkaloidal content in Cinchona powder was found to be ……..%.

10.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. Q. ..…... (Question numbers to be allotted by the teacher.)

1. What advantages does the soxhelation have over other extraction processes?
2. Can water be used for extraction of alkaloids from Cinchona, give reasons?
3. What are alkaloids and which class of alkaloids is present in Cinchona.
4. Which major alkaloids are present in Cinchona?
5. Write the category of Cinchona alkaloids.
6. Write the importance of treatment of drug with calcium hydroxide.
7. Write two differences between dried and soft extracts.

(Space for answers)

INTRODUCTION TO CREAMS

Creams are homogenous, semi- solid or viscous preparations intended for external application to the skin or certain mucous membranes for protective, therapeutic or prophylactic purposes especially where an occlusive effect is not necessary.

All the skin care creams can be classified on different basis: 

1. According to function, e.g. cleansing, foundation, massage, etc.
2. According to characteristic properties, e.g. cold creams, vanishing creams, etc.
3. According to the nature or type of emulsion.
4. According to the therapeutic value, e.g. Insect repellant creams, topical protectant.

The most widely accepted classification is based on function. According to the functions the creams can be classified as follows: 

1. Cleansing and cold creams.
2. Foundation and vanishing creams.
3. Night and massage creams.
4. Hand and body creams.
5. All purpose and general creams.

Cleansing creams: 

Cleansing cream is required for removal of facial make up, surface grime, oil and water and oil soluble soil efficiently, mainly from the face and throat.

Cold creams: 

Cold cream is an emulsion which when applied on the skin; a cooling affect is produced due to slow evaporation of water present in the emulsion.

Foundation creams: 

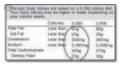
These provide a smooth emollient base or foundation before the application of face powder and other make-up preparations. They help the powder to adhere to the skin due to possession of good holding property.

Vanishing creams: 

Oil in water emulsions which when applied to the skin leaves an almost invisible layer on it. They provide emollient action, and a protective action against environment by leaving a semi-occlusive residual film on the skin.

Storage: 

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

Labeling: 

The label states

1. That the cream is sterile, where necessary.
2. The name and concentration of any added antimicrobial preservative.
3. The storage conditions.

Experiment No. 25

1.0 Title:

To prepare, evaluate and submit 20 grams of Vanishing Cream.

2.0 Prior Concepts:

Classification of creams on the basis of their applications.

3.0 New Concepts:

Proposition 1: Vanishing Cream
Vanishing Cream is an O/W type of an emulsion.

Proposition 2: Oil in Water (O/W) emulsion
Oil globules are dispersed in to the water. Oil phase is called as dispersed phase and water is called as the continuous phase or dispersion medium.

4.0 Learning Objectives:

Intellectual Skills:

To understand the role of different excipients.

Motor Skills:
Skill for weighing.
Skill for mixing liquids at hot temperatures.
Skill for homogenous mixing

5.0 Apparatus:

2 Beakers (100 ml), Measuring cylinder (50 ml), Spatula, Pipette, Water bath.

6.0 Formulation table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Stearic acid	18.0 g		
2. Glycerin	3.0 g		
3. Lanolin	2.0 g		
4. Triethonalamine	1.0 g		
5. Methyl paraben	0.18 g		
6. Propyl paraben	0.02 g		
7. Perfume	q.s.		
8. Water	75.8ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Methyl paraben is used in large quantity for preservative action if used alone. To reduce the quantity of methyl paraben, a very small amount (0.02%) potent Propyl paraben is used. Methyl paraben is used with Propyl Paraben in the ratio of [9:1 to 10:1].

1. Melt Stearic acid and lanolin at 60^0 C.
2. Mix water, glycerin and triethonalamine and warm up to 60^0 C in to second beaker.
3. Mix the two with continuous stirring.
4. Add the preservative and perfume.
5. Mix them thoroughly in order to obtain a uniform product.

Category: Vanishing cream.
Storage: Store in well-closed container, in cool place. Do not freeze.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Vanishing cream	Appearance	White	
	Fragrance	Perfumed	
	pH	5 – 8	
	Consistency	Smooth	
	Washability	Easily washed	

10.0 Result:

……gm of …….. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Give the precaution required to be taken during mixing of oily phase and aqueous phase.
2. Give the advantage for use of combination of methyl paraben and propyl paraben as preservative.
3. Write the definition of vanishing creams.
4. Explain the use of triethanolamine.
5. Write two ingredients that can be used to replace triethanolamine in the formulation.

(Space for answers)

(Space for answers)

Experiment No. 26

1.0 Title:

To prepare, evaluate and submit 15 grams of Cold Cream.

2.0 Prior Concepts:

Types of emulsions, classification of creams on the basis of their applications.

3.0 New Concepts:

Proposition 1: Bees wax-Borax system:
The preparations containing combination of beeswax and borax does not require any secondary emulsifier, used for both o/w and w/o creams.

4.0 Learning Objectives:

Intellectual Skills:

To understand the role of different excipients.

Motor Skills:
Skill for weighing and measurement.
Skill for making semisolid emulsions.
Skill for mixing.

5.0 Apparatus:

Two Beakers (100 ml), Measuring cylinder (50 ml), Spatula, Pipette (1ml), Water bath.

6.0 Formulation table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Bees wax	16.0 gm		
2. Liquid paraffin	50.0 g		
3. Borax	0.8 g		
4. Water	33.0 g		
5. Methyl paraben	0.18 g		
6. Propyl paraben	0.02 g		
7. Perfume	q.s.		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

In this beeswax-borax type preparation borax reacts with the free fatty acids present in the beeswax and products soft soap which acts as the emulsifying agent and emulsifies the oil phase containing beeswax, mineral oil, paraffin etc, in the aqueous phase.

During formulation heated aqueous phase in added to oily phase, addition of oily phase to aqueous phase, it results in clump formation.

1. Melt beeswax, liquid paraffin and propyl paraben in order of increasing melting point.
2. Dissolve methyl paraben, borax in water at 75°C. Filter if required.
3. Add aqueous phase to oily phase with continuous stirring.
4. Cool with stirring to room temperature.

5. Add perfume to the preparation at room temperature.
6. Transfer the cream to the container while hot.

Category: Cold cream.

Storage: Store in well-closed container.

8.0 Labeling of formulation:

(Make a label using computer software, and stick it in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Cold cream	Appearance Fragrance pH Consistency Washability	White Perfumed 5 – 8 Smooth Less than Vanishing Cream	

10.0 Result:

……gm of …….. preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Explain the importance of bees wax-borax system.
2. Give the precaution required to be taken during mixing of oily phase and aqueous phase.
3. Give the two advantages of liquid paraffin over vegetable oils.
4. Give two marketed preparations of cold creams.
5. State the meaning of preservatives.
6. Write two differences between cold cream and vanishing cream.
7. Write the storage conditions for creams.
8. Why we use word cold for this preparation?

(Space for answers)

(Space for answers)

Experiment No. 27

1.0 Title:

To prepare, evaluate and submit 15 grams of Buffered Cream B.P.

2.0 Prior Concepts:

Types of Creams, Pharmaceutical aids.

3.0 New Concepts:

Proposition 1: Buffers

Buffers are the substances, which maintains the pH between a specific pH range. The range of pH varies for every buffer substance.

Proposition 2: Importance of pH adjustment in topical formulations

For enhancement of stability of Active Pharmaceutical Ingredients (APIs).
To decrease skin irritation.
To enhance penetration of APIs.

4.0 Learning Objectives:

Intellectual Skills:

To understand the concept of buffering action.

Motor Skills:

Skill for preparation of ointment using fusion method,
Skill for mixing of hot liquids.

5.0 Apparatus:

Two Beakers (100 ml), Stopper bottle (50 ml), Measuring cylinder (50 ml), Spatula, Pipette (1 ml), Water bath.

6.0 Formulation Table:

For Buffered Cream

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Emulsifying Ointment	300.0g		
2. Disodium Hydrogen Phosphate Decahydrate	25.0g		
3. Citric Acid Monohydrate	5.0g		
4. Chlorocresol	1.0g		
5. Purified Water, q.s.	1000.0g		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

For Emulsifying Ointment

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Emulsifying Wax	300.0g		
2. White Soft Paraffin	500.0g		
3. Liquid Paraffin	200.0g		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Buffered cream is used as pharmaceutical aid. Simply suspending or dissolving the Active Pharmaceutical Ingredient in to this cream can prepare other medicated creams. Emulsifying ointment is used to form an O/W emulsion. Emulsifying wax is used during preparation of emulsifying ointment. Emulsifying wax is a mixture of cetostearyl alcohol, sodium lauryl sulphate and purified water.

For Preparation of Emulsifying Ointment

1. Melt emulsifying wax, white soft paraffin and liquid paraffin together and stir until cold. **For Preparation of Buffered Cream**
2. Melt the emulsifying ointment with the aid of gentle heat.
3. In a stopper bottle, heat about 650 g of purified water to about 60°C; add the chlorocresol and when it melts, vigorously shake the stopper bottle to effect dissolution.
4. Dissolve the Disodium Hydrogen Phosphate Decahydrate and the Citric Acid Monohydrate in the Chlorocresol solution.
5. Add the aqueous phase to the melted ointment when both are at about 600C.
6. Stir gently until cool, add sufficient Purified Water to produce 1000g and mix.

Category: Pharmaceutical aid.

Storage: Store in well-closed container.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Buffered Cream B.P.	Appearance pH Consistency	White 6-8 Smooth	

10.0 Result:

……gm of …….. preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. Q. ..…. (Question numbers to be allotted by the teacher.)

1. Define buffers.
2. Write any two official creams, which contains emulsifying ointment.
3. Write the full form of API.
4. Write the composition of emulsifying wax.
5. Name the surfactant used in Buffered Cream B.P.
6. How creams are different from ointments.
7. Define Pharmaceutical Aids, with two examples.
8. What are paraffins and name the preservative used in this preparation

(Space for answers)


INTRODUCTION TO COSMETICS


"Cosmetic means any article intended to be rubbed, poured, sprinkled, or sprayed on, or introduced in to, or otherwise applied to the human body, there of for cleaning, beautifying, promoting attractiveness, or altering the appearance and include any article intended for use as a component of cosmetic".

Classification on the basis of the part or organ of the body on which they are to be applied:

Parts or organs of the body	Examples
1. Skin	Creams, deodorants, Lotion, Powders.
2. Hair	Beard softeners, shampoos, and shaving preparations, hair colours, conditioners
3. Nails	Manicure preparations like nail polish and polish removers.
4. Teeth and mouth	Tooth powders, tooth pastes.
5. Miscellaneous	Eye preparations, insect repellants etc.

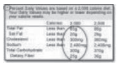
LOTIONS

Lotions are liquid or semi liquid preparations intended for application to the skin surface. Lotions can be suspensions, 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 acutely inflamed areas. The cooling effect may be enhanced by the inclusion of alcohol.

Even though lotions usually are applied without friction, the insoluble matter should be divided very finely. Variety of ingredients is added to the preparation to produce better dispersions or to improve its cooling, soothing, drying or protective properties.

Main ingredients: 

Anti microbial preservatives, stabilizers, thickening agents.

Labeling: 

1. The names and concentration of the active ingredients.
2. For cutaneous application that are intended to be applied to the unbroken skin without friction.
3. “FOR EXTERNAL USE ONLY”.
4. “SHAKE WELL BEFORE USE”.
5. Expiry date.
6. Storage conditions.

Containers: 

Wide mouth container, screw capped, fluted jar, coloured or colourless according to preparation.

Evaluation parameters:

Appearance, colour, homogeneity, odour, pH, resuspendibility, consistency, particle-size distribution.

Experiment No. 28

1.0 Title:

To prepare, evaluate and submit 25ml of Calamine Lotion I.P.

2.0 Prior Concepts:

Classification of topical agents.

3.0 New Concepts:

Proposition 1: Protectants / Protective agents:
These are the substances that prevents the UV- rays to reach the skin either by absorbing or by reflecting them.

4.0 Learning Objectives:

Intellectual Skills:

To understand the role of protective agents.

Motor Skills:
Skill for trituration.
Skill for transferring contents from mortar to container.

5.0 Apparatus:

Beaker (100 ml), Measuring cylinder (50 ml), Spatula, Pipette (1ml), Water bath, mortar and pastel.

6.0 Formulation Table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Calamine	150 g		
2. Zinc oxide	50 g		
3. Bentonite	30 g		
4. Sodium citrate	5 g		
5. Liquefied phenol	5 ml		
6. Glycerin	50 ml		
7. Purified water, freshly boiled and cooled sufficient to produce	1000 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Glycerin is added to promote adherence of the residual powder left after evaporation of vehicle on the skin surface. Suspending agents such as bentonite or sodium carboxy methyl cellulose (Na-CMC) is added to assist the dispersion of insoluble powders in the lotions. Calamine and zinc oxide are used as protectants. Liquid phenol is added as mild analgesic and soothing agent. Rose water is used as a suitable vehicle and perfume for lotions for treatment of an inflamed or sensitive area of skin.

1. Triturate the calamine, zinc oxide and bentonite with a solution of the sodium citrate in about 700 ml of purified water.
2. Add the liquefied phenol, glycerin and sufficient water to produce 1000 ml.

Category: Protective agent.
Storage: Store in well-closed containers in a cool place. Do not freeze.

8.0 Labeling of formulation:

(Make a label using computer software, and stick it in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Calamine zinc oxide lotion	Appearance	Pink coloured, free from grittiness	
	Fragrance	Perfumed	
	pH	5-8	
	Consistency	Semi liquid	
	Rate of Sedimentation	Low	

10.0 Result:

……ml of ……. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Write the ideal qualities of Lotions.
2. Give classification of liquid dosage forms.
3. Define protective agents, in which parts of world they are generally used.
4. Define sedimentation ratio.
5. Write the procedure for finding rate of sedimentation.
6. Write two brand names of the marketed preparations.
7. What will happen if lotions are stored at temperatures between 20C and 80 C?
8. Define shelf life; what is generally the shelf life of lotions.

(Space for answers)

(Space for answers)

SHAMPOOS

A shampoo is a cosmetic preparation useful for cleaning the hair and scalp. In addition to cleansing, the shampoo performs various functions like making the hair more glossy and preventing excessive drying of hair.

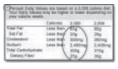
Qualities of an ideal shampoo:

- Capable of removing grease, dirt and skin debris from the hair and scalp.
- Non- toxic.
- Non- irritant.
- Effective in small amounts.
- Produce sufficient foam both in hard water and soft water.
- Should not make the hand rough and chapped.
- Should be easily removed by rinsing with water.

Formulation Ingredients:

Surfactants, Conditioning agents, thickening agents, solubilizing agents, opacifying agents, preservatives, Active pharmaceutical ingredients (optional).

Labeling:



"FOR EXTERNAL USE ONLY".

Keep away from the reach of children.

Medicated or non- medicated.

Directions for use: Wet hair with water; massage shampoo gently on hair and scalp. Rinse and repeat if required.

Storage: Store in cool place. Replace cap tightly after use.

Containers:

Narrow mouth bottle, wide mouth bottle, pouch, and plastic collapsible tubes.

Experiment No. 29

1.0 Title:

To prepare, evaluate and submit 20ml of Clear Shampoo.

2.0 Prior Concepts:

Types of Shampoo, Humectants, Thickening agents.

3.0 New Concepts:

Proposition 1: Conditioning Agents

Used in lubricating the hair and improves the texture of the hair.

Proposition 2: Surface Active Agents

Substances, which decrease the interfacial tension between two immiscible substances and enhance their miscibility.

4.0 Learning Objectives:

Intellectual Skills:

To understand the requirements for formulation of shampoo.

Motor Skills:

Skill for weighing.
Skill for dispersing polymer.
Skill to make up the volume.

5.0 Apparatus:

Beaker (100 ml), Measuring cylinder (100 ml), Spatula, Pipette (1ml), Water bath, Glass rod.

6.0 Formulation Table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Sodium Lauryl Sulphate (SLS)	10.0%		
2. Sodium citrate	1.0%		
3. Hydroxy Propyl Methyl cellulose (HPMC K 100)	3 .0%		
4. Glycerin	5.0%		
6. Methyl Paraben	0.18%		
7. Propyl Paraben	0.02%		
8. Perfume	q.s.		
9. Colour	q.s.		
10. Purified Water	100.0%		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \text{...}$$

7.0 Stepwise procedure

Sodium Lauryl sulphate is a surface-active agent used as a cleansing and foaming agent. Sodium citrate is added as viscosity modifier. Glycerin is added to prevent the dryness of formulation and a conditioning agent. HPMC- K100 is added as a thickening agent.

1. Weigh all the solid ingredients.
2. Dissolve SLS in 75% of purified water.
3. Add Methyl Paraben, Propyl Paraben and glycerin to the above-prepared solution.
4. Add colour and perfume to the preparation.
5. Disperse HPMC in the above solution with continuous stirring for 20 minutes at 60°C.
6. Cool the preparation.
7. Add the water up to required volume.

Category: Hair Cleansing agent.

Storage: Replace cap tightly after use.

8.0 Labeling of formulation:

(Make a label using computer software, and stick it in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Clear Shampoo	Appearance Fragrance pH Consistency	Free from grittiness Perfumed 5-8 Semi liquid	

10.0 Result:

……ml of ……. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... (Question numbers to be allotted by the teacher.)

1. State four ideal properties of Shampoo.
2. Name the ingredient in the above preparation used for cleansing action.
3. What advantage does shampoo have over ordinary soap, used for hair washing.
4. Give three marketed anti-dandruff shampoo.
5. Write the role with mechanism of Hydroxy Propyl Methyl cellulose.
6. Write the classification of Shampoos.
7. What effect can be seen if glycerin is not added in to this preparation?

(Space for answers)

TOOTH PASTE

Paste

Pastes are semi-solid preparations intended for external application to the skin. The pastes are generally very thick and stiff due to high solid content. They do not melt at ordinary temperature and thus form a protective coating over the area where they are applied.

Toothpaste is a dentifrice used in 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.

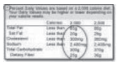
Qualities of Good Dentifrice

- Economical
- Non-Toxic
- Sweetened and Flavored
- Give fresh and clean sensation.
- Efficient in removing food substances, plaque and other foreign particles.

Formulation Excipients

Abrasives, Binders, Detergents, Flavoring agents, Humectants, Preservatives, Sweetning agents.

Labeling:



" FOR EXTERNAL USE ONLY"

Replace the cap after use.

Experiment No. 30

1.0 Title:

To prepare, evaluate and submit 20 grams of Toothpaste.

2.0 Prior Concepts:

Classification of dosage forms, detergents.

3.0 New Concepts:

Proposition 1: Abrasives

Abrasives are used to remove debris and residual stains from the teeth surface without damaging them. The cleansing power of an abrasive depends on the size, shape, hardness and brittleness.

Proposition 2: Humectants.

Humectants are the substances used to retain water in to the preparations and prevent them from dryness.

4.0 Learning Objectives:

Intellectual Skills:

To understand the requirements for formulation of Tooth Paste.

Motor Skills:

Skill for Weighing.
Skill for mixing.
Skill for filling preparation in to collapsible tubes.

5.0 Apparatus:

Measuring cylinder (50 ml), Spatula, Pipette (1ml), Mortar and Pastel.

6.0 Formulation Table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Dicalcium phosphate	35.0%		
2. Calcium Carbonate	14.0%		
3. Glycerin	20.0%		
4. Gum tragacanth	1.2%		
6. Saccharin	0.05%		
7. Sodium lauryl sulphate	10.0%		
8. Purified Water	19.75%		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

1. Weigh all the powdered ingredients.
2. Triturate all the powdered ingredients in to mortar, for size reduction and uniform mixing.
3. Add mixture of glycerin and water with continuous trituration until a smooth paste is formed.

Category: Tooth Paste.

Storage: Replace cap tightly after use.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Tooth Paste	Appearance	Semi-solid free from grittiness	
	Fragrance	Perfumed	

10.0 Result:

……gm of …… preparation is submitted in …… container with neat label.

11.0 Questions :

Answer Q 1 (Compulsory) Q. …..... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. How pastes are differing from creams and ointments
2. Write two brand names of medicated toothpaste and with name of their Active Pharmaceutical Ingredient (API).
3. Write four factors, which define the abrasive nature of substances.
4. What type of detergents are used in toothpaste?
5. Which is better for cleaning teeth: Paste or Gel, Give reasons?
6. Which preparation require more preservative: Lotion or Paste, Give reasons?

(Space for answers)

(Space for answers)

HAIR GROOMING GEL

Hair is an important component of overall appearance of a person whether a man or woman. However clean or well dressed the person may be, untidy hair will give a messy overall impression. So, hair grooming aids are important group of cosmetics and are used by both men and women to keep the hair in order for good looking and also to enhance overall appearance.

Various hair-grooming aids used are:

1. Brilliantine's and hair oil – These preparations completely adhere to the hair surface and hold the hair in position and make them lustrous.
2. Hair Setting lotion/ gel- These products, after application, dry to form invisible continuous elastic film that keeps the hair firmly positioned.
3. Hair creams – It can be either water- in- oil or oil- in -water.
4. Hair sprays – dispensed in aerosol containers.

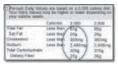
Ideal Properties of Hair Grooming Agents

1. Non- sticky
2. Non-irritant.
3. Economical
4. Easily removed on washing.
5. Give the desired effect for prolong period of time.
6. Give nourishment to the hair.
7. Does not dry quickly on exposure to environment.

Main ingredients:

Therapeutic agents, Thickening agents, Humectants, Alcohol, Anti microbial preservatives, Stabilizers.

Labeling:



" FOR EXTERNAL USE ONLY"
Replace the cap after use.

Experiment No. 31

1.0 Title:

To prepare, evaluate and submit 25gms of Hair Grooming Gel.

2.0 Prior Concepts:

Humectants, pH measurement using pH indicator paper.

3.0 New Concepts:

Proposition 1: Gels

Gels are semisolid preparations made using substances (called gelling agents) that undergo a high degree of cross-linking on association with dispersing medium. The cross linking of the dispersed phase will alter the viscosity of the dispersing phase by restricting the movement of the dispersing medium.

Gels contain high proportion of water (70-99%); therefore they are easily applied and washed away from the skin surface. Gels are generally transparent, which imparts elegance to preparations.

4.0 Learning Objectives:

Intellectual Skills:

To understand the requirements for formulation of gels.

Motor Skills:

Skill for neutralization, pH measurement, stirring.

5.0 Apparatus:

Beaker (100 ml), Measuring cylinder (100 ml), Spatula, Pipette (1ml), Electronic-weighing balance.

6.0 Formulation Table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Glycerin	5.0%		
2. Isopropyl Alcohol (IPA)	10.0%		
3. Carbomer (Carbopol 980 NF)	1.2%		
4. Citric acid	1.0%		
5. Disodium EDTA	0.1%		
6. Methyl Paraben	0.18%		
7. Propyl Paraben	0.02%		
8. Colour (Water soluble)	q.s.		
9. Purified Water	100.0%		
10. Sodium Hydroxide (10%)	q.s.		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Carbomer is a generic name for a family of polymers known as Carbopol. Carbomers require a “neutralizer” or a pH-adjusting chemical to create the gel after the gelling agent has been wetted in the dispersing medium. Carbopol form acidic aqueous solutions at pH around 3.0. They thicken at higher pH around 5 or 6. Carbopol is very hygroscopic (quickly absorbs moisture from atmosphere), therefore proper handling is required.

Citric acid is added to maintain pH around 3 for better dispersion of polymer (Carbopol) and Disodium EDTA is added to sequester metal ions present in water, which otherwise interfere in swelling of Carbopol.

1. Weigh Carbopol in absolutely dry conditions.
2. In 50% of the water, dissolve citric acid and Disodium EDTA.
3. Disperse Carbopol 980 NF vigorously in above aqueous solution using spatula or overhead stirrer for around 30 minutes.
4. Keep aside the dispersed polymer solution for 30 minutes.
5. Add mixture of glycerin, Isopropyl alcohol, methyl paraben, propyl paraben, and remaining water in to the polymer mixture and mix it homogenously.
6. Neutralize the above mixture using 10% NaOH, up to pH 7.
7. Check the pH after each addition of NaOH using pH paper.

Category: Hair Cleansing agent.

Storage: Replace cap tightly after use.

8.0 Labeling of formulation:

(Make a label using computer software, and stick it in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Hair grooming Gel	Apperance pH Spreadibility Washability	Transparent 6-7 Uniform Easily washed	

10.0 Result:

……gm of ……. preparation is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Define gels.
2. Write the mechanism of increase in viscosity using gelling agents.
3. Which formulation requires more preservative gels or creams?
4. Write any two gelling agents.
5. In industries, for formulation of topical preparations mainly Isopropyl alcohol is used with very limited use of ethanol, write reasons?
6. Write four uses of glycerin in pharmaceutical preparations?
7. Write the use of citric acid.
8. Write two brand names of hair gels?

(Space for answers)

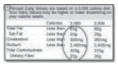
LIPSTICKS

Lipsticks are dispersions of colouring matter in a base consisting of a suitable blend of oils, fats and waxes suitably perfumed and flavoured, moulded in the form of a stick and enclosed in a case.

Good Lipsticks

- Cover the lips adequately with some gloss.
- Last for long time.
- Makes the lips soft.
- Free from grittiness.
- Non-drying.
- Non-irritating.
- High retention of colour intensity.
- Desirable degree of plasticity.
- Pleasant odour and flavour.

Labeling:



"FOR EXTERNAL USE ONLY" or "NOT FOR INGESTION"
Therapeutic use, if any
Storage conditions
Application

Storage

Keep Away From Heat And Flame, store in cool temperature.

Experiment No. 32

1.0 Title:

To prepare, evaluate and submit four lipsticks.

2.0 Prior Concepts:

Moulding, Weighing, uniformity of colour distribution

3.0 New Concepts:

Proposition 1: Evaluation of lipsticks

1. **Pin Holes-** Ideal lipsticks are devoid of Pin Holes on the exposed surface. Presence of pinholes decreases the elegance of lipsticks extremely.
2. **Color Uniformity**
3. **Softening temperature-** It is the temperature at which the lipstick starts melting or becomes soften.

Procedure- Place 2 cm long piece of lipstick in a test tube, stand a thermometer above the surface of the lipstick, heat the test tube in water bath and record the temperature at which the thermometer pierce into the piece of lipstick.

4.0 Learning Objectives:

Intellectual Skills:

To understand the evaluation parameters of lipsticks.

Motor Skills:

Skill for formation of moulding and flaming.

5.0 Apparatus:

Beaker (250 ml), Measuring cylinder (50 ml), Pipette (1ml), Water bath, thermometer, test tube.

6.0 Formulation Table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Carnauba Wax	10.0 g		
2. White Bees wax	10.0 g		
3. Cocoa Butter	10.0 g		
4. Lanolin	5.0 g		
5. Castor Oil	50.0 g		
6. Isopropyl myristate	5.0 g		
7. Cetyl alcohol	5.0 g		
8. Liquid Paraffin	2.0 g		
9. Titanium Dioxide	3.0 g		
10. Colours	q.s.		
11. Perfumes	q.s.		
12. Butyl Hydroxy toluene (BHT)/ Butyl hydroxy aniline (BHA)	0.05%		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Gloss and hardness of lipsticks are largely dependent on the characteristics and quantity of the waxes used. Mixtures of waxes are incorporated to prepare lipsticks of optimum softening

temperature. Castor oil is used as a plasitizer. Castor oil is preferred over other vegetable oils because of its good qualities. A refined grade castor oil is odourless, tasteless and less prone to oxidation. Isopropyl myristate is used as wetting agent to facilitate smooth application. Cetyl alcohol is used as emollient. Liquid paraffin is used as lubricant to facilitate removal of sticks from the moulds after pouring. Titanium dioxide is used as pigment to intensify the colour.

1. Weigh the required quantities of all the ingredients (except colours) and mix in geometric proportion in a porcelain dish or beaker.
2. Place the porcelain dish in a water bath till all the ingredients melt.
3. Disperse the colours homogenously in to the melted mass.
4. Lubricate the mould with paraffin oil.
5. Pour the molten mass in to individual mould, fill it up to top and allow some mixture to overflow. It prevents formation of pinholes during freezing.
6. Place the filled moulds in ice bath or freezer.
7. Scrap the top layer with help of sharp knife, and remove the lipstick from the mould.
8. Pass the lipstick through the flame in quick fashion; it gives gloss to the surface layer of the lipstick.
9. Perform the softening temperature test.
10. Place the lipsticks in to lipstick containers.

Category: Skin Colorant.

Storage: Keep away from heat and flame.

8.0 Labeling of formulation:

(Make a label using computer software, and stick it in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Lipstick	Appearance Fragrance Softening Temperature Colour Uniformity	Free from Pinholes Perfumed Not less than 55^0C Uniform	

10.0 Result:

……no. of ……preparation is submitted in……. container with neat label.

11.0 Questions :

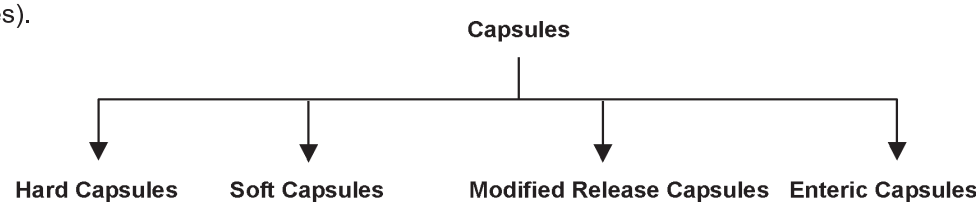
Answer Q. ..…. Q. …..... Q. ..….. (Question numbers to be allotted by the teacher.)

1. Write the evaluation test for lipsticks.
2. Write the reason for slight overflow of mixture during filling in to mould.
3. Define flaming, and why it is performed.
4. Write the precautions need to be taken while performing experiment.
5. Write the role of liquid paraffin.
6. Why mixture of waxes used in formulation of lipsticks?

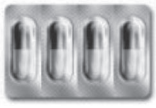
(Space for answers)

INTRODUCTION TO CAPSULES

Capsule is solid unit dosage form in which drug or drugs with or without excipients are enclosed in a hard or soft water soluble shell or a container of gelatin or of any other suitable substance (example: cellulose derivatives).



Hard Gelatin Capsule:



Hard gelatin capsule shells are used in most commercial medicated capsules. The empty capsules shells are made of gelatin blends, plasticizers, preservatives etc. They can be clear, colourless and essentially tasteless or they may be coloured with various approved dyes and made opaque by adding agents such as titanium dioxide. Hard gelatin capsule shells are made up of sections, the body and the cap.

Capsule size:

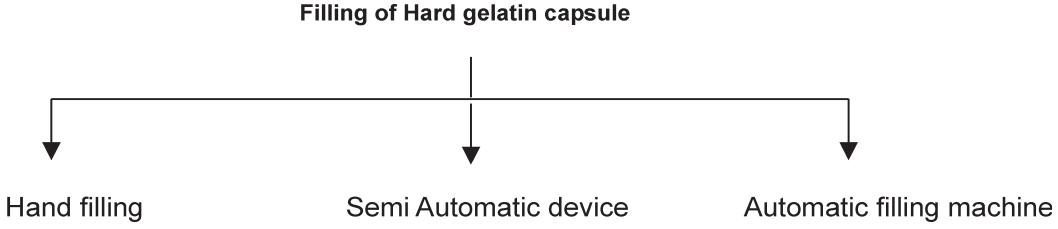
Empty gelatin capsules are manufactured in various lengths, diameter and capacities. The size selected for use is determined by the amount of fill material to be encapsulated. The bulk density and compressibility of the fill will largely determine to what extent it may be packed into a capsule shell.

For human use empty capsules ranging in size from 000 (the largest) to 5 (the smallest) are commercially available. Larger capsules are available for veterinary use.

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

Development the formulation and Selection of capsule size:

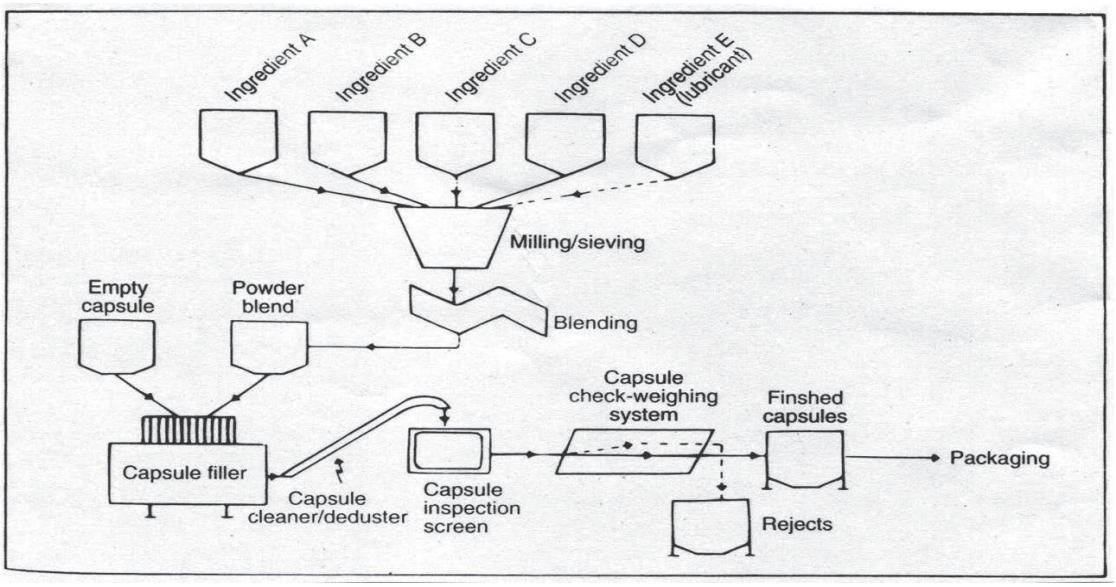
1. The goal is to prepare a capsule with accurate dosage, good bioavailability, easy to fill and production, stability and elegance.
2. In dry formulation the active and inactive components must be blended thoroughly to ensure an uniform powder. This can be achieved by size reduction, and effective blending.
3. A diluent as filler may be added to the formulation to produce the proper capsule fill volume. Lactose, microcrystalline cellulose and starch are commonly used diluents . Apart from providing bulk these materials provide cohesion to the powders.
4. Disintegrating agents are also added in the formulation to facilitate the breakup and distribution of the capsule content.



Cleaning and Polishing of capsules:

Small amount of powder may adhere to the outside of capsule after filling. These should be removed by rubbing them with a clean gauze or cloth. On a large-scale capsule-filling machine are affixed with a vacuum cleaning arrangement that removes extraneous material (dusting).

Diagram:



Soft Gelatin Capsule:

Soft gelatin capsules may be oblong, oval or round. They may be single coloured and may be imprinted with identifying markings (marketed preparation: Seven seas, Pudin Hara).

Soft gelatin capsules are used to encapsulate liquids, suspensions, pasty materials, dry powders and preformed tablets. Soft gelatin capsules are pharmaceutically elegant and are easily swallowed.

Experiment No. 33

1.0 Title:

To prepare, evaluate and submit 5 Chloramphenicol Capsule I.P.

2.0 Prior Concepts:

Types of dosage forms, advantages of capsules.

3.0 New Concepts:

Enteric coated capsule, Sustained release capsules, Rectal capsule, Capsule containing Ophthalmic ointment, Encapsulation Bio-availability cohesion.

Proposition 1: Chloramphenicol capsules are hard gelatin capsules.

Proposition 2:

Types of Gelatin Capsule: — Hard Gelatin Capsule; Soft Gelatin Capsule

Proposition 3: Storage

Capsules are normally strip or blister packed. But in laboratory, they can be packed in wide mouth bottle with dehumidifying agent.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of solid dosage form.
2. To understand the concept of unit dosage form.
3. To understand the advantages of capsules.
4. To understand the different techniques involve in filling of capsule.

Motor Skills:

1. Skill for calculating and weighing the diluents required for filling capsules.
2. Skill for Sealing of capsules.
3. Skill for Cleaning and Polishing of capsules.

5.0 Apparatus:

Electronic balance, Mortar and Pestle, Thick cloth, Spatula, White tile.

6.0 Formulation Table:

Sr. No.	Ingredients	Quantity given/ capsule	Quantity taken (No. of capsules x Quantity given)	Use of ingredients
1.	Chloramphenicol I.P.	250 mg		
2.	Starch	5.0 mg		
3.	Magnesium Stearate	2.5 mg		
4.	Talc	2.5 mg		
5.	Lactose	40 mg		

7.0 Stepwise procedure

1. Calculate the weight for one extra capsule i.e. for 6 capsules.
2. Weigh required quantity of all the ingredients and uniformly mix in mortar pestle.
3. Sieve all the ingredients by passing through 20 # sieve.
4. Divide the powders in six equal portions.
5. Fill the powders in each capsule.
6. Seal the capsule clean it and polish it.

7. Perform uniformity of weight test on all 5 capsules (for experimental purpose).
8. Perform disintegration test on 2 capsules (for experimental purpose).
9. Submit the remaining capsules in suitable container with neat label.

Category: Antibacterial.

Dose: One or two capsules a day.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Chlorophenicol capsule I.P.	Description	Polished without brittle appearance	
	Weight variation	As per I.P.	
	Disintegration time	Max. 15 minutes.	

10.0 Result:

……numbers of capsules…….. is submitted in …….. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. State the category of Chloramphenicol capsule.
2. If 250 mg of Chloramphenicol along with 200 mg of diluent has to be filled in capsule which capsule size you will use.
3. Draw the well-labeled diagram of hand filling capsule machine.
4. State the evaluation test required for capsules.
5. State the limit of disintegration time for hard gelatin capsule?
6. If the active ingredient is 10 mg then which additional evaluation test you will perform?
7. Name the marketed preparation of Chloramphenicol capsule.

(Space for answers)

(Space for answers)

MICROENCAPSULATION

Microencapsulation is a rapidly expanding technology. It is a means of applying relatively thin coatings to small particles of solids or droplets of liquids and dispersions.

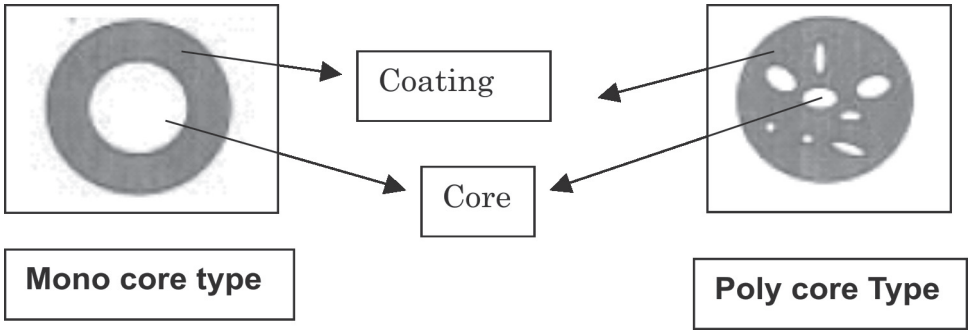
Microencapsulation 

Particle size range of Coated particles is from several tenths of a micron to 5000 micron in size.

Applications 

1. Converting Liquids to solids
2. Altering Colloidal and surface characteristics.
3. Providing environmental protection.
4. Controlling the release.
5. For taste masking
6. To decrease the incompatibility.

Diagrammatic view of Microencapsules 



Core Materials

The core material defined as the specific material to be coated, it can be liquid or solid in nature. It can include single ingredient or mixture of API and excipients.

Coating Materials

The coating materials should be capable of forming a film that is cohesive with the core materials, be chemically compatible with core material. It provides the desired coating properties such as strength, flexibility, impermeability, optical properties and stability.

Experiment No. 34

1.0 Title:

To prepare Liquid Paraffin Microencapsules by coacervation phase separation method.

2.0 Prior Concepts:

Microscopy.

3.0 New Concepts:

Proposition 1: Encapsulation

Means of applying thin coatings to particles.

Proposition 2: Coacervation Phase Separation method.

It consists of three steps carried out under continuous agitation.

1. Formation of three immiscible chemical phases.
2. Deposition of Coating Material on core material.
3. Rigidisation of coating.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand concept of encapsulation.
2. To understand the concept of precipitation.

Motor Skills:

1. Skill for handling mechanical stirrer.
2. Skill for online process control and evaluation.

5.0 Apparatus:

Glass beaker (250 ml), Volumetric cylinder (100 ml), Volumetric pipette (1ml), Compound Microscope, Glass slide, mechanical stirrer, Glass rod, Funnel, Dispensing balance.

6.0 Formulation Table:

Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. Liquid Paraffin	10 ml		
2. Polyvinyl Alcohol (PVA)	400 mg		
3. Sodium Sulphate solution (20% w/v)	q.s.		
4. Sudan Red II Dye	q.s.		

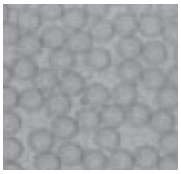
$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

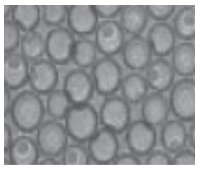
Liquid Paraffin is used orally for laxative action but it has unpalatable taste. To mask bitter taste of oil, it can be microencapsulated and dispensed as solid dosage form.

1. Dissolve PVA in 100 ml of distill water using heat with continuous stirring. Filter if necessary.
2. Cool the above solution to room temperature. Stir the PVA solution continuously by mechanical stirrer.
3. To liquid paraffin mix Sudan red II dye. Excess amount of dye should be avoided.
4. Add the coloured liquid paraffin in to PVA solution dropwise with continuous stirring.
5. Observe the liquid paraffin droplets under microscope at 10X.

6. Add 20% sodium sulphate solution, 2 ml at a time, until black layer of PVA encapsulates liquid paraffin droplets. Stir the mixture continuously using mechanical stirrer at 1000 rpm.
7. Observe the different stages of Microencapsulation under 10X.



Before Encapsulation



After Encapsulation

Category: Laxative
Storage: Store in tightly closed wide mouth bottle.

8.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Liquid paraffin Microcapsules	Description	Liquid paraffin globules surrounded by PVA layer	

9.0 Result:

…….. is formed, confirmed by microscopy evaluation.

10.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. (Question numbers to be allotted by the teacher.)

1. State the meaning of microencapsulation.
2. Write the role of Sodium sulphate.
3. State the advantages of microencapsulation.
4. Write the different techniques used for microencapsulation.
5. Write the steps involved in Coacervation Phase Separation method.
6. Write the rationale of microencapsulating liquid paraffin.

(Space for answers)

Experiment No. 35

1.0 Title:

To prepare and submit 5 Magnesium Oxide Capsules U.S.P.

2.0 Prior Concepts:

Types of dosage forms, advantages of capsules.

3.0 New Concepts:

Enteric coated capsule, Sustained release capsules, Rectal capsule, Capsule containing Ophthalmic ointment, Microencapsulation, Bioavailability.

Proposition 1:

Magnesium oxide capsules are hard gelatin capsules.

Proposition 2:

Types of Gelatin Capsule: — Hard Gelatin Capsule; Soft Gelatin Capsule

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of solid unit dosage form.
2. To understand the advantages of capsules.
3. To understand the different techniques involve in filling of capsule.

Motor Skills:

1. Skill for calculating and weighing the diluents required for filling capsules.
2. Skill for Sealing of capsules.
3. Skill for Cleaning and Polishing of capsules.

5.0 Apparatus:

Dispensing balance, Mortar and Pestle, Thick cloth, Spatula, White tile.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (No. of capsules x Quantity given)	Use of ingredients
1.	Magnesium oxide	250 mg		
2.	Lactose q.s.	(z – y) mg		

7.0 Stepwise procedure

Light magnesium oxide is bulky. On exposure to air, it rapidly absorbs moisture and carbon dioxide.

1. Weigh the required quantity of all the ingredients.
2. Mix them thoroughly in mortar and pass through 20 # sieve.
3. Make a rectangular block of the powder on a butter paper.
4. Divide the powder in 5 equal portions.
5. Fill each portion in a capsule.
6. Seal the capsule, clean and polish the capsule.
7. Perform uniformity of weight test on all 5 capsules (for experimental purpose).
8. Perform disintegration test on 2 tablets (for experimental purpose).
9. Submit the remaining capsules in suitable container with neat label.

Calculations:

Lactose per capsule.

1. Weigh the empty capsule = x mg.
2. Fill 250mg of Magnesium oxide in capsule, weigh = y mg = (x + 250 mg)
3. Fill the empty space left after filling Magnesium oxide with lactose so that the powder is tightly filled, weigh. = z mg
4. Lactose required per capsule = (z – y) mg.

Category: Antacid and Osmotic Laxative.

Dose: As antacid, 300 to 600 mg; as laxative, 2 to 4 g.

Storage: Stored in tightly closed container.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Magnesium oxide capsule U.S.P.	Description	Polished without brittle appearance	
	Weight variation	As per USP	
	Disintegration time	15 minutes	

10.0 Result:

……numbers of capsules…….. is submitted in ……. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. ….... Q. ..…... Q. ..…... (Question numbers to be allotted by the teacher.)

1. If the average net contents the capsule is 425 mg. What deviation in terms of mg will be allowed so that it passes the uniformity of weight as per I.P.?
2. State the limit of disintegration time of magnesium oxide capsule
3. Name the diluent used in preparation of magnesium oxide capsule.
4. Which capsule size is recommended, If the average net content of the drug along with the excipients is 650 mg.
5. Write the disintegration test for enteric-coated capsules.
6. State the category of magnesium oxide capsule.
7. Enumerate the general evaluation test required for capsules.

(Space for answers)

(Space for answers)

INTRODUCTION TO TABLETS

Compressed tablets are defined as solid unit dosage form made by compaction of a formulation containing the drug and certain fillers or excipients.

There are various types of tablets designed for specific uses or function.

1. Tablets to be swallowed.
2. Chewable tablets formulated to be chewed rather than swallowed eg. Antacid and vitamin.
3. Buccal tablets designed to dissolve in a buccal pouch.
4. Sublingual tablets for rapid dissolution under the tongue.
5. Effervescent tablets are formulated to dissolve in water with effervescence.

Properties of Tablets:

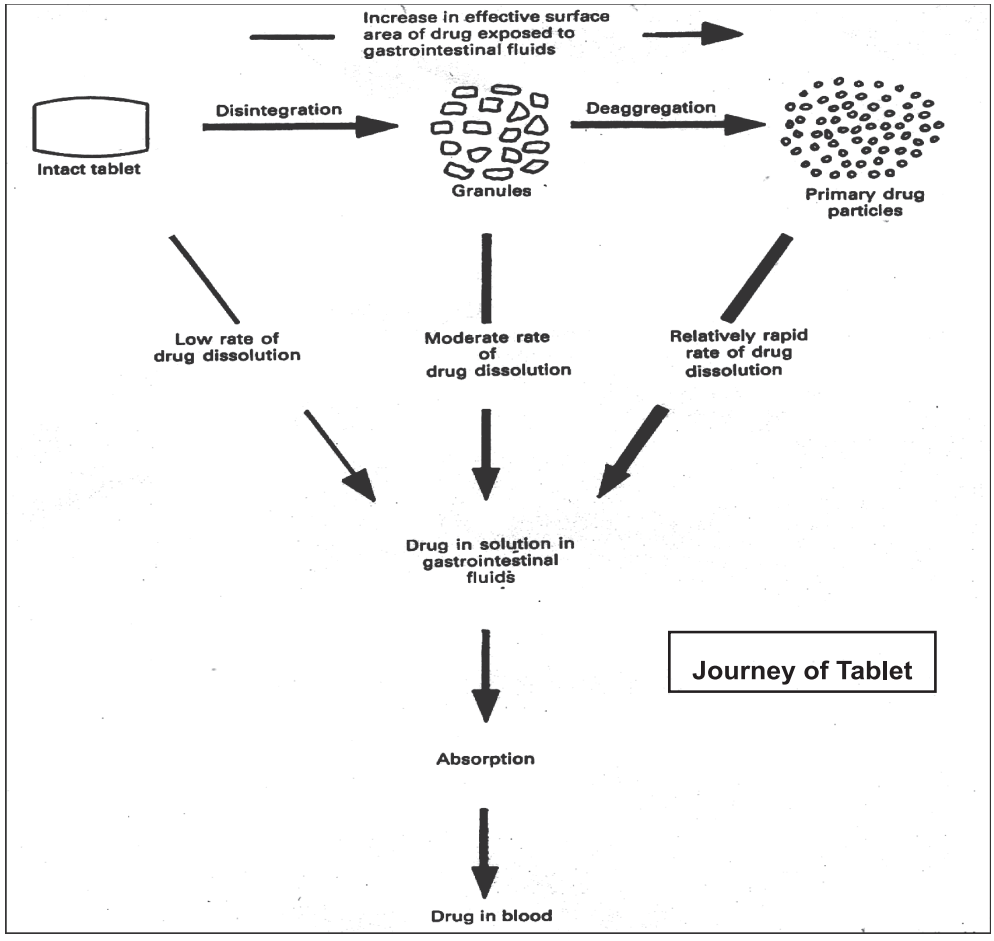
Whatever be the method of manufacturing the resulting tablet must meet number of physical and biological standards.

1. The tablets must be sufficiently strong and resistant to shock and abrasion to withstand handling during manufacturing, packaging, shipping and use. This property is measured by hardness and friability test.
2. Tablets must comply with test for uniformity of weight and uniformity of content.
3. The drug content of the tablet must be bioavailable. This is measured by disintegration test and dissolution test.
4. The tablet must be elegant in appearance and must have the characteristic shapes, colour and other marking necessary to identify the product.
5. Tablets must retain all of their functional attributes that include drug stability and efficacy.

Formulation of tablets:

The size and to some extent, the shape of the tablet are determined by the active ingredients, Drug having very small dosage in terms of microgram eg. folic acid, digitoxin required the addition of fillers called excipients. Excipients are specified according to be function they perform in tablet. They are classified as:

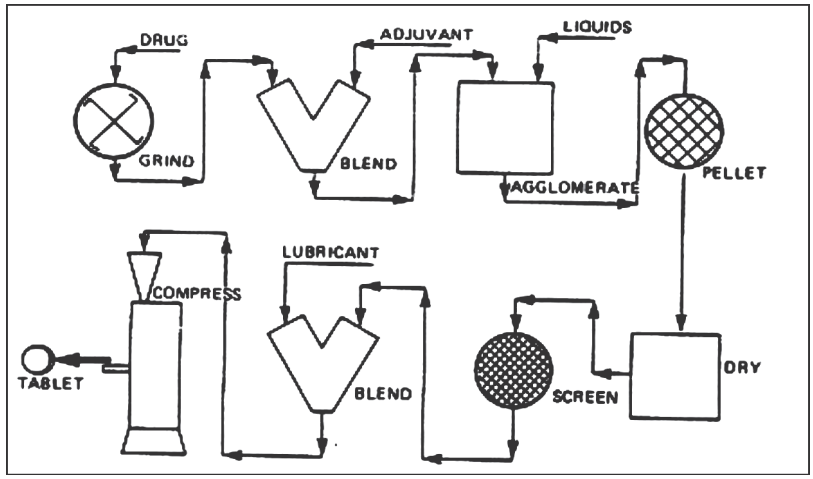
1. Diluents:
   - Soluble eg. Lactose, Sucrose.
   - Insoluble eg. Calcium phosphates, calcium carbonate
2. Binders: eg. Gelatin 10%, Starch paste 10 %.
3. Disintegrants: Starch, Guar gum.
4. Lubricant: Magnesium Stearate.
5. Glidant: Talc, Magnesium carbonate.
6. Antiadherent: Magnesium Stearate.



Tablets are prepared by three methods

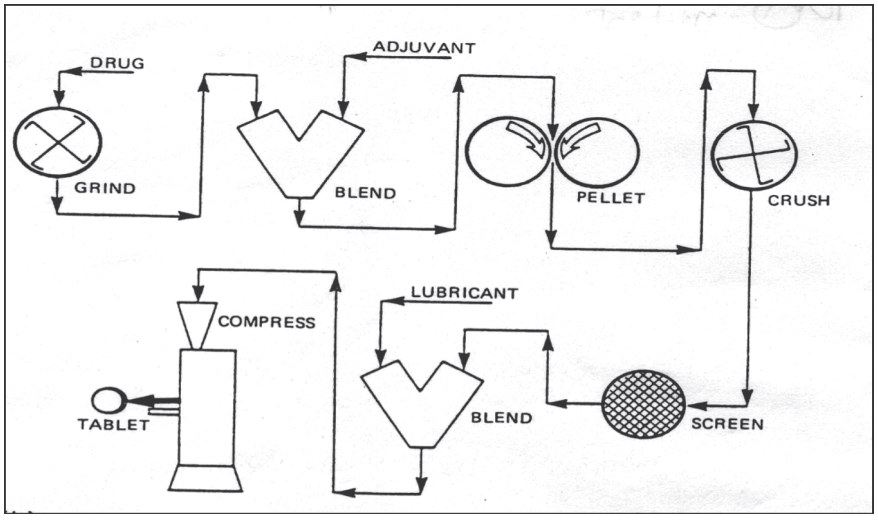
- Wet Granulation
- Dry Granulation
- Direct Compression

1. Wet Granulation:



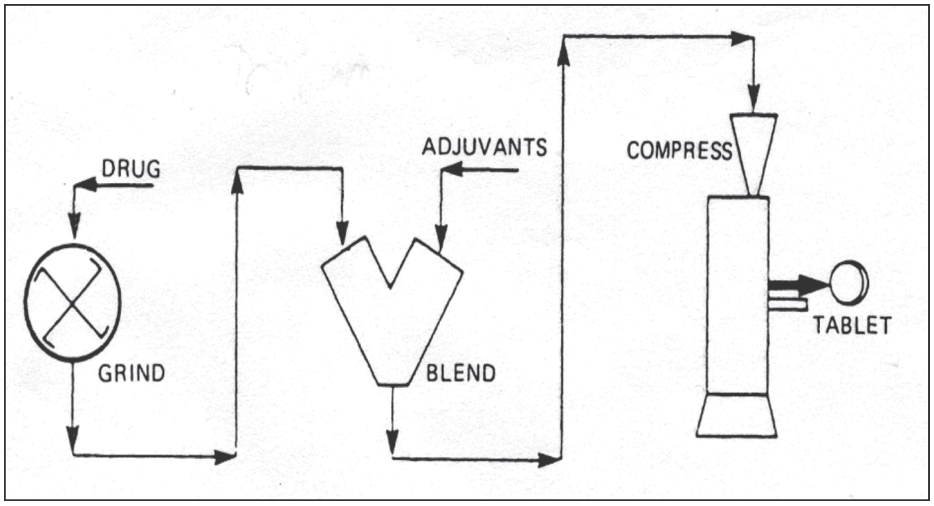
Unit operation for Wet Granulation

2. Dry Granulation:



Unit operation for Dry Granulation

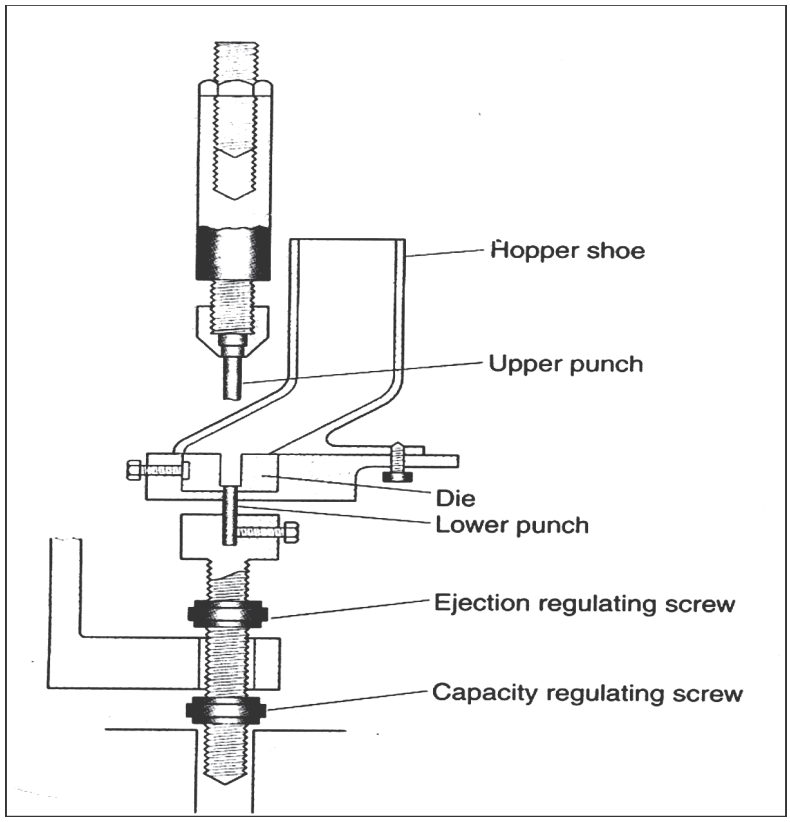
3. Direct compression:



Unit operation for Direct Compression

While manufacturing of tablets various defects arises such as:

1. Binding.
2. Sticking.
3. Capping and lamination.
4. Chipping and cracking.
5. Mottling.
6. Weight variation.
7. Hardness variation.
8. Double impression.
9. Tablet expansion.



SINGLE PUNCH COMPRESSION MACHINE

Experiment No. 36

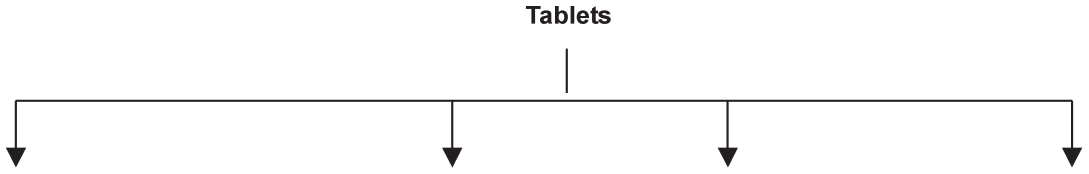
1.0 Title:

To prepare, evaluate and submit granules ready for compression of 10 Compound Sodium Bicarbonate Tablets I.P.

2.0 Prior Concepts:

Moulded tablets and compressed tablets

3.0 New Concepts:



Tablets ingested orally	Tablet for oral cavity	Tablets used to prepare solution	Tablets administrated by other routes
1. Compressed tablet	1. Buccal tablet	1. Effervescent tablet	1. Implantation tablet
2. Multiple compressed tablet	2. Sublingual tablet	2. Dispensing tablet	2. Vaginal tablet
3. Sustained action tablet	3. Lozenges	3. Hypodermic tablet	
4. Enteric coated tablet	4. Dental cones	4. Tablet titurates	
5. Sugar coated tablet			
6. Film coated tablet			
7. Chewable tablet			

Proposition 1:

Sodium bicarbonate tablets are chewable antacid tablets.

Proportion 2: Storage

Sodium bicarbonate tablets are normally strip or blister packed. But for laboratory purpose the granules can be submitted in a wide mouth bottle.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the different types of tablets.
2. To understand the concept of chewable antacid tablets.
3. To understand the use of additives in tablet formulation.
4. To understand the different granulation processes eg. wet granulation, dry granulation, and direct compression.

Motor Skills:

1. Skill for weighing the ingredients.
2. Skill for uniformly mixing the ingredients and forming a coherent mass.
3. Skill for sieving.
4. Skill for calculating the lubricant and Anti adherent
5. Skill for compressing the granules into the tablets.

5.0 Apparatus:

Dispensing balance, Mortar and Pestle, Sieves 60 #, 10 #, 22 #, 44 #, Oven.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given/ tablet	Quantity taken (No. of tablets x Quantity given)	Use of ingredients
1. 2. 3.	Sodium bicarbonate Mentha oil Starch paste (10%)	0.320 g 0.004 ml q.s.		

7.0 Stepwise procedure

Compound sodium bicarbonate tablet contains 0.32 g of sodium bicarbonate and mentha oil. The dose of drug is sufficient for granulation therefore diluent is not required. It is prepared in form of lozenges to be sucked in the mouth so no disintegrating agent is necessary. Since the material itself does not have coherent properties, a granulating agent i.e. 10% starch is used. It is prepared by moist granulation method.

1. Weigh required quantity of sodium bicarbonate powder and pass through 60 # sieve.
2. Add starch paste little by little with constant mixing so that a coherent mass is formed, which crumples on application of slight pressure.
3. Pass the wet mass through 10 # sieve and dry the granules at 60°C for 1 hour.
4. Pass all the dried granules through 22 # sieve, below which 44 # sieve is kept.
5. The granules retained over 44 # sieve are collected and the powder which passes through 44 # sieve are fines.
6. Weigh the granules.
7. Add 10 % fines, 1 % talc and 1 % magnesium stereate and spray the mentha oil (previously dissolved in small amount of alcohol). Mix the granules and powder uniformly.
8. The granules are ready for compression and can be compressed into tablets.

Category: Antacid

Dose: 2 to 6 tablets per day as required.

Storage: The granules should be stored in well close container in a cool place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Granules ready for compression of sodium bicarbonate tablets	Description Colour Odour Nature of granules	Granular powder White Odour of peppermint Free flowing granules	

Calculations:

1. Weight of sodium bicarbonate (a) = ……g
2. Weight of butter paper + starch paste before granulation =……g
3. Weight of butter paper + starch paste after granulation =……g
4. Weight of starch paste used =…… g
5. Drug (1)+ starch paste used (4), i.e. total mixture (X g) =……..+……..=…… g
6. Weight of dry granules = …… g
7. Weight of 10 % fines =… …… g

   Weight of dry granules step (6) + weight of fines step (7) (Y g) =…….....g

   X grams of dough mass contains. …….(a grams) of drug

   Y grams of mass contains (Y/X) a =……..(b grams) of drug.

   Total No. of tablets $= \frac{b}{0.320}$ =…….Tablets
8. Weight of 1 % magnesium stereate = …… g
9. Weight of 1 % talc =……..g

   = …… g

Total weight = Weight of granules (6) + weight of fines (7) + weight of Magnesium Stearate (8) + weight of talc (9) =

= ……+……+……+……+…….. =……(Z gm)

Weight of each tablet $\frac{\text{Total weight}}{\text{Total No. of tables}} = \frac{Z}{\text{Total No. of tables}}$ = ……

10.0 Result:

……..grams of granules ready for compression of ……..are submitted in …….. container with neat label.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. Q. ..….. (Question numbers to be allotted by the teacher.)

1. Name the different additives used in formulation of tablet.
2. Should sodium bicarbonate tablet be evaluated for disintegration test? And why?
3. Name at least three binders used for wet granulation.
4. State the use of talc and magnesium stereate.
5. Is there a need to add disintegrating agent during wet granulation in sodium bicarbonate granules.
6. What is the disintegration time of tablet as per I.P.?
7. State the evaluation test required for tablets.
8. While compression if the granules stick to the punch. What remedial measure you will take?
9. Name two marketed chewable tablets.
10. State the use of mentha oil in the preparation.

(Space for answers)

(Space for answers)

Experiment No. 37

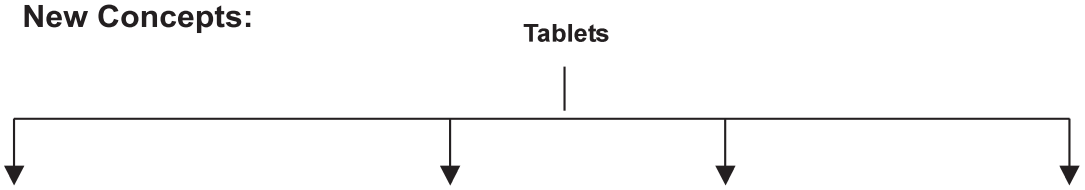
1.0 Title:

To prepare, evaluate and submit granules ready for compression of 10 Calcium Lactate Tablets. I.P.

2.0 Prior Concepts:

Moulded tablets and compressed tablets

3.0 New Concepts:



Tablets ingested orally	Tablet for oral cavity	Tablets used to prepare solution	Tablets administrated by other routes
1. Compressed tablet	1. Buccal tablet	1. Effervescent tablet	1. Implantation tablet
2. Multiple compressed tablet	2. Sublingual tablet	2. Dispensing tablet	2. Vaginal tablet
3. Sustained action tablet	3. Lozenges	3. Hypodermic tablet	
4. Enteric coated tablet	4. Dental cones	4. Tablet titurates	
5. Sugar coated tablet			
6. Film coated tablet			
7. Chewable tablet			

Proposition 1:

Calcium lactate tablets are calcium supplement tablets.

Proportion 2: Storage

Calcium lactate tablets are normally strip packed. But for laboratory purpose the granules can be submitted in a wide mouth bottle.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the different types of tablets.
2. To understand the use of different additive in tablet formulation.
3. To understand the different granulation processes eg. Wet granulation, Dry granulation, Direct Compression.

Motor Skills:

1. Skill for weighing the ingredients.
2. Skill for uniformly mixing the ingredients and forming a coherent mass.
3. Skill for sieving.
4. Skill for calculating the lubricant and Anti adherent and disintegrating agent
5. Skill for compressing the granules into the tablets.

5.0 Apparatus:

Dispensing balance, Mortar and Pestle, Sieves 60 #, 10 #, 22 #, 44 #, Oven.

6.0 Formulation Table:

Sr. No.	Ingredients	Quantity given/ tablet	Quantity taken (No. of tablets x Quantity given)	Use of ingredients
1.	Calcium lactate	600 mg		
2.	Starch	5 %		
3.	Isopropyl alcohol	q.s.		

7.0 Stepwise procedure

Calcium lactate tablets containing 600 mg of calcium lactate, which is sufficient for compression therefore there is no need of adding the diluent.

Calcium lactate itself has the binding property therefore isopropyl alcohol is used as granulating agent and if starch paste is used the tablets so obtained are quite hard. Calcium lactate tablets are used as source of calcium in calcium deficiency.

The granules are prepared by dry granulation method

1. Weigh require quantity of calcium lactate and starch powder (2.5%) and pass through 60 # sieve.
2. Add isopropyl alcohol, which act as a binder drop by drop and with uniform mixing till a coherent mass is formed.
3. Pass the coherent mass through 10 # sieve and dry the granules at 60 0C for 15 minutes.
4. Pass all the dried granules through 22 # sieve below which 44 # sieve is kept.
5. The granules retained on 44 # sieve are desired granules and the powder, which passes through 44 # are fines.
6. Weigh the granules.
7. Calculate and add 10 % fines, 1 % talc and 1 % magnesium stereate, 2.5% starch
8. Mix the granules and powder uniformly with the help of spatula.
9. The granules are ready for compression and can be compressed into tablets.

Category: Calcium replenisher.
Dose: Up to 8 grams daily, in divided doses.
Storage: Stored in well close container in a cool place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Granules ready for compression of Calcium lactate tablets	Description Odour Nature of granules	White granular powder Odourless Free flowing	

Calculations:

1. Weight of Calcium lactate (a gm) = ……g
2. Weight of starch powder (2.5%) as disintegrating agent = ……g
   Drug + starch powder i.e. total mixture (X g) =……g
3. Weight of dry granules = …… g
4. Weigh of 10 % fines = …… g
   Weight of dry granules+ fines (Y g) = ……..g
   X grams of dough mass contains. ……(a grams) of drug
   Y grams of mass contains (Y/X) a =……..(b grams) of drug.
   Total No. of tablets $= \frac{b}{0.600}$ =……Tablets

5. Weight of 1 % magnesium stereate = ... g
6. Weigh of 1 % talc = ... g
7. Weight of 2.5 % starch as disintegrating agent = ... g

Total weight = Weight of granules (3) + fines(4) + weight of Magnesium stereate (5)+ Weight of talc(6) + Weight of 2.5% starch

= .....+.....+.....+.....+..... =.....(Z gm)

Weight of each tablet $\frac{\text{Total weight}}{\text{Total No. of tables}} = \frac{Z}{\text{Total No. of tables}}$ = ...

10.0 Result:

.....grams of granules ready for compression of .....are submitted in ..... container with neat label.

11.0 Questions :

Answer Q. ..... Q. ..... Q. ..... Q. ..... (Question numbers to be allotted by the teacher.)

1. State the disintegration time of calcium lactate tablet.
2. Why are the granules not prepared by wet granulation method?
3. State two marketed preparation of calcium lactate tablet.
4. Name the equipment used for drying the granules.
5. Name the equipment used for mixing the powders in the industries.
6. Draw neat and well label diagram of fluid-bed dryer.
7. State the different stages at which the disintegrating agent is to be added.

(Space for answers)

Experiment No. 38

1.0 Title:

To evaluate and submit granules ready for compression of 20 Paracetamol Tablets. I. P.

2.0 Prior Concepts:

Moulded tablets, Compressed tablets and methods of granulation.

3.0 New Concepts:

Proposition 1:

Paracetamol tablets are Analgesic Antipyretic tablets.

Proportion 2: Storage

Storage: Paracetamol tablets are normally strip packed. But for laboratory purpose the granules can be submitted in a wide mouth bottle.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the different types of tablets.
2. To understand the term Analgesic and Antipyretic.
3. To understand the different granulation processes e.g. wet granulation. Dry granulation, direct compression.

Motor Skills:

1. Skill for weighing the ingredients.
2. Skill for uniformly mixing the ingredients.
3. Skill for compressing the tablets.
4. Skill for sieving
5. Skill for calculating the lubricant and disintegrating agent.

5.0 Apparatus:

Dispensing balance, Mortar and Pestle, Single punch tableting machine, sieves, dryer.

6.0 Formulation Table: (As per I.P.):

Sr. No.	Ingredients	Quantity given/ tablet	Quantity taken (No. of tablets x Quantity given)	Use of ingredients
1.	Paracetamol	500 mg		
2.	Lactose	75 mg		
3.	Starch	20 mg		
4.	Starch paste 10 %	q.s.		

7.0 Stepwise procedure

Paracetamol tablets are analgesic, anti pyretic tablets. They contains not less than 95% and more than 105% of stated amount of paracetamol.

The granules are prepared by wet granulation method

1. Weigh the require quantity of Paracetamol, Lactose and starch powder and pass through 60 # sieve.
2. Add starch paste little by little so that a coherent mass is formed which crumples on slight application of pressure.
3. Pass the coherent mass through 10 # sieve and dry the granules at 60°C for 1hour.
4. Pass all the dried granules through 22 # sieve below which 44 # sieve is kept.
5. The granules retained on 44 # sieve are the desired granules and the powder which passes through 44 # are fines.
6. Weigh the granules.

7. Calculate and add 10 % fines, 5 % starch, 1 % talc and 1 % magnesium stereate.
8. Mix the granules and powder uniformly with the help of spatula.
9. The granules are ready for compression and can be compressed into tablets.

Category: Analgesic, Antipyretic.
Dose: 1 to 2 tablets as required.
Storage: Stored in well close container in a cool place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Granules ready for compression of Paracetamol tablets	Description Odour Nature of granules	White granular powder Odourless Free flowing	

Calculations:

1. Weight of Paracetamol (a) = ……g
2. Weight of butter paper + starch paste before granulation =……g
3. Weight of butter paper + starch paste after granulation =……g
4. Weight of starch paste used =…… g
5. Drug (1)+ starch paste used (4), i.e. total mixture (X g) =……+……=……g
6. Weight of dry granules =…… g
7. Weight of 10 % fines =…. …….. g
   Weight of dry granules (6) + weight of fines (7) (Y g) =…….. g
   X grams of dough mass contains. ……(a grams) of drug
   Y grams of mass contains (Y/X) a =……..(b grams) of drug.
   Total No. of tablets $= \frac{b}{0.500}$ =…….Tablets
8. Weight of 1 % magnesium stereate = …… g
9. Weight of 1 % talc =……..g
10. Weight of 5% starch = …… g

Total weight = Weight of granules (6) + weight of fines (7) + weight of Magnesium Stearate (8) + weight of talc (9) + Weight of 5% starch

= ……+……+……+……+…….. =……(Z gm)

Weight of each tablet $\frac{\text{Total weight}}{\text{Total No. of tables}} = \frac{Z}{\text{Total No. of tables}}$ = ……

10.0 Result:

…….grams of granules ready for compression of ……..are submitted in …….. container with neat label.

11.0 Questions :

Answer Q. ..…... Q. …..... Q. ..…... Q. ..…... (Question numbers to be allotted by the teacher.)

1. State two uses of starch.
2. Give the other name of paracetamol.
3. Give the two-marketed preparations of paracetamol.
4. Define antipyretics.
5. Classify tablets on basis of route of administration.
6. Draw flow chart of manufacturing process of paracetamol tablet.
7. If the paracetamol tablets are prepared by direct compression, state the formulation of tablet.
8. Write two other dosage forms of Paracetamol available in the market.

(Space for answers)

Experiment No. 39

1.0 Title:

To evaluate the given tablets as per I.P.standard.

2.0 Prior Concepts:

Use of vernier calipers.

3.0 New Concepts:

Proportion 1: Evaluation of tablets

Non-Official Tests

1. Dimensions.
2. Hardness test.
3. Friability test.

Official Tests

1. Content of active ingredients.
2. Uniformity of weight.
3. Uniformity of content.
4. Disintegration test.
5. Dissolution test.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the importance of evaluation test.
2. To understand the concept of different evaluation test.

Motor Skills:

1. Skill for measuring the diameter and thickness with the help of vernier calipers.
2. Skill for the finding the hardness of tablet using Monsanto hardness tester.
3. Skill for conducting the friability test.
4. Skill for performing weight variation.
5. Skill for calculating the upper and lower limit in weight variation test.
6. Skill for carrying out disintegration test.

5.0 Apparatus:

Digital electronic balance, Vernier caliper, Friability apparatus, Monsanto hardness tester.

6.0 Stepwise procedure

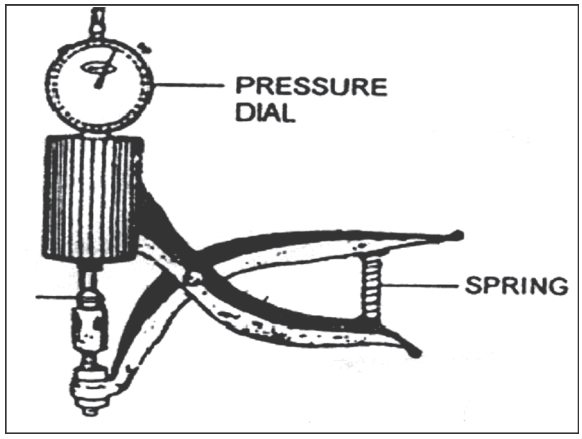
Nonofficial Test:

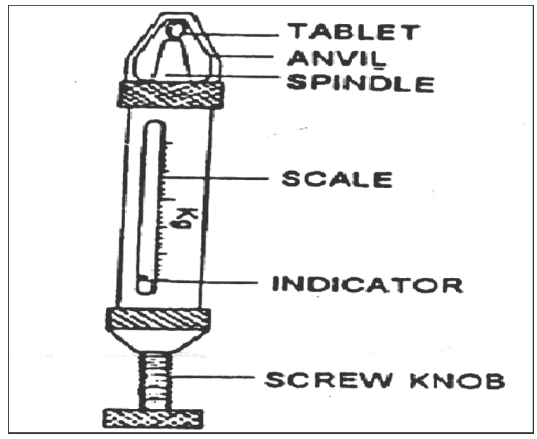
1. Dimensions:

With the help of vernier caliper find out the thickness and diameter of 10 tablets.

2. Hardness:

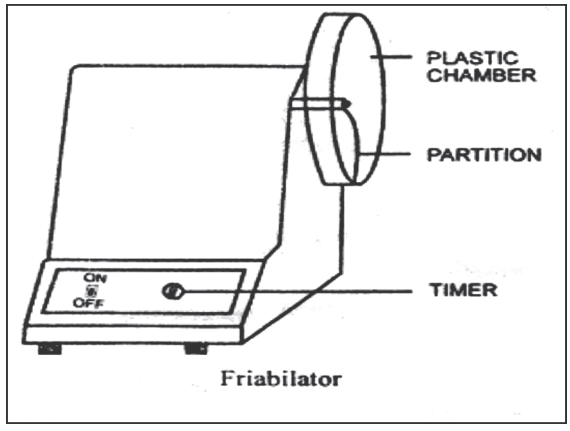
Place the tablets between the jaws of Monsanto hardness tester and slowly go on rotating the screw until the tablet breaks. Note down the reading in terms of kg/cm^2 and make the recording of 5 tablets. The hardness should be more than 4 Kg/cm^2.





3. Friability test:

Weigh 20 tablets and place it in friabilator, run the friabilator for 4 minutes @ 25 rotations/ Minute or 100 rotations, again weigh the tablets and calculate the percentage loss in weight.

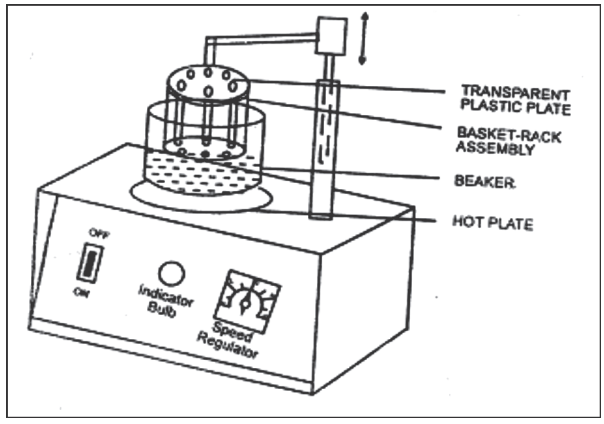


Friabilator

7.0 Official Test as per I.P.:

1. Disintegration test:

Place 6 tablets into each tube, add a disc to each tube. Suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified time. The tablets pass the test if all of them have disintegrated.



Passing Criteria:

Specified limits for disintegration according to IP 1996

Sr. No.	Type of Tablet	Time Limit
1.	Oral Uncoated Tablets	15 minutes
2.	Film Coated Tablets	30 minutes
3.	Sugar Coated Tablets	60 minutes
4.	Soluble Tablets	3 minutes
5.	Effervescent Tablets	5 minutes
6.	Enteric Coated Tablets In acidic medium pH 1.2	Should not disintegrate for 120 minutes.
	In phosphate buffer pH 6.8	Must disintegrate within 60 minutes

2. Uniformity of Weight:

Weigh 20 tablets selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviates by more than twice the percentage.

Sr. No.	Average Weight of Tablets	Percentage Deviation
1.	80 mg or less	10
2.	More than 80mg but less than 250 mg	7.5
3.	250 mg or more	5

8.0 Observation and evaluation:

1. Dimension:

No. of tablets	1	2	3	4	5	6	7	8	9	10
Diameter in mm										
Thickness in mm										

Result: The Diameter was found to be _____
The thickness was found to be_____

2. Dimension:

No. of tablets	1	2	3	4	5
Hardness in Kg/cm^2					

Result: The tablets pass/ fails the Hardness test.

3. Friability:

Weight of 20 tablets, X = ... gm
Weight of tablets after test, Y = ... gm
Loss in weight, X – Y = ... gm
Percentage Loss in Weight = (X-Y/X) x 100

Limit: It should be less than 1% w/w.
Result: The tablet pass/ fails the friability test.

9.0 Official Test:

1. **Disintegration time:** Maximum limit is 15 minutes

   Result: The tablets pass/ fails the disintegration test.

2. **Uniformity of Weight:**

Tablet No.	1	2	3	4	5	6	7	8	9	10
Weigh in gms										
Pass/Fail										
Tablet No.	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Weigh in gms										
Pass/Fail										

Average weight = $\frac{\text{Weight of 20 tablets}}{20}$

Limits: Lower limit……

Upper limit ……

Result: The given tablets pass/ fail the test for uniformity of weight.

10.0 Result:

The tablets ……the evaluation tests as per I.P.

11.0 Questions :

Answer Q. ..….. Q. ….... Q. ..….. Q. ..….. (Question numbers to be allotted by the teacher.)

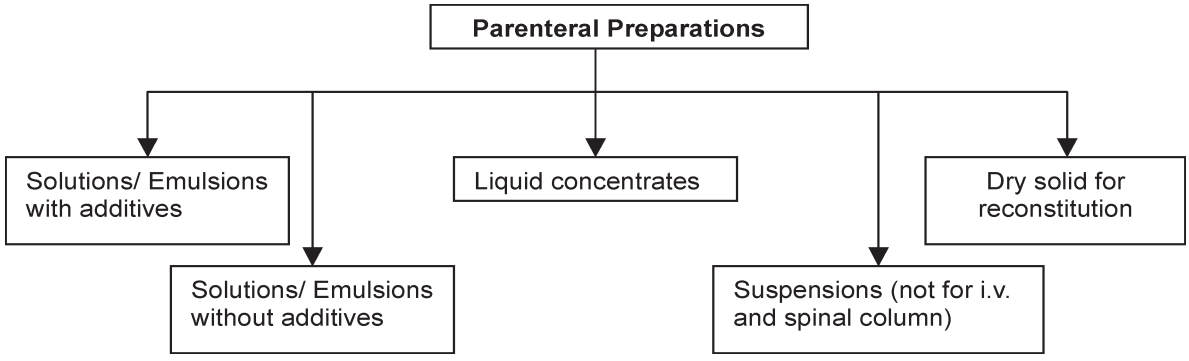
1. State the disintegration time for sugar coated tablet?
2. State the disintegration time for enteric-coated tablet?
3. Normally in what range is hardness required for good compressible tablet.
4. Which test is to be performed to judge the mechanical strength of tablet?
5. If the tablet weighs 150 mg. what are its lower and upper limits for performing uniformity of weight test.
6. If the 2 tablets fail in disintegration test as per I.P., then what further analysis has to be carried out?
7. In which cases uniformity of content is required to be carried out?
8. For good tablet what should be the friability test limit?
9. State the least count of vernier calliper?

(Space for answers)

(Space for answers)

INTRODUCTION TO PREPARATION INVOLVING STERILIZATION

Parenteral 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.



Parenteral dosage form must posses the following characteristics:

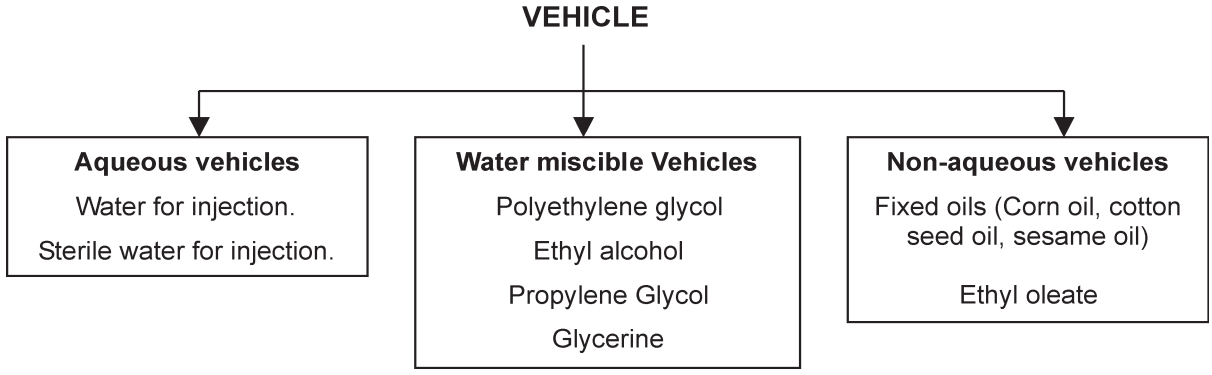
1. Freedom from living microbes.
2. Freedom from microbial products such as toxins, pyrogens.
3. Freedom from physical contaminants such as particulate matter, fibres, cellulose, glass, rubber, metal, plastic particles, undissolved chemicals, rust, etc.
4. Freedom from chemical contaminants.
5. Parenterals should be neutral in pH.

Formulation of Parenteral dosage form:

1. Medicament
2. Vehicle
3. Additive

Primary consideration in selection of vehicle as:

1. Stability
2. Solubility
3. Safety (GRAS approved- Generally regarded as safe)



Additives:

1. Preservative eg. chlorocresol 0.1 %w/v, phenyl mercuric nitrate 0.001 % w/v, phenyl mercuric acetate 0.001 w/v.
2. Antioxidants eg. sodium metabisulphite, tocopherol, ascorbic acid, Butylated hydroxy anisole (BHA), Butylated hydroxy toluene (BHT).
3. Chelating agent eg. EDTA.

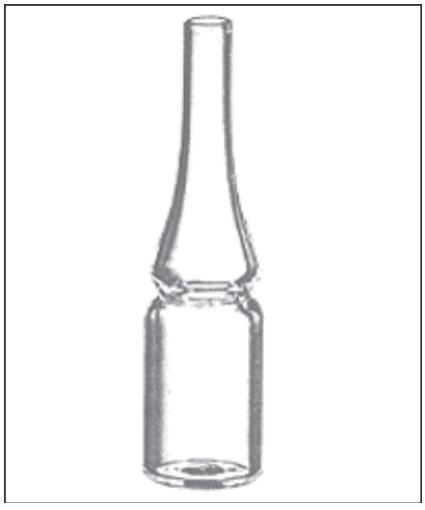
4. Buffering agent eg. acetate buffer, citrate buffer, phosphate buffer.
5. Isotonicity contributor eg. sodium chloride, dextrose.
6. Wetting agent eg. Tween 80, Sorbitan trioleate.
7. Suspending agent eg. Polyvinyl pyrrolidone, acacia
8. Emulsifying agent eg. Lecithin.
9. Viscosity contributor eg. Glycerin.

Container:

Ideal properties of Injectable containers:

1. Sufficiently transparent.
2. Maintain quality and quantity during storage.
3. Non- permeable and yield no foreign substance into preparation.

Injections are supplied in single dose container 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 single dose by sterile syringes without affecting quality of remaining solution.



Ampoule before sealing

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 provide for resealing of the vial after the needle is withdrawn. Rubber closure is held in position by aluminum seal. When antimicrobial preservative is used, the closure should be placed in solution of preservative.

Sealing of Ampoules:

Ampoules are sealed by melting a portion of the glass neck. Two types of seals are employed normally:

1. Tip seal (bead seal), 2. Pull seal.

1. 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 uniform bead, the ampoules neck must be heated evenly on all sides by rotating the ampoules in a single flame.

2. Pull seal:

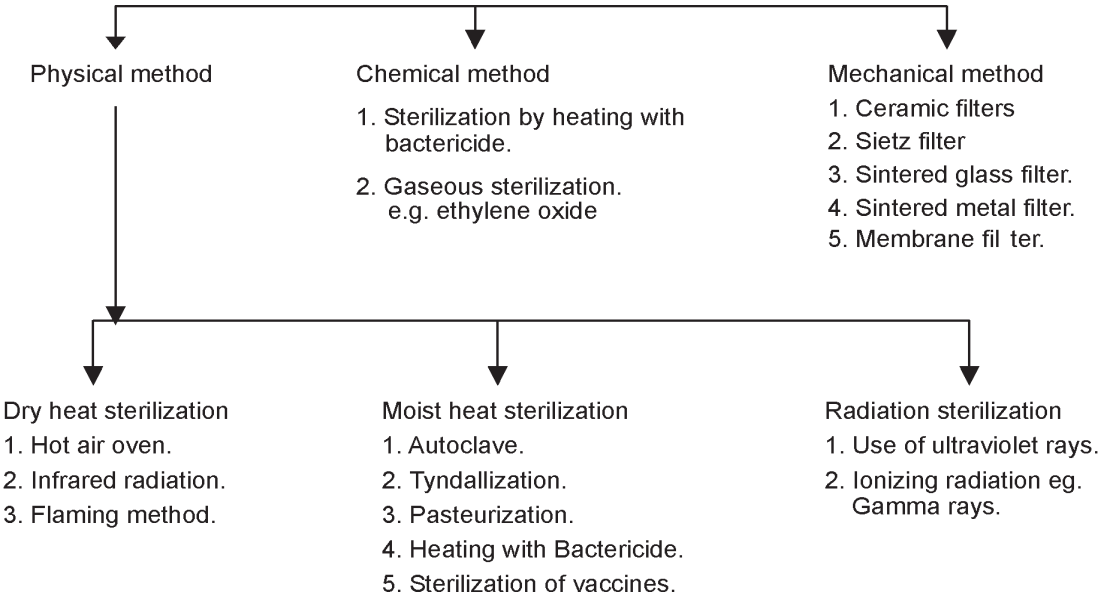
Pull seals are made by heating the neck of the ampoule below the tip, leaving enough of tip for grasping with forceps or other mechanical devices.

Different sterilization technique for parenterals:

Sterilization is process of complete destruction of all microorganisms along with spores present in a system. The products free from living microorganisms and their spores are called sterile products.

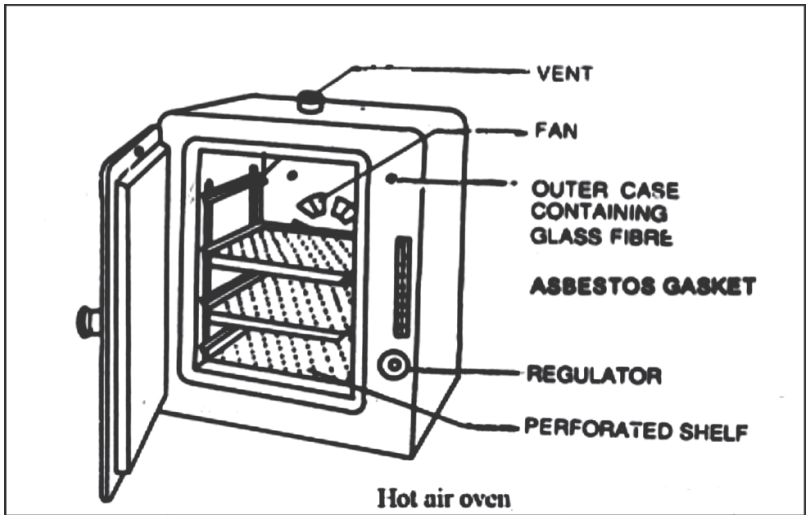
Method of sterilization:

Sterilization divided into three main groups.



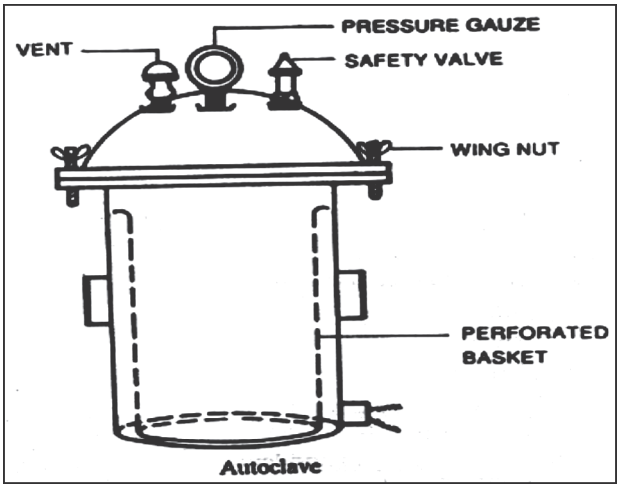
Most commonly used methods employed in laboratory for sterilization.

1. Hot air oven: It is done at temperature 160°C for 2 hours. It is used for sterilization of glass vials, ampoules, metal equipments, glasswares like pipettes, petridishes, ointment base etc.



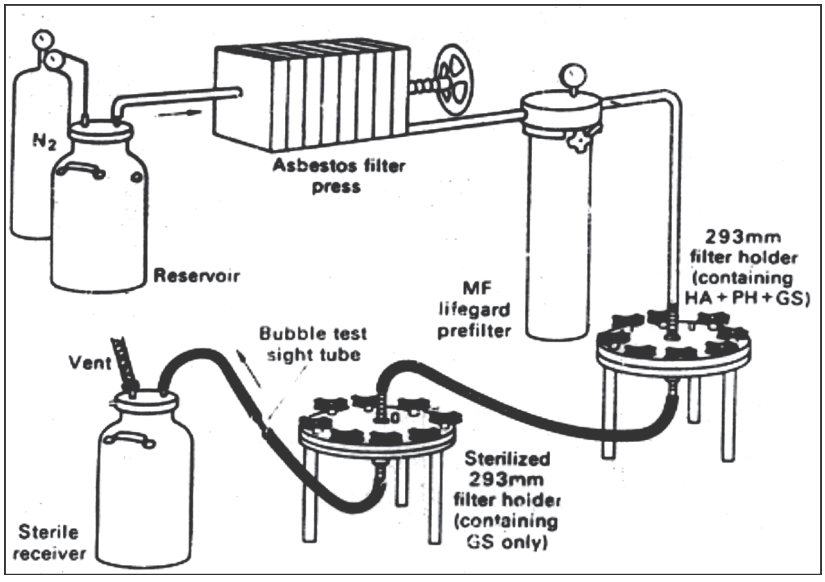
Hot air oven

2. Moist heat sterilization : By using autoclave at temperature 121°C for 15 lbs pressure for 20-30 minutes. It is used for sterilization of rubber closers, glass wares, plastic containers, terminal sterilization of official injections and eye drop.



3. **Heating with bactericide :** It is used for sterilization of official injection. It consists of heating solution in their final container in boiling water or steam at 98-100°C for 30 minutes with bactericides. The permitted bactericides are 0.2 % chlorocresol, 0.002% phenyl mercuric nitrate.

4. **Filtration through bacteria proof filters:** Filtration of official injections and eye drop through sintered glass filter. These are manufactured from powdered borosilicate glass and available in 5 grades G1 to G5. For sterile filtration G3 (15 to 40u) to G5 grade (2u) is used.



Membrane filtration technique used in industry.

Labeling: Label of preparation states:

1. The name of preparation.
2. The percentage of content of drug of a liquid preparation..
3. The amount of active ingredient in a dry preparation.
4. The volume of liquid to be added to prepare an injection or suspension from a dry preparation.
5. The route of administration.
6. A statement of storage condition and expiry date.
7. The name and proportions of all substances added to increase stability or usefulness.

Processing of Parenterals (Aseptic Techniques)

The numerous stringent requirements of a parenteral products call for a vigilant processing program. The entire handling has to be ordered in such a way that the product remains free from the various contaminants that come from the environment and personnel

The raw material should be of special grades of purity. Many manufactures supply material of the parenteral grade quality.

In processing the product the following controls should be exercised.

1. Environmental control
2. Air control
3. Personnel control

1. Environmental control:

The environment in which parenteral products are prepared, sterilized and packed must be comparatively free from particulate contamination and microbial contamination.

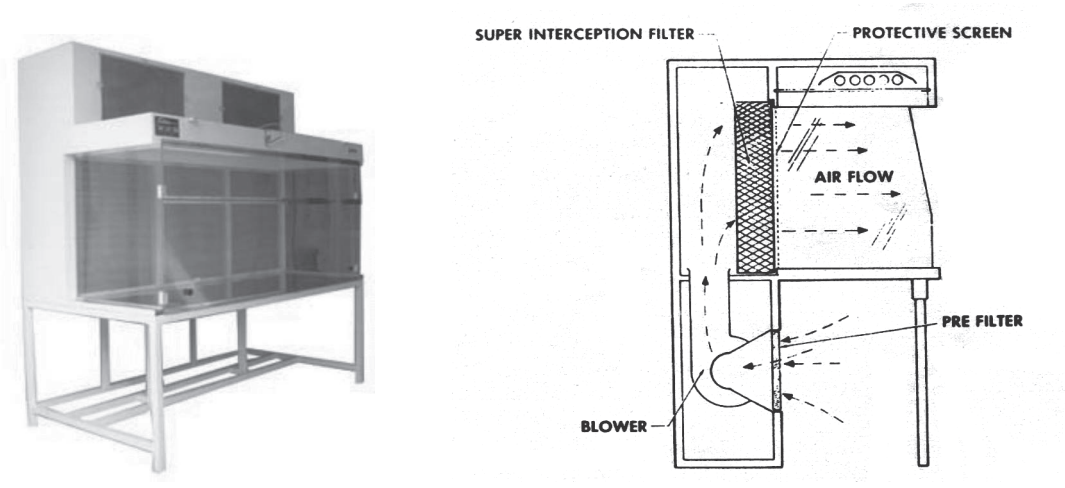
1. For an aseptic area, a clean room with total environmental control, ie. Control of temperature, humidity, particulate contaminations, microbial contaminations.
2. Construction of area should be such that it prevents leakage of air into or out of clean room.
3. The surface walls, floors, ceiling should be smooth, impervious and unbroken in order to minimize shedding and accumulation of particles.
4. It should permit repeated use of disinfectant like IPA 70 % (Iso propyl alcohol), cidex, Lysol (2-5%), Aarshol (Iodophore 1 %)
5. Wall, floor, ceiling should be painted with germicidal paint.
6. Glass panels fitted into walls permit greater visibility and facilitate supervision from non-sterile area.
7. Entry of material or person into area should be through airlock. Airlock is space with two or more doors only one of which is opened at a time.

2. Air Control:

Air in sterile area should be ultra clean, which is obtained by air filtration. Air filtration is done by following two ways :

1. Prefiltration: which is done to remove coarse particles and prevent load on HEPA filter. Prefilters are made up of glass wool, cloth, shredded plastic.
2. Final filtration of air is done through HEPA filters ie. High Efficiency Particulate Air Filter HEPA filter are made up of cellulose acetate or cellulose nitrate polymer or glass filters. These filters have high efficiency of 99.97 % in removing particles of 0.3 um size at average velocity of 100 feet/minute. These are fitted either horizontally in walls or vertically in ceiling with unidirectional flow, HEPA filters are operated under positive pressure with laminar flow.
3. Laminar air flow hood : The main critical operations as sterility testing or filling of injections should be carried out under LAF (Laminar air flow hood or bench).

Laminar airflow hood is system in which air is filtered within a confined space in parallel layers with uniform velocity of 100 square feet/minute causing sweeping of contaminants with airflow.



Laminar Air Flow Hood

3. Personnel control:

1. Operators working in sterile area should be neat, reliable, alert and should have good manual dexterity.
2. Minimum number of persons are allow to work in sterile area.
3. Personnel should wear protective clothing while working in sterile area which are provided for protection of products against contamination.
4. The clothing should be made up of synthetic polymer like Dacron, polyester, polymides, which should not shred particles.
5. The clothes include surgical mask, headgear, one piece of overall suit to cover whole body, particles free gloves and overshoes.
6. They should be sterilized by moist heat sterilization before wearing.

Personnel working in sterile area

Before entering aseptic area following preparatory procedure should be followed.

1. Removal of outside street clothes and wearing sterilized aseptic clothing.
2. Scrubbing hands and arms with disinfectant soap and then enter in sterile area.
3. Personnel should be aware of aseptic techniques. They should work systematically with rhythmic moment so that no particulate are generated.

Experiment No. 40

1.0 Title:

To prepare, evaluate and submit 2 ampoules each contains 10ml Sterile Water For Injection I.P.

2.0 Prior Concepts:

Preparation of different non-sterile solutions, volumetric measurements.

3.0 New Concepts:

Proportion 1:

Sterile water for injection I.P. prepared by distillation method and filled by using aseptic techniques..

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of distillation used for manufacturing sterile water for injection.
2. To understand the concept of pyrogen free water.

Motor Skills:

1. Skill for measurement.
2. Skill for aseptic techniques and sterile manufacturing.
3. Skill for distillation.

5.0 Apparatus:

Distillation assembly with baffles, gloves, facemask, syringe, ampoules, jet burner, forceps.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1.	Water for injection			

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Sterile water for injection I.P. is a single dose preparation in container not larger than one litre size. Sterile water for injection is free from all microbial contaminates and should be free from pyrogens. It should be free from particulate matter, fibers, dust particles, etc.

Baffles are used in preparation of water for injection to avoid entrapment of droplets carrying pyrogens otherwise it will contaminate distillate.

1. Water for injection is distilled water free from pyrogens. It does not contain any bactericide or bacteriostatic agent.
2. It is prepared by distillation using baffled still or may be prepared by reverse osmosis.
3. When it is prepared by distillation, the first portion of distillate is discarded and remaining portion is collected.
4. Fill water for injection in to two 10 ml ampoules.
5. Seal the ampoules using burner and forceps.
6. Sterilize the ampoules using autoclave at 121^0C, 15 lbs for 30 minutes.
7. Observe the ampoules for particulate matter.

Dose: No specific dose, since it is used as a vehicle.
Category: Pharmaceutical aid (solvent). Used for reconstitution.
Storage: Store in single dose container not larger than one litre size.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Sterile water for injection I.P.	Description Odour Particulate matter Leaker test	Clear Odourless No particles No leakage should be found.	

10.0 Result:

…… ml of ……. is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..….. (Question numbers to be allotted by the teacher.)

1. State the requirements for water for injection I.P.?
2. State the different methods of preparation of water for injection I.P.?
3. What are pyrogens?
4. State the use of baffles in preparation of water for injection?
5. State the difference between purified water, water for injection and sterile water for injection I.P.?

(Space for answers)

(Space for answers)

Experiment No. 41

1.0 Title:

To prepare, evaluate and submit 2 ampoules each of 10 ml Sodium Chloride Injection I.P.

2.0 Prior Concepts:

Preparation of non-sterile solutions, volumetric measurements.

3.0 New Concepts:

Proportion 1:

1. Different sterilization techniques for Parenteral preparations.
2. Sodium chloride injection I.P. prepared and filled using Aseptic techniques.
3. The solution is terminally sterilized by autoclaving method.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of manufacturing parenterals using Aseptic techniques.
2. To understand the concept of sterilization using filtration.
3. To understand the concept of terminal sterilization of injections (autoclaving).

Motor Skills:

1. Skill for measurement.
2. Skill for aseptic technique and sterile manufacturing.
3. Skill for sterile filtration.
4. Skill for sealing the ampoule.

5.0 Apparatus:

Volumetric cylinder(100 ml), Beaker(250 ml), conical flask(100 ml), Syringe, Autoclave, Stirrer, Spatula, Dispensing balance, Sintered glass filter, Face mask, Gloves, Jet burner, Forceps.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. 2.	Sodium chloride I.P. Sterile water for injection	0.9 % w/v quantity sufficient		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Sodium chloride injection I.P. is sterile, pyrogen free isotonic solution of sodium chloride in water for Injection I.P. It contains not less than 0.85 % w/v and not more than 0.95% w/v of sodium chloride. It contains no antimicrobial agent.

1. Weigh accurately required quantity of sodium chloride.
2. Dissolve it in water for injection.
3. Filter the solution through sintered glass filter (No 3 to 5).
4. Fill the solution in ampoules with the help of syringe taking precaution to minimize bacterial contamination.
5. Alternatively the solution may be filled in clean, dry infusion bottle (approximately 500 ml capacity) and rubber bung is used to close the infusion bottle.
6. Bottles are then placed in an autoclave 121^0C (15psi pressure) for 30 minutes.

Category: Fluid and electrolyte replenisher, Isotonic vehicle.
Dose: Ranges upto 500 ml or more (intravenously).
Storage: Keep in cool and dark place. If ampoule show any colour change or particles discard the ampoule.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Sodium Chloride Injection I.P.	Description Odour Particulate matter Leaker test pH	Clear Odourless No particles No leakage should be found. Between 4.5 to 7	

10.0 Result:

…… ml of ……. is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... Q. ..….. (Question numbers to be allotted by the teacher.)

1. What are the requirements for parenteral preparation?
2. Name the filters used for sterile filtration.
3. Describe the method for parenteral manufacturing?
4. Define infusions.
5. State the labeling requirement for sterile preparations?
6. State the category of sodium chloride injection.
7. State the concentration of sodium chloride injection so that it is isotonic.
8. Draw a well label diagram of water still used for preparation of water for injection.

(Space for answers)

(Space for answers)

Experiment No. 42

1.0 Title:

To prepare, evaluate and submit 2 ampoules each of 10ml Dextrose Injection I.P. Synonym: Dextrose intravenous infusion, Glucose intravenous infusion.

2.0 Prior Concepts:

Preparation of different non-sterile solutions, volumetric measurements.

3.0 New Concepts:

Proportion 1:

Dextrose injection I.P. prepared and filled in ampoules using Aseptic techniques

Proportion 2:

The solution is terminally sterilized by autoclaving method.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of manufacturing parenterals using Aseptic techniques.
2. To understand the concept of sterilization using filtration.
3. To understand the concept of terminal sterilization of injections (autoclaving).

Motor Skills:

1. Skill for measurement.
2. Skill for Aseptic technique and sterile manufacturing.
3. Skill for sterilization by filtration.
4. Skill for sealing the ampoules.

5.0 Apparatus:

Volumetric cylinder (100 ml), Beaker (250 ml), conical flask (100 ml), Syringe, Autoclave, Stirrer, Spatula, Dispensing balance, Sintered glass filter, Face mask, Gloves, Ampoules. Jet burner, Forceps.

6.0 Formulation Table: (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1.	Dextrose I.P.	5 g		
2.	Water for injection quantity sufficient to produce	100 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \text{..}$$

7.0 Stepwise procedure

Dextrose injection I.P. is sterile, pyrogen free isotonic solution of dextrose in water for Injection. Dextrose injection is use as nutrient and fluid replenisher for patients who cannot take food by mouth. It is available in different concentrations of 5%, 10%, 25% and 50%. The solution is administered intravenenously and hence, it has to be isotonic with plasma having same osmotic pressure as plasma.

Procedure:

1. Weigh accurately required quantity of Dextrose.
2. Dissolve dextrose in water for injection I.P.

3. Filter the solution through suitable filter to remove particulate matter.
4. Filter the solution finely through sintered glass filter to remove bacterial contamination.
5. Fill the solution in sterile ampoule with the help of syringe taking precaution to minimize bacterial contamination.
6. Alternatively the solution may be filled in clean, dry infusion bottle (approximately 500 ml capacity) and rubber bang is used to close the infusion bottle.
7. Terminal sterilization of solution is done by autoclaving at temperature of 121^0C, 15 psi pressure, for 20-30 minutes.

Usual strength : 5% w/v, 10% w/v,25% w/v, and 50% w/v.
Category : Nutrient, fluid replenisher.
Storage : Store in single dose container in a cool place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Dextrose injection I.P.	Description Colour Particulate matter testing Leaker testing pH	Clear Colourless Free from Particles No leakage should be found Between 3.5 to 6.5	

10.0 Result:

…… ml of ……. is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. ….... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Define Parenterals.
2. What are the Aseptic techniques?
3. State the different quality control test performed for Parenterals?
4. Why particulate matter testing is required for Parenterals?
5. State the type of container to be used for Parenterals?
6. State the different methods of ampoule sealing?
7. What is terminal sterilization? Give different method of terminal sterilization.

(Space for answers)

INTRODUCTION TO OPHTHALMIC PREPARATIONS

Ophthalmic preparations include sterile solutions or suspensions intended for topical dropwise instillation in the eye or ointments for topical application to the eye area.

Requirements for Eye Drops:

1. Sterile.
2. Free from foreign particles to avoid irritation to eye.
3. Neutral
4. Isotonic with lachrymal secretion.

Formulation of Eye Drops:

1. **Medicament**
2. **Preservative:**
   A suitable preservative like phenyl mercuric nitrate (0.002 %w/v), Benzalkonium chloride (0.01%w/v) and chlorhexidine acetate (0.01%w/v) may be used to prevent bacterial or fungal growth. When the preparation itself have sufficient antimicrobial properties, the antimicrobial preservative is not added. If preparation does not contain any antimicrobial preservative it should be packed in single dose container. Eye drops used for surgical procedure should not contain antimicrobial preservative and should be packed in single dose container.
3. **Antioxidants:**
   Eye drops usually contains substances having antiseptic, anti-inflammatory, anaesthetic and miotic properties. When active ingredient is susceptible to oxidative degradation, antioxidant may be added but care should be taken to ensure compatibility between antioxidant and other ingredients of the preparation.
4. **Buffers:**
   Ophthalmic preparations should be formulated at a pH equivalent to tear fluid value of 7.4. The buffer system selected should have a capacity adequate to maintain pH within the stability range for the duration of the product shelf life. Also it should not cause stinging or discomfort on instillation. Eg. phosphate buffer.
5. **Tonicity contributor:**
   Tonicity refers to the osmotic pressure exerted by salts in aqueous solution. An ophthalmic solution is isotonic when its tonicity is equal to that of a 0.9%w/v sodium chloride solution.
6. **Viscosity contributor:**
   Ophthalmic solution and suspension may contain viscosity imparting polymers to thicken the tear film and increase corneal contact time i.e. reduce the rate of tear fluid drainage. For suspensions the increased viscosity also serves to reduce settling of particles between uses and at the same time maintain their suspension for uniform dosing eg. methyl cellulose, hydroxy propyl methyl cellulose, hydroxy ethyl cellulose and polyvinyl alcohol.

Containers:

The eye drops are packed in vertically fluted bottles made up of neutral glass container or plastic containers. The bottles are fitted with a bakelite cap carrying a dropper. The bottles made up of neutral glass must confirm alkalinity limit test. The bottles must not impart particles to the contents and the closure should not absorb the active constituents or preservative added to eye drops.

Eye drops are sterilized by one of following method:

All apparatus used must be sterile and filling in final container is carried out aseptically.

Method 1:
Sterilization of solution is carried out by filtration followed by aseptic transfer.

Method 2:
Sterilization is carried out in final container in an autoclave at 121^0C for 20 minutes at 15psi pressure.

Method 3:
Heating at 98^0C to 100^0C for 30 minutes in final container along with one antimicrobial substance and any other preservative specified in individual monograph.

Labeling:

Label should contain.

1. Name of drug.
2. Name and concentration of preservative.
3. Warning.

The words “For external use only” be added to the label.
In addition to this following instruction should appear on label.

1. Use within one month after opening.
2. Do not touch tip of the dropper.
3. If irritation persists discontinue the use and consult physician.

Experiment No. 43

1.0 Title:

To prepare, evaluate and submit 10 ml of Atropine Sulphate Eye Drops I.P.

2.0 Prior Concepts:

Preparation of injections, sterilization, Aseptic techniques.

3.0 New Concepts:

Proposition 1:

Atropine sulphate eye drops are prepared & terminally sterilised.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of ophthalmic manufacturing using aseptic techniques.
2. To understand the concept of sterile filtration.
3. To understand the concept of terminal sterilization of eye drop.

Motor Skills:

1. Skill for measurement.
2. Skill for aseptic technique and sterile manufacturing.
3. Skill for sterile filtration.
4. Skill for terminal sterilization.
5. skill for labeling of eye drops

5.0 Apparatus:

Volumetric cylinder (100 ml), Beaker (250 ml), Conical flask (100 ml), Autoclave, Spatula, Dispensing balance, Sintered glass filter, Face mask, Gloves, Vial, Rubber closure.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1.	Atropine sulphate I.P.	1 gm		
2.	Phenyl mercuric nitrate	0.002 gm		
3.	Distilled water quantity sufficient to produce	100 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \text{...}$$

7.0 Stepwise procedure

Atropine sulphate ophthalmic solution is a sterile, aqueous solution contains 1% w/v of atropine sulphate and 0.002 % w/v of phenyl mercuric nitrate. The pH of the preparation should be between 3.5 and 6.0. Atropine sulphate is stable in acidic pH. If the pH is more than 6.0, the drug hydrolyses and atropine base is precipitated causing turbidity in solution or atropine (which is an alkaloid) formed may further hydrolyses and degrade. Dilute Sulphuric acid is added to adjust the pH of the preparation between 3.5 and 6.0 because atropine sulphate is stable in acidic medium. The pH cannot be lower than 3.5 because the preparation then may cause eye irritation and damage the cornea. Atropine sulphate is parasympatholytic and is used prior to ophthalmic examination or ophthalmic surgery.

1. Dissolve atropine sulphate in 3/4th volume of preparation using distilled water.
2. Adjust the pH of the preparation between 3.5 to 5.0 using dilute sulphuric acid.
3. Make up the required volume.

4. Filter the solution through sintered glass filter.
5. The solution is sterilized by heating in an autoclave or by filtration.

Category: Parasympatholytic (anticholingeric)
Storage: Store in a cool place, protected from light.
Label: NOT FOR INJECTION, FOR EXTERNAL USE ONLY.
Warning: If irritation persists or increases discontinue use and consult the physician.
Use within one month after opening the container.
Do not touch the dropper tip or other dispensing tip to any surface as this may contaminate the Solution
To be sold by retail only on the prescription of a registered medical practioner only.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Atropine sulphate eye drop I.P.	Description Odour Particles pH	Clear Odourless No particles Between 3.0 to 5.5	

10.0 Result:

…… ml of ……. is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. Q. ..…. (Question numbers to be allotted by the teacher.)

1. State the requirements for ophthalmic preparations?
2. Describe the process use for ophthalmic manufacturing.
3. Write labeling requirements for ophthalmic preparations?
4. What are different terminal sterilization process used for ophthalmics?
5. Give formulation of ophthalmic preparations.
6. Why is it necessary to maintain pH between 3.0 to 5.5?
7. Name the different preservative used and concentration in which they are used in ophthalmic preparation.
8. State the porosity of different membrane filters.
9. What do you mean by term parasympatholytics?

(Space for answers)

Experiment No. 44

1.0 Title:

To prepare, evaluate and submit 10 ml Boric acid Eye Lotion.

2.0 Prior Concepts:

Preparation of injections, sterilization, Aseptic techniques.

3.0 New Concepts:

Proposition 1:

Boric Acid eye lotion is sterilised by autoclauing.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of ophthalmic manufacturing using aseptic techniques.
2. To understand the concept of sterile filtration.
3. To understand the concept of terminal sterilization of eye drop.

Motor Skills:

1. Skill for measurement.
2. Skill for aseptic technique and sterile manufacturing.
3. Skill for sterile filtration.
4. Skill for terminal sterilization.
5. Skill for labeling of eye lotion.

5.0 Apparatus:

Volumetric cylinder (100 ml), Beaker (250 ml), Conical flask (100 ml), Autoclave, Spatula, Dispensing balance, Sintered glass filter, Face mask, Gloves, Vial, Rubber closure.

6.0 Formulation Table (As per B.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1.	Boric acid I.P.	1 % w/v		
2.	Sodium bicarbonate I.P.	0.25 % w/v		
3.	Sodium chloride I.P.	0.25 % w/v		
4.	Distilled water	quantity sufficient		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Boric acid has antibacterial and antifungal properties. Aqueous solution is used as mouth wash, eye lotions, skin lotions .Because boric acid is excreted very slowly, repeated dose by whatever route, causes toxicity. Sodium bicarbonate is added to raise the pH of the preparation, so that it is not too acidic. Sodium chloride is added to make the solution isotonic.

1. Dissolve boric acid in little amount of warm distilled water. (Warm the solution if necessary to dissolve boric acid)
2. Dissolve sodium bicarbonate and sodium chloride together in freshly boiled and cooled distilled water.
3. Mix above two solutions and make up the volume with freshly boiled and cooled distilled water.

4. Fill the solution in sterile glass vial and put rubber closure and aluminium seal. The container should accompany a dropper made of polyethylene or a rubber teat.
5. Sterilize the solution in final container by autoclaving.

Category: Local anti-infective.
Storage: Store in well-closed container.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Boric acid eye lotion I.P.	Description Odour Clarity testing	Clear Odourless No particles	

10.0 Result:

…… ml of …… is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. ….... Q. ..….. Q. ..…. (Question numbers to be allotted by the teacher.)

1. Name the different preservative and their concentration used in ophthalmic preparations.
2. Why preservatives are required in eye drops?
3. State the different container used for dispensing ophthalmic preparation?
4. What are different terminal sterilization process used for eye drops?
5. Differentiate between eye drops and eye lotion.
6. State the role of sodium bicarbonate and sodium chloride in boric acid eye lotion I.P?
7. Define isotonic solutions: What is the effect, if tonicity is not adjusted in eye drops.
8. State the different methods for adjusting isotonicity of formulation.
9. State the category of boric acid eye lotion. Explain.
10. Explain the term aseptic techniques?
11. What is terminal sterilization?

(Space for answers)

(Space for answers)

Experiment No. 45

1.0 Title:

To prepare, evaluate and submit 10 gram of Atropine Sulphate Eye Ointment I.P.

2.0 Prior Concepts:

Preparation of eye drops, sterilization, Aseptic techniques.

3.0 New Concepts:

Proposition 1: Atropine sulphate eye ointment is prepared by using Aseptic techniques.

1. Method of preparation of eye ointment base.
2. Sterilization of ointment base.
3. Semi solid mixing and incorporation of active ingredients.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of eye ointment manufacturing using aseptic technique.
2. To understand the concept of ointment mixing.

Motor Skills:

1. Skill for measurement.
2. Skill for aseptic technique and sterile manufacturing.
3. Skill for ointment mixing.
4. Skill for ointment filling.

5.0 Apparatus:

Volumetric cylinder (25 ml), Beaker (100 ml), Spatula, Dispensing balance, Facemask, Gloves, Hot air oven, Butter paper, Mortar and pestle, Ointment tubes, Crimping machine.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1.	Atropine sulphate I.P.	1 % w/w		
2.	Sterile eye ointment base	q.s.		

The base has following composition:

Liquid paraffin	10 gm
Wool fat	10 gm
Yellow soft paraffin	80 gm

7.0 Stepwise procedure

Atropine sulphate ophthalmic ointment is atropine sulphate in a suitable ointment base. It contains not less than 90.0%w/v and not more than 110%w/v of the labeled amount of atropine sulphate. It is sterile product therefore aseptic techniques are used.

Atropine sulphate is parasympatholytic and is used prior to ophthalmic examination or ophthalmic surgery. Yellow soft paraffin is used because it is unbleached and does not cause irritation of the eye. The base has the proper consistency .It should not be very hard and does not irritate the eye.

While preparing ophthalmic ointment aseptic techniques are used.

1. Melt together the wool fat, yellow soft paraffin and liquid paraffin.
2. Filter the hot mixture through a coarse filter paper placed in a heated funnel.
3. Sterilize the base by heating at 150°C for 2 hours in hot air oven.
4. Prepare sterile solution of atropine sulphate in the smallest quantity of water for injection.

5. Triturate this solution with melted base of eye ointment using sterile mortar and pestle under Laminar air flow in Aseptic area.
6. Weigh empty sterile ointment tube.
7. Fill the atropine sulphate ointment in tube by weight using spatula.
8. After filling, do the crimping of tube from an end.

Category: Parasympatholytic (Anticholingeric)

Labeling instructions:

1. If irritation persists or increases, discontinue the use and consult physician.
2. Do not touch the tip of the dropper as it may contaminate the contents.
3. Use the preparation within four weeks, after opening the container.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Atropine sulphate eye ointment I.P.	Description Odour Particles	Clear Odourless No particles	

10.0 Result:

…… grams of ……. is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. …..... Q. ..…... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Why white soft paraffin is not used in the preparation of eye ointment base?
2. State the role of liquid paraffin and wool fat in eye ointment base?
3. State the aseptic techniques used in preparation of atropine sulphate eye ointment?
4. State the method of preparation of atropine sulphate ointment I.P.
5. State the sterilization process of eye ointment base.
6. State the category of atropine sulphate eye ointment.
7. Why preservative is not added in atropine sulphate eye ointment?

(Space for answers)

(Space for answers)

Experiment No. 46

1.0 Title:

To prepare, evaluate and submit 10 ml of Zinc Sulphate Eye Drops I.P.

2.0 Prior Concepts:

Preparation of injections, sterilization, Aseptic techniques.

3.0 New Concepts:

Proposition 1: Zinc sulphate eye drop prepared and terminally sterilised.

1. Method of preparation of eye drop.
2. Filling in vial and terminal sterilization.
3. Labeling of eye drop.

4.0 Learning Objectives:

Intellectual Skills:

1. To understand the concept of ophthalmic manufacturing using aseptic techniques.
2. To understand the concept of sterile filtration.
3. To understand the concept of terminal sterilization of eye drop.

Motor Skills:

1. Skill for measurement.
2. Skill for aseptic technique and sterile manufacturing.
3. Skill for sterile filtration.
4. Skill for terminal sterilization.

5.0 Apparatus:

Volumetric cylinder (100 ml), Beaker (250 ml), Conical flask (100 ml), Autoclave, Spatula, Dispensing balance, Sintered glass filter, Face mask, Gloves, Vial, Rubber closure.

6.0 Formulation Table (As per I.P.):

Sr. No.	Ingredients	Quantity given	Quantity taken (Factor x Quantity given)	Use of ingredients
1. 2. 3.	Zinc sulphate. Phenyl mercuric nitrate Purified water quantity sufficient to produce	0.25 gm 0.002 gm 100 ml		

$$\text{Factor} = \frac{\text{Required quantity}}{\text{Quantity given}} = \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots$$

7.0 Stepwise procedure

Zinc sulphate eye drop contains not less than 0.22% and not more than 0.28% w/v zinc sulphate. It is used as astringent and mild antiseptic. It is used for treating inflammation and infection of eye such as conjunctivitis. It contains 0.002% w/v phenyl mercuric nitrate as a preservatives.

Eye drops can be sterilizes by following methods:

1. Autoclaving,
2. Sterilization by aseptic techniques,
3. Heating with bactericide for 30 minutes at 98 – 100^0c.

Procedure:

1. Prepare the stock solution phenyl mercuric nitrate in purified water.
2. Pipette out required quantity of phenyl mercuric nitrate and dissolve in purified water.

2. Dissolve zinc sulphate in above solution.
3. Filter the solution and transfer to final container.
4. Seal and sterilize by one of following method.
   a. Autoclaving
   b. Sterilize solution by filtration and transfer aseptically to sterile container.
   c. Sterilize by maintaining at 98 – 100^0C for 30 mins.

Category: Astringent and mild antiseptic.

Storage: Store in a cool place.

8.0 Labeling of formulation:

(Students shall write all aspects of labeling in the space provided below.)

9.0 Observation and evaluation:

Name of Preparation	Test	Specification	Observation
Zinc sulphate eye drops I.P.	Description Odour Clarity test	Clear Odourless No particles	

10.0 Result:

…… ml of ……. is submitted in ……. container with neat label complying the evaluation test.

11.0 Questions :

Answer Q. ..…. Q. …... Q. ..…. (Question numbers to be allotted by the teacher.)

1. Give formulation of zinc sulphate eye drop I.P.
2. State the different preservatives used in ophthalmic preparation and in what concentration?
3. State the role of buffering agent and tonicity contributor in ophthalmic preparation?
4. State the different methods of preparation of eye drop?
5. What is category of zinc sulphate eye drop I.P.? Explain.

(Space for answers)

(Space for answers)

Experiment No. 47

1.0 Title:

Report of visit to Pharmaceutical Industry.

2.0 Prior Concepts:

Pharmaceutical industries have various areas like:

1. Storage Area
2. Changing Room
3. Washing Area
4. Production Area
5. Aseptic Area
6. Quality Control Department
7. Packaging and Labeling Area
8. Quarantine Area

3.0 New Concepts:

Proposition 1:

Purpose of visit is to collect information about various departments.

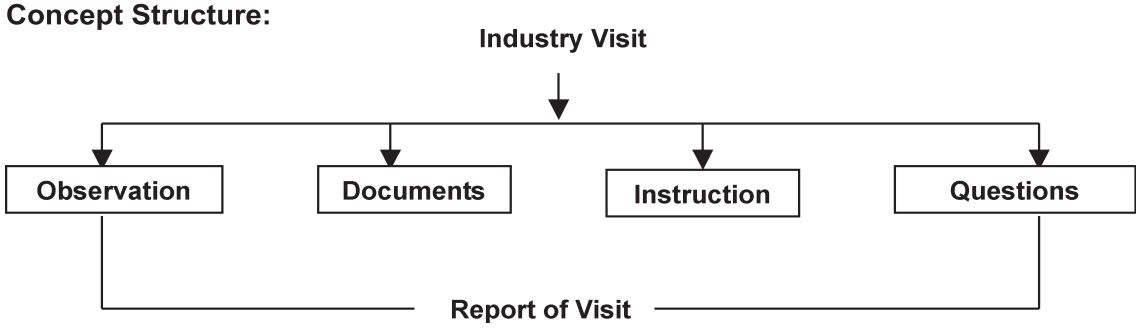
Proposition 2:

To study the layout of different departments.

Proposition 3:

To study the different equipment and it's working, use to carryout different operations in pharmaceutical industry.

Concept Structure:



4.0 Learning Objectives:

After the visit the students will be able to:

1. To identify the different equipments.
2. Understand the principle and working of different equipment.
3. List the different processes and their sequences used in manufacturing.
4. Draw a general out line of different departments.
5. Understand the organization structure of industry.
6. Understand the precautionary measures taken during operation of different machines.

5.0 Apparatus:

Diary, Pen, Pencil, Clean Apron and Cap.

6.0 Stepwise procedure

The industry visit will give the practical knowledge to the students, they will be able to understand the working of the different department and the passage of raw material from the time it enters the premises, until it is transferred into different dosage form and the co-ordination of different department, for effective running of industry.

1. Take permission from the proper authority of the plant/ Industry for the visit.
2. Inform students about the date, time and location of the visit and make arrangement of transportation to the site.
3. Identify the tools suitable for gathering the required information.
4. Reach the plant or industry at scheduled date and time.
5. Students to read the format for visit report in advance and make record of information to be collected during visit in the diary.
6. During the industrial visit collect information using different techniques; such as drawing, display module, critical observation, effective listening, by taking interview, etc.
7. Write a report on visit, using the information collected in the format given below.

Format for visit report

Date and time of visit:

1. Name and address of industry:

_____

_____

2. Two main products of the industry with their category:

_____

_____

3. Monthly or annual production output of two main products:

_____

_____

4. List down the major raw materials required by industry: (State requirement of 2-3 raw materials for each day from where the raw material is procured, any special storage arrangement for raw material).

_____

_____

_____

_____

_____

5. Complete the table:

Location	Ambient Temperature
Outside Industry	
Storage Area	
Manufacturing Area	
Quality control	

6. List ten major equipments with their model description and its function.

Sr. No.	Name of Equipment	Model	Function of utility
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

7. List five major processes of plant or industry.

I. _____

II. _____

III. _____

IV. _____

V. _____

8. Draw the plant layout of the industry.

9. List five equipments used in Quality Control Department and state it uses.

I. _____

II. _____

III. _____

IV. _____

V. _____

10. Write two duties of production supervisor.

_____

_____

11. Write three functions of Quality control department.

12. Write full form of SOPs and state its significance.

13. Write down the hierarchy of organizational structure.

14. Write down the objectives achieved through the industry visit.

15. Write down additional information collected during the industrial visit (if any).

PATTERN FOR ANNUAL PRACTICAL EXAMINATION

Class: F.Y.D.Pharm | Subject: Pharmaceutics-I

Max. Marks: 80 | Time: 3 Hrs.

Q1. Write Synopsis on the following: **(16)**

a. Theory based question (from practical manual.)

b. Theory based question (from practical manual.)

c. Mention the name, role of the ingredients, storage conditions, and category of the said formulation.

d. Mention the name, role of the ingredients, storage conditions, and category of the said formulation.

Q2. Prepare, evaluate and submit following formulation with proper labeling:

a. Minor Experiment-1 (one from the prescribed list) **(12)**

b. Minor Experiment-2 (one from the prescribed list) **(18)**

Q3. Prepare, evaluate and submit following formulation with proper labeling:

a. Major Experiment (from the prescribed list) **(24)**

Q4. Viva-Voce (pertaining to practical curriculum) **(10)**

ructions

Evaluation of the students is carried out by both external as well as internal examiner on equal marks distribution. Marks distribution shall be as follows:

Internal Examiner (40 marks)

a. Synopsis, Q1 (16 marks)
b. Major Experiment, Q3 (24 marks)

External Examiner (40 marks)

a. Minor Experiments, Q2 (12+18=30 marks)
b. Viva-voce, Q4 (10 marks)

Guidelines for synopsis

Total Marks for synopsis is 16 marks. Time allotted for completion of synopsis is 20 minutes. Synopsis carry four questions of 4 mark each.

1. Synopsis shall consist of two short questions pertaining to the theory of any category of the Preparations.

a. Definition/ Explanation with classification (1)
Example: Lotion

b. Principle of method of preparation, it includes the role of ingredients, the explanation of formulation variables. (2)
Example: Co-solvency

c. Evaluation parameters (1)
Example: viscosity, clarity, disintegration time, etc.

2. Two questions of synopsis may be given on the official preparations with following points:

a. Name of the ingredients (1)
b. Role of each excipient (1)
c. Storage condition (1)
d. Category, Directions for use (1)

~~Guidelines for Minor Experiment-1~~

Total Marks for minor experiment-1 is 12 marks.

List of Minor Experiments -1

1. Aromatic waters
2. Spirits
3. Ophthalmic preparations
4. Capsules

Parameters for evaluation

1. Aromatic waters 2. Spirits 3. Ophthalmic preparation (12)

a. Calculation of formulation (1)

b. 1. Container (1)
2. Liner (1)

c. Prescribed volume of the preparation (1)

d. Quality of the preparation
1. Colour/ odour (2)
2. Particulate matter (1)

e. Labeling
1. Presentation/size of the label (1)
2. Strength/ percentage Content (1)
3. Storage (1)
4. Directions of use, Dose (1)
5. Batch Mfg. Record (1)

4. Capsules

1. Calculations of formula (1)
2. Calculation of displacement value (2)
3. Filling and sealing (2)
4. Weight uniformity (on 5 capsules) (2)
5. Labeling:
i. Presentation/size of the label (1)
ii. Strength/ percentage Content (1)
iii. Storage (1)
iv. Directions of use, Dose (1)
v. Batch Mfg. Record (1)

~~Guidelines for Minor Experiment-2~~

Total Marks for minor experiment-2 is 18 marks.

List of Minor Experiments –2 (18)

1. Evaluation of Tablets
2. Solutions
3. Creams / cosmetics

Parameters for evaluation

1. Evaluation of Tablets

1.	Uniformity of weight/ Friability test	(10)
2.	Disintegration time/ thickness	(4)
3.	Tablet Hardness	(4)

2. Evaluation of solution

a.	Calculation of formulation		(2)
b.	1.	Container	(2)
	2.	Liner	(1)
c.	Prescribed volume of the preparation		(1)
d.	Quality of the preparation		
	1.	Colour/ odour /pH	(3)
	2.	Particulate matter	(2)
e.	Labeling		
	1.	Presentation/size of the label	(2)
	2.	Strength/ percentage Content	(2)
	3.	Storage	(1)
	4.	Directions of use, Dose	(1)
	5.	Batch Mfg. Record	(1)

3. Creams / Cosmetics (18)

a.	Calculation of formula		(2)
b.	1.	Container	(1)
	2.	Liner	(1)
c.	Quality of the preparation		
	1.	Clarity/ colour/ odour/ grittiness	(2)
	2.	Consistency (flow property)	(2)
	3.	Spreading	(2)
	4.	Stickiness	(2)
d.	Labeling		
	1.	Presentation/size of the label	(2)
	2.	Strength/ percentage Content	(1)
	3.	Storage	(1)
	4.	Directions of use, Dose	(1)
	5.	Batch Mfg. Record	(1)

Guidelines for Major Experiment

Total Marks for major experiment is 24 marks.

List of Major Experiments

1. Formulation and evaluation of granules ready for compression.
2. Formulation and evaluation of parenteral preparation (sealed ampoules ready for sterilization).

Parameters for evaluation

1. Formulation and evaluation of granules ready for compression.

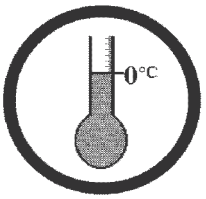
a.	Calculation of formula		(4)
b.	Calculation of fines and lubricating agents		(3)
c.	Quality of granules		
	I.	Fragility	(4)
	II.	Uniformity of size	(4)
	III.	Properly dried	(4)
d.	Labeling		
	i.	Presentation/size of the label	(1)
	ii.	Strength/ percentage Content	(1)
	iii.	Storage	(1)
	iv.	Directions of use, Dose	(1)
	v.	Batch Mfg. Record	(1)

2. Formulation parenteral preparation (sealed ampoules ready for sterilization).

a.	Sealing		(8)
b.	Prescribed quantity		(3)
c.	Quality of the preparation		
	1.	Clarity/ colour/ odour	(4)
	2.	Particulate matter	(4)
d.	Labeling		
	1.	Presentation/size of the label	(1)
	2.	Strength/ percentage Content	(1)
	3.	Storage	(1)
	4.	Directions of use, Dose	(1)
	5.	Batch Mfg. Record	(1)

Dangerous/ Poison

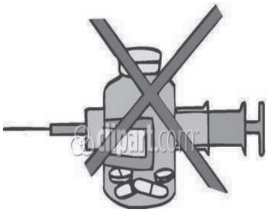
Irritant to Eyes



Store at cold Temperature

Pharmacy

Corrosive Chemicals



Stop To Self Medication

Inflammable

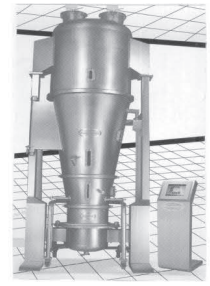
Pharmacy

Recyclable

Commonly Used Symbols

Autoclave

Bulk Density Apparatus



Fluidized Bed Dryer

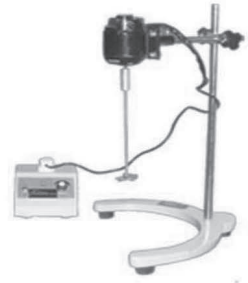
Distillation Unit

Friabilator

Dissolution apparatus

Electronic Balance

Disintegration tester



Overhead stirrer

Sieve Shaker

HEPA Filter

pH Meter

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PHARMACIST'S OATH

- I swear by the Code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of health care team.
- I shall uphold the laws and standards governing my profession.
- I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and public health.
- I shall follow the system, which I consider best for pharmaceutical care and counseling of patient.
- I shall endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
- I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
- I shall associate with organizations having their objectives for betterment of Profession of Pharmacy and make contribution to carry out the work of those organizations.
- While I continue to keep this oath unviolated, may it be granted to me to enjoy life and practice of pharmacy respected by all, at all times!
- Should I trespass and violate this oath, may the reverse be my lot!

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