MARRI LAXMAN REDDY INSTITUTE OF PHARMACY

*(Approved by AICTE & PCI, New Delhi and Affiliated to JNTUH)*

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# *PHYSICAL PHARMACEUTICS – I*

## LAB MANUAL

## B. PHARMACY I-I

# About MLRIP


To be an educational Institute of par excellence and produce competent pharmacy professionals to serve the community through research and the ever-increasing needs of Industry.


1. Imparting quality education and innovative research for various career opportunities.
2. Creating conducive academic environment to produce competent pharmacy professionals.
3. Indoctrination of students adorned with high human values and make them aware of their responsibility as health care professionals.

**Program Educational Objectives**

**PEO 1:** To produce graduates with sound theoretical knowledge and technical skills required for their career opportunities in various domains.

**PEO 2:** To incite the students towards research and to address the challenges with their innovative contributions for the benefit of the mankind.

**PEO 3:** To instill the essence of professionalism, ethical commitment to become a health care professional with sound integrity and adherence to the core human values in the service of the society.


1. **Pharmacy Knowledge:** Possess knowledge and comprehension of the core and basic knowledge associated with the profession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.
2. **Planning Abilities:** Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.
3. **Problem analysis:** Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, while solving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions.
4. **Modern tool usage:** Learn, select, and apply appropriate methods and procedures, resources, and modern pharmacy-related computing tools with an understanding of the limitations.
5. **Leadership skills:** Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and well-being.
6. **Professional Identity:** Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).
7. **Pharmaceutical Ethics:** Honour personal values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions.
8. **Communication:** Communicate effectively with the pharmacy community and with society at large, such as, being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions.
9. **The Pharmacist and society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the professional pharmacy practice.
10. **Environment and sustainability:** Understand the impact of the professional pharmacy solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for sustainable development.
11. **Life-long learning:** Recognize the need for and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-assess and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## BP109P. PHARMACEUTICS - I (Practical)

**4 Hours / week**

**1. Syrups**

a) Syrup IP b) Compound syrup of Ferrous phosphate BPC

**2. Elixirs**

a) Piperazine citrate elixir b) Paracetmol pediatric elixir

**3. Linctus**

a) Terpin hydrate linctus IP b) Iodine Throat Paint (Mandle's paint)

**4. Solutions**

a) Strong solution of ammonium acetate b) Cresol with soap solution c) Lugol's Solution

**5. Suspensions**

a) Calamine lotion b) Magnesium Hydroxide mixture c) Aluminum hydroxide gel

**6. Emulsions**

a) Turpentine Liniment b) Liquid paraffin emulsion

**7. Powders and Granules**

a) ORS powder (WHO) b) Effervescent granules c) Dusting powder d) Divided powder

**8. Suppositories**

a) Glycero gelatin suppository b) Cocoa butter suppository c) Zinc oxide suppository

**9. Semisolids**

a) Sulphur ointment b) Non staining iodine ointment with methyl salicylate c) Carbopol gel

**10. Gargles and Mouthwashes**

a) Iodine gargle b) Chlorhexidine mouthwash

## GOOD LABORATORY PRACTICES

1. Wear neat and ironed laboratory apron while working
2. Come well prepared by reading the principle and procedure for the experiment concerned.
3. Read the procedure and/or consult lab in-charges for solving your problem or clearing your doubts.
4. Maintain the discipline and norms in the laboratory.
5. Use clean glass wares and wash the glassware after completion of lab.
6. Use strong acids, alkalies and other corrosives carefully.
7. Do not displace the reagents from their respective places.
8. Do not interchange pipettes/ glass tubes from one reagent to the other without thorough cleaning.
9. Use the gas whenever necessary, close gas tap when not required.
10. Submit laboratory record for correction in every practical class
11. Take signature from your lecturer for all the observations.
12. Leave the laboratory only after cleaning your work bench.

## WEIGHING TECHNIQUES

1. Check the balance for cleanliness and see that it is in order.
2. Do not weigh the sample directly on the pan
3. Use weighing paper (wax paper) for weighing.
4. Use stopper weighing bottle to weigh volatile (e.g. Iodine) or hygroscopic (e.g. Sodium hydroxide) sample.
5. Leave the balance neat and clean.

## SYRUPS – INTRODUCTION

**Definition:** Syrups are defined as oral liquids, which are sweet and viscous and then often contain added flavoring and coloring agents into which medicaments are incorporated. Syrups as such do not have any medicinal value, but used as vehicle for dispensing the drug.

According to I.P. the concentration of sugar in syrup is 66.7% w/w.

According to USP the concentration of sugar in syrup is 85% w/v.

**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:**

Syrups are classified into two types namely 'Medicinal' and 'Flavored syrups'

**Medicinal syrups:** Pure drugs and extracts are added to the syrup

E.g.: Paracetamol syrup (I.P)

E.g.: Ephedrine hydrochloride syrup (N.F.)

**Flavored syrups:** Aromatic or flavored substances are added to the syrup

Eg: Orange syrup (B.P.),

Lemon syrup (B.P.C)

**Preparation of Syrups:**

They are prepared by two methods

1) Solution method. E.g.: Simple syrup
2) Extraction method. E.g.: Tolu syrup

**Advantages:**

- Syrups retard oxidation of drugs; because sucrose itself gets hydrolyzed to laevulose and dextrose which are reducing sugars.
- They are sweet in taste. Therefore bitter taste of drugs can be reduced.
- Syrups prevent microbial decomposition of many vegetable drugs.

**Disadvantages:**

- On continuous intake syrups promote dental decay and cause gingivitis because it is a very good supplement for bacterial growth
- Syrups are not suitable for diabetic patients and patients who are on a restricted calorie intake.
- Aluminum salts cannot be included in syrups as these are incompatible with sucrose
- Syrups are not suitable for acidic drugs as they promote crystallization of sucrose.

## 1. SIMPLE SYRUP

**Aim:** To prepare and submit 10ml of simple syrup.

**Apparatus**: Beakers, Glass rod, Measuring cylinder, funnel and spatula

**Category:** Sweetening agent.

**Formula:**

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Sucrose | 66.7 gm |
| 2 | Purified water | q. s. to 100 ml |

**Principle:** Simple syrup (IP) is a concentrated or nearly saturated solution of sucrose in purified water. According to IP the concentration of sucrose is 66.7% w/w. The solubility of sugar in water is slow; at such a high concentration. Therefore the solution is heated to increase the rate of dissolution. If necessary, Methyl paraben at a concentration not higher than 0.15% may be used as preservative. Simple syrup is sweet in taste and used as vehicle in formulations containing nauseous bitter substances. Simple syrup as such does not have any medicinal value but used as vehicle for dispensing the drugs. Sucrose is a disaccharide, which partially hydrolyzed in to monosaccharide as glucose and fructose. These monosaccharides are called as invert sugars and reaction is called as inversion.

**Procedure:** Weigh the required quantity of sucrose and add required quantity of water. Then heat the mixture with occasional stirring. Take a precaution of not to overheat solution as it leads to crystallization of sugar. Add sufficient amount of purified water to get the final volume of the syrup. Filter if necessary, and then syrup is transferred into amber color container and labeled it.

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

**Storage**: Stored in a tightly closed container in a cool place.

**Auxiliary label**: “STORE AT COOL TEMPERATURE, NOT EXCEEDING $25^0$C IN DARK PLACE.

**Report:**

## 2. COMPOUND SYRUP OF FERROUS PHOSPHATE

**Aim:** To prepare and submit 10ml of syrup of ferrous phosphate

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

**Category:** Calcium and iron tonic (Haematinic)

**Formula:**

| S. No | Ingredients | Official Formula(BPC) |
|---|---|---|
| 1 | Iron turnings | 0.4 gm |
| 2 | Phosphoric acid | 4.8 ml |
| 3 | Calcium carbonate | 1.36 gm |
| 4 | Potassium bicarbonate | 0.1 gm |
| 5 | Sodium phosphate | 0.1 gm |
| 6 | Sucrose | 70 gm |
| 7 | Orange water | 5 ml |
| 8 | Purified water | q.s. to 100 ml |

**Principle:**

Iron is required to form hemoglobin in the blood that provides oxygen to the body. Calcium carbonate provides the calcium ion to the body. Phosphoric acid helps in dissolving the iron in the solution. This solution is filtered to remove the salts of iron and carbon from solution. Sucrose in purified water is sweet in taste and used as vehicle in formulations containing nauseous bitter substances. Orange water will act as flavoring agent.

**Procedure:**

In a small flask, take 25 ml of purified water along with 20 ml of Phosphoric acid and add iron turning which is heated on water bath until gets dissolved. Calcium carbonate, Potassium bicarbonate and Sodium phosphate are triturated together with small amount of Phosphoric acid. This mixture is added to the iron phosphate solution. Weigh required quantity of sucrose and add distilled water then boiled until it forms as syrup. Take a precaution of not to overheat solution as it leads to crystallization of sugar. Add sufficient purified water to get the required volume after cooling the solution. Filter if necessary, and then syrup is added with orange water and finally add this solution to the above prepared mixture of iron phosphate.

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

**Storage**: Stored in a tightly closed container in a cool place

**Direction:** As directed by physician

**Report:**

## 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 turbidity or 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 in a solution that contains 15 to 50% by volume of ethyl alcohol.

### Medicated elixirs

- Antihistaminic elixirs: used against allergy: Chloramphenіramine 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 state 10 – 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 in alcohol, 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.

**Adjuncts**

***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 syrup and 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 preservative action.
- High concentration of syrup has high osmotic pressure thus acts as preservative.
- Chloroform Water, Chloroform Spirit have preservative action.
- Benzoic acid, methyl parahydroxybenzoate acid (methyl paraben) or propyl parahydroxynenzoate (propyl paraben) may be used as additional preservatives.

## 3. PIPERAZINE CITRATE ELIXIR

**Aim:** To prepare the10 ml of piperazine citrate elixir.

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Anti helmintic

**Formula:**

| S. No | Ingredients | Official formula(I.P.) |
|---|---|---|
| 1 | Piperazine citrate | 18 gm |
| 2 | Chloroform spirit | 0.5ml |
| 3 | Glycerin | 10 ml |
| 4 | Syrup | 50 ml |
| 5 | Purified water | q. s. to100ml |

**Principle:** Elixirs are flavored hydro alcoholic solutions to which glycerin often is added to enhance the solvent properties. The alcohol which is present in the chloroform spirit act as a preservative. Piperazine citrate is unpleasant taste which is masked with the syrup to prevent the unpleasant taste of elixir.

**Procedure:** Piperazine citrate is dissolved in small amount of purified water. Glycerin, 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.

**Report:**

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

## 4. PARACETMOL PEDIATRIC ELIXIR

**Aim:** To prepare 10 ml of paracetmol pediatric elixir.

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Analgesic and antipyretic

**Formula:**

| S. No | Ingredients | Official formula(I.P.) |
|---|---|---|
| 1 | Paracetmol | 2.4 gm |
| 2 | Ethanol (96%) | 10ml |
| 3 | Chloroform water | 2 ml |
| 4 | Syrup | 28 ml |
| 5 | Glycerin | q. s. to 100ml |

**Principle:** Elixirs are flavored hydro alcoholic solutions to which glycerin often is added to enhance the solvent properties. The alcohol which is present in the chloroform spirit act as a preservative. Paracetmol is unpleasant taste which is masked with the syrup to prevent the unpleasant taste of elixir. The addition of aqueous solutions to elixirs may cause turbidity or separation by lessening the alcohol concentration.

**Procedure:** Dissolve the Paracetmol in the mixture of ethanol and chloroform water. Then add the syrup with continuous stirring and shake it. Finally add the glycerin to make up 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:** 5-10ml daily in divided doses to be taken in morning and night.

**Report:**

**Note:** The term Analgesics encompasses a class of drugs that are designed to relieve pain without causing the loss of consciousness.

## 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 contain other 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 like chloroform water, benzoic acid.
- Flavoring agents and flavor enhancers-lemon syrup.
- Coloring agents-compound tatrazine solution.
- Stabilizers-Syrups.
- Vehicles-Syrup, glycerin, chloroform water.

## 5. TERPIN HYDRATE LINCTUS

**Aim:** To prepare 10 ml of terpin hydrate linctus.

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Expectorant

**Formula:**

| S. No | Ingredients | Official formula(I.P.) |
|---|---|---|
| 1 | Terpin hydrate | 1.5 gm |
| 2 | Glycerol | 12 ml |
| 3 | Syrup | q. s to 30 ml |

**Principle:** Terpin hydrate is an expectorant, used to loosen mucus in patients presenting with acute or chronic bronchitis. Glycerol provides the soothing effect on the throat and increases the viscous nature of the preparation. Syrup will mask the bitterness of the terpin and act as solvent for the preparation.

**Procedure:** Dissolve the Terpin hydrate in the sufficient quantity of glycerol. Then add the syrup with continuous stirring and make up the final volume of the preparation.

**Dispensing:** Transfer the linctus to a 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:** 5-10ml daily in divided doses to be taken in morning and night.

**Report:**

**Note:** Expectorants are the drugs that loosen and clear mucus from the respiratory tract.

## 6. IODINE THROAT PAINT (MANDL'S PAINT)

**Aim:** To prepare 10 ml of iodine throat paint.

**Apparatus:** Motor and Pestle, measuring cylinder, spatula.

**Formula:**

| S. No | Ingredients | Official formula(B.P.) |
|---|---|---|
| 1 | Potassium iodide | 2.4gm |
| 2 | Iodine | 1.2gm |
| 3 | Alcohol (90%) | 4.0ml |
| 4 | Purified water | 2.4ml |
| 5 | Glycerin | q.s. to 100ml |

**Principle:** Iodine is slightly soluble in water, but it is soluble in presence of potassium Iodide and forms polyiodides. These polyiodides are highly soluble in water and hence produce monophonic liquid. Alcohol (90%) acts as co solvent, to increase the solubility of iodine. It is also used to dissolve glycerin is viscous in nature hence Mandl's paint will remain in contact with mucous membrane of throat for longer time, it also acts as humectant and soothing agent.

**Procedure:** Triturate iodine in glass mortar, to get fine powder and accurately weigh the required amount of iodine. Dissolve potassium iodine in water. To this solution, add iodine powder by stirring. Dissolve the portion of glycerin in alcohol and add this solution to the above iodine and potassium iodide solution, with continuous stirring and adjust the final volume with remaining portion of glycerin.

**Dispensing:** Mandl's paint contains volatile ingredients like iodine, alcohol (90%) and iodine is sensitive to the light. Hence transfer the paint to an amber colored, wide mouthed, glass bottle, close it tightly with plastic screw cap polish and label. Supply with camel hair brush.

**Direction:** Apply with camel hair brush, every four hours.

**Auxiliary label:** FOR EXTERNAL USE ONLY. SHAKE WELL BEFORE USE.

**Storage:** store in a cool and dark place.

**Category:** Mandl's paint is used in the treatment of pharyngitis, laryngitis, tonsillitis and sore throat.

**Report:**

## 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:**

| S. No | Type | Examples | Uses |
|---|---|---|---|
| 1 | Water | a. Potable water<br>b. Freshly boiled and cooled water<br>c. Purified water<br>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 weak preservative. |
| | | d) Anise water | Flavoring agent and carminative |
| | | e) Dill water | Flavoring agent, carminative (particularly for 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 many liquid preparations. |

| | | | |
|---|---|---|---|
| 4. | Elixirs | Non medicated elixirs<br>a) Low alcoholic elixirs<br>b) High alcoholic elixirs<br>c) Iso-alcoholic elixirs | Aromatics and vehicles for many oral liquid preparations. |
| 5. | Syrups | a) Orange syrup<br>b) Raspberry syrup<br>c) Cherry syrup<br>d) Glycyrrhiza syrup<br>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<br>1) blue color<br>2) brown color<br>3) black color<br>4)green color<br>5) red color<br>6) yellow color<br>7) orange color | <br>**Brilliant blue, indigo carmine**<br>**Resorcin brown**<br>**Naphthol blue(black)**<br>**Quinazolinone green, fast green, brilliant green**<br>**Amaranth, erythrosine**<br>**Sunset yellow, tartrazine yellow**<br>**Orange "G"** |

**7. Flocculating, suspending and wetting agents:**

| S.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<br>Sodium carboxy methyl cellulose<br>Hydroxyl ethyl cellulose<br>Hydroxyl propyl cellulose<br>Hydroxyl propyl methyl cellulose<br>Micro crystalline cellulose |
| | | c. inorganic agents | Clays, bentonite, kaolin, aluminium hydroxide |
| | | d. synthetic agents | Colloidal silicon dioxide.<br>Carbomer (carboxy vinyl polymer) |
| 3. | Wetting agents | -------- | Alcohol, glycerin, Tragacanth mucilage, sodium alginate, bentonite dispersion, surfactants having HLB value between 7 to 9, sodium lauryl sulphate, sodium dioctyl sulpho succinate |

**8. Emulsifying agents**

| S.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 wool fat, serum albumin. |
| **2** | Semi-synthetic polysaccharides | ----- | Methyl cellulose, carboxy methyl cellulose, sodium carboxy methyl cellulose, hydroxyl propyl methyl cellulose, micro crystalline cellulose |
| 3 | Synthetic substances | a. anionic | SLS, polypeptidecondensates, 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.

## 7. CRESOL WITH SOAP SOLUTION

**Aim:** To prepare 10 ml of cresol with soap solution.

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Disinfectant

**Formula:**

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Cresol | 50ml |
| 2 | Vegetable oil | 18 ml |
| 3 | Potassium Hydroxide | 4 gm |
| 4 | Purified water | q. s. to 100ml |

**Principle:** Solubility of cresol in water is only 2% w/v Cresol with soap solution contains 50%v/v of cresol. So, we require a surfactant to Solubilize cresol. It is prepared by saponification of mixture of vegetable oil and potassium hydroxide. This on heating brings about saponification to get the salt of higher fatty acids. The vegetable oil may be cotton seed, soya bean or similar oils which have saponification value not greater than 2.5 and iodine value not less than 100.

**Procedure:** Dissolve potassium hydroxide in one-fourth of purified water. Add vegetable oil and heat it on a water bath. Heating is continued until a small portion when added in water dissolves completely without Separation of any oil globules. Add cresol little by little to the mixture to get a clear solution. Add sufficient amount of purified water to make up the volume.

**Dispensing:** Transfer the solution 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 and protect from sunlight.

**Report:**

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

## 8. STRONG AMMONIUM ACETATE SOLUTION

**Aim:** To prepare and submit10 ml of strong ammonium acetate solution.

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Diaphoretic

**Formula:**

| S. No | Ingredients | Official Formula |
|---|---|---|
| 1. | Glacial Acetic Acid | 45ml |
| 2. | Ammonium Bicarbonate | 47gm |
| 3. | Ammonia Solution | 10 ml |
| 4. | Purified water | q.s. to 100ml |

**Principle:** Ammonium bicarbonate reacts with glacial acetic acid to give ammonium acetate.

$NH_4HCO_3 + CH_3COOH \Longrightarrow CH_3COONH_4 + H_2O + CO_2$

In the above reaction, not all acid is neutralized. Glacial acetic acid which is neutralized with water must be used to produce a solution of derived strength. Ammonia must be used to complete neutralization.

$CH_3COOH + NH_3 \Longrightarrow CH_3COONH_4$

By adding ammonia the pH of solution is maintained between 7.6 - 8.0. The pH of neutralization is found by mixing one drop of solution with the indicator bromothymol blue and thymol blue separately. The color which is produced after adding indicator

| | | |
|---|---|---|
| Bromothymol blue | pH 6 | pH 7.6 |
| | Yellow | Blue |
| Thymol blue | pH 8 | pH 9.6 |
| | Yellow | Blue |

**Procedure:** Mix glacial acetic acid with required quantity of purified water and ammonium bicarbonate till it dissolves. Add sufficient quantity of ammonia solution drop by drop until one drop of resulting solution gives full blue color with one drop of thymol blue. After adjusting pH, transfer the solution into measuring cylinder and make up the final volume with purified water.

**Dispensing:** Transfer the solution 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 and protect from sunlight.

**Direction:** 1 to 5 ml daily in divided doses to be taken in two times a day.

**Report:**

**Note:** Diaphoretic a substance that produces or encourages perspiration (sweating).

## 9. LUGOL'S SOLUTION (AQUEOUS IODINE SOLUTION)

**Aim:** To prepare and dispense10 ml of aqueous iodine solution.

**Apparatus:** beakers, glass rod, measuring cylinder.

**Synonym**: Lugol's solution

**Formula:**

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Iodine | 5 gm |
| 2 | Potassium iodide | 10 gm |
| 3 | Purified water | q. s. to 100ml |

**Principle:** Aqueous iodine solution contains 5%w/v of iodine 10% w/v of potassium iodide. Since, iodine is sparingly soluble in water; the solubility of iodine is increased by forming complex with potassium iodide. The complex form is more soluble than iodine in water. Iodine reacts with potassium iodide and forms complexes as polyiodides. These are highly soluble in water. Higher polyiodides are more soluble than lower polyiodides.

$$KI + n\,I_2 \rightarrow KI.nI_2$$

Potassium iodide  Iodine  Polyiodides

**Procedure:** Dissolve potassium iodide in small quantity of water and add iodine to the solution. Stir well to dissolve iodine and make the final volume with water.

**Category:** Source of iodine in treatment of goiter

**Dispensing:** Transfer the solution in to amber colored, narrow mouthed, glass bottle, close it thoroughly with plastic screw cap, polish and label.

**Storage**: Store in a cool and dark place.

**Report:**

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

## SUSPENSIONS-INTRODUCTION

A Pharmaceutical suspension is a coarse dispersion in which internal phase (therapeutically active ingredient) is dispersed uniformly throughout the external phase. The internal phase consisting 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 to re-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.

## 10. CALAMINE LOTION

**Aim:** To prepare 10ml of calamine lotion

**Apparatus:** Mortar and pestle, Measuring cylinder, spatula.

**Category:** Skin protectant.

**Formula:**

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1. | Calamine | 15gm |
| 2. | Zinc oxide | 5gm |
| 3. | Bentonite | 3gm |
| 4. | Sodium citrate | 0.5gm |
| 5. | Liquid phenol | 0.5ml |
| 6. | Glycerin | 5ml |
| 7. | Purified water | q. s. to100 ml |

**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 $3/4^{th}$ 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

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

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

**Report:**

## 11. MAGNESIUM HYDROXIDE MIXTURE

**Aim:** To prepare 10ml of magnesium hydroxide mixture.

**Apparatus:** Mortar and pestle, Measuring cylinder, spatula, beaker, glass rod.

**Category:** Antacid

| S.No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Magnesium Sulphate | 4.8 gm |
| 2 | Sodium Hydroxide | 1.5 gm |
| 3 | Light Magnesium Oxide | 5.3 gm |
| 4 | Chloroform | 0.3 ml |
| 5 | Purified Water | q.s. to 100 ml |

**Principle:** Pharmaceutical suspension is a coarse dispersion in which internal phase (therapeutically active ingredient) is dispersed uniformly throughout the external phase. The internal phase consisting 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. Magnesium hydroxide mixture cannot be prepared directly by suspending magnesium hydroxide powder in water because it absorbs carbon dioxide and moisture from the atmosphere. Hence it is prepared by the reaction between Magnesium Sulphate, Sodium Hydroxide and Light Magnesium Oxide. To improve the palatability of the mixture 0.1% of citric acid is added and chloroform act as preservative.

**Procedure:** Dissolve the Sodium hydroxide in smaller amount of Purified Water, add the Light Magnesium Oxide, mix to form a smooth cream and then add sufficient amount of Purified Water to produce final volume. Pour this suspension in a thin stream into a solution of the Magnesium Sulphate dissolved in Purified Water, stir continuously during the mixing. Allow the precipitate to subside, remove the clear liquid, transfer the residue to a calico strainer, (filter mesh made with porcelain) allow to drain and wash the precipitate with Purified Water until the washings give only a slight reaction for sulphates. Mix the washed precipitate with Purified

Water, dissolve the Chloroform in the mixture and add sufficient amount of Purified Water to produce final volume.

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

**Direction:** 10 ml of mixture is to be taken for two times in a day.

**Storage:** Stored at cool place and do not stored in refrigerator.

**Auxiliary label**: SHAKE WELL BEFORE USE.

**Report:**

## 12. ALUMINIUM HYDROXIDE GEL

**Aim:** To prepare 10ml of aluminum hydroxide gel suspension.

**Apparatus:** Mortar and pestle, Measuring cylinder, spatula, beaker, glass rod.

**Category:** Antacid

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Aluminium hydroxide gel | 1.6 gm |
| 2 | Sodium benzoate | 0.1 gm |
| 3 | Peppermint water | q. s. to 20 ml |

**Principle:** Pharmaceutical suspension is a coarse dispersion in which internal phase (therapeutically active ingredient) is dispersed uniformly throughout the external phase. The internal phase consisting 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. Aluminum hydroxide gel in water forms as dispersion because it is insoluble in water. Sodium benzoate act as preservative and peppermint water is added to make final volume of preparation that provides flavor to the formulation.

**Procedure:** Dissolve the weighed quantity of Aluminum hydroxide in sufficient amount of Peppermint water along with sodium benzoate in a beaker with continuous stirring. Pour this suspension in a thin stream into the measuring cylinder and add remaining amount of Peppermint water to produce final volume of the suspension.

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

**Direction:** 5 ml of suspension is to be taken for two times after meals in a day.

**Storage:** Stored at cool place and do not stored in refrigerator.

**Auxiliary label**: SHAKE WELL BEFORE USE.

**Report:**

## 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 longer period, 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 is masked 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 drug compared 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 aqueous phase.

These types of emulsions can be prepared by proper selection of emulsifying agents, depending on HLB scale.

**Primary emulsion ratio:**

| S. 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 of droplets 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:**

| S. No | Type | | Examples |
|---|---|---|---|
| 1 | Natural emulsifying agents | A)From vegetable sources<br><br>B) from animal source | Gum acacia, karaya gum, tragacanth gum, agar, pectin, starch, irish moss, alginate, gaur gum, soya bean<br><br>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 | Alkoxyalkylamines, 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 | ------- | Polyethyleneglycols, cholesterol, alcohol, lecithin. |

**2. 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.

**3. Anti –oxidants:** During storage of emulsions, many oils and animal fats may undergo oxidation 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.

**4. 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.

## 13. LIQUID PARAFFIN EMULSION

**Aim:** To prepare 10ml of liquid paraffin emulsion

**Apparatus:** Mortar and pestle, Measuring cylinder, glass rod, spatula.

**Category:** laxative.

**Formula:**

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Liquid paraffin | 10ml |
| 2 | Gum | 2.5 gm |
| 3 | Water | q. s .for 30ml |

**Principle:** An Emulsion is a biphasic preparation containing two immiscible liquids which are made miscible of third substance is known as emulsifying agent. Liquid paraffin is used as a laxative in this emulsion. This is an emulsion of a mineral oil like liquid paraffin, with a water acts as laxative by lubricating the stool. It is prepared as o/w type emulsion, using gum acacia as an emulsifying agent by dry gum method. Since liquid paraffin is a mineral oil, primary emulsion ratio will be 3:2:1.

**Procedure:** Take required quantity of acacia gum and transfer into a mortar and triturate with gum so as to form a mucilage then to this add liquid paraffin in small quantity at a time thoroughly triturate after each addition. The emulsion is triturated uniformly until it becomes white creamy mixture. Add required quantity of vehicle in a small quantity at a time with constant trituration so as to get a homogeneous product finally make up with a required volume of water. Then transfer into a container and label.

**Auxiliary label:** SHAKE WELL BEFORE USE

**Dispensing:** Transfer this emulsion to a narrow mouthed, amber colored glass or plastic bottle closed with closure and labeled.

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

**Direction:** Two teaspoonfuls to be taken, at night.

**Report:**

**Note:** Laxative is a drug that stimulates evacuation of the bowels.

## 14. TURPENTINE LINIMENT

**Aim:** To prepare 10ml of turpentine liniment

**Apparatus:** Mortar and pestle, Measuring cylinder, glass rod, spatula.

**Category:** Counter irritant

**Formula:**

| S. No | Ingredients | Official Formula(I.P.) |
|---|---|---|
| 1 | Turpentine oil | 60ml |
| 2 | Soft soap | 9g |
| 3 | Camphor | 5g |
| 4 | Purified water | q. s. to 100ml |

**Principle:** This is oil in water type of emulsion. Camphor is insoluble in water, but soluble in turpentine oil. Since turpentine oil is insoluble in water, it has to be emulsified with appropriate emulsifying agent that is Soft soap. Turpentine oil has antiseptic, analgesic and counter irritant action and purified water acts as a vehicle.

**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.

**Auxiliary label:** For external use only. Not to be applied on wounds and broken skin. Shake well before use.

**Report:**

**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

## GARGLES AND MOUTHWASHES INTRODUCTION

Gargles are aqueous and hydro alcoholic solution which is used to treat or prevent throat infection. Gargles are intended to bring the medicament into close contact with the mucous surface of the throat. As the contact period of gargle and the mucous surface is short, the preparation must be fast acting. They are dispensed in concentrated form with directions for dilution with warm water. They are brought into intimate contact with the mucous membrane of the throat and allow remaining for few moments. Gargles restore the tone of relaxed throat and stimulate the flow of saliva, which relieves dryness of the mouth.

Gargles contain medicaments like

- Antiseptics: Borax
- Antibiotics: Chloramphenicol
- Astringents: Potassium chlorate, Benzalkonium chlorate
- Bactericides: Phenol, Thymol.
- Local anesthetics: Benzocaine

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

**Direction:** They are dispensed in concentrated form or dilution with warm water before use.

**Labeling**: The label should include use only as directed. Avoid contact with the eyes. NOT TO BE SWALLOWED. Dilute with warm water.

**Storage:** Store at room temperature Keep out of the reach of children.Store away from direct sunlight, heat and moisture.

Mouth washes are aqueous solution which are used for its deodorants, refreshing or antiseptic property in the buccal cavity. Mouth washes generally contain antibiotic agents or astringent, alcohol, glycerin, sweeteners and surfactants, flavoring and coloring agents. Examples: - Alkaline phenol mouth wash, Hydrogen peroxide mouth wash

**Formulation:** It consists of

Vehicles: chloroform water, peppermint water.

Sweetening agents: simple syrup

Flavoring agents: aromatic water

Coloring agents: Amaranth solution

Surfactants: sodium lauryl sulphate, Tween 80

Humectants: glycerin

**Preparation of Mouthwashes:** It is prepared by simple solution method.

**Dispensing:** Mouth washes should be dispensed in amber colored, narrow mouthed bottle tightly closed with colored plastic screw cap.

**Labeling:** The label should include use only as directed. Avoid contact with the eyes. NOT TO BE SWALLOWED. Dilute with warm water.

**Direction:** Dilution with warm water before use.

**Storage:** Store at room temperature away from sunlight.

## 15. CHLORHEXIDINE MOUTHWASH

**Aim:** To prepare 10 ml of chlorhexidine mouth wash

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Treatment of mouth and throat infections

**Formula:**

| S. No | Ingredients | Official Formula(BPC) |
|---|---|---|
| 1. | Chlorhexidine gluconate | 0.12 gm |
| 2. | Brilliant Blue | q. s. |
| 3. | Sorbitol | 3 gm |
| 4. | Ethanol | 5 ml |
| 5. | Peppermint water | q. s. to 100ml |

**Principle:** Mouth washes are aqueous solution which are used for its deodorants, refreshing or antiseptic property in the buccal cavity. Mouth washes generally contain antibiotic agents or astringent, sweeteners and coloring agents. Chlorhexidine Gluconate is a disinfectant and topical anti-infective agent to prevent oral plaque. Ethanol will dissolves the chlorhexidine gluconate and Sorbitol act as sweetening agent. Brilliant Blue acts as coloring agent to give attractive color to the mouth wash.

**Procedure:** Mix the Chlorhexidine Gluconate in sufficient quantity of ethanol and add the Brilliant Blue little by little with continuous stirring to form a solution. Finally add sufficient amount of Sorbitol and Peppermint water to make up the volume and transferred in a suitable container.

**Dispensing:** Chlorhexidine mouth wash should be dispensed in amber colored, narrow mouthed bottle tightly closed with colored plastic screw cap.

**Direction:** 10 ml of mouthwash was taken twice in a day and diluted with warm water before use.

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

**Auxiliary label:** NOT TO BE SWALLOWED IN LAGE QUANTITIES.FOR ORAL USE ONLY.

**Report:**

## 16. IODINE GARGLE

**Aim:** To prepare 10 ml of Iodine gargle.

**Apparatus:** Beakers, glass rod, measuring cylinder.

**Category:** Antiseptic

**Formula:**

| S. No | Ingredients | Official Formula |
|---|---|---|
| 1. | Povidone Iodine | 1 gm |
| 2. | Purified water(boiled and cooled) | q.s. to 100 ml |

**Principle:** Gargles are aqueous and hydro alcoholic solution which is used to treat or prevent throat infection. Gargles are intended to bring the medicament into close contact with the mucous surface of the throat. Povidone Iodine will act as antiseptic that helps in prevention of oral infections.

**Procedure:** Mix the Povidone Iodine in sufficient quantity of purified water (boiled and cooled) with continuous stirring to form a solution. Finally add remaining amount of purified water to make up the volume and transferred in a suitable container.

**Dispensing:** Povidone Iodine gargle should be dispensed in amber colored, narrow mouthed bottle tightly closed with colored plastic screw cap.

**Direction:** 10 ml of gargle was taken twice in a day and diluted with warm water before use.

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

**Auxiliary label:** NOT TO BE SWALLOWED IN LAGE QUANTITIES.FOR ORAL USE ONLY.

**Report:**

## POWDERS AND GRANULES 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 include

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

**A (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 stream of 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 calcium phosphate
- 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 of paper.

**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. Some time *double wrapping* is required, especially if the powder is hygroscopic. In this case waxed paper is used as inner wrapper, then the demy wrapper as 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 is more time consuming compared to tablets

Granules are defined as a dosage form composed of dry aggregates of powder particles that may contain one or more APIs, with or without other ingredients. They may be swallowed as such, dispersed in food, or dissolved in water. Granules are frequently compacted into tablets or filled into capsules, with or without additional ingredients. Effervescent granules are popular delivery systems for many pharmaceutical products such as antacids, analgesics, and cough/cold formulations. They are fast dissolving, highly soluble, stable, convenient dosage forms. The granules are added into a glass of water just before administration and the drug solution or dispersion is to be drunk immediately. The granules are quickly dispersed by internal liberation of Carbon dioxide in water due to interaction between acid with alkali metal carbonates or bicarbonates in the presence of water. Due to liberation in Carbon dioxide gas, the dissolution of the API in water as well as taste masking effect is enhanced.

**Formulation:** The Effervescent granules are specially prepared solid dosage form usually contains medicament, acid and base for internal use. E.g. Citric acid, Tartaric acid and Sodium bicarbonate.

**Advantages:**

- To prevent segregation of the constituents of powder Mix
- To improve the flow properties of the powder mix
- To improve the compaction characteristics of powder mix
- Granules have higher porosity than powders
- To improve the compressibility of powders

- Good tasting, sparkling drinks containing ingredients which do not normally taste good in liquid form.

**Limitations of effervescent formulations**

- It cannot be given to the children because of possibility of gas ($CO_2$) toxicity.
- If packaging is not done properly then there are chances of degradation by environmental moisture.
- It has shorter shelf life as compared to other solid dosage forms.
- It requires special machinery requirements for manufacturing.
- This dosage form is costly then tablets.

**Preparation of effervescent granules:** These granules are prepared by two methods:

A) Fusion method:

• In the fusion method, the one molecule of water present in each molecule of citric acid acts as the binding agent for the powder mixture.

• Before mixing the powders, the citric acid crystals are powdered and then mixed with the other powders of the same sieve size to ensure uniformity of the mixture.

• The sieves and the mixing equipment should be made of stainless steel or other material resistant to the effect of the acids.

• The mixing of the powders is performed as rapidly as is practical, preferably in an environment of low humidity to avoid absorption of moisture and a premature chemical reaction.

• After mixing, the powder is placed on a suitable dish in an oven at 34°C to 40°C.

• During the heating process, an acid resistant spatula is used to turn the powder.

• The heat releases the water of crystallization from the citric acid, which, in turn, dissolves a portion of the powder mixture, setting the chemical reaction and consequently releasing some carbon dioxide.

• This causes the softened mass of powder to become somewhat spongy, and when it has reached the proper consistency (as bread dough), it is removed from the oven and rubbed through a sieve to produce granules of the desired size.

• No. 4 sieve produces large granules, No. 8 sieve prepares medium size granules, and No. 10 sieve prepares small granules.

• The granules are dried at a temperature not exceeding 54°C and are immediately placed in containers and tightly sealed.

B) Wet method:

• The wet method differs from the fusion method in that the source of binding agent is not the water of crystallization from the citric acid but the water added to alcohol as the moistening agent, forming the pliable mass for granulation.

• In this method, all of the powders may be anhydrous as long as water is added to the moistening liquid.

• Just enough liquid is added (in portions) to prepare a mass of proper consistency; then the granules are prepared by passing the mass into the required sieve and dried.

**Dispensing:**Weigh require quantity of granules and transfer into narrow mouthed bottle tightly closed with colored plastic screw cap.

**Direction:** Add two spoon full of granules, to a glass of water with stirring and drink the solution.

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

## 17. ORS POWDER

**Aim:** To prepare the ORS powder

**Apparatus:** Mortar and pestle, spatula.

**Category:** Rehydrating salt.

**Formula:**

| S.No | Ingredients | Official Formula(WHO) for 100 ml of water |
|---|---|---|
| 1 | Sodium chloride | 0.26 gm |
| 2 | Glucose | 1.35 gm |
| 3 | Potassium chloride | 0.15 gm |
| 4. | Tri sodium citrate dihydrate | 0.29 gm |

**Principle:** Diarrhoea in children usually gets better on its own, it causes loss of water and salts. This may lead to dehydration, which can be dangerous, especially in very young children, because it is difficult to see the signs of dehydration. Your child may be dehydrated if they have any of the following symptoms fewer like child is urinating less often, they are less active than normal, a dry mouth, crying without tears, a sunken soft spot on the top of a baby's head. Oral rehydration salts do not treat the diarrhoea itself, but they replace the salts and water that are lost, and so reduce the effects of dehydration.

**Procedure:** Mix all the ingredients in a mortar and triturated until a fine powder is obtained. This powder was transferred into white glazed paper (demy paper) and wrapped. Then these wrapped sachets are kept in a paper box and dispensed. Some time double wrapping is required, especially if the powder is hygroscopic. In this case waxed paper is used as inner wrapper, then the demy wrapper as the outer wrapper.

**Dispensing:** The packed sachets are transferred into wide mouthed bottle tightly closed with colored plastic screw cap.

**Direction:** Add one sachet of powder, to a glass of water with stirring and drink the solution.

**Storage:** Store in a cool and dry place.

**Report:**

## 18. SODIUM PHOSPHATE EFFERVESCENT GRANULES

**Aim:** To prepare the sodium phosphate effervescent granules.

**Apparatus:** Mortar and pestle, spatula.

**Category:** Saline purgative.

**Formula:**

| S.No | Ingredients | Official Formula for 100 ml of water |
|---|---|---|
| 1 | Sodium phosphate (anhydrous) | 5 g |
| 2 | Sodium bicarbonate | 5 g |
| 3 | Tartaric acid | 2.4g |
| 4. | Citric acid | 2.1 g |

**Principle:** Effervescent granules prepared with tartaric acid only produce granules which are powdery and the final product will have a salty taste. On the other hand, if only citric acid is used, the mass will be sticky and difficult to manipulate. Therefore a combination of the two acids is used to make a better granulation mixture. Sodium bicarbonate reacts with the acids when the preparation is added to water. The evolved carbon dioxide produces the effervescence. Citric and tartaric acids: The quantity of these acids is slightly more than is necessary to neutralize the sodium bicarbonate because effervescent preparations are more palatable if slightly acidic. Sodium phosphate is used as saline purgative.

**Procedure:** Mix the weighed powders in an ascending order of weights starting with the smallest weight in a mortar. Moisten the powder mixture with alcohol 96 %, which will act as a binder to form a damp mass. Add extra binder if needed and mix continuously until the mass will retain its shape when molded into a ball. Force the mass through a sieve of suitable size. Dry the moist granules in a temperature not exceeding 55 $^{0}$C or in an open-air if the humidity is low. Transfer the dried granules into a wide-mouthed glass bottle, close and stick on the label.

**Dispensing:** The packed sachets of effervescent granules are transferred into wide mouthed bottle tightly closed with colored plastic screw cap.

**Direction:** Add one sachet of effervescent granules, to a glass of water with stirring and drink the solution.

**Storage:** Store in a dry place and away from sunlight.

**Report:**

## 19. ZINC STARCH AND TALC DUSTING POWDER

**Aim:** To prepare the zinc starch and talc dusting powder.

**Apparatus:** Mortar and pestle, spatula.

**Category:** Antiseptic dusting powder.

**Formula:**

| S. No | Ingredients | Official Formula (I.P.) |
|---|---|---|
| 1 | Zinc oxide | 4 gm |
| 2 | Starch | 4 gm |
| 3 | Talc | 8 gm |

**Principle:** Dusting powder is a sterile cutaneous powder containing starch and purified talc in which the talc is sterilized before incorporation with the starch, or the final product is subject to a suitable terminal sterilization procedure. Dusting powders are applied to the skin for a surface effect such as drying or lubrication. Some dusting powders incorporate medicaments, giving them antibacterial or Antiseptic action.

**Procedure:** Weigh the calculated amounts of Zinc Oxide, Starch and Talc. Transfer the Starch to a porcelain mortar. Add the Zinc Oxide to the Starch in the mortar and mix using a pestle. Add the Purified Talc to the powders in the mortar and continue mixing. Transfer the mixed powder to an amber glass jar. Label and dispense to the patient.

**Dispensing:** Transfer the dusting powder into a re closable perforated plastic container.

**Direction:** Sprinkle lightly on the affected area, two-three times a day.

**Storage:** Store in a dry place and away from sunlight.

**Auxiliary label:** FOR EXTERNAL USE ONLY.

**Report:**

## 20. ASPIRIN DIVIDED POWDER

**Aim:** To prepare the aspirin divided powder

**Apparatus:** Mortar and pestle, spatula.

**Category:** Analgesic and Anti pyretic

**Formula:**

| S. No | Ingredients | Official Formula (I.P.) |
|---|---|---|
| 1 | Aspirin | 5 gm |
| 2 | Citric acid | 0.5 gm |
| 3 | Calcium carbonate | 1.5 gm |

**Principle:** Oral Divided powders may be formulated as divided powders, with each dose packaged individually or undivided, as a bulk powder. Oral divided powders may contain one or more active ingredients together mixed with inert diluents. A pharmaceutical balance is used to measure a minimum quantity, which is usually taken to be 200 mg. Aspirin will act as Analgesic and Anti pyretic. Citric acid and calcium carbonate together form as carbonated solution when added with water that helps high solubility of aspirin.

**Procedure:** Weigh the calculated amounts of Aspirin, Citric acid and calcium carbonate and Transfer into a porcelain mortar and triturate the mixture using a pestle. Transfer the mixed powder to an amber glass jar. Label and dispense to the patient.

**Dispensing:** Transfer the divided powder into a individual double wrapped sachets and stored in container.

**Direction:** Dissolve the powder in water and take the solution for two times a day.

**Storage:** Store in a dry place and away from sunlight.

**Auxiliary label:** KEEP OUT OF THE REACH OF CHILDREN.

**Report:**

## SEMISOLIDS – INTRODUCTION

Ointments are semi-solid preparation meant for external application to the skin or mucous membrane they usually contain a medicament or medicaments dissolved or suspended or emulsified in an ointment base.

**Ointment Base:** The ointment base is that substance or part of an ointment which serves as carrier or vehicle for the medicament it should be inert, powder less and smooth

- It should be physically and chemically stable
- It should be comparable with the skin and with the incorporated medicaments
- It should be off such a consisting i.e. spreads and softens when applied to the skin with stress.
- It should not produce irritation on sensitization of the skin

***Classification of ointments Bases***

**1. Oleaginous Bases**: These bases consisting of water in soluble hydro carbon, vegetable oils, animal fats and waxes. The constituents of hydrocarbon bases are soft paraffin, hard and liquid paraffin

**Soft paraffin (petrolatum):** It is a purified mixture of semi – solid hydrocarbons obtained from petroleum. There are two verities of soft paraffin 1) yellow ii) white

**Hard paraffin**: It is a purified mixture of solid hydrocarbon obtained from petrolatum. It is used to harden or soften the ointment base

**Liquid paraffin**: It consists of a mixture of liquid hydrocarbons obtained from petroleum by distillation. It is also known as mineral oil or liquid paraffin.

**2. Absorption Bases:** These bases are generally anhydrous substances which have the property of absorbing (emulsifying) consider quantities which have the property of absorbing (emulsifying) consider quantities of water.

The absorption bases are of two types

**3. Emulsions base:** These bases are semisolid (or) have a cream like consistency.

W/O type: The w/o type of bases are greasy and sticky

O/W type: These can be easily removed from skin

**Water soluble bases: example:** Poly ethylene glycol [**PEG]**

**Preparation of ointments**:

The ointments can be prepared by the following method.

**Trituration Method:**

It is the most commonly used method for preparation of ointments. This method is used when base is soft and medicament is insoluble in a base.

- Finely powder with the solid medicaments
- Weigh the required quantity of an ointment base

Triturate the solid medicaments with the small amount of the base on an ointment slab with the help of stainless steel ointment spatula until a homogeneous product is formed.

Add remaining quantities of the base until the medicament is uniformly mixed with it. When large quantity of liquid is to be incorporated pestle and mortar should be used

**Fusion method:**

When an ointment base contains a number of solid ingredients of different melting point such as wild bee's wax stearic acid to melt them in decreasing order to their M.P.The medicament is incorporated slowly to the melted mass stir thoroughly until in mass cold down and homogeneous product is formed.

**Chemical Reaction Method:**

Certain chemical Reactions are involved in the preparation of several ointments.

Eg: Iodine ointment Iodine may be present in free from or in combined with ointment base

**Emulsification method:** In this method the fats, oil, waxes are melted together on a water bath at the temperature of 70$^{o}$C the solution is slowly added to the melted bases with continuous stirring until the product cools down and semi-solid mass is formed.

**Dispensing:** Ointments should be stored in tightly closed and completely filled containers. Changes in temperature can lead to the crystallization of the drug and to changes in the ointment base. They are usually dispensed in jars of glass or plastic material or in collapsible tubes.

**Storage:** Store in a cool place and away from sunlight as it melts at higher temperature.

**Auxiliary label:** FOR EXTERNAL USE ONLY.

## 21. SULPHUR OINTMENT

**Aim:** To prepare 10 gm of sulphur ointment.

**Apparatus:** Mortar and pestle, Beaker, glass rod, spatula.

**Category:** Antiseptic

**Formula:**

| S. No | Ingredients | Official Formula (B.P.) |
|---|---|---|
| 1 | Sulphur powder | 1.2 gm |
| 2 | Simple ointment | q.s. to 10 gm |

Simple ointment formula for 10 gm:

Wool fat - 0.5 gm

Hard Paraffin - 0.5 gm

Ceto stearyl alcohol - 0.5 gm

White soft paraffin - 8.5 gm

**Principle:** Simple ointment prepared with white soft paraffin should be used white ointments. Simple ointment prepared with yellow soft paraffin should be used in colored ointments. It is employed chiefly as a pharmaceutical aid and forms basis of ointments. Wool fat provides emollient action. By itself it is not readily absorbed but when mixed with soft paraffin or suitable vegetable oil it forms the cream which penetrate the skin and facilitates the absorption of therapeutically active ingredient. Hard paraffin works as stiffening agent. Cetosteryl alcohol improves the emollient properties of simple ointment.White or yellow soft paraffin form protective ointment basis for surface action. They are also useful as an emollient.

**Procedure:** Weigh the required amount of ingredients of simple ointment and melt the ingredients in the beaker. To this mixture add the sulphur powder and stir the contents continuously until a semisolid mass is obtained without sign of any particles of sulphur. Gradually incorporate the remaining quantity of simple ointment and mix thoroughly to get a homogenous smooth ointment.

**Dispensing:** Sulphur is sensitive to the light. Hence transfer the prescribed quantity of ointment, to a light resistant ointment collapsible tube, close it thoroughly and labeled.

**Direction:** Apply the ointment to the affected area, whenever necessary as directed by the physician.

**Storage:** Store in a cool place and away from sunlight as it melts at higher temperature.

**Auxiliary label:** FOR EXTERNAL USE ONLY.

**Report:**

## 22. NON STAINING IODINE OINTMENT

**Aim:** To prepare 10 gm of non staining iodine ointment.

**Apparatus:** Glass mortar and pestle, Beaker, glass rod, spatula.

**Category:** Local analgesic

**Formula:**

| S. No | Ingredients | Official Formula (B.P.C) |
|---|---|---|
| 1 | Iodine | 0.48 gm |
| 2 | Oleic acid | 0.96 ml |
| 3 | Arachis oil | 1.5 ml |
| 4 | Yellow soft paraffin | q.s. to 10 gm |

**Principle:** For the preparation of ointment, arachis oil alone cannot be used, because it does not contain sufficient unsaturated linkages, to make complex with iodine .Therefore oleic acid is used, along with arachis oil, which provides sufficient unsaturated fatty acids and has oleoginic linkages. Fixed oils and vegetable oils absorb iodine which combines with the double bonds of the unsaturated constituents and forms di-iodostearic acid.

$$\underset{\text{Oleic acid}}{CH_3(CH_2)_2.CH=CH.(CH_2)_7.COOH} + I_2 \rightarrow \underset{\text{di-iodostearic acid}}{CH_3.(CH_2)_2.CHI\ CHI.(CH_2)_7.COOH}$$

The addition of yellow soft paraffin in the initial stage i.e, along with arachis oil and oleic acid, slows down the reaction between the fatty acids and iodine. Therefore yellow soft paraffin should be melted separately and added at the end of the preparation. Iodine is volatile in nature and heating should not be done above $50^0$C. At room temperature, reaction is slow hence it is heated. At initial stage mixture is brown color but at the final stage it turns into greenish black color due to the complexation between fatty acids and iodine. It may require 2-4 hours for completion of reaction.

**Procedure:** Iodine is finely powdered in a glass mortar and required amount of arachis oil and oleic acid is added in a glass-stoppered conical flask and stirred well. The oil is heated at $50^0$C in a water-bath and stirred continuously. Heating is continued until the brown color is changed to greenish-black this may take several hours (2-4 hours). Soft paraffin is warmed to $40^0$C. The iodized oil is added and mixed well. No more heat is applied because this causes deposition of a

resinous substance. The preparation is packed in a warm, wide-mouthed, amber color, glass bottle. It is allowed to cool without further stirring.

**Dispensing:** Iodine is sensitive to the light. Hence transfer the prescribed quantity of ointment, to a light resistant wide mouthed small glass jar and allow for cool without stirring and after cooling close with plastic screw cap and labeled.

**Direction:** Apply the ointment to the affected area, whenever necessary as directed by the physician.

**Storage:** Store in a cool place and away from sunlight as it melts at higher temperature.

**Auxiliary label:** FOR EXTERNAL USE ONLY.

**Report:**

## 23. CARBOPOL GEL

**Aim:** To prepare the carbopol gel.

**Apparatus:** Beaker, glass rod, spatula, water bath.

**Category:** Gelling agent

**Formula:**

| S. No | Ingredients | Official Formula |
|---|---|---|
| 1 | Carbopol 940 | 0.5 gm |
| 2 | Propyl paraben | 0.1 gm |
| 3 | Purified water | q.s. to 10 gm |

**Principle:** Carbopol is a water soluble polymer, used as an emulsifying, stabilizing, suspending, thickening and gelling agent in many industries. Propyl paraben is used as preservative.

**Procedure:** The Carbopol gel was prepared by direct dispersion method. In this method firstly, propyl paraben was dissolved in water at 80ºC to form a solution and then accurately weighed quantity of carbopol 940 was dispersed in water at 40ºC with constant stirring. This carbopol solution was added to the propylparaben solution with continuous stirring until a semisolid gel is obtained.

**Dispensing:** Transfer the prescribed quantity of gel, to a light resistant ointment collapsible tube, close it thoroughly and labeled.

**Storage:** Store in a cool place and away from sunlight as it melts at higher temperature.

**Auxiliary label:** FOR EXTERNAL USE ONLY.

**Report:**

## 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 at room 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:

| S.No | Type | Weight | Shape |
|---|---|---|---|
| 1. | Rectal suppositories | Small: 1 gm<br>Medium: 2gm<br>Large:4 gm | Rod<br>Wedge<br>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.
- People suffering from severe nausea or vomiting.

**Disadvantages:**

- The problem of patient acceptability.
- Suppositories are not suitable for patients suffering from diarrhea.
- In some cases the total amount of the drug must be given will be either too irritating or in greater 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,

**(a)Fatty or oleaginous bases**, such as cocoa butter, hydrogenated fatty acids of vegetable oils, semi synthesized fatty acids such as Fattibase (triglycerides from palm, palm kernel, and coconut oils 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).

**(b) 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 three methods:

(a)Molding from a melt,

(b) Compression

(c) 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.

The steps for the molding method include:

(a) Melting the base,

(b) Incorporating the medicaments,

(c) Pouring the melt into the molds,

(d) Allowing the melt to cool and congeal into suppositories,

(e) Removing the formed suppositories from the mold. The molding method is applicable to cocoa butter, glycerinated gelatin, polyethylene glycol, and most other bases.

Depending on the type of formulation, suppository molds may require lubrication before the melt is poured to facilitate easy removal of the molded suppositories and cleaning of the mold afterwards. As a general rule, a fatty lubricant such as liquid paraffin is used for water-soluble bases and a water-soluble lubricant such as soft-soap ethanol solution (soft soap: glycerin: 90% ethanol 1:1: 5) is used for fatty bases.

Every mold is capable of holding a specific volume of materials in each of its openings. Because of the difference in the density of the base materials, the weight of a suppository made of a cocoa butter base will differ from the weight of the suppository prepared in the same mold with a polyethylene glycol base. Similarly, any added medicinal agents will alter the density of the base and the weight of the resulting suppository differs from that prepared with the base material alone.

Therefore, the pharmacist should calibrate each suppository mold with a common base so that a medicated suppository will contain the proper amount of a medicament. Displacement value (DV, also called density factor, *f*), which is defined as the ratio between the weight of a medicament and the weight of the base of the same volume is determined and used for this purpose.

For example, the *f* of iodoform with respect to cocoa butter is 3.6, indicating that 3.6 g of iodoform occupies the same volume as 1 g cocoa butter. Therefore, *f* can also be defined as the ratio of the density of the active drug to that of the base.

For suppositories with a large density difference or with a high active content, it is necessary to determine the *f* value. When the density of the active drug and the base is known, *f* can be calculated using the following equation:

$$f = \frac{density of\ the\ active\ drug}{density of\ the\ base}$$

On the other hand, when the density of the active drug and the base is unknown, *f* can be calculated using the following equation,

$$f = \frac{W}{G-(M-W)} \qquad (1)$$

Where 'W' is the weight of the active ingredient in each suppository, G is the weight of the pure base suppository, M is weight of the suppository with X% of the active ingredient.

Based on the displacement value, the amount of base (E) to be added in each suppository can be calculated using the following equation:

$$E = G - \frac{W}{f} \qquad (2)$$

It is important to note that the same drug substance has the different displacement values for different bases. Therefore, the base type should be specified when mentioning the displacement value.

**Formulation:** The formulation of suppositories include

i) Base: These are of three types

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

Water soluble suppositoriesBase:Eg: Macrogol bases, glycerol gelatin bases

Water dispersal suppositoriesBase:Eg: Witepsol

ii) Hardening Agents: Macrogol bases.

iii) Thickening Agents: Eg: Bentonite

iv) Emulsifying Agents: Eg: Polysorbates, woolfat

v) Preservatives: Eg: Methyl and propyl hydroxyl Benzoates

vi) 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.

## 24. GLYCERO GELATIN SUPPOSITORIES

**Aim:** To prepare glycero gelatin suppositories.

**Apparatus:** Suppository mould, Beaker, glass rod, spatula.

**Category:** Mild laxative in infants.

**Formula:**

| S. No | Ingredients | Official Formula (B.P) for 6 suppositories |
|---|---|---|
| 1 | Gelatin | 1.92 gm |
| 2 | Glycerin | 6.5 ml |
| 3 | Purified water | q. s. to 12 ml |

**Principle:** Glycero gelatin is a mixture of glycerol and water made into a stiff jelly by adding gelatin. It is used for the preparation of jellies and suppositories. The stiffness of the mass depends upon the proportion of gelatin used which is adjusted according to its use. The base being hydrophilic in nature slowly dissolves in the aqueous secretions and provides a slow continuous release of medicament. Gelatin is used as gelling agent to give stiffness to the suppositories and Glycerin is used as humectant.

**Procedure:** Lubricate the mould with liquid paraffin and keep the mould inverted on the ice. Heat the glycerin for 100 $^{0}$C in a china dish on the water bath. Add the gelatin of the formulation in evaporating dish and swell in 20ml of distilled water for 30min to make it soft. Add glycerol, and heat the mixture in water bath to make gelatin dissolve; keep heating until the semisolid gel is formed. Maintain the base at 100 $^{0}$C for one hour, to make it sterilized. Pour this mixture into the molds of suppository smeared with liquid paraffin immediately. After they are cooled, scrape off the unnecessary parts. Place the moulds in the refrigerator for 30 minutes. Finally remove suppositories from moulds and wrapped in butter paper slightly coated with lubricant to prevent the sticking of suppositories.

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

**Direction:** Glycero gelatin suppositories should be moistened with water, before inserting into the body cavity to enhance the lubrication and decreases irritation.

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

**Auxiliary label:** For rectal use only.

**Report:**

## 25. COCOA BUTTER SUPPOSITORIES

**Aim:** To prepare cocoa butter suppositories.

**Apparatus:** Suppository mould, Beaker, glass rod, spatula.

**Category:** Antiseptic

**Formula:**

| S. No | Ingredients | Official Formula (B.P) for 4 suppositories |
|---|---|---|
| 1 | Cocoa butter | 3.6 gm |
| 2 | Eucalyptus oil | 0.4 ml |

**Principle:** Cocoa butter is the fat obtained from the roasted seed of Theobroma cocoa. Cocoa butter melts between 30°C to 36°C, it is an ideal suppository base. It is readily liquefiable on warming and rapid setting on cooling. Two factors when preparing suppositories with cocoa butter base. First, this base must not be heated above 35°C because cocoa butter is a polymorphic compound and if overheated convert to a metastable structure that melts in the 25° to 30°C range. Thus, the finished suppositories would melt at room temperature and not be usable. The second factor is the change in melting point caused by adding certain drugs to cocoa butter suppositories. For example, chloral hydrate and phenol tend to lower the melting point. It may be necessary to add spermaceti or beeswax to raise the melting point of finished suppositories back to the desired range.

**Procedure:** Lubricate the mould with liquid paraffin and Cocoa butter is made into small pieces are taken in a china dish and heated on the water bath until two-third portion of base is melted and melt the remaining portion with continuous stirring. It is cooled and adds eucalyptus oil to the melted base with continuous stirring. Pour this mixture into the moulds of suppository smeared with liquid paraffin immediately. Leave the moulds for 5 minutes for setting and cut the excess from the mould. Then they are placed in the refrigerator for 30 minutes. Finally remove suppositories from moulds and wrapped in butter paper slightly coated with lubricant to prevent the sticking of suppositories.

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

**Direction:** Cocoa butter suppositories should be moistened with water, before inserting into the body cavity to enhance the lubrication and decreases irritation.

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

**Auxiliary label:** For rectal use only.

**Report:**

## 26. ZINC OXIDE SUPPOSITORIES

**Aim:** To prepare zinc oxide suppositories.

**Apparatus:** Suppository mould, Beaker, glass rod, spatula.

**Category:** Astringent and Soothing agent

**Formula:**

| S. No | Ingredients | Official Formula (B.P) for 4 suppositories |
|---|---|---|
| 1 | Zinc oxide | 0.24 gm |
| 2 | Gelatin | 0.67 gm |
| 3 | Glycerin | 2.5 ml |
| 4 | Purified water | 1 ml |

**Principle:** Zinc oxide will act as soothing agent. Glycerin promotes the peristaltic movement of lower bowel and act as humectants. Gelatin gives stiffness to the suppositories. Zinc oxide is widely used to treat a variety of skin conditions, including dermatitis, itching due to eczema, diaper rash and acne.

**Procedure:** Lubricate the mould with liquid paraffin and keep the mould inverted on the ice. Heat the glycerin for 100 $^{0}$C in a china dish on the water bath. Add the gelatin of the formulation in china dish and swell in 20ml of distilled water for 30min to make it soft. Add glycerol, and heat the mixture in water bath to make gelatin dissolve; keep heating until the semisolid gel is formed. Maintain the base at 100 $^{0}$C for one hour, to make it sterilized. Add the required amount of zinc oxide to the above mixture with continuous stirring to prevent the air entrapment. Pour this mixture into the moulds of suppository smeared with liquid paraffin immediately. After they are cooled, scrape off the unnecessary parts. Place the moulds in the refrigerator for 30 minutes. Finally remove suppositories from moulds and wrapped in butter paper slightly coated with lubricant to prevent the sticking of suppositories.

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

**Direction:** Zinc oxide suppositories should be moistened with water, before inserting into the body cavity to enhance the lubrication and decreases irritation.

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

**Auxiliary label:** For rectal use only.

**Report:**