East Point College of Pharmacy

East Point Campus, Jnana Prabha, Virgo Nagar Post
Bengaluru – 560049, Karnataka

Approved
by
Pharmacy Council of India, New Delhi

Affiliated
to
Rajiv Gandhi University of Health Sciences
Karnataka
Bengaluru – 560 041
India

LAB MANUAL

PHARMACEUTICS
PHARM D
1st Year

EAST POINT COLLEGE OF PHARMACY
East Point Campus, Jnana Prabha, Virgo Nagar Post,
Bengaluru – 560049, Karnataka

PROGRAM OUTCOMES
DOCTOR OF PHARMACY
PO1: Comprehensive Pharmaceutical Knowledge
Acquire and demonstrate a deep understanding of fundamental concepts in pharmacotherapeutics, clinical pharmacy, pharmacoepidemiology, clinical pharmacokinetics, therapeutic drug monitoring, as well as behavioral, social, and administrative pharmacy. Showcase advanced proficiency by designing and executing effective medication therapy management plans.
PO2: Strategic Planning Proficiency
Cultivate the capability to formulate and execute plans, proficiently organizing tasks to meet deadlines. Demonstrate adeptness in time management, resource allocation, delegation, and organizational skills. Exhibit competence in clinical decision-making by seamlessly integrating pharmaceutical knowledge with patient-specific factors to enhance healthcare outcomes.
PO3: Problem Solving Proficiency
Apply the principles of scientific inquiry, engaging in analytical, clear, and critical thinking to address challenges and make informed decisions in routine clinical practice. Graduates will demonstrate adept communication skills, counseling patients on medication usage, potential side effects, and lifestyle adjustments, fostering patient comprehension and adherence.
PO4: Leadership and Entrepreneurship
Demonstrate leadership skills and entrepreneurial spirit, contributing to the growth and development of the pharmaceutical profession and industry.
PO5: Professional Identity
Exhibit a strong professional identity including a commitment to ethical practice, effective communication, and leadership in advocating for optimal patient care, continuous professional development, and active engagement with the broader healthcare professionals, promoters and stakeholders.
PO6: Adherence to Ethical Standards
Uphold the highest ethical standards in pharmaceutical practice, adhering to the Pharmacy Council of India's code of ethics and promoting patient welfare.
PO7: Communication
Demonstrate effective communication skills, sustaining clear and empathetic interactions with patients, healthcare professionals, and diverse stakeholders. They will proficiently convey pharmaceutical information, contributing to collaborative and patient-centered care. This emphasis on communication ensures graduates are well-equipped to navigate complex healthcare scenarios and advocate for optimal therapeutic outcomes.
PO8: Community Engagement
Participate in community engagement activities, applying pharmaceutical knowledge to address healthcare needs and improve the overall well-being of the community.
PO9: Environment and Sustainability
Demonstrate a profound understanding of environmental issues in the pharmaceutical domain, applying sustainable practices in research, development, and clinical settings. They will champion eco-friendly approaches, fostering a commitment to minimizing ecological impact and promoting responsible stewardship of natural resources.
PO10: Clinical Research Skills
Proficient in conducting clinical research, applying ethical principles, and contributing to advancements in pharmaceutical sciences and healthcare.
PO11: Continuous Professional Development
Embrace a commitment to lifelong learning, staying abreast of advancements in pharmaceutical sciences, healthcare policies, and technological innovations.

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PROGRAM SPECIFIC OUTCOMES	
DOCTOR OF PHARMACY	
PSO1	Acquire a thorough foundational knowledge in pharmaceutical sciences, including pharmacology, pharmaceutics, pharmaceutical chemistry, pharmacognosy and pharmaceutical analysis to excel in further academic pursuits
PSO2	Acquire and apply the pharmacotherapeutic concepts for better patient care enhancing employability across various sectors including clinical research organizations, academic and hospitals
PSO3	Equip with entrepreneurial skills and knowledge of pharmacoepidemiological studies and regulatory aspects to initiate and run successful ventures in the healthcare sector

Course:	**Code: 1.2P** **Pharmaceutics**
CO1	Able to understand principles involved in the preparation of different types of dosage forms
CO2	Able to formulate and evaluate the types of liquid dosage forms
CO3	Able to prepare the solid powder dosage forms
CO4	Reproduce the overview of the dosage forms and Viva voice

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Table of Content

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Sl No	Category	Definition's
1.	Abrasive	An agent that wears away external layers.
2.	Absorbent	A drug that takes up other chemicals in to its substance useful in reducing the free availability of toxic chemicals.
3.	Adsorbent	A drug that binds other chemicals on to its surface, useful in reducing the free availability of toxic chemicals.
4.	Analgesic	A Drug that suppresses pain perception with out inducing unconsciousness.
5.	Antacids	A drug that neutralizes excess gastric acid.
6.	Anthelmentic	A drug that eradicates intestinal; worm infestations.
7.	Antibacterial	A drug that kills or inhibits pathogenic bacteria.
8.	Antiemetic	A drug that suppresses nausea and vomiting.
9.	Antiflatulent	A drug that reduces gastrointestinal gases.
10.	Antipyretics	A drug that reduces elevated body temperature in fever.
11.	Antitussives	A drug that suppresses cough.
12.	Astringent	A drug that precipitates proteins and toughens and shrinks tissues.
13.	Antidote	A drug that reduces the effect of ingested poisons (or drug over doses) by adsorbing toxic material
14.	Antibiotic	A drug , originally of microbial origin, used to kill or inhibit bacterial and other infections.
15.	Antiamebic	A drug that kills or inhibits protozoan parasite such as Entamoeba Histolytica, causative agent of amebiasis
16.	Carminative	An agent that expels gas from stomach.
17.	Catharatic	An agent that promotes defecation and stronger than laxatives
18.	Decongestant	An adrenergic drug used to orally or topically to induce Vasoconstriction in nasal passages
19.	Demulcent	A bland viscous liquid usually water based, used to coat and soothen damaged or inflamed skin or mucous membranes.
20.	Expectorant	A drug that increases respiratory tract secretions, lowers their Viscosity and promotes removal.
21.	Hematinic	A drug that forms haemoglobin formation by supplying iron.
22.	Local irritant	A drug that reacts weakly and non specifically with biological tissues, used topically to induce a mild inflammatory response.
23.	Laxative	A drug that promotes defecation, usually stronger than cathartic.
24.	Purgative	A mild laxative.
25.	Cathartic	A drastic purgative
26.	Diaphoretic	It causes increased perspiration
27.	Scabicide	An agent suitable for eradication of itch caused by microbes and fungi.
28.	Sedative	A CNS depressant suitable for inducing mild relaxation.
29.	CNS stimulant	A drug that increases the functional state of CNS system, sometime used in convulsive therapy for mental disorders
30.	Respiratory stimulant	A drug that selectively stimulates stimulation either by peripheral initiation of respiratory reflexes or by selective CNS system stimulation.
31.	Topical agents	A drug applied to body surface for local therapeutic action
32.	Rubefacient	Agents which improve local blood circulation

PHARMACEUTICS LABORATORY RULES AND SAFETY PRECAUTIONS

1. Never work alone in the laboratory.
2. Always wear a good quality, neat and clean white Apron during your practical classes.
3. Unauthorized experiments are prohibited.
4. Being Practical notebook and other accessories and keep it neat and tidy.
5. Plan your Practicals step by step.
6. Know the location and use of the fire extinguisher and first aid kit.
7. Report all injuries to your instructor at once.
8. Never taste chemicals, solutions or use prepared formulations.
9. When diluting concentrated acid or base always add the concentrated acid or base to water (never the reverse), while stirring the solution. Be very careful with sulfuric acid.
10. Keep an orderly, clean laboratory desk.
11. Place unneeded books, etc. on the shelves at the side of the laboratory.
12. The students will be provided necessary apparatus for which He/She will be held responsible for any loss, Breakage or Missing articles.
13. Thoroughly clean the apparatus required in the Practical work, uncleaned apparatus may not give good results only specified apparatus required for particular work should be used.
14. Always read the label twice before taking any chemical from the bottle. If you are not sure if you have the right chemical, ask!
15. When pouring reagents, hold the bottle so the label points upwards facing the palm of the hand.
16. Avoid using an excess of reagent.
17. Keep the balance infront of you, Clean the Pans, Adjust if necessary. Place a piece of butter paper on either side of the Pans.Always use forceps for lifting the weights. Put weights on the right hand pan and material on the left hand pan.
18. Do not weigh less than 100mg on the dispensing balance because these balance are not very sensitive.
19. Due to possible contamination of the contents of a whole stock bottle, never return unused chemicals to the stock bottle.
20. Always check your glassware before you use it. If it is broken or cracked, exchange it for a new one.
21. If corrosive chemicals or liquids come in contact with the skin or clothing, flood with copious amounts of water for an extended period of time.
22. Spilled chemicals should be wiped up immediately.
23. The prepared product should corked, Labeled and Polished. Good quality of paper and adhesive should be used for fixing the label on the container.
24. All the entries must be recorded as soon as the practical work is completed. Observation notebook must be complete in every aspect and it should be submitted on the same day to the teacher concerned of Signature.
25. When you are ready to leave the laboratory, clean the apparatus used with detergent water and return, your bench area should be rinsed off with a wet sponge and water, gas valve shut off.
26. Store room is out of bounds to students. If you require apparatus, ask your instructor for it.
27. Do not walk in the laboratory bare footed.
28. Do not use wet hand during weighing.
29. Put all waste materials in the dust-bin after the work is finished, the students should clean the apparatus and return it.
30. The seats should be cleaned, Also see the seats all kept clean during practical work as well

GENERAL INSTRUCTIONS TO BE FOLLOWED WHILE CARRYING OUT EXPERIMENTS

1. Wear clean lab coat**.**
2. Always carry required materials (butter paper, spatula, scissors, gum, match box, suitable containers for the product, calculator, colour pens, executive bond papers, clean lab napkin and stationary).
3. Bring tutorial book, record book and observation book.
4. Read official formula and calculate the working formula.
5. After getting the working formula corrected by the teacher start the preparation.
6. Ensure all the apparatus used for the preparation are cleaned and dried.
7. Weigh or measure the ingredients after reading table of content.
8. Even if it is not mentioned monophasic liquids must be subjected to filtration to remove any undissolved solid orimpurity.
9. Size of the label should not be too small or too big for the container. It should be below the neck and above the base of the container.

PHARMACEUTICS LABORATORY REQUIREMENTS

Students must bring the following requirements to the practical class:

1. Apron
2. Observation book/Synopsis book
3. Record book
4. Stationary – pen, pencil, scale, eraser, colour pen/pencil, scissors, glue.
5. Napkin (2)
6. Stickers for labels
7. Adhesive papers
8. Butter paper
9. Match box/lighter
10. Spatula
11. Calculator
12. Narrow mouth amber coloured glass/plastic bottle (capacity 50ml)
13. Narrow mouth colourless glass/plastic bottle (capacity 50ml)
14. Wide mouth plastic container (capacity 20g)
15. Other requirements as instructed by the teacher

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General Format for a Label

<table>
<tr><td colspan="3">TITLE OF THE PREPARATION (Ex: Piperazine Citrate Elixir B P)
Quantity of preparation (Ex: 50ml)</td></tr>
<tr><td colspan="2">SYNONYM (if any):</td><td rowspan="7">*Mfg Date:
Exp Date:
Mfg Batch No:
Mfd Lic No:
Mfd By:
Mfd Address:</td></tr>
<tr><td>COMPOSITION:</td><td>Xxxxxx</td><td>…….g</td></tr>
<tr><td></td><td>Yyyyyy</td><td>…….g</td></tr>
<tr><td></td><td>Zzzzzz</td><td>…….ml</td></tr>
<tr><td>CATEGORY:</td><td colspan="2"></td></tr>
<tr><td>DOSE:</td><td colspan="2"></td></tr>
<tr><td>STORAGE:</td><td colspan="2"></td></tr>
<tr><td>DIRECTIONS:</td><td colspan="2"></td></tr>
<tr><td colspan="3">Mfg Date:
Exp Date:
Mfd By:</td><td>Mfg Batch No:
Mfd Lic No:
Mfd Address:</td></tr>
</table>

*** The manufacturing details may be written only at one place, either at the bottom or to the side of the label depending on the container and the preparation.**

Terminology:

Pharmacy: The word pharmacy is derived from the Greek word "Pharmakon" meaning medicine or drug. Pharmacy is the science and art of preparing and dispensing medicines and providing drug related information.

Pharmaceutics: It is the branch of pharmaceutical sciences concerned with design and manufacture of safe, effective and stable dosage forms.

Drug: Drug refers to articles intended for use in diagnosis, sure, mitigation, treatment or prevention of disease in man or other animals and articles (other than food) intended to affect the structure or any function of the body of man or other animals. It is generally called as API (Active Pharmaceutical Ingredient) in a dosage form.

Excipients: Excipients (additives, adjuvants, and pharmaceutical aids) are defined as substances other than API which have been approximately evaluated for safety and are intentionally included in a drug delivery system to aid in processing or enhance any other attribute of the overall stability, safety, effectiveness or delivery of the drug during storage or use. They must have no adverse influence in the therapeutic efficacy of the active ingredients and must not interfere with the tests and assays of the Pharmacopoeia. Care should be taken to ensure that such substances are free from harmful organisms.

Dosage form: A dosage form/ formulation/ drug product/ finished pharmaceutical product/ preparation is a combination of drug(s) and excipients mixed in predetermined proportions and suitably processed to yield a product which is safe, effective, stable and patient acceptable.

Pharmacopoeia: It is a book of standards. It provides standards and denotes tests for the identity, quality or purity; ensures, as far as possible, uniformity in physical properties and active constituents for drugs and medicines. It is a collection of authoritative procedures of analysis and specifications for drugs and medicines.

Official: The word 'official' wherever used with reference to the Pharmacopeia, is synonymous with 'Pharmacopoeial', with 'IP' and with 'Compendial'. The designation IP on conjunction with the official title on the label of an article is an indication that the article purports to comply with IP standards.

Solubility Index

Description	Parts of solvent required to dissolve 1 part of solute
Very soluble	<1
Freely soluble	1 – 10
Soluble	10 – 30
Sparingly soluble	30 – 100
Slightly soluble	100 – 1000
Very slightly soluble	1000 - 10000
Practically soluble	> 10000 parts

Quantitative product strength

Percentage weight in volume (% w/v)	No of grams of a constituent present in 100ml of a preparation
Percentage weight in weight (% w/w)	No of grams of a constituent present in 100g of a preparation
Percentage volume in volume (% v/v)	No of ml of a constituent present in 100ml of a preparation

Operational aspects:

Weighing: Determination of the weight of any material using calibrated balance is called weighing. There are various types of balances available viz. pan balance, scale balance, digital balance, torsion balance, etc. The suitability of various balances to weigh a given weight a given quantity has to be justified. Care has to be taken while weighing. Where substances are to be 'accurately weighed', the weighing is to be performed so as to limit the error to not more than 0.1%. For example, a quantity of 50mg is to be weighed so that the error does not exceed 50mg.

Measuring: Determining the volume of a liquid using suitable measuring device. Various volumetric apparatus include measuring cyclinder, conical measure, cylindrical measure, pipette, beaker, volumetric flask, etc. Appropriate apparatus has to be chosen based on the accuracy of the measurement required. Class A and class B apparatus are defined in the pharmacopoeia.

Filtration: Passing of the liquid through a suitable filter paper till the filtrate is clear. This is used for removing very fine insoluble solids and is called 'fine filtration'. The filter paper has to be wet with the liquid medium (solvent). Then the mixture has to be passed through it. Else the filter paper will absorb the contents from the preparation.

Straining: Passing a liquid substance through a porous or perforated device or material in order to separate out any coarse solid matter. This is also called coarse filtration.

Drying: Removal of moisture (or any solvent) from the material or equipment being used.

Size reduction: Reducing the particle size of solid material. This can be done by trituration and levigation. Mortar and pestle are usually employed. Milling equipment may be used for large scale purpose and if very fine particle size is required. Trituration method is used where the material is comminuted thoroughly by rubbing or grinding against a hard surface. Levigation is similar trituration but a liquid medium in which the solid is insoluble is employed while grinding the solid to a fine smooth powder.

Size separation: Generally sieves are used to separate the various sizes particles in a powder.

Containers:

A container for a pharmacopoeial article is intended to contain a drug substance or drug product with which it is, or may be indirect contact. The closure is a part of the container. Containers may be made of glass or plastic. Glass employed is soda lime glass and plastic employed is polyethylene (low or high density), polypropylene, polyvinyl chloride, polystyrene and to a lesser extent polyethylene phthalate. The materials are suitably processed and may contain various additives.

Air tight containers: A container that is impermeable to solids, liquids and gases under ordinary conditions of handling, storage and transport. If the container is intended to be opened on more than once, it must be so designed that it remains airtight after re-closure.

Hermetically sealed containers: A container that is impervious to air or any other gas under normal conditions of handling, shipment, storage and distribution, e.g. sealed glass ampoule, gas cyclinder etc.

Light-resistant container: A container that protects the contents from the effects of actinic light by virtue of the specific properties of the material of which it is made. Alternatively, a clear and colorless or a translucent container may be light-resistant by means of an opaque (light-resistant) covering and/or stored in a dark place; in such cases, the label on the container should bear a statement that the opaque covering or storage in dark place is needed until the contents have been used up.

Multi-dose container: A container that holds a quantity of the preparation suitable for two or more doses.

Sealed container: It is a container closed by fusion of the material of the container.

Sealed dose container: A container that holds a quantity of the preparation intended for total or partial use as a single administration.

Tamper-evident container: A container fitted with a device or mechanism that reveals irreversibly whether the container has been opened.

Tightly closed container: A tightly closed container protects the contents from contamination by extraneous liquids, solids or vapors, from loss or deterioration of the article from effervescence, deliquescence or evaporation under normal conditions of handling, shipment, storage and distribution. A tightly closed container must be capable of being tightly reclosed after use. Where a tightly closed container is specified, a hermetically sealed container may be used for a single dose of an article.

Well closed container: A well closed container protects the contents from extraneous solids and liquids and from loss of the article under normal conditions of handling, shipment, storage and distribution.

Fluted container: Container with a series of long, rounded lines that are cut into the surface. This container does not have a smooth feel on touching due to the lines. They are used to dispense preparation for external use. Preparation must not be consumed internally.

Storage Conditions:

Freezer: Temperature is maintained between -20oC to -10oC.

Cold place: Any temperature not exceeding 8 oC. A refrigerator is a cold place in which the temperature is maintained between 2oC to 8oC.

Cool place: Any temperature between 8oC and 15 oC. An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator, unless otherwise specified by the individual monograph.

Room Temperature: The temperature prevailing in a working area.

Controlled Room Temperature: Thermostatically controlled room temperature is between 20oC to 25oC. An article, for which storage at controlled room temperature is directed may alternatively be stored in a cool place, unless otherwise specified in the individual monograph or on the label.

Warm: Any temperature between 30^{o}C to 40^{o}C.

Excessive Heat: Any temperature above 40^{o}C.

Protection from freezing: Where, in addition to the risk of breakage of the container, freezing subjects an article to loss of strength or potency, or to destructive label bears an appropriate instruction to protect the article from freezing.

Powder description:

Indian pharmacopoeia has prescribed standards for powders for pharmaceutical purpose. Accordingly, degree of coarseness or fitness is expressed with reference to the nominal aperture size of sieve through which powder is able to pass.

Coarse Powder: It is powder in which all the particles pass through sieve.No.10 (having nominal mesh aperture of 1.7 mm) and not more than 40 percent through a sieve.No.44 (having nominal mesh aperture of 355 µm). It is also referred to as a 10/44 powder.

Moderately coarse powder: It is powder in which all the particles pass through sieve.No.22 (having nominal mesh aperture of 710 µm) and not more than 40 percent through a sieve.No.60 (having nominal mesh aperture of 250 µm). It is also referred to as a 22/60 powder.

Moderately fine powder: It is powder in which all the particles pass through sieve.No.44 (having nominal mesh aperture of 355 µm) and not more than 40 percent through a sieve.No.85 (having nominal mesh aperture of 180 µm). It is also referred to as a 44/85 powder.

Fine powder: It is powder in which all the particles pass through sieve.No.85 (having nominal mesh aperture of 180 µm).

Very fine powder: It is powder in which all the particles pass through sieve.No.120 (having nominal mesh aperture of 125 µm).

Micro fine powder: It is powder in which all the particles pass through a sieve with a nominal mesh aperture of 45 µm.

Superfine powder: It is powder in which not less than 90% by numbers of the particles are less than 10 µm in size.

SYRUP

SYRUPS

INTRODUCTION

Definition: Syrups are concentrated oral solutions of sugar or nearly saturated solutions of sucrose in water or other aqueous liquids. About 85% w/v or 65% w/w syrups will retard the growth of microorganisms. It is important to note that sucrose concentration should not reach the saturation point as a saturated solution of the sucrose may lead to crystallization of a small amount of sucrose due to change of physical condition viz., temperature. Dilute solution of sucrose provides an excellent nutritional source for yeast, moulds and other microorganisms. When heat is employed for the preparation of syrups, in small portion changes in dextrose and levulose occur. This phenomenon is called as inversion. Sucrose solution is optically active & rotates polarized light to right, while on heat optical activity decrease; rotate the light to left due to formation of other compounds (dextrose and levulose).The rate of inversion is enhanced by the presence of acids and hydrogen ions, which acts as a catalyst.

Formulatory ingredients used in the preparation of Syrups are

1) Vehicle – E.g.: Water, Glycerin
2) Coloring agents – E.g.: Amaranth, Tatrazine
3) Preservatives – E.g.: Sodium benzoate, Methyl paraben, Propyl paraben
4) Flavoring agents - E.g.: - Tincture of lemon, Tincture of ginger
5) Stabilizers – E.g.: Glycerin, Sorbital

Classification of Syrups:

Simple syrup: It contains sucrose in purified water alone or in combination of other polyols such as glycerin or sorbitol. These substances are added in syrups to reduce the crystallization of sucrose or enhance the solubility of excipients (e.g. simple syrup etc.)

Medicated syrups: It contains some added medicinal substances in the syrups and is used for therapeutic purpose (e.g. ephedrine sulphate syrup, chlorpheneramine maleate syrup).

Flavored syrups: It contains various aromatic or pleasantly flavored substances but are non-medicated and generally used as vehicle or as a flavoring agent or for preservation. (e.g. cherry syrups, tolu balsam syrup, cocoa syrup etc.)

METHODS OF PREPARATION

Preparation of the syrup depends on the physical and chemical characteristics of the substance employed for its preparation. Four methods are commonly used for preparation of syrups.

1. Agitation without heat: This method is used for the preparation of syrup containing volatile substances. In this process active substance is added in solution and agitated in a glass-stoppered bottle. Closing of bottle is necessary to protect the syrup from contamination and loss of solution during the process. For large quantities, glass lined tank with mechanical agitators is employed for the preparation of syrups. This method is used for the preparation of wide variety of syrups. Cough syrups are commonly prepared by this process (e.g. guainefenesin syrup, codeine syrup, ephedrine sulfate syrup etc.).

2. Solution with heat: This process is generally preferred as it is simple & less time consuming method, particularly if the constituents are not affected by heat and have non volatile in nature. In this process sucrose is added in the aqueous solution and heated till the sucrose is dissolved completely. Adding remaining amount of distilled water makes up volume of the solution. If the syrups containing any protogeneous substances are coagulated, it can be separated subsequently by straining. The concentration of the syrup is measured using saccharometer at warm condition if the specific gravity of the solution is known. Excessive heating of syrup is not suitable because more inversion of sucrose occurs with the increase in temperature. Syrups can not be

sterilized in autoclave without carmelization. This solution is converted in yellowish to brown color due to formation of caramel by the effect of heat on sucrose.

3. Addition of a medicated liquid: This method is put to use in those cases in which tinctures, fluid extracts or other medicated substances in liquid forms are added to syrup to medicate it. In this process some time precipitation takes place due to presence of resinous and oily substances. It is necessary to take care that medicated substance should not get precipitate in this process.

4. Percolation: In this process, purified water or an aqueous solution is allowed to pass steady through a bed of crystalline sucrose. A plug of cotton is put in the neck of the percolator and purified water or aqueous solution is added in the percolator containing sucrose. The flow rate is controlled by the stopcock and maintained such that drops appear in rapid succession. If required, a small portion of liquid is re-passed through the percolator to dissolve the sugar completely in the liquid or aqueous solvent.

ADVANTAGES

1. They provide a pleasant means of administering a liquid form of a disagreeable tasting drug.

2. They are very much liked by youngsters & children due to their pleasant taste.

3. Any water soluble drug which is stable in aqueous solution may be added to flavored syrup.

4. Syrup contains little or no alcohol.

5. They are used as vehicles in extemporaneous compounding.

6. If the concentration of sugar in syrup is more than 85% w/v, they act as self- preservative.

DISADVANTAGES

1. They are not suitable for patients who are on a restricted intake or those who are diabetic.

2. They may cause an increase in dental caries and gingivitis.

Examples: Orange syrup, lemon syrup, pediatric paracetamol syrup, senna syrup.

PRESERVATIVES

USP suggests that syrup should be kept at low temperature, about 25oC. Concentration without super saturation is suitable for preservation. Following preservatives are used to prevent bacterial and mould growth viz., methylparaben, sodium benzoate, benzoic acid, glycerin etc., in combination of alkyl esters of P-hydroxybenzoic acid are effective to inhibit the yeast growth in syrups.

LABELLING

Label of the syrup should have following information such as

- Category
- Composition
- Date of manufacturing
- Expiry date
- Storage conditions

STORAGE

Syrups should be kept in well-closed containers and stored at temperature below 30^0C. Bottle should be completely filled, carefully sealed and stored in cool dark place.

Experiment No :01

SIMPLE SYRUP

Aim: To prepare and submit 20ml of simple syrup.

Requirements: Bunsen burner, funnel, filter paper, beaker, glass rod, water bath, measuring cylinder, weighing balance and chemicals listed in the formula.

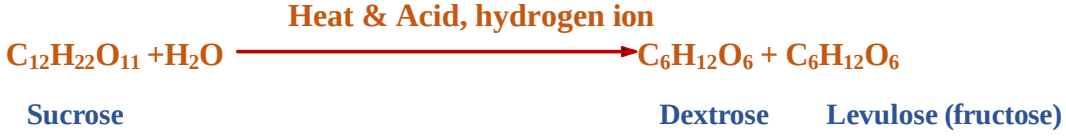
Category: Sweetening agent, Pharmaceutical aid

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Sucrose	667g	13.34g	Sweetening agent
2	Purified water q.s	1000g	20ml	Vehicle

Principle: Simple syrup IP is a concentrated nearly saturated, viscous solution of sucrose in purified water. It contains 66.7% w/w sucrose in purified water. Simple syrup IP differ from syrup USP in terms of concentration of sucrose used to prepare it. Syrup USP contains 85% w/v sucrose in purified water. Simple syrup acts as self-preservative, because it is concentrated solution of sucrose and no additional water is available for growth of microorganisms. Sucrose at 66.7% w/w strength in syrup exerts high osmotic pressure which it withdraws water from microorganism and causes their dehydration followed by their death.

Simple syrup IP is prepared by solution by heat method. Overheating is avoided because it will cause caramelization. When overheat is used in the preparation of syrups, inversion of a slight portion of the sucrose may take place. This reaction is termed as 'inversion' because 'invert sugar' (dextrose + levulose) is formed.



- Invert sugar is sweeter than sucrose. Hydrogen ions act as catalyst in the reaction.
- The sucrose in the 66.7% w/w solution must be at least 95% inverted.

- The invert syrup, when mixed with suitable proportion with syrup, prevents the deposition of crystals of sucrose under most conditions of storage.
- Invert sugars are readily fermentable than sucrose tend to dark in color.

Procedure:

1. Depending on the quantity of preparation to be submitted, the working formula is calculated. (Calculation is done for excess than the quantity to be submitted to overcome loss during preparation)
2. A clean dry 100ml empty glass beaker is weighed and weight is noted
3. The weight of the beaker is tarred.
4. _____g of sucrose is weighed in the same beaker.
5. To the beaker containing sucrose _____ml of water is added.
6. The beaker is removed from the balance placed on a tripod stand and heated over a bunsen burner employing over wire gauze (if needed).
7. The syrup is strained in the hot condition (to remove any extraneous materials) into another clean dry beaker.
8. The syrup is allowed to cool down to room temperature.
9. A dry, narrow mouthed container is placed on a balance and tarred. The quantity of syrup to be submitted is carefully transferred into the container without spilling onto the balance.
10. The container is capped labeled & submitted.

Precautions:

- Overheating of sugar solution should be avoided because sugar will caramelize. This is indicated by black color of the solution.
- Hot syrup should not be packed in the final container because the water vapor will condense on the surface leading to lesser concentration of sucrose, which acts as a nutrient medium and leads to microbial contamination.

Category: Pharmaceutical aid as sweetening agent & vehicle.

Dose: Non-medicated preparation, hence no dosage specifications.

Storage: Store in a well closed container in a cool temperature not exceeding 25^{o}C.

Label: **"SHAKE WELL BEFORE USE"**

Direction: Non-medicated preparation, hence no dosage specifications.

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……. ml of Simple Syrup IP

Experiment No: 02

SYRUP OF EPHEDRINE HCl NF

Aim: To prepare and submit 20ml of Syrup of Ephedrine Hcl NF.

Requirements: Bunsen burner, funnel, filter paper, beaker, glass rod, water bath, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Expectorant (used to treat cough, helps in expelling the sputum from lungs by thinning the mucous and also lubricates the irritated respiratory tract)

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Ephedrine hydrochloride	4gm	0.08gm	Expectorant
2	Syrup qs to	1000ml	20ml	Vehicle

Preparation of syrup: Weigh 667gm of sucrose, dissolve in 700ml of water by heating & make up the volume to 1000ml with water.

Principle: Ephedrine HCI is an expectorant drug that increases respiratory tract secretion and by lowering its viscosity these agents helps to expel the allergens. Hence these are used in cough preparations.

Procedure:

- Dissolve required amount of ephedrine in small amount of syrup.
- Filter into previously calibrated bottle to remove un dissolved solid
- Make up the volume to the required level with syrup
- Label and dispense

Category: Expectorant

Dose: 5-10 ml

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

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Syrup of Ephedrine Hcl

Experiment No:03

SYRUP OF VASAKA IP

Aim: To prepare and submit 20ml of Syrup of Vasaka IP.

Requirements: Bunsen burner, funnel, filter paper, beaker, glass rod, water bath, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Expectorant (used to treat cough, helps in expelling the sputum from lungs by thinning the mucous and also lubricates the irritated respiratory tract)

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Vasaka liquid extract	500 ml	10 ml	Expectorant
2	Glycerine	100 ml	2 ml	Vehicle
3	Syrup qs to	1000 ml	20ml	Sweetening agent and Vehicle

Preparation of syrup: Weigh 667gm of sucrose, dissolve in 700ml of water by heating & make up the volume to 1000ml with water.

Principle: Vasaka is an expectorant drug that increases respiratory tract secretion and by lowering its viscosity these agents helps to expel the allergens. Hence these are used in cough preparations. Vasaka liquid extract can be obtained by percolation process. Glycerine imparts viscosity to the preparation, which increases the contact of preparation in throat. Vasaka liquid extract contains 15-18% of alcohol which acts as preservative. Simple syrup is the solvent and sweetening agent.

Procedure:

- Measure required amount of vasaka liquid extract, mix with glycerine
- Filter if needed into previously calibrated bottle to remove undissolved solid
- Make up the volume to the required level with syrup
- Label and dispense

Category: Expectorant

Dose: 2-4 ml

Storage: Store in a well closed container in cool and dry place

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Syrup of Vasaka IP

Experiment No: 04

SYRUP OF FERROUS PHOSPHATE

Aim: To prepare and submit 20ml of syrup of ferrous phosphate

Apparatus: Beaker, Glass rod, measuring cylinder, conical flask, water bath.

Category: Calcium and iron tonic (Haematinic)

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Sucrose	700 g	14 g	Sweetening agent
2	Calcium carbonate	13.6 g	272 mg	Supplement
3	Iron turnings	4.3 g	86 mg	Supplement
4	Cochineal	3.5 g	70 mg	Colouring agent
5	Potassium bicarbonate	1g	20 mg	Supplement
6	Sodium phosphate	1g	20 mg	Supplement
7	Orange flavor water	50 ml	1ml	Flavoring agent
8	Phosphoric acid	48 ml	0.96 ml	Supplement
9	Purified water qs to	1000 ml	20 ml	Vehicle

Principle: Insufficiency of iron in body leads to anemia. In such conditions this preparation is given as iron supplement. Iron is given in the form of ferrous (iron upon reacting with phosphoric acid gets converted into ferrous form) as it is easily absorbed by body. Anemia is also associated with electrolyte deficiency. To compensate the same, salts such as sodium & potassium are included in the preparation. Calcium in the form of carbonate is included as additional supplement. Sucrose is the sweetening agent, orange water as flavor, Cochineal coloring agent (obtained from insect imparts red color) and water acts as solvent. Heating on water bath is recommended to minimize volatilization of water. If the reaction mixture is dried, solid blocks are formed which is not possible to dissolve again in water. Oxidation during heating cannot occur as long as hydrogen gas is evolving.

$$Fe + 2H3PQ4 \rightarrow Fe\,(H2P04)2 + H2\uparrow$$

Excess of phosphoric acid reacts with potassium bi carbonate, sodium phosphate and calcium carbonate to yield respective acid phosphates.

$$CaCO_3 + 2H_3PO_4 \longrightarrow Ca\,(H2P04)2 + H20 + C02\uparrow$$

$$KHCO_3 + H_3PO_4 \longrightarrow KH2P04 + H20 + C02\uparrow$$

$$Na_2HPO_4 + H_3PO_4 \longrightarrow 2NaH2P04$$

Procedure:

- Heat gently on a water bath in a small flask 0.5 ml of water with 0.4 ml of phosphoric acid along with small pieces of iron turnings.
- Triturate calcium carbonate, potassium bicarbonate and sodium phosphate with remaining quantity of phosphoric acid and 1.6 ml of water.
- To the triturated mixture add the solution of iron phosphate (prepared in first step)
- Boil Cochineal with 7.5 ml of water, add sucrose and again boil to dissolve the same.
- Cool the syrup, strain and make up the volume to 16 ml
- Filter into this syrup above prepared iron phosphate solution containing different salts (triturated mixture).
- Add orange flavor water and water quantity sufficient to 20 ml.
- Allow it to settle for 48h, filter if necessary

Category: Haematinic (used to treat iron deficiency anemia, increases hemoglobin content of blood) and calcium supplement

Dose: 2-8 ml

Storage: Store in a well closed container in cool and dry place

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of syrup of ferrous phosphate

Experiment No:05

ORANGE SYRUP

Aim: To prepare and submit 20ml of Orange syrup.

Requirements: Bunsen burner, funnel, filter paper, beaker, glass rod, water bath, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Sweetening agent, Pharmaceutical aid

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Orange tincture	50ml	1 ml	Flavoring agent
2	Syrup up qs to	1000ml	20ml	Sweetening agent &Vehicle

Preparation of orange tincture: Orange tincture is prepared by extracting volatile oil from the orange peel by maceration with 90% alcohol.

Preparation of syrup: Weigh 667gm of sucrose, dissolve in 700ml of water by heating & make up the volume to 1000ml with water.

Principle: Orange syrup is an example for non-medicated syrup. It is used as a flavoring agent. Orange tincture is the alcoholic extract of orange peel. Syrup acts as vehicle and sweetening agent. The preparation should be stored in well closed container in cool place to avoid vaporization of volatile oil.

Procedure:

- Pipette out required amount of orange tincture into a beaker
- Add small amount of syrup & mix
- Filter to remove un dissolved solid
- Add into previously calibrated bottle
- Make up the volume with syrup to the required level
- Label and dispense

Category: Pharmaceutical aid as sweetening & flavoring agent
Storage: Store in a well closed container in cool and dry place
Report: Prepared & submitted ……ml of Orange Syrup IP

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ELIXIRS

ELIXIRS

INTRODUCTION

Elixirs are defined by the USP as "clear, sweetened, hydro alcoholic liquids intended for oral use." Their alcohol content ranges from 5-40% (10-80 proof), e.g. Phenobarbital Elixir, USP. Elixirs are flavored hydro alcoholic solutions to which glycerin often is added to enhance the solvent properties and act as a preservative. The alcoholic contents of elixirs varies widely; actually a few commercial elixirs contain no alcohol, while other elixirs may contain as much as 40% alcohol. The concentration of alcohol is determined by the amount required to maintain the drug or volatile oil in solution. The addition of aqueous solutions to elixirs may cause turbidityor separation by lessening the alcohol concentration.

Non-medicated elixirs

They are used as solvents or vehicles for the preparation of medicated elixirs: aromatic elixirs, isoalcoholic elixirs (NF), or compound benzaldehyde elixirs (NF). Active ingredient dissolved ina solution that contains 15 to 50% by volume of ethyl alcohol.

Medicated elixirs

- Antihistaminic elixirs: used against allergy: Chloramphenirамine maleate elixirs (USP), diphenhydramine HCl elixirs.
- Sedative and hypnotic elixirs: sedatives induce drowsiness, and hypnotics induce sleep: pediatric chloral hydrate elixirs.
- Expectorant: used to facilitate productive cough (cough with sputum): Terpin hydrate elixirs.
- Miscellaneous: Acetaminophen (paracetamol) elixirs, which are used as analgesics.

FORMULATION

An elixir is a hydro-alcoholic solution of at least one active ingredient. The alcohol is mainly used to

- Solubilize the active ingredients and some excipients
- Retard the crystallization of sugar
- Preserve the finished product
- Provide a sharpness to the taste
- Aid in masking the unpleasant taste of the active ingredients

The lowest alcoholic quantity that will dissolve completely the active ingredient(s) and give a clear solution is generally chosen. High concentrations of alcohol give burning taste to the final product. An elixir may also contain the following excipients:

- Sugar and/or sugar substitutes like the sugar polyols glycerol and sorbitol.
- Preservatives like parabens, benzoates and antioxidants like butylated hydroxytoluene (BHT) and sodium metabisulfite.
- Buffering agents
- Chelating agents like sodium ethylene diamine tetra acetic acid (EDTA)
- Flavoring agents and flavor enhancers
- Coloring agents

Vehicle is the main part of the preparation that carries the drug.

- **Production of a clear solution:** Flavoring agents containing essential oils or precipitates from plant extract may produce faint cloudiness. To keep the essential oils in solution state10 – 20% of alcohol is added. Glycerol (i.e. glycerin) is added to keep the essential oil in to solution and to dissolve some ingredients of plant extracts like tannins and their oxidation products.
- **Solution of medicament of low water solubility:** If the drug is not completely soluble in water then a mixed solvent is used to dissolve the drug (i.e. medicament). E.g. phenobarbitone is dissolved in alcohol, glycerol and water; paracetamol is dissolved inalcohol, propylene glycol and glycerol. Alcohol is avoided in paediatric elixirs hence in paediatric Paracetamol Elixir propylene glycol is used as the main solvent.
- **Production of a palatable preparation:** The vehicle of many elixirs is syrup or flavored syrup.

Adjuvants

Chemical Stabilizers: Some special chemicals are required to make the elixir stable.
E.g. Citirc acid, disodium edetate etc.

Coloring agents: Many elixirs are attractively colored by coal tar dyes.
E.g. Amaranth (magenta red), Compound Tartrazine (saffron),and Tartrazine (Green).

Flavoring agents: Sweetening agents and fruit flavors are used.
Sweetening agents: e.g. Plain and flavored sucrose syrup, glycerol, sorbitol, invert syrupand saccharin sodium.

Fruit flavor: Blackcurrant syrup (to mask bitter taste of drug), Raspberry Syrup (to mask bitter taste of drug), Compound Orange Syrup (to mask sour and bitter taste of drugs).

Preservatives: To reduce the mould growth and fermentation preservatives are added.

- Vehicle containing 20%v/v alcohol, propylene glycol or glycerol have preservativeaction.
- High concentration of syrup has high osmotic pressure thus acts as preservative.
- Chloroform Water, Chloroform Spirit have preservative action.
- Benzoic acid, methyl parahydroxy benzoate acid (methyl paraben) or propyl para hydroxybenzoate (propyl paraben) may be used as additional preservatives.

Experiment No:06

PIPERAZINE CITRATE ELIXIR

Aim: To prepare the 20 ml of Piperazine Citrate Elixir.

Requirements: Beakers, glass rod, measuring cylinder and chemicals listed in the formula.

Category: Anthelmintic

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Piperizine citrate	180 gm	3.6 gm	Anthelmintic
2	Chloroform spirit	6 ml	0.12 ml	Preservatives
3	Glycerol	100ml	2 ml	Sweetening agent
4	Orange oil	0.25 ml	0.005 ml	Flavouring agent
5	Syrup	500ml	10 ml	Pharmaceutical aid
6	Water qs to	lOOOml	20ml	Vehicle

Principle: Elixirs are pleasantly flavored sweetened hydro alcoholic solutions for oral use. Piperizine Citrate is an anthelmintic drug that paralyzes the worms wh ich gets expelled due to peristaltic movement of intestine. Chloroform spirit acts as flavoring agent and preservative. Glycerol makes the preparation viscous and adds on taste. Orange oil acts as flavor and syrup as sweetening agent.

Procedure: Piperazine citrate is dissolved in small amount of purified water. Glycerol, syrup and chloroform spirit are mixed. Sufficient volume of water is added to produce the final volume.

Dispensing: Transfer the elixir to a clear or amber colored, narrow mouthed glass bottle, close it thoroughly with metallic screw cap, polish and label.

Storage: Store in a closed container at a temperature not exceeding 25°C.

Direction: 4-15ml daily in divided doses to be taken at night.

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Piperazine Citrate Elixir.

Note: Anthelmintic is a type of drug or herbal preparation given to destroy the parasitic worms or expel them from the body.

Experiment No:07

CASCARA ELIXIR B.P.C

Aim: To prepare the 20 ml of Cascara Elixir.

Requirements: Beakers, glass rod, measuring cylinder, Iodine flask, Iodine flask, Separating funnel, Tripod stand, Wire Gauze, Water bath and chemicals listed in the formula.

Category: Purgative

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Cascara coarse powder	1000 gm	100 gm	Purgative
2	Saccharin sodium	1 gm	0.1 gm	Sweetening agent
3	Light magnesium oxide	50 gm	5 gm	PH modifier
4	Liquorice coarse powder	125 gm	12.5 gm	Antioxidant, Anti ulcer & Anti inflammatory
5	Coriander oil	0.15 ml	0.015 ml	Digestive aid
6	Anise oil	0.2 ml	0.02 ml	Flavouring agent
7	Alcohol 90%	12.5 ml	0.125 ml	Preservatives
8	Glycerine	300 ml	30 ml	Sweetening agent & Viscosity inducer
9	Water up to	1000 ml	100ml	Vehicle

Principle: Cascara powder is obtained from bark of Cascara Sagrada. It is used as purgative. Elixir is prepared by percolation process using water as menstrum. Since cascara has nauseating odor and bitter taste saccharin sodium and liquorice powder are added as sweetening agent. Light magnesium oxide converts bitter substance into less bitter magnesium salt. Coriander and anise oil acts as flavor to mask bitter taste of drug. Since these oils are soluble in alcohol, it is used as co solvent in the preparation. Alcohol acts as preservative as well. Glycerine adds on taste and imparts viscosity to the preparation.

Procedure:

- Moisten the mixture of cascara, liquorice and light magnesium oxide with boiling water.
- Stir thoroughly and macerate for 24 hrs
- Pack moderately in a percolator and percolate with boiling water until drug is exhausted

- Evaporate the percolate on a water bath
- Dissolve saccharine sodium in water, flavoring oils in alcohol
- Mix both the solutions with glycerin.
- Add this to concentrated percolate and make up the volume with water

Category: Purgative (a strong laxative- causes vigorous evacuation of bowel)

Dose: 2-5 ml

Storage: Store in a well closed container in cool place

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Cascara Elixir.

Experiment No. 8

PARACETAMOL ELIXIR B P C

Aim: To prepare the 20 ml of paracetamol Elixir.

Requirements: Beakers, glass rod, measuring cylinder, Tripod stand, Wire Gauze, Water bath and chemicals listed in the formula.

Category: Analgesic and Antipyretic

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Paracetamol	24gm	0.48gm	Analgesic and antipyretic
2	Amaranth solution	2ml	0.04ml	Colouring agent
3	Chloroform spirit	20ml	0.4ml	Preservatives
4	Alcohol (95%)	100 ml	2ml	Solvent
5	Invert syrup	275ml	5.5 ml	Sweetening agent
6	Propylene glycol	100 ml	2ml	Stabilizer & humectant
7	Con. Raspberry syrup	25 ml	0.5 ml	Flavouring agent
8	Glycerine qs to	1000ml	20ml	Vehicle

Preparation of Invert syrup: Weigh 667gm of invert sugar, dissolve in 700ml of water by heating & make up the volume to 1000 ml with water.

Principle: Paracetamol has low water solubility; hence it is dissolved in a mixture of alcohol, propylene glycol and chloroform spirit (co solvents). As this preparation is meant for children, amount of alcohol is limited. But at this concentration of alcohol paracetamol is not completely soluble and hence mixture of solvents is used. Chloroform spirit and alcohol together acts as preservative. Amaranth solution acts as coloring agent, concentrated raspberry syrup and invert syrup as sweetening agent. Glycerine adds on taste and acts as viscous vehicle.

Since sucrose is insoluble in alcohol, instead of simple syrup invert syrup is used to avoid precipitation of sucrose.

Procedure:

- Dissolve paracetamol in a mixture of alcohol, propylene glycol and chloroform spirit
- To this add invert syrup, concentrated raspberry syrup, amaranth solution and mix
- Transfer the content into a previously tared container using funnel and filter paper
- Make up the volume to the required level with glycerine.

Category: Analgesic (relieve pain without causing loss of consciousness) and antipyretic (reduces elevated body temperature to normal level)

Dose: 1-5 ml

Storage: Store in well closed light resistant container

Caution: Do not use for more than two days. To be given under medical supervision for infants.

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Paracetamol Elixir.

LINCTUSES

LINCTUSES

INTRODUCTION

Linctuses are viscous, liquid oral preparations that are usually prescribed for the relief of cough. They usually contain a high proportion of syrup and glycerol which have a demulcent effect on the membranes of the throat. The dose volume is usually small (5 ml). In order to prolong the demulcent action, they should be taken undiluted and should be labeled by **"*to be swallowed slowly without the addition of water*".**

Syrups are concentrated aqueous solutions of a sugar usually sucrose in water or other aqueous polyols like glycerol or Sorbitol. When purified water alone is used in making the solution of sucrose, the preparation is known as syrup or simple syrup. Syrups also could containother polyols such as glycerol, Sorbitol, alcohol and flavored substances. Syrups as such are not intended to be administered as such but are used as a vehicle for other ingredient because of its flavoring and sweetening properties.

The linctuses may contain the following excipients:

- Preservatives: - Chloroform water, Benzoic acid.
- Flavoring agents and flavor enhancers:- Lemon syrup.
- Coloring agents:- Compound Tatrazine solution.
- Stabilizers: -Syrups.
- Vehicles: -Syrup, glycerin, chloroform water.

Experiment No:09

SIMPLE LINCTUS B.P.C

Aim: To prepare the 20 ml of Simple Linctus.

Requirements: Beakers, glass rod, measuring cylinder,Tripod stand, Wire Gauze, Water bath and chemicals listed in the formula.

Category: Demulcent

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Citric acid monohydrate	25gm	0.5 gm	Demulcent
2	Cone. Anise water	10ml	0.2ml	Flavouring agent
3	Amaranth solution	15 ml	0.3 ml	Colouring agent
4	Chloroform spirit	60ml	1.2ml	Preservatives
5	Syrup up to	1000 ml	20ml	Sweetening agent & Vehicle

Preparation of syrup: Weigh 667gm of sucrose, dissolve in 700ml of water by heating & make up the volume to 1000ml with water.

Principle: Simple linctus contains citric acid mono hydrate as active ingredient, which acts as demulcent. Concentrated anise water is added to give a pleasant odour. Amaranth solution is a colouring agent. Chloroform spirit acts as preservative. Simple syrup is used as vehicle and sweetening agent.

Procedure:

- Dissolve citric acid monohydrate in part of simple syrup.
- Add rest of the ingredients in this solution
- Transfer into a calibrated bottle using funnel and filter paper
- Make up the volume to the level with syrup
- Label and dispense

Category: Demulcent (relieves irritation of mucous membrane of throat by forming protective film)
Dose: 5 ml four times a day
Storage: store in a well closed air tight container in cool and dry place
Direction: sip and swallow slowly without dilution.
Route of administration: Given orally when used in formulations.
Report: Prepared & submitted ……ml of Simple Linctus.

Experiment No: 10

PEDIATRIC SIMPLE LINCTUS B.P.C

Aim: To prepare the 20 ml of Pediatric Simple Linctus.

Requirements: Beakers, glass rod, measuring cylinder, Tripod stand, Wire Gauze, Water bath and chemicals listed in the formula.

Category: Demulcent

Formula:

Sl.No	Ingredients	Official formula	Working formula	Uses
1	Simple linctus	250ml	5 ml	Demulcent
2	Syrup up to	1000 ml	20ml	Vehicle

Preparation of syrup: Weigh 667gm of sucrose, dissolve in 700ml of water by heating & make up the volume to 1000 ml with water.

Preparation of simple linctus: Dissolve citric acid in part of syrup, add concentrated anise water, amaranth solution & chloroform spirit. Mix well and make up the volume with simple syrup.

Principle: It is used as demulcent for children in the treatment of cough. Since children need lesser dose than adult, simple linctus is diluted with simple syrup. Simple syrup acts as sweetening agent.

Procedure:

- Mix simple linctus with simple syrup
- Filter into a previously calibrated bottle
- Make up the volume in with syrup
- Label and dispense

Category: Demulcent
Dose: 5-10 ml
Storage: store in a well closed air tight container in cool and dry place
Direction: sip and swallow slowly without dilution.
Route of administration: Given orally when used in formulations.
Report: Prepared & submitted ……ml of Pediatric Simple Linctus.

SOLUTIONS

SOLUTIONS

INTRODUCTION

Solution is a clear homogeneous mixture, which is prepared by dissolving solid, liquid or gas in another liquid. In a solution, the component which is present in large amount is known as solvent and the component present in lesser amount is known as solute. Solutions may be used internally, externally or parenterally. Solutions are sub-classified into four types depending on their use as,

i) Solutions meant for internal (oral) use.

ii) Solutions used only in mouth and throat.

iii) Solutions applied to the body surfaces.

For the preparation of solutions along with medicament, following additives are used

1) Vehicles:

Sl.No	Type	Examples	Uses
1	Water	a) Potable water b) Freshly boiled and cooled water c) Purified water d) Distilled water	Used for most of the liquid preparations,where flavoring is not required.
2.	Aromatic waters	a) Chloroform water	Flavoring agent and preservative
		b) Cinnamon water	Flavoring agent and carminative.
		c) Peppermint water	Flavoring agent, carminative and weakpreservative.
		d) Anise water	Flavoring agent and carminative
		e) Dill water	Flavoring agent, carminative (particularlyfor infants in gripe water).
3.	Alcohols	a) Ethanol	Solvent, co solvent for many liquid preparations like elixirs, lotions, liniments.
		b) Glycerin	Solvent, co solvent for many oral preparations and external preparations.
		c) Polyethylene glycol(PEG)	Solvent for liquid preparations like Elixirs,lotions, liniments and syrups.
		d) Sorbitol	Solvent, vehicle for many liquid preparations.
		e) Propylene glycol	Solvent, co solvent and vehicle for manyliquid preparations.

4.	Elixirs	Non medicated elixirs a) Low alcoholicelixirs b) High alcoholicelixirs c) Iso-alcoholic elixirs	Aromatics and vehicles for many oralliquid preparations.
5.	Syrups	a) Orange syrup b) Raspberry syrup c) Cherry syrup d) Glycyrrhiza syrup e) Coca syrup	Most of the syrups are used as sweetening agent, flavoring agent and vehicles in oral liquid preparations.

2) Preservatives:

Benzalkonium chloride	Dichlorophenol
Benzoic acid	Methyl paraben
Cetrimide	Phenol
Chlorbutanol	Phenyl mercuric nitrate
Chloro benzoic acid	Propionic acid
Chloro cresol	Propyl paraben
Dichloro acetic acid	Salicylic acid
Dichloro mete xylenol	Sodium benzoate

3) Antioxidants (stabilizers)

Ascorbic acid	Maleic acid
Beta-naphthol	Propyl gallate
Butylated hydroxyl anisole (BHA)	Sodium bisulphite
Butylated hydroxyl toluene (BHT)	Sodium metabisulphite
Citric acid	Sodium sulphite
Cysteine	Sodium thiosulphate
Gallic acid	thioglycerol
Lecithin	Thiourea

4) Sweetening agents:

Cyclamates	Maltose
Dextrose(glucose)	Malt extarct
D-fructose	Saccharin
Glycyrrihiza glycerin	Sodium saccharin
Glycyrrihiza extract	Sorbitol
Lactose	Sucrose
Tolu balsam	Liquid glucose

5) Flavoring agents:

FLAVOURS	**OILS**	**SPIRITS**
Banana flavor	Anise oil	Aromatic spirit of ammonia
Cardamom flavor	Caraway oil	Chloroform spirit
Ginger flavor	Clove oil	Compound orange spirit
Orange flavor	Lemon oil	Lemon spirit
Pineapple flavor	Orange oil	Peppermint spirit
Vanilla flavor	Peppermint oil	
Chocolate flavor	Rose oil	

6) Coloring agents:

a) Natural colors	Carotene, Chlorophyll, Cochineal, Curcumin, Red and yellow ferric oxide, Titanium dioxide
b) Artificial color	Caramel
c) Coal tar colors 1) blue color 2) brown color 3) black color 4) green color 5) red color 6) yellow color 7) orange color	 Brilliant blue, indigo carmine Resorcin brown Naphthol blue(black) Quinazolinone green, fast green, brilliant green Amaranth, erythrosine Sunset yellow, tartrazine yellow Orange “G”

1. Flocculating, suspending and wetting agents:

Sl. No	Type	Examples	
1.	Flocculating agents	a. Surfactants	Tweens, Spans
		b. Electrolytes	Aluminium Chloride, Potassium Phosphate
		c. hydrophilic polymers	hydrocolloids, bentonite, alginates, carbowaxes, silicates
2.	Suspending and thickening agents	a. natural polysaccharides	Gum acacia, gum tragacanth, guar gum, sodium alginate, starch, xantham gum
		b. semisynthetic polysaccharides	Methyl cellulose Sodium carboxy methyl cellulose Hydroxyl ethyl cellulose Hydroxyl propyl cellulose Hydroxyl propyl methyl celluloseMicro crystalline cellulose
		c. Inorganic agents	Clays, bentonite, kaolin, aluminium hydroxide
		d. synthetic agents	Colloidal silicon dioxide. Carbomer (carboxy vinyl polymer)
3.	Wetting agents	--------	Alcohol, glycerin, Tragacanth mucilage, sodium alginate,bentonite dispersion, surfactants having HLB valuebetween 7 to 9, sodium laurylsulphate, sodium dioctyl sulphosuccinate

2. Emulsifying agents

Sl.NO	TYPE	EXAMPLES	
1	Natural emulsifying agents	a. From vegetable source	Gum acacia, karaya gum, tragacanth,agar, pectin, starch, alginate, gaur gum, soya bean.
		b. From animal source	Gelatin, egg yolk, casein, lecithin woolfat, serum albumin.
2	Semi-synthetic polysaccharides	-----	Methyl cellulose, carboxy methylcellulose, sodium carboxy methyl cellulose, hydroxyl propyl methyl cellulose, micro crystalline cellulose
3	Synthetic substances	a. anionic	SLS, polypeptide condensates, trioleyl phosphate, sarcosinates, sulfosuccinates, soaps.
		b. Cationic	Alkoxyalkylamines, benzalkonium chloride, cetrimide, benzethonium chloride.
		c. non-ionic	Polyoxyethylene, polyoxyethylene alkyl ethers, polyoxypropylene, sorbitan esters, glyceryl esters, sucrose esters, polyoxyethylene fatty acid esters, macrogol esters and ethers
4	Inorganic substances	----	Magnesium oxide, milk of magnesia, magnesium trisilicate, magnesium aluminium silicate, bentonite.
5	Alcoholic substances	------	Polyethylene glycols (carbowaxes), cholesterol, lauryl alcohol, lecithin.

Methods of Preparation: The following methods are used for the preparation of solutions

1) Simple dissolution
2) Solution by chemical reaction
3) Solution by extraction

Advantages:

- The solution is the only form in which a compound can be obtained.
  Eg: H_2O_2 solutions
- The Solution is more stable and convenient that the solid component.
  Eg: Ferric chloride solution
- The solution provides a convenient form for prescribing and dispensing substances

Disadvantages:

- Bulk volume of solution to be consumed is high when compound to solids of equivalent dose.
- Cost of solutions per unit dose is relatively high when compared to solids dosage forms.
  E.g.: Aspirin solution undergoes rapidly hydrolysis compared to aspirin tablets.

Experiment No:11

CRESOL WITH SOAP SOLUTION

Aim: To prepare and submit 20 ml of Cresol with Soap Solution

Requirements: Bunsen burner, water bath, beaker, dropper, funnel, filter paper, glass rod, test tubes, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Disinfectant

Synonym: Lysol solution

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Cresol	500ml	10ml	Disinfectant
2	Vegetable oil	180 ml	3.6 ml	Source of fatty acids
3	Potassium Hydroxide	42 gm	0.84 gm	Alkali
4	Purified water q.s	1000ml	20ml	Vehicle

Principle:

Cresol is solution soluble in water to extent 2% v/v. But Lysol containing 50% v/v is very effective disinfectant. It kills microorganisms as it possess bactericidal and detergent properties. Solubility of cresol in water can be enhanced by using soap.

Soaps are surfactants, at high concentration of soap; the surfactant molecules saturate the surface and start forming aggregates in solution micelles. These micelles have hydrophobic core which can solubilize the hydrophobic substance. Above critical micelle concentration cresol, cresol gets selectively entrapped inside spherical micelles. The solubility of cresol is increased. Soap is prepared by a saponification reaction between alkali and vegetable oil (fatty acids). The vegetable oils may be cotton seed, linseed oil, soybean oil or similar oils which have a saponification value greater than 205 and iodine value not less than 100 (excluding coconut oil and palm kernels oil). The alkali is potassium hydroxide or sodium hydroxide solution may be used.

Triesters (triglycerides) + Strong base (KOH) $\xrightarrow[\text{Heat}]{\text{Hydrolysis}}$ **Soap (cleavage of ester bond & releases fatty acid salt and glycerol)**

Cresol with soap solution cannot be used on human beings because of its necrotic effect to animal tissue. Even 5 to 10% aqueous solution of cresol irritate the skin of many people.

Procedure:

1. Depending on the quantity of preparation to be submitted, the working formula is calculated.
2. Potassium hydroxide is dissolved in 1/4th the quantity of purified water.
3. Vegetable oil is added to above alkali solution, heat on a water bath mix thoroughly.
4. Heating is continued until completion of a saponification reaction. Prolonged heating is necessary to complete saponification. This can be confirmed by the following miscibility test.

Test	Observation	Inference
A few drops of reaction mixture + a few drops of water	Remained completely miscible	Saponification completed stop heating continue
	Remained immiscible	Heating until complete saponification

5. Cresol is added and mixed thoroughly.
6. Makeup volume to desired level using purified water.
7. Transfer the contents into a previously cleaned and marked bottle (light resistant container) using a funnel and filter paper.
8. Label the container & dispense.

Category: Disinfectant

Label: "FOR EXTERNAL USE ONLY" "FOR TOILET USE ONLY"

Dispensing: Transfer the solution to a clear or amber colored, narrow mouthed glass bottle, closeit thoroughly with metallic screw cap, polish and label.

Storage: Store in a closed container at a temperature not exceeding 25°C and protect from sunlight.

Note: Disinfectant is an agent freeing from infection or infection-producing microorganisms.

Report: Prepared & submitted ……ml of Cresol with Soap Solution

Experiment No: 12

STRONG SOLUTION OF FERRIC CHLORIDE BPC

Aim: To prepare and submit 20 ml of Strong Solution of Ferric Chloride BPC

Requirements: Beaker, conical flask, water bath, funnel, filter paper, glass rod, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Haematinic

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Iron	210 g	4g	Supplement
2	Nitric acid (Concentrated)	90 ml	1.71 ml	pH modifier
3	Hydrochloric acid (concentrated)	230 ml	23.5 ml	Catalyst
4	Water qs to	1000 ml	20 ml	Vehicle

Principle: Iron when heated with con. Hydrochloric acid it forms ferrous chloride alongside hydrogen gas. Gentle heating is preferred till evolution of hydrogen gas ceases to ensure completion of reaction.

$$Fe + 2HCl \longrightarrow FeCl_2 + H_2$$

Ferrous chloride

Impurities from iron such as carbon and carbides are removed by filtration. In the second stage ferrous chloride oxidizes to ferric chloride in presence of Hydrochloric acid (iron in reduced form is volatile).

$$2FeCl_2 + Cl_2 \longrightarrow 2FeCl_3$$

(From HCl) **Ferric chloride**

Further oxidation is made complete using nitric acid, since ferrous chloride is volatile.

$$3FeCl_2 + 3HCl + HNO_3 \longrightarrow 3FeCl_3 + 2H_2O + NO$$

The liquid when evaporated yields Ferric oxychloride precipitate due to hydrolysis of ferric chloride

$$FeCl_3 + H_2O \longleftrightarrow Fe(OH)Cl_2 + HCl$$

Ferric oxychloride

Recognition of precipitate is difficult unless appreciable quantity has been formed. However, the pungent fumes of HCI are more easily recognized and are a better indication of when to cease evaporation.

A specified quantity of hydrochloric acid is then ad$FeCl_3 + H_2O$ded to dissolve oxychloride inthe form of ferric chloride.

$$Fe(OH)Cl_2 + HCl \longrightarrow FeCl3 + H_2O$$

Ferric oxychloride **Ferric chloride**

Procedure:

- Add iron into a flask containing 8 ml of water and 14.3 ml of HCI.
- Heat gently until effervescence ceases, boil and filter undissolved iron
- Wash the content of flask and filter
- Add 8 ml of HCI to filtrate, mix and pour the solution in slow continuous stream into nitric acid (If needed with gentle heating)
- Evaporate the product, once precipitate begins to form, add HCI and sufficient water to produce 20 ml

Category: Haematinic (increases hemoglobin content of blood, used to treat iron deficiency anemia)

Dose: 0.3-1 ml

Storage: Store in a well closed container in cool place.

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Strong Solution of Ferric Chloride BPC.

Experiment No:13

AQUEOUS IODINE SOLUTION

Aim: To prepare and submit 20 ml of Aqueous Iodine solution.

Requirements: Beaker, mortar & Pestle, funnel, filter paper, glass rod, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Source of iodine, to treat goiter and topical antiseptic

Synonym: Lugol's Solution

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Iodine	50g	1g	Iodine source & antiseptic
2	Potassium Iodide	100g	2g	Complexing agent
3	Purified water q.s	1000ml	20ml	Vehicle

Principle:

Iodine is known for its germicidal activity but aqueous iodine solution is administered as a source of iodine in prevention of hypothyroidism. Iodine prevents microbial growth by halogenations and oxidations of bacterial cell protein. Iodine is slightly soluble in water and therefore potassium iodide is added in this preparation to form poly-iodides namely KI.I2, KI2 and KI3 which are water soluble. Poly- iodides are soluble in water by ion-induced dipole type of interactions. Higher poly-iodides are formed in concentrated solution and therefore iodide and potassium iodides are dissolved in small portion of water. Finally the volume is made up to target using water.

$$I_2 + KI \longrightarrow KI.I_2$$

$$I_2 + 2KI \longrightarrow 2KI_2$$

$$2I_2 + 2KI \longrightarrow 2KI_3$$

Iodine Potassium iodide Mono and poly-iodides

Procedure:

- Depending on the quantity of preparation to be submitted, the working formula is calculated.
- Dissolve potassium iodide in water in glass mortar.
- Add iodine in potassium iodide solution and triturate with glass pastel.
- Makeup volume to desired level using purified water.
- Transfer the contents into a previously cleaned and marked bottle (amber color iodine resistant glass container) using a funnel and filter paper.
- Label the container & dispense.

Category: Source of iodine, to treat goiter and topical antiseptic.

Dose: 0.3 to 1ml

Storage: Store in a well closed amber color iodine resistant glass container in a cool place.

Route of administration: Given orally when used in formulations.

Report: Prepared & submitted ……ml of Aqueous Iodine solution.

Note: Goiter is enlargement of the thyroid gland, causing a swelling in the front part of the neck

Experiment No: 14

STRONG SOLUTION OF IODINE

Aim: To prepare and submit 20 ml of Strong Solution of Iodine.

Requirements: Beaker, mortar & Pestle, funnel, filter paper, glass rod, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Antiseptic

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Iodine	100g	2g	Iodine source & antiseptic
2	Potassium Iodide	60g	1.2g	Complexing agent
3	Purified water q.s	100ml	2ml	Solvent
4	Alcohol 90% up to	1000ml	20ml	Vehicle

Principle: Iodine is sparingly soluble in water. In presence of potassium iodide, iodine form complex called polyiodides. These polyiodides have higher water solubility. Hence potassium iodide is added only to increase solubility of iodine in water.

$$I_2 + KI \longrightarrow KI.I_2$$

$$I_2 + 2KI \longrightarrow 2KI_2$$

$$2I_2 + 2KI \longrightarrow 2KI_3$$

Iodine **Potassium iodide** **Mono and poly-iodides**

Since iodine and alcohol are volatile in nature, the preparation should be stored in well closed iodine resistant container. Since this preparation is used for its antiseptic property, alcohol is employed as solvent.

Procedure:

- Dissolve potassium iodide and iodine in water
- Transfer into a previously calibrated bottle using funnel and filter paper Make up the volume to the desired level with alcohol
- Label and dispense

Category: Antiseptic (arrests the growth of microorganisms on living tissue)

Strength: Iodine 10%w/v and potassium iodide 6% w/v

Storage: Store in well closed iodine resistant container.

Route of administration: For External use only.

Report: Prepared & submitted ……ml of Strong Solution of Iodine.

Experiment No: 15

STRONG SOLUTION OF AMMONIUM ACETATE IP

Aim: To prepare and submit 20 ml of Strong Solution of Ammonium Aacetate IP.

Requirements: Beaker, funnel, filter paper, glass rod, measuring cylinder, test tubes, bromo- thymol blue indicator, thymol blue indicator, weighing balance and chemicals listed in the formula.

Category: Mild expectorant, Diaphoretic & Diuretic

Formula:

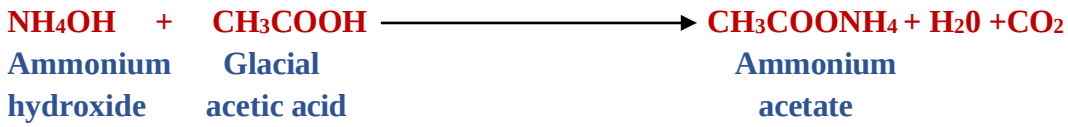
Sl. No	Ingredients	Official formula	Working formula	Uses
1	Glacial Acetic Acid	453g	9.4 gm (8.66ml)	Begins the reaction
2	Ammonium Bicarbonate	470g	9.4gm	Begins the reaction
3	Strong solution of Ammonium	100ml	2ml	To adjust pH
4	Purified water q.s	1000ml	20ml	Vehicle

Principle:

Strong ammonium acetate solution is used as diaphoretic, diuretic and expectorant. This preparation contains 57.5% w/v of ammonium acetate. Glacial acetic acid is diluted with water and ammonium bicarbonate is added in small amounts.

In the preparation following chemical reaction takes place.

Excess acid neutralization,



A large open vessel is used to allow easy escape of the carbon dioxide and avoid spillage due to frothing. The acid is incompletely neutralized by ammonium bicarbonate, because the reaction ceases as the solution becomes concentrated. Therefore, strong ammonia solution is added carefully until one drop of the preparation diluted with 10drops of purified water gives a full blue color with bromo-thymol blue or a full yellow color with thymol blue indicator solutions.

Indicators	pH Ranges	Colour Changes
Bromo thymol blue	pH 6.0 to 7.6	Yellow-green-blue
Thymol blue	pH 8.0 to 9.6	Yellow -blue

Care must be taken not to contaminate the preparation with the indicators. Finally, the preparation is adjusted up to volume with purified water.

Strong solution of ammonium acetate dissolves leads salts and should be packed in lead free bottles.

Procedure:

1. Depending on the quantity of preparation to be submitted, the working formula is calculated.
2. Glacial acetic acid is mixed with the 1/3rd the quantity of purified water. [Glacial acetic acid density wt/ml is 1.048-1.051g (1.0495) at 20°C].
3. To this add solution, ammonium bicarbonate powder is added in small quantities, till the whole quantity dissolves.
4. Sufficient strong ammonia solution is added to neutralize unreacted acetic acid. Neutralization can be confirmed by the following tests.

Tests	Observation	Inference
1 drop of solution + 10 drops of water + 1 drop of Bromo- thymol blue solution in first test tube	Yellow color pH 6.0	Continue adding ammonia solution
	Green color	Stop adding strong ammonia solution.
	Blue color >pH 7.6	Carryout the test with fresh solution as given next column
1 drop of solution + 10 drops of water + 1 drop of thymol blue solution in second test tube	Yellow color	Neutralization completed pH 7.6-8.0
	Blue color	pH>8.0 excess of ammonia is available glacial acetic acid is added and test in column 1 is repeated.

5. The final required volume is then adjusted by adding more purified water.
6. The preparation is transferred into tightly closed lead-free glass container as preparation interacts with lead salts.
7. The container is capped labeled & submitted.

Category: Mild expectorant, Diaphoretic & Diuretic

Dose: In concentrated solutions 1 to 4ml, in dilute solutions 8 to 30ml.

Storage: It should be stored in air tight lead-free glass container in a cool

Route of administration: Oral route

Report: Prepared & submitted .....ml of Strong Solution of Ammonium Acetate IP

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LINIMENT

LINIMENTS

INTRODUCTION

Liniments are solutions or mixture of various substances in oil, alcoholic solution of soap or emulsions or occasionally semi-solid preparations intended for external application and should be labeled accordingly. They are applied with rubbing or massaged into the skin as counter irritating or stimulating agents to the effected area and because of this were known as embrocations. Some liniments are applied on a warm dressing or with a brush like analyzer and soothing type.

Dental liniments, which are no longer official are solutions of active substances and are applied on to the gums by rubbing. Liniments are usually applied with friction and rubbing of the skin, the oil or soap base proving for easy of application and massage. Alcoholic liniments are used generally for their rubefacient, counter irritant, mildly astringent and shows penetrating effects. These types of liniments easily penetrate to the skin than those with oil base. The oily liniments therefore, are slow in their action but are more useful when massaged. The function of liniment depends on the additives but most of liniments may function solely as protective coating on the affected area. Liniment should not be applied to the broken or bruised skin because they would be very irritant especially if the solvent used is alcohol.

They may contain following substances such as

(a) Analgesic

(b) Antimicrobial

(c) Rubefacient

(d) Counter irritant

(e) Stimulants

(f) Soothing agents.

Alcohol is primarily used as solvent. It enhances the penetration of the medicaments into the skin and has counter irritants or rubefacient action. Counter irritants are used to mask pain from fibrositis, sciatica, neuralgia and similar complaints by producing warmth, tingling and numbness. When rubbed onto the skin, they also cause redness, are called as rubefacients.

Cottonseed oil and arachis oil are less irritant than alcohol and spread more easily on the skin.

Two types of vehicles are used for the preparation of liniments.

1. Alcohol e.g. soap liniment and aconite liniment.
2. Oils e.g. camphor liniment and methylsalicylate.

Labelling: It should comply with the general requirements for labeling. In addition, the label on the container should indicate

"FOR EXTERNAL USE ONLY" "SHAKE WELL BEFORE USE"

"NOT TO BE APPLIED TO WOUNDS OR BROKEN SKIN"

"STORE IN COOL PLACE"

"INFLAMMABLE"

Container: Narrow mouthed screw capped colored bottles can be used for storing liniments.

Experiment No:16

TURPENTINE LINIMENT IP

Aim: To prepare and submit 20 ml of Turpentine Liniment IP.

Requirements: Weighing balance, mortar and pestle, beaker, measuring cyclinder, bottle and chemicals listed in the formula.

Category: Counter irritant & rubefacient

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Soft Soap	90g	1.8 gm	Emulsifying agent
2	Camphor	50g	1gm	Counter irritant
3	Turpentine oil	650ml	13ml	Counter irritant & rubefacient
4	Purified water q.s	1000ml	20ml	Vehicle

Principle:

Turpentine liniment is an o/w emulsion type of liniment. Turpentine is a fluid obtained by the distillation of resin obtained from live trees, mainly pines. It is used as a counter irritant and rubefacient. Turpentine oil forms the internal phase of the emulsion and water is the continuous phase. Camphor is soluble in turpentine oil, not in water. At the same, turpentine liniment is insoluble in water. Therefore, an emulsion is prepared using soft soap as the emulsifying agent. Camphor also acts as counter irritant and used for obtaining relief from pains and sprains. Freshly rectified turpentine oil should always be used otherwise good emulsion is not observed or may become disclosed upon storage.

Procedure: Mix Soft soap in sufficient quantity of purified water and makes the solution of camphor in turpentine oil. Mix to the Soft soap solution little by little with triturating until a creamy emulsion is formed. Add sufficient amount of purified water to make up the volume and transferred in a container.

Dispensing: Turpentine liniment should be dispensed in amber colored, narrow mouthed bottle tightly closed with colored plastic screw cap.

Storage: Store in a dry place and protect from light.

Note: Counter irritant

An agent that causes irritation or a mild inflammation of the skin to relieve symptoms of a deep-seated inflammatory process. An agent used to enhance blood flow to affected area

Precautions:

Turpentine oil is flammable. Harmful by inhalation, on contact with skin and if swallowed. Irritating to the eyes and skin.

Soft soap produces much lather and care has to be taken to disperse the air before packing.

Category: Counter irritant & rubefacient

Label: **"FOR EXTERNAL USE ONLY"**

"DO NOT APPLY ON BROKEN SKIN"
"SHAKE WELL BEFORE USE"

Route of administration: Topical administration

Report: Prepared & submitted…… ml of Turpentine Liniment IP.

Experiment No:17

CAMPHOR LINIMENT IP

Aim: To prepare and submit 20 ml of Camphor Liniment IP.

Requirements: Weighing balance, mortar and pestle, beaker, measuring cylinder, bottle and chemicals listed in the formula.

Category: Counter irritant

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Camphor	200g	4gm	Counter irritant
2	Arachis oil	800ml	16ml	Vehicle

Specific gravity of arachis oil- 0.91g/cc

Principle: Liniments are oily or alcoholic solutions or emulsions for application on to the unbroken skin with friction. They are used as counter irritant, rubefacient and soothing agent (bringing comfort).

Camphor liniment is an oily solution. Oily liniments are less irritant than alcoholic liniments and spread more easily on skin. Camphor is counter irritant, rubefacient and antipruritic (prevent itching). Arachis oil is used as solvent for camphor and provides lubrication during massage.

Procedure:

- Place camphor in dry wide mouthed bottle, add oil and close the stopper
- Heat on water bath till camphor dissolves with occasional shaking (do not allow water to boil in the bath)
- Allow the solution to cool, transfer into bottle, label and dispense

Category: Counter irritant (agent applied locally to produce superficial inflammation with the objective of reducing inflammation in deeper adjacent structures) to relieve pain.

Storage: Store ina well closed amber colored glass container incool place

Label: **"FOR EXTERNAL USE ONLY"**

"DO NOT APPLY ON BROKEN SKIN"

"SHAKE WELL BEFORE USE"

Route of administration: Topical administration

Report: Prepared & submitted…… ml of Camphor Liniment IP.

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SUSPENSIONS

SUSPENSIONS

INTRODUCTION

A Pharmaceutical suspension is a coarse dispersion in which internal phase (therapeuticallyactive ingredient) is dispersed uniformly throughout the external phase. The internal phaseconsisting of insoluble solid particles having a range of size(0.5 to 5 microns) which is maintained uniformly throughout the suspending vehicle with aid of single or combination of suspending agent. The external phase (suspending medium) is generally aqueous in some instance, may be an organic or oily liquid for non oral use.

Classification:

Based On General Classes

- Oral suspension e.g.: Paracetamol suspension antacids, Tetracycline HCl.
- Externally applied suspension e.g.: Calamine lotion.
- Parenteral suspension e.g.: Procaine penicillin G Insulin Zinc Suspension

Based on Proportion of Solid Particles

- Dilute suspension (2 to10%w/v solid) E.g.: cortisone acetate, predinisolone acetate
- Concentrated suspension (50%w/v solid) E.g.: zinc oxide suspension

Based on Electro kinetic Nature of Solid Particles

- Flocculated suspension
- Deflocculated suspension

Based on Size of Solid Particles

- Colloidal suspensions (< 1 micron) -Suspensions having particle sizes of suspended solid less than about 1micron in size are called as colloidal suspensions
- Coarse suspensions (>1 micron)-Suspensions having particle sizes of greater than about 1micron in diameter are called as coarse suspensions.
- Nano suspensions (10 ng) - Suspensions are the biphasic colloidal dispersions of nanosized drug particles stabilized by surfactants. Size of the drug particles is less than 1mm.

Advantages:

- Suspension can improve chemical stability of certain drug. E.g. Procaine penicillin G.
- Drug in suspension exhibits higher rate of bioavailability than other dosage forms.
- Duration and onset of action can be controlled. E.g. Protamine Zinc-Insulin suspension.
- Suspension can mask the unpleasant/ bitter taste of drug. E.g. Chloramphenicol

Disadvantages:

- Physical stability, sedimentation and compaction can causes problems.
- It is bulky sufficient care must be taken during handling and transport.
- It is difficult to formulate. Uniform and accurate dose cannot be achieved unless suspensions are packed in unit dosage form.

Flocculated Suspensions: In flocculated suspension, formed flocs (loose aggregates) will cause increase in sedimentation rate due to increase in size of sedimenting particles. Hence the flocculated suspensions sediment more rapidly. Here, the sedimentation depends not only on the size of the flocs but also on the porosity of flocs.

Deflocculated suspensions: In deflocculated suspension, individual particles are settling. Rate of sedimentation is slow, which prevents entrapping of liquid medium which makes it difficult tore-disperse by agitation. This phenomenon called 'caking' or 'claying'. In deflocculated suspension larger particles settle fast and smaller remain in supernatant liquid so supernatant appears cloudy.

Formulation of suspensions:

- Wetting agents -They are added to disperse solids in continuous liquid phase.
- Flocculating agents -They are added to floc the drug particles
- Thickeners -They are added to increase the viscosity of suspension.
- Buffers and pH adjusting agents -They are added to stabilize the suspension to a desired PH range.
- Coloring agents- They are added to impart desired color to suspension and improve elegance.
- Preservatives- They are added to prevent microbial growth.
- External liquid vehicle- They are added to construct structure of the final suspension.

Experiment No:18

CALAMINE LOTION I.P

Aim: To prepare and submit 20 ml of calamine lotion I. P

Requirements: Beaker Glass rod, Mortar & Pestle and Measuring cylinder

Category: Skin Protectant

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Calamine	150 g	3 g	Antiseptic, Astringent
2	Zinc oxide	50 g	1g	Astringent
3	Bentonite	30 g	0.6 g	Suspending agent
4	Sodium citrate	5 g	0.1g	Deflocculating agent
5	Liquefied Phenol	5 ml	0.1 ml	Antiseptic
6	Glycerol	50 ml	1ml	Humectant
7	Rose Water up to	1000 ml	20 ml	Perfumed solvent

Principle: Lotions may be used for local action as cooling, smoothing, protective purpose. Calamine and zinc oxide acts as skin protective and astringent. Calamine is chemically zinc oxide, colored pink (or) reddish brown containing ferric oxide. It is insoluble and in diffusible in water. Bentonite is colloidal hydrated aluminum having capacity to absorb water. Sodium citrate acts as anti-oxidant and buffer phenol (0.2 to 2.5%) acts as antiseptic, preservative and local anesthetic. Glycerin is humectants after evaporation of water, glycerin holds calamine and zinc oxide as fine powder on the skin and also increases the viscosity of suspension. Calamine lotion is used for relief from itching which may be due to allergy or worm infection.

Procedure: Calamine, zinc oxide and Bentonite were finely powdered in ascending order of their weights. Sodium citrate was dissolved in 3/4th volume of purified water. This solution was added to powdered mixture and triturated. Phenol and glycerin were mixed and then added to calamine mixture. This was transferred into a bottle and final volume was adjusted with purified water and labeled.

Dispensing: Transfer the lotion to a clear or amber colored, narrow mouthed glass bottle, close it thoroughly with metallic screw cap, polish and label.

Storage: Stored in a well closed container

Category: Skin Protectant

Auxiliary label: "FOR EXTERNAL USE ONLY", "SHAKE WELL BEFORE USE".

Direction: Apply on effected area without friction as directed by physician

Route of administration: Topical administration

Report: Prepared & submitted…… ml of Calamine lotion IP.

Experiment No:19

MAGNESIUM HYDROXIDE MIXTURE BP

Aim: To prepare and submit 20 ml of Magnesium Hydroxide Mixture BP

Synonym: Milk of Magnesia

Requirements: Beaker, funnel, glass rod, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Skin Protectant

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Magnesium sulphate	47.5g	0.95g	Brings precipitation reaction
2	Sodium Hydroxide	15g	0.3g	Brings precipitation reaction
3	Light Magnesium Oxide	52.5g	1.05g	Brings hydration
4	Chloroform spirit	25ml	0.05ml	Preservative
5	Purified water q.s	1000ml	20ml	Vehicle

Principle:

Magnesium hydroxide mixture BP is an aqueous colloidal dispersion of magnesium hydroxide.

It is used as an antacid and as an osmotic laxative. It may be prepared by two methods.

1. By precipitation reaction between magnesium sulphate and sodium hydroxide.

2. By hydration of magnesium oxide.

The second method, hydration of magnesium oxide takes 48hours for completion. The two reactions are carried out to maintain the required pour ability of the product. Product obtained entirely by hydration of magnesium oxide become very viscous and un-pourable on keeping, while product made by precipitation alone sediment quickly yet remains fluid i.e. it has lesser viscosity. Mixtures prepared by employing both methods together i.e. by precipitation and hydration are not excessively thick and do not separate rapidly. The removal of sulphate ions from the mixture is necessary because sulphates when given orally in

hypertonic solution draw water from the tissues into the intestine. This increases peristalsis and induces a profuse watery stool. Therefore removal of sulphate is necessary. Chloroform is used as preservative. The preparation has a pH of about 10 and therefore it attacks containers of lime soda glass. The U.S.P allows inclusions of citric acid up to 0.1% to minimize this effect. It also acts as a flavour to the mixture. The preparation must not be stored in a cool place because low temperature causes aggregation of the particles and gives the preparation a granular appearance.

Procedure:

Dissolve sodium hydroxide in sufficient water, add light magnesium oxide, mix to form a smooth paste. Add water to produce to produce about 250 ml. Pour this in a thin stream into the solution of magnesium sulphate (in about 250 ml) with stirring. Allow the precipitate to settle, decant the clear supernatant. Wash the precipitate repeatedly with distilled water until removal of sulphate ion Once sulphate ions are removed, clear liquid is drained. Precipitate is mixed with citric acid and chloroform, transferred to the container Make up the volume with water, label and dispense

Category: Antacid at lower dose; laxative at higher dose.

Dose: 1-4ml as antacid, 8-16ml as laxative

Storage: Store at room temperature. Do not store in a cool place.

Label: **"SHAKE WELL BEFORE USE"**

"DO NOT STORE IN REFRIGATOR"

"STORE IN A BLUE PLASTIC CONATINER"

Route of administration: Oral route

Report: Prepared & submitted …..ml of Magnesium Hydroxide Mixture BP

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EMULSIONS

EMULSIONS

INTRODUCTION

An emulsion is defined as "biphasic or heterogeneous liquid preparation containing two immiscible liquids, one of which is dispersed as minute globules in another liquid. The diameter of dispersed globules ranges from 0.1 to 100 microns. The liquid which is converted into minute globules is called as 'dispersed phase" or 'internal phase" and the liquid which is present in higher portion is called as 'dispersed medium" or 'external phase" Emulsion posses a minimum thermodynamic stability, because two immiscible liquids cannot be remain dispersed for a longerperiod, droplets of dispersed phase quickly coalesce and the two liquids get separated. Therefore emulsifying agent is added, to increase the stability of emulsion. It forms a film around the globules and keeps the globules of dispersed phase separately, from other globules and prevents coalescence.

Classification

Oil in water type (O/W): In this type of emulsions, oil is dispersed as minute globules in the water, these emulsions are prepared by using emulsifying agents like gum acacia, tragacanth, methyl cellulose, soaps formed from monovalent bases like Na+, K+ and NH4+.O/W type emulsions are mainly used for internal(oral)use because, the unpleasant taste and odour ismasked by emulsification and oil being in a finely dispersed state, it is more quickly absorbed in GIT.

Water in oil type (W/O): In this type of emulsions, water is dispersed as minute globules in the oil. These emulsions are prepared by using emulsifying agents like bees wax, wool fat, resins, synthetic compounds and soaps formed from divalent bases like Ca++, Mg++and Zn++.These emulsions are mainly used for external purpose as lotions, liniments, creams and emulsified ointments.

Special type of emulsions (depending on the globule size):

Micro-emulsions: These emulsions are emulsions, which contain globules of size less than 0.1µm droplets of such dimensions cannot reflect light, hence globules are invisible to the naked eyes and therefore micro-emulsions appear, as transparent solutions. These emulsions are physically more stable, compared to conventional emulsions. Micro emulsions are used for preparation of both internal and external purpose and they show increased bioavailability of drugcompared to conventional emulsions. e.g.: Etoposide emulsion, Methotrexate emulsion.

Multiple emulsions (double emulsion): Multiple emulsions are complex type of emulsions. These are also called as "emulsion-with-emulsion." multiple emulsions are represented as, o/w/o type emulsion and w/o/w type emulsion.

o/w/o emulsions: In this type of emulsion, o/w type of emulsion is re-dispersed in the oil phase.

w/o/w emulsions: In this type of emulsion, w/o type of emulsion is re-dispersed in the aqueousphase. These types of emulsions can be prepared by proper selection of emulsifying agents, dependingon HLB scale.

Primary emulsion ratio:

Sl. No	Type of oil	Oil / water /gum ratio	Examples
1	Fixed	4:2:1	Arachis oil, Castor oil
2	Mineral	3:2:1	Liquid paraffin, Liquid petroleum
3	Volatile	2:2:1	Eucalyptus oil, Peppermint oil

Applications: In multiple emulsions, the drug is entrapped (incorporated) in the inner most phase. Hence the drug must cross two phase boundaries, before getting absorbed. Hence this mechanism is used in the preparation of controlled (sustained) release emulsions meant for the both, internal or oral use and 'depot therapy', as intramuscular injections.

Formulation of emulsions:

1. Emulsifying agents/emulsifiers/emulgents:

Emulsifying agent is a substance, which reduces the interfacial tension between oily phase and aqueous phase and forms a film around the dispersed globules, hence prevents the coalescence ofdroplets and thus makes them, miscible with each other to get a stable emulsion. There an ideal emulsifying agent, must possess the following ideal properties:

- It should be capable of reducing the interfacial tension, between the two immiscible liquids.
- It should form complete and coherent film, around dispersed globules, so as to prevent their coalescence.
- It should be compatible with other ingredients of the preparation.
- It should be non-toxic and chemically stable.
- It should be capable of producing and maintaining the required consistency (viscosity) of the emulsion.

Emulsifying Agents are classified as:

SL. No	Type	Source	Examples
1	Natural emulsifying agents	A) From vegetablesources B) From animal source	Gum acacia, karaya gum, tragacanth gum, agar, pectin, starch, irish moss, alginate, gaur gum, soya bean Gelatin, egg yolk, casein, wool fat, serum albumin.
2	Semi-synthetic substances	----------	Methyl cellulose, carboxy methyl cellulose, sodium carboxy methyl cellulose, HPMC,MCC
3	Synthetic substances	A) anionic	SLS, polypeptide condensates, trioleyl phosphate, sarcosinates
		B) cationic	Alkoxyalkyl amines, benzalkonium chloride, cetrimide, benzethonium chloride.
		C) non-ionic	Polyoxyethylene, polyoxyethylene alkylethers, polyoxypropylene,sorbitan esters, glyceryl esters,sucrose esters, polyoxyethylene fatty acid esters
4	Inorganic substances	-------	Magnesium oxide, milk of magnesia, magnesium trisilicate, magnesium aluminium silicate, bentonite.
5	Alcoholic substances	-------	Polyethylene glycols, cholesterol, alcohol, lecithin.

1. Preservatives:

Emulsions are prepared by using different emulsifying agents like carbohydrates, proteins, non- ionic surfactants, which may leads to the growth of bacteria, fungi and moulds in presence of water. This leads to the contamination and breakdown (cracking) of emulsions. To prevent this problem, preservatives should be incorporated.

E.g.: benzoic acid (0.1-0.2%), chloroform (0.25%), methyl paraben (0.1-0.2%), propyl paraben (0.1-0.2%), chlorocresol (0.1%), cetrimide (0.002-0.01%), sodium benzoate.

2. Anti –oxidants:

During storage of emulsions, many oils and animal fats may undergooxidation by atmospheric oxygen and leads to rancidity. To avoid these undesirable changes, suitable anti-oxidants are used.

E.g.: Tocopherol, ascorbic acid, citric acid, catechol, gallic acid, propyl gallate, ethyl gallate.

3. Flavoring agents:

To prevent the unpleasant taste of some emulsifying agents and fixed oils, flavoring agents like vanillin, benzaldehyde spirit and aromatic waters like chloroform water, cinnamon water, peppermint water are used..

A combination of flavoring and sweetening agent provides greater palatability to the emulsion.

Method of Preparation:

Primary emulsion: It is an initial thick emulsion, which is obtained by trituration of oil, water and gum, either by dry gum or wet gum method, where the globules of internal phase of emulsion is reduced to their minimum size. The formation of primary emulsion is indicated by getting a white or nearly white (product) cream and a clicking or cracking sound is produced. Once the primary emulsion is formed, it is then diluted with the vehicle up to final volume by light trituration.

Dry Gum Method: In this method, oil is first triturated with gum and then water is added, to make a primary emulsion. Calculate the quantities of oil, water and gum required for primary emulsion, depending on the nature of oil. For this method always use dry measure, mortar and pestle. Take measured quantity of oil and gum in a mortar and mix them gently with pestle just, to disperse the gum in oil uniformly. Add a measured quantity of water at once and triturate vigorously in a single direction without stopping, until a clicking sound is produced and product becomes thick white or nearly white, due to the internal light reflection. At this stage, product is called as primary emulsion. The primary emulsion is then diluted, with remaining amount of aqueous vehicle (water), to make it pourable. Transfer the content to a measure, and make up the final volume with water.

Wet gum method: This method is used, only when the emulsifying agents are available in mucilage form themselves or they are required to be used in their mucilage forms. In this method, gum is first triturated with water, to form mucilage and then triturated with oil to make primary emulsion. Calculate the quantities of oil, water and gum for primary emulsion, depending on nature of the oil. Take a measure quantity of gum and water in a mortar and triturate, to form mucilage. To the mucilage, add oil in small portions with light trituration in a single direction. When whole amount of oil has been added, triturate vigorously until a thick,

white or nearly white product is formed and clicking sound is produced. To the primary emulsion, incorporate water in small portions with trituration, to make it pourable. Transfer the content to a measure and make up the final volume with water.

Note: wet gum method has not become much popular compared to dry gum method because, It does not gives stable emulsion (more chances of breaking of emulsion). This method is slower process than dry gum method.

Bottle method: It is a modified method of dry gum method. Bottle method is used for the preparation of emulsions of volatile oils and other non-viscous oils.

The proportions for primary emulsion ratio is, oil:water: gum is 2:2:1. Measure the required quantity of the oil and transfer into a large bottle. Add the required amount of powdered gum acacia and close it thoroughly with the cap. Shake the bottle vigorously, until the oil and gum are mixed thoroughly. Add measured quantity of water and shake until, a uniform emulsion is formed.

Advantages

- Unpalatable oils can be administered in palatable form.
- Unpalatable oil-soluble drugs can be administered in palatable form.
- The aqueous phase is easily flavored.
- The oily sensation is easily removed.
- The rate of absorption is increased.
- It is possible to include two incompatible ingredients, one in each phase of the emulsion.

Disadvantages

- Preparation needs to be shaken well before use.
- A measuring device is needed for administration.
- A degree of technical accuracy is needed to measure a dose.
- Storage conditions may affect stability.
- Difficult to transport and prone to container breakages.
- Liable to microbial contamination which can lead to cracking.

Experiment No:20

COD LIVER OIL EMLUSION

Aim: To prepare and submit 20 ml of Cod Liver Oil Emulsion.

Requirements: Beaker, Mortar & Pestle, funnel, glass rod, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Source of Vitamin A & D

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Cod liver oil	30 ml	6 ml	Vitamin A and D.
2	Acacia powder	7.5 gm	1.5 g	Emulsifying agent
3	Chloroform	0.2 ml	0.04 ml	Preservative
4	Cinnamon water qs to	100 ml	20 ml	Flavored vehicle

Principle: This is an o/w emulsion. Cod liver oil is a fixed oil expressed from the fresh liver of codfish. It is rich in vitamin A and D. Acacia is used as an emulsifying agent. Chloroform acts as preservative, cinnamon water as flavored vehicle. Primary emulsion formula is 4:2:1 (oil: water: gum)

Procedure:

- Make mucilage of acacia with water (3ml)
- Add Cod liver oilinparts to the above mucilage with trituration
- Continue trituration till a stable white primary emulsion is formed (till clicking sound is heard)
- Add chloroform and triturate
- Transfer to wide mouthed bottle, make up the volume with flavored water
- Label and dispense

Category: Source of Vitamin A & D

Dose: 10 ml three times a day

Storage: Store incool and dry place

Direction: Shake well before use

Route of administration: Oral route

Report: Prepared & submitted …..ml of Cod Liver Oil Emulsion.

Experiment No:21

LIQUID PARAFFIN EMULSION

Aim: To prepare and submit 20 ml of Liquid Paraffin Emulsion

Requirements: Beaker, funnel, Mortar & Pestle, glass rod, measuring cylinder, weighing balance and chemicals listed in the formula.

Category: Laxative

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Liquid Paraffin	500 ml	10 ml	Laxative
2	Indian gum inpowder	125 gm	2.5 gm	Emulgent
3	Tragacanth gum inpowder	5 gm	0.1gm	Emulgent
4	Sodium benzoate	5 gm	0.1gm	Preservative
5	Vanillin	0.5 gm	0.01gm	Flavoring agent
6	Glycerin	125 ml	2.5 ml	Humectant
7	Chloroform	2.5 ml	0.05ml	Preservative
8	Water up to	1000 ml	20 ml	Vehicle

Principle:

Emulsion may be defined as a disperse system consisting of two immiscible liquids one of which is distributed in small globules throughout the other, the system being stabilized by the presence of a third substance called the emulsifying agent. Liquid paraffin is a mineral oil. It is used as laxative. It has to be formulated into an o/w emulsion. Liquid paraffin is dispersed phase. Water is continuous phase. Gum acacia & gum tragacanth acts as emulsifying agent. Vanillin is a flavouring agent. Sodium benzoate and chloroform are preservatives. Glycerin acts as an emulsifying agent and viscous solvent.

Procedure:

1. Depending on the quantity of preparation to be submitted, the working formula is calculated.
2. Triturate required quantity of liquid paraffin, chloroform with gum acacia, tragacanth gum and vanillin.
3. Add 1ml of purified water and triturate until a creamy emulsion is formed. Add 0.1 g sodium benzoate and 2.5 ml of glycerine dissolved in 4ml of purified water
4. Rinse mortar and pestle with small amount of water and makeup the volume to desired level with water.
5. Transfer the contents into a previously cleaned and marked bottle (light resistant container) using a funnel and filter paper.
6. Label the container & dispense.

Precautions:

- While preparing primary emulsion, oil, gum, mortar and pestle, should be perfectly dry.
- Directions of trituration must not be changed while preparing the emulsion.
- Gum must not be added all at once to the oil. It has to be sprinkled gradually.

Category: Laxative

Dose: 8-30ml

Label: "SHAKE WELL BEFORE USE"

Storage: Store in a well closed air tight container.

Route of administration: Oral route.

Report: Prepared & submitted……ml of Liquid Paraffin Emulsion.

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POWDER

POWDERS

INTRODUCTION

Pharmaceutical powders are solid dosage forms of medicament, in which one or more drugs are dispensed in a finely divided state, with or without excipients, powders are available in crystalline or amorphous form and they can be used either internally or externally.

Formulation:

The formulation of powders includes

- Hygroscopic substances: Ammonium citrate, sodium iodide
- Effervescent substances: Caffeine, citric acid, ferrous sulphate
- Eutectic substances reducing aids: Menthol, thymol camphor
- Diluents: Sucrose, lactose, starch, magnesium carbonate
- Processing aids: Effervescent salts, disintegrating salts
- Functional aids: Glidant, granulating agents, adsorbents
- Organoleptic additives liquids: Fruit juice with sugars or volatile oils
- Liquids: Tinctures, volatile flavor oils

Classification:

1. Bulk powder for internal use
2. Bulk powder for external use, e .g. dusting powders and insufflations.
3. Divided powders

1. Bulk powder for internal use: Whenever several powder ingredients are present the powders are mixed in ascending order of bulk in a mortar. At each addition, a quantity that is approximately equal the bulk already existed in the mortar is added. Example: Compound magnesium trisilicate powder.

2. Bulk powder for external use: Classification

A. Dusting powder, (a) Medical powder (b) Surgical dusting powder
B. Insufflations
C. Dentifrices (tooth powder)

A. (a) Medical dusting powder: These are used for superficial skin conditions. They are not sterile. They are not applied on open wounds or broken skin. After mixing the powders in a mortar it passed through a mesh no. 120 to remove gritty particles. Then it is stored in a suitable container. Example: Starch salicylic acid dusting powder.

(b) Surgical dusting powder: These are used in body cavities and major wounds, on burns and on the umbilical cords of newborns, hence they must be sterile. They often contain an antibacterial agent and the diluent may be sterilized maize starch. Example: Chlorhexidine
B.P.C. surgical dusting powder.

B. Insufflations: Finely divided powders intended for application to body cavities such as tooth socket, ears, nose and throat are known as insufflations. The apparatus is used to deliver a streamof finely divided powder particles to the site of application is called an insufflator.

C. Dentifrices (tooth powders): Powders used to clean the teeth are called *dentifrices*. It is applied with a tooth brush. They contain

- A suitable detergent – hard soap powder
- A suitable abrasive agent – calcium sulfate, magnesium carbonate, dibasic calciumphosphate
- Sweetening agent – sodium saccharin
- Flavoring agent – peppermint oil, clove oil etc

3. Divided powders: In this form of powder, each dose is separately enclosed in a piece ofpaper.

Classification:

- Simple powder: Contains only one ingredient.
- Compound powder: Contains more than one ingredient.

Packing: For wrapping the powders, white glazed paper (demy paper) is generally used. The powder wrappers are stacked in a paper box and dispensed. Sometime *double wrapping* is required, especially if the powder is hygroscopic. In this case waxed paper is used as inner wrapper, then the demy wrapper a the outer wrapper.

Advantages:

- Powders are generally more stable than liquid dosage forms because chemical reactions takes place more slowly in solid form when compared to liquid form
- Problems of compatibility are less
- They can be easily administered to children and old persons who have difficulty in swallowing formulations like tablets and capsules
- Powders are easier to carry and transport

Disadvantages:

- Accurate measurement of dose is difficult specially in case of powders
- Powders are not a suitable dosage forms for dispensing filter – taste, nauseous and unpalatable drugs
- Preparation and dispensing of powders are more time consuming compared to tablets

Experiment No:22

EUTECTIC POWDER

Aim: To prepare and submit 1g of Eutectic Powder

Requirements: Spatula, Mortar & Pestle weighing balance and chemicals listed in the formula.

Category: Nasal decongestant

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Camphor	5g	50m g	Decongestant
2	Menthol	5g	50 mg	Respiratory relief
3	Ammonium chloride	30g	300 mg	Expectorant
4	Light magnesium carbonate	60g	600mg	Diluant

Principle: Two powders when brought in physical contact with each other, if liquefies then they are called as eutectic powders. Liquefaction may be due to lowering of melting point of individual solids as one substance may act as impurity to other. Examples of eutectic solids are menthol, camphor Thymol, salicylic acid, aspirin, phenol etc. If eutectic substance to be dispensed as powders, to prevent liquefaction diluents can be used. These diluents avoid physical contact between eutectic substances. Some commonly used diluents are light magnesium carbonate, ammonium chloride, starch, lactose, talc, magnesium oxide etc. Alternately eutectic substances be mixed together and formed liquid can be then sorbed into suitable diluents.

Procedure:

Mix camphor with ammonium chloride and menthol with light carbonate separately by light trituration in excess quantity. Individual mixtures are combined together with light trituration in a mortar. Weigh required quantity of blend and pack by double wrap technique. Dispense in a labeled envelop Discard the excess powder blend

Category: Nasal decongestant

Storage: Store in cool and dry place

Direction: Used as an Insufflation

Route of administration: Nasal route.

Report: Prepared & submitted……g of Eutectic Powder.

Experiment No:23

EXPLOSIVE POWDER

Aim: To prepare and submit 1g of Explosive Powder

Requirements: Spatula, Mortar & Pestle weighing balance and chemicals listed in the formula.

Category: Antiseptic & Astringent

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Potassium chlorate	10g	500 mg	Oxidizing agent
2	Tannie acid	5 g	250 mg	Reducing agent
3	Sucrose	5 g	250 mg	Sweetening agent

Principle: Trituration of oxidizing agent with reducing agent result in violent explosion. To avoid explosion, it is advised to adopt spatulation or tumbling during mixing as there will not be friction between the solids. Here potassium chlorate is the oxidizing agent and tannic acid is the reducing agent. Other potential explosive materials are sodium peroxide, potassium nitrate, potassium dichromate (oxidizing agents) sulphur, sulphides and charcoal (reducing agent). Both potassium chlorate and tannic acid are antiseptic and astringent. They are used in oral cavity for treating stomat itis, pharyngitis, tonsillitis and ulcerative lesions of oral cavity. They are found in tooth paste, gargle and mouthwashes. Sucrose acts as sweetening agent. This powder formulation can be mixed with water and be used as gargle in the above said conditions.

Procedure:

- Mix in excess potassium chlorate and tannic acid in a mortar with little pressure by spatulation on a butter paper
- Add sucrose to the above mixture and mix well
- Weigh1g of blend and pack by double wrap technique
- Dispense in a labeled envelop
- Discard the excess powder blend

Category: Antiseptic and astringent

Storage: Store in cool and dry place

Direction: Add the powder in a glass of warm water and use as gargle

Report: Prepared & submitted……g of Explosive Powder.

Experiment No:24

DUSTING POWDER

Aim: To prepare and submit 1g of Dusting Powder

Requirements: Spatula, Mortar & Pestle weighing balance and chemicals listed in the formula.

Category: Antiseptic, Antifungal, Protective & adsorbent

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Zinc oxide	250 g	250 mg	Astringent & Anti-bacterial
2	Starchpowder	250 g	250 mg	Absorbent & Diluent
3	Purified talc, sterilized	500 g	500 mg	Absorbent

Principle:

Dusting powders come under bulk powders for external use. They are of 2 types:

- Medicated dusting powder: Used for application on intact skin and hence need not be sterilized.
- Surgical dusting powder: Used in treatment of burns, wounds or broken skin.

Medical dusting powders are used mainly for superficial skin conditions & sterility is not essential, however some mineral ingredients such as talc may be contaminated with tetanus bacteria & should therefore be sterilized before mixing with other ingredients. Medical dusting powder is not intended for application to open wounds or broken skin & should be labeled accordingly. Surgical dusting powders are used in body cavities & major wounds or burns umbilical cord of infant. Hence they must be sterilized. In this preparation, zinc oxide acts as astringent & antibacterial. Starch acts an absorbent & diluent. Purified Talc acts as an absorbent

Procedure:

Depending on the quantity of preparation to be submitted, the working formula is calculated. Fine powders of zinc oxide, salicylic acid and starch are each weighed. (Geometric dilution technique is followed to achieve a uniform blend. Blending may be carried out either by spatulation or by trituration). Salicylic acid is taken into the mortar to which an equal bulk of zinc oxide is added and gently triturated. The remaining zinc oxide is then added and mixed. Quantity of starch equivalent to the bulk of the powders in the mortar is added and blended. Finally remaining starch is added and blended.

The powder is passed through sieve #120 in order to get small particles which are less likely to irritate tissues. Required quantity of the powder is transferred into a wide mouthed jar with a reclosable perforated lid, labeled and submitted.

Category: Antiseptic, Antifungal, Protective & adsorbent

Label:

"FOR EXTERNAL USE ONLY"

"NOT TO BE APPLIED TO RAW OR WEEPING SURFACE"

Storage: Store in a well closed container protected from moisture (sifter-top container).

Report: Prepared & submitted ….g of Dusting Powder.

Experiment No:25

INSUFFLATION

Aim: To prepare and submit 1g of Insufflation.

Requirements: Spatula, Mortar & Pestle weighing balance and chemicals listed in the formula.

Category: Nasal decongestant

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Camphor	5 g	50 mg	Decongestant
2	Menthol	5 g	50 mg	Respiratory relief
3	Ammonium chloride	30 g	300 mg	Expectorant
4	Light magnesium carbonate	61g	600 mg	Excipient

Principle:

Insufflation powders fine powders meant for administration into the body cavities such as nose, ear and vagina. They are administered with the help of a device called insufflators. These powders are dispensed in wide mouth container from which required quantity is transferred to insufflator, which blows the powder into body cavity. Menthol and camphor are eutectic solids, thus to prevent liquefaction ion diluents ammonium chloride and light magnesium carbonates are added.

Procedure:

- Mix camphor with ammonium chloride and menthol with light carbonate separately by light triturat ion in excess quantity.
- Individual mixtures are combined together with light triturate ion in a mortar.
- Weigh required quantity of blend and pack by double wrap technique.
- Dispense in a labeled envelop.
- Discard the excess powder blend.

Category: Nasal decongestant

Label: "FOR NASAL USE ONLY"

Storage: Store in a well closed container.

Report: Prepared & submitted …..g of Insufflation.

SUPPOSITORIES

SUPPOSITORIES

INTRODUCTION

Suppository is a solid dosage form intended for insertion into body orifices where they melt, soften, or dissolve and produce local or systemic therapeutic effects. Suppositories are commonly used rectally and vaginally but occasionally urethral. They are prepared with different shapes and weights. Rectal suppositories are usually 32 mm long, cylindrical in shape, and have one or both ends tapered. Some rectal suppositories are shaped like a bullet or little finger. Vaginal suppositories are usually globular, oviform, or cone shaped.

Suppositories are mainly composed of the medication and a base. Suppository bases play an important role in the release of the medication from the product and the resultant bioavailability of the drug. One of the most important properties for a suppository base is that it remains solid atroom temperature but softens, melts or dissolves readily at body temperature so that the drug is available for absorption after insertion of product.

SHAPES AND TYPES OF SUPPOSITORIES:

Sl.No	Type	Weight	Shape
1.	Rectal suppositories	Small: 1 gm Medium: 2gm Large:4 gm	Rod Wedge Oval
2.	Pessaries (vaginal suppositories)	4-8gm	Spherical
3.	Urethral bougies	2-4 gm	Cylindrical
4.	Nasal bougies	1 gm	Thin and Cylindrical
5.	Ear cones	1 gm	Cone

Advantages:

- Can exert local effect on rectal mucosa.
- Used to promote evacuation of bowel.
- Avoid any gastrointestinal irritation.
- Can be used in unconscious patients (e.g. during fitting).
- Can be used for systemic absorption of drugs and avoid first-pass metabolism.
- Babies or old people who cannot swallow oral medication.
- Post operative people who cannot be administered oral medication.

Disadvantages:

- The problem of patient acceptability.
- Suppositories are not suitable for patients suffering from diarrhoea.
- In some cases, the total amount of the drug must be given will be either too irritating or ingreater amount than reasonably can be placed into suppository.
- Incomplete absorption may be obtained because suppository usually promotes evacuation of the bowel.

Properties of an Ideal Suppositories Base

- It should melt at body temperature or dissolve or disperse in body fluids.
- It should release any medicament readily.
- It should keep its shape when being handled.
- It should be non-toxic and non-irritant to the mucous membrane.
- It should be stable on storage.
- It should be compatible with any added medicament.
- It should be stable if heated above its melting point.
- It should be easily moulded and should not adhere to the mould.
- It should be easily mouldable by pouring or cold compression.

Suppository bases are classified into two categories:

- **Fatty or oleaginous bases**, such as cocoa butter, hydrogenated fatty acids of vegetable oils, semi synthesized fatty acids such as Faty base (triglycerides from palm, palm kernel, and coconutoils with self-emulsifying glyceryl monostearate and polyoxyl stearate), Wecobee bases (triglycerides derived from coconut oil) and Witepsol bases (triglycerides of saturated fatty acids C12-C18 with varied portions of the corresponding partial glycerides).
- **Water-soluble or water-miscible bases,** such as glycerinated gelatin, polyethylene glycols and polyoxyl 40 stearate (S-40). Some surface active agents may be added in the bases to facilitate drug release and absorption.

Suppositories can be produced by 3 methods:

- Molding from a melt
- Compression
- Hand rolling and shaping.

For fatty bases, either one of these methods can be used. For water-soluble or water-miscible bases, molding is the most frequently used method.

Formulation: The formulation of suppositories include

1. Base: These are of three types

   Fatty suppositories Bases: Eg: theobromo oil, synthetic hard fat base

   Water soluble suppositories Base: Eg: Macrogol bases, glycerol gelatin bases

   Water dispersal suppositories Base: Eg: Witepsol
2. Hardening Agents: Macrogol bases.
3. Thickening Agents: Eg: Bentonite
4. Emulsifying Agents: Eg: Polysorbates, woolfat
5. Preservatives: Eg: Methyl and propyl hydroxyl Benzoates
6. Anti-oxidants: Eg: Butylated hydroxyl anisole

Dispensing: Each suppository should be wrapped in grease proof paper or butter paper. Glass or plastic screw-topped jars are possibly the best choice of container for extemporaneously prepared suppositories. Cardboard cartons may be used but these offer little protection from moisture or heat. They are therefore not suitable for hygroscopic materials.

Label: For rectal use only or for vaginal use only, whichever is appropriate.

Storage: Store in a cool place or store in refrigerator.

Experiment No:26

BORIC ACID SUPPOSITORIES

Aim: To prepare and submit 5 Boric acid suppositories.

Requirements: Beaker, stirrer, measuring cylinder, china dish, water bath, weighing balance and chemicals listed in the formula.

Category: Local Anti infective (Anti bacterial and Anti fungal)

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Boric acid	200 mg	1.2 g	Anti infective
2	Cocoa Butter	Quantity sufficient	11.2g	Emollient

Principle: Since cocoa butter does not contract sufficiently on cooling, to facilitate easy removal of suppositories the moulds are lubricated. To preserve the stable form of base, it is heated on water bath till 2/3rd gets melted. Boric acid is insoluble in cocoa butter hence it is uniformly dispersed in molten base with stirring. Agitation and quick pouring is essential to avoid settling of insoluble solid and solidification of base in dish, respectively. To prevent formation of depression in the suppository upon cooling, overfilling is advised. Since suppositories do not fracture upon sudden cooling, congealing can be done on ice.

Procedure:

- Calculate the quantity of ingredients for 1 extra suppository to allow the unavoidable wastage (for 6 suppositories)
- Heat calculated amount of cocoa butter in a dish on a water bath.
- Take out the dish when 2/3rd of base is melted, add boric acid and mix well (powdered drug should be missed with part of molten base on warm ointment slab by spatulation. Resulting mass should be transferred back to dish with continuous agitation and heat gently if needed).
- Pour the molten mass into previously cleaned and lubricated mould kept on ice till over flow.
- After complete solidification of mass, trim off the excess mass with a knife.
- Open the mould and remove the suppositories.
- Wipe the excess oil with filter paper, wrap individual suppository with butter paper.
- Pack in partitioned cardboard box.

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Category: Local anti infective (Anti bacterial and antifungal)

Storage: Store in cool place

Direction: For rectum, insert one at night

Report: Prepared & submitted….. of Boric acid suppositories.

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Bengaluru – 560049, Karnataka

Experiment No:27

CHLORAL HYDRATE SUPPOSITORIES

Aim: To prepare and submit 5 Chloral hydrate suppositories.

Requirements: China dish Glass rod , Pestle and mortar, Spatula, Suppository moulds, Tiles, Water bath, Liquid paraffin ,Ice.

Note: Use 2g mould, displacement value of chloral hydrate is 1.5

Category: Hypnotic (CNS depressant, produce calmingeffect without inducing sleep)

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1	Chloral hydrate	200 mg	1.2 g	Sedative &hypnotics
2	Cocoa Butter	Quantitysufficient	11.2g	Emollient

Principle: Since cocoa butter does not contract sufficiently on cooling, to facilitate easy removal of Suppositories the moulds are lubricated. To preserve the stable β form of base, itis heated on water bath till 2/3rd get smelted. Chloral hydrate is insoluble in cocoa butter hence it is uniformly dispersed in molten base with stirring. Agitation and quick pouring is essentialto avoid settling of insoluble solid and solidification of base in dish, respectively. Toprevent formation of depression in the suppository upon cooling, over filling is advised. Since suppositories do not fracture upon sudden cooling, congealing can be done once.

Procedure:

- Calculate the quantity of ingredients for 1 extra suppository to allow the unavoidable wastage (for 6 suppositories).
- Heat calculated amount of cocoa butter in a dish on a water bath.
- Take out the dish when 2/3rd of base is melted, add chloral hydrate and mix well (powdered drug should be missed with part of molten base on warm ointment slab by spatulation.
- Resultingmass should be transferred back to dish with continuous agitation and heat gently if needed).
- Pour the molten mass into previously cleaned and lubricated mould kept on ice till over flow
- After complete solidification of mass, trim off the excess mass with a knife
- Open the mould and remove the suppositories
- Wipe the excess oil with filter paper, wrap individual suppository with butter paper
- Pack in partitioned cardboard box.

Category: Hypnotic (CNS depressant, produce calming effect without inducing sleep)
Storage: Store in cool place
Direction: For Rectum, insert one at night.
Report: Prepared & submitted….. of Chloral hydrate suppositories.

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INCOMPATIBILITY

EAST POINT COLLEGE OF PHARMACY
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Bengaluru – 560049, Karnataka

Experiment No:28

PHYSICAL INCOMPATIBILITY

Aim: To identify and correct Physical Incompatibility between oil and water

Requirements: Beaker Glass rod, Measuring cylinder Pestle and mortar

Category: Source of Vitamin A & D

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1.	Cod liver oil	30 ml	6 ml	Vitamin A,D
2.	Acacia powder	7.5 gm	1.5 g	Emulsifier
3.	Chloroform	0.2 ml	0.04 ml	Solvent
4.	Cinnamon water qs to	100ml	20 ml	Antioxidant

Principle: Combination of oil and water results in physical incompatibility due to immiscibility. However, incompatibility can be corrected by mixing them using emulsifying agent (emulsification). Thus the mixture of oil and water can be dispensed as stable emulsion.

Procedure:

- Make mucilage of acacia with water (3ml)
- Add Cod liver oil in parts to the above mucilage with trituration
- Continue trituration till a stable white primary emulsion is formed (till clicking sound is heard)
- Add chloroform and triturate
- Transfer to wide mouthed bottle, make up the volume with flavored water
- Label and dispense

Dose: 10 ml three times a day

Direction: Shake well before use

Storage: Store in cool and dry place

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Experiment No:29

CHEMICALINCOMPATIBILITY

Aim: To Identify and correct chemical incompatibility between oxidizingand reducing agents

Requirements: Spatula and listed in the formula

Category: Antiseptic and astringent

Formula:

Sl. No	Ingredients	Official formula	Working formula	Uses
1.	Potassium chlorate	10 g	500 mg	Oxidizing agent
2.	Tannie acid	5 g	250 mg	Alkaline substances
3.	Sucrose	5 g	250 mg	Preservation
4.	Potassium chlorate	10 g	500 mg	Oxidizing agent

Principle: An oxidizing and a reducing agent when mixed by a process involving friction results in violent explosion. Explosion is due to Redox reaction between the ingredients. Since potassium chlorate is an oxidizing agent and tannic acid is a reducing agent the preparation becomes a classical example of chemical incompatibility. However, incompatibility can be corrected by employing a mixing process that avoids friction, such as tumbling or spatulation.

Procedure:

- Mix in excess potassium chlorate and tannic acid on a butter paper by spatulation Add sucrose to the above mixture and mix well
- Weigh g of blend and pack by double wrap technique
- Dispense in a labeled envelop
- Discard the excess powder blend

Direction: Add the powder in a glass of warm water and use as gargle

Storage: Store in cool and dry place

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Experiment No:30

THERAPEUTIC INCOMPATIBILITY

Aim: To identify and correct therapeutic incompatibility between Aspirin and Probenecid

Requirements: Aspirin, Probenecid

R_x

Aspirin - 1.5 g

Probenecid - 1g

Principle: Above prescription is an example for therapeutic incompatibility due to antagonistic effect of combination drugs which neutralizes the effect of each drug. These drugs are used to treat Gout (an inflammatory condition associated with severe pain and tenderness in joints and is characterized by increased blood uric acid level). The pain and tenderness is due to accumulated uric acid in joints.

Treatment protocol includes an analgesic to relieve the pain and a drug to reduce blood uric acid level. Aspirin (analgesic) if given with Probenecid (uric acid reducer) results in therapeutic incompatibility due to their antagonistic property.

Prescribing Ibuprofen, an equally effective analgesic over Aspirin can prevent incompatibility.

Direction: Bring to the notice of the prescriber regarding incompatibility and replace Aspirin with Ibuprofen

Storage: Store in cool and dry place

Vision and Mission of the Institution

Vision

The East Point College of Pharmacy aspires to be a globally acclaimed institution, **recognized** for **excellence in** pharmaceutical education, research and nurturing students for **holistic development.**

Mission

M1 Create pharmacy graduates through **quality education**

M2 Promote innovation, **creativity**, and excellence **in teaching**, learning, and **research**

M3 **Inspire** integrity, teamwork, critical thinking**, personal** development, and ethics in **students** and lay **the** foundation for lifelong learning

M4 **Serve** the **healthcare, technological, scientific**, and **economic** needs of then **society**.