



JHARKHAND
Rai University

Established by an Act of Govt. of Jharkhand
as per Section 2f of UGC Act, 1956

PRACTICAL LAB MANUAL

LAB MANUAL PHARMACEUTICS I

(B. Pharm Ist Year)

| Sr. No | Name of Experiment |
|--------|---|
| 1. | To prepare and submit Simple Mixture Containing Ferric Ammonium Citrate |
| 2. | To prepare and submit Simple Mixture Containing Acetyl Salicylic Acid |
| 3. | To prepare and submit the Simple Mixture Containing Ammonium chloride. |
| 4. | To prepare and submit Mixture Containing Diffusible Solids. |
| 5. | To prepare and submit Kaolin Mixture B.P |
| 6. | To prepare and submit Mixture Containing Diffusible solids |
| 7. | To prepare and submit Mixture Containing Indiffusible Solids |
| 8. | To prepare and submit Mixture Containing Slightly Soluble Liquid |
| 9. | To prepare and submit Mixture Containing Small Dose of Potent Medicament. |
| 10. | To prepare and submit Official Mixture B.P |
| 11. | To prepare and submit Simple Syrup. |
| 12. | To prepare and submit Codeine Linctus B.P.C |
| 13. | To prepare and submit Chloral Hydrate Elixir |
| 14. | To prepare and submit Throat Paint. |
| 15. | To prepare and submit Mandl's Paint. |
| 16. | To prepare and submit Gargles. |
| 17. | To prepare and submit Mouthwash |
| 18. | To prepare and submit Ear Drops |
| 19. | To prepare and submit Ear Drops. |
| 20. | To prepare and submit Nasal Drops |
| 21. | To prepare and submit Nasal Drops. |

| Sr. No | Name of Experiment |
|----------------------------------|---|
| 22. | To prepare and submit Inhalation |
| 23. | To prepare and submit Potassium Permanganate Solution (Douche). |
| 24. | To prepare and submit Eye Drops |
| 25. | To prepare and submit Eye Lotion. |
| Introduction to Emulsions | |
| 26. | To prepare and submit Emulsion Containing Castor Oil. |
| 27. | To identify the type of given Emulsion by Dilution Method. |
| 28. | To prepare and submit Emulsion with Turpentine Oil. |
| 29. | To identify the given Emulsion by Dye Test. |
| 30. | To prepare and submit Emulsion with arachis Oil |
| 31. | To prepare and submit Emulsion with Soluble Substance. |
| 32. | To prepare and submit Emulsion with Small Portion of Oily Substance. |
| 33. | To prepare and submit Emulsion with Substance Insoluble in Oil and Water. |
| 34. | To prepare and submit Emulsion with Liquid Paraffin. |
| 35. | To identify the given Emulsion by Dye Test. |
| 36. | To prepare and submit Emulsion with Olive Oil |
| 37. | To prepare and submit Emulsion with Soluble Substance. |
| 38. | To prepare and submit Emulsion with Small Portion of Oily Substance. |
| 39. | To prepare and submit Emulsion with Substance Insoluble in Oil and Water. |
| 40. | To prepare and submit Emulsion with Liquid Paraffin. |
| 41. | To prepare and submit Organic Soap Emulsion |
| 42. | To prepare and submit Emulsion (Lime Cream Type). |

| Sr. No | Name of Experiment |
|--|--|
| 43. | To prepare and submit Turpentine Liniment B.P. |
| 44. | To prepare and submit Liniment Ammonia Soap Type. |
| 45. | To prepare and submit White Liniment B.P. |
| 46. | To prepare and submit Benzyl Benzoate Application B.P. |
| 47. | To prepare and submit Linimen |
| 48. | To prepare and submit Camphorated Oil |
| 49. | To prepare and submit Turpentine and Acetic Acid Liniment. |
| 50. | To prepare and submit Calamine Lotion. |
| 51. | To prepare and submit Sulphur Lotion. |
| 52. | To prepare and submit Emulsion for Rectal Use |
| Introduction to Semi solid dosage forms | |
| 53. | To prepare and Dispense Emulsifying Wax I.P |
| 54. | To prepare and submit Simple Ointment I.P. |
| 55. | To prepare and submit Sulphur Ointment B.P. |
| 56. | To prepare and submit Zinc Oxide Ointment B.P. |
| 57. | To prepare and submit Methyl Salicylate Ointment B.P. |
| 58. | To prepare and submit Paraffin Ointment I.P. |
| 59. | To prepare and submit Emulsifying Ointment I.P. |
| 60. | To prepare and submit Staining Ointment |
| 61. | To prepare and submit NOS-Staining Iodine Ointment. |
| 62. | To prepare and submit Calamine Ointment B.P.C. |
| 63. | To prepare and submit Cetrimide Cream B.P. |
| 64. | To prepare and submit Zinc Cream. |
| 65. | To prepare and submit Unna's Paste. |
| 66. | To prepare and submit Zinc Oxide and Salicylic Acid Paste B.P. |

| Sr. No | Name of Experiment |
|--------|--|
| 67. | To prepare and submit Bassorin Paste. |
| 68. | To prepare and submit Dithranol Paste. |
| 69. | To prepare and submit Jelly. |
| 70. | To prepare and submit Kaolin Poultices B.P.C. |
| | Introduction to Suppositories and Pesseries. |
| 71. | To prepare and submit Soap-Glycerin Suppository B.P.C. |
| 72. | To prepare and submit Glycerol Suppository B.P. |
| 73. | To prepare and submit Suppository Containing Soluble Solids |
| 74. | To prepare and submit Pessaries of Cocoa Butter Containing Liquid |
| 75. | To prepare and submit Pessaries of Cocoa Butter Containing Insoluble Medicaments. |
| 76. | Introduction to Solid Dosage forms: Powders and oral unit Dosage form. |
| 77. | To prepare and submit Powder. |
| 78. | To prepare and submit Powder |
| 79. | To prepare and submit Powder |
| 80. | To prepare and submit Gregory's Powder |
| 81. | To prepare and submit Effervescent Granules Containing Iron and Ammonium Citrate. |
| 82. | To prepare and submit Compound Magnesium Trisilicate Oral Powder B.P. |
| 83. | To prepare and submit Tablet Triturates |
| 84. | To prepare and submit tooth powder |
| 85. | To prepare and submit Insufflations. |
| 86. | To prepare and submit Boric Acid Containing 1% of Iodine |
| 87. | To prepare and submit Boric Acid Containing 1% of Iodine |
| 88. | To prepare and submit Dusting Powder |
| | Introduction to incompatibility To identify the type of incompatibility and Perform Accordingly |
| 89. | To identify the type of incompatibility and Perform Accordingly. |

| Sr. No | Name of Experiment |
|---------------|--|
| 90. | To identify the type of incompatibility and Perform Accordingly. |
| 91. | To identify the type of Incompatibility and Perform Accordingly |
| 92. | To identify the type of Incompatibility and Perform Accordingly |
| 93. | To identify the type of Incompatibility and Perform Accordingly |
| 94. | To identify the type of Incompatibility and Perform Accordingly |
| 95. | To identify the type of Incompatibility and Perform Accordingly |
| 96. | To identify the type of Incompatibility and Perform Accordingly |
| 97. | To identify the type of Incompatibility and Perform Accordingly |
| 78. | To identify the type of Incompatibility and Perform Accordingly |
| 99. | To identify the type of Incompatibility and Perform Accordingly |
| 100. | To identify the type of Incompatibility and Perform Accordingly |

Prescription

Prescription is an order written by a physician, dentist or any other registered medical practitioner to a pharmacist to compound and dispense a specific medication for the patient. The order is accompanied by directions for the pharmacist that what type of preparation is to be prepared and how much is to be prepared. It is also accompanied with the directions for the patient that how much medicament is to be taken, how many times or at what time and how it is to be taken.

The prescription provides a common link of mutual interest between the physicians, the pharmacist and the patient. It is the duty of the pharmacist to serve the medication needs of the patient according to the intention of the prescriber. It is not sufficient that the pharmacist should only compound the specific medication but he should make the patient understand about the proper administration of the drug and ensure that the patient sticks to these instructions. At the same time the pharmacist must maintain and respect the confidentiality of both the physician regarding the treatment given as well as that of the patient regarding the nature of his illness and the medication taken by him.

Prescriptions were generally written in latin language which was understood allover the world, so that the ingredients of the prescriptions remain unknown to the patient to avoid self medication. Still the use of latin abbreviations in the prescription writing is very common specially in dosage instructions.

The modern tendency in prescribing drugs is to make prescriptions simple. Instead of prescribing a mixture of numerous drugs, the prescription of a single drug with definite and specific action is desired. More stress is laid on the readymade preparations which are available in the market.

Parts of a Prescription:

A typical prescription consists of the following parts:

1. *Date*

Date must be written on the prescription by the prescriber at the same time when it is written. This helps the pharmacist to know that when the medicines were dispensed last time if the prescription is brought for redispensing of the medicines.

2. *Name, age, sex and address of the patient*

These particulars help the pharmacist that the medicine has been delivered to the right person and correct dose has been given to the children. The address of the patient is recorded to help for any reference at a later stage or to contact the patient in case of any emergency.

3. *Superscription*

It is represented by a symbol \mathcal{R} an abbreviation of latin word 'recipe' which means 'take thou' or 'you take'. The line on \mathcal{R} is said to designate Jupiter, the God of healing.

4. *Inscription*

This is the main part of prescription. It contains the names and quantities of the prescribed ingredients. It is usually divided into:

- (a) The base or the active medicament which is intended to produce the therapeutic effect.
- (b) The adjuvant which is included either to enhance the action of the medicament or to make the product more palatable.
- (c) The vehicle which is either used to dissolve the solid substances and/or to increase the volume of the preparation for ease of administration.

5. *Subscription*

This part contains the prescriber's directions to the pharmacist regarding the dosage form to be prepared and number of doses to be dispensed.

6. *Signature*

It is usually abbreviated as "Sig" and consists of the directions to be given to the patient regarding the method of administration or application, quantity to be used, number of times in a day, at what time and the vehicle with which it is to be used. These directions must be transferred to the label of the bottle.

7. *Signature of the prescriber:*

The prescription must be signed by the prescriber with his own hand. His address and registration number should be written in the case of dangerous drugs.

An example of a typical prescription

General Hospital

Date: 17.7.1990

Name: Sh. Parmod Kumar

Age: 45 years

Sex: Male

Address: 927, Sector 23 Chandigarh.

R.

Sodium bicarbonate 1.0 gm

Aromatic spirit of ammonia 1.5 ml

Cardamom tincture 1.0 ml

Spirit Chloroform 1.5 ml

Water to 15.0 ml

Fiat: mistura . Mitte doses tres.

Sig: Unus post cibos sumenda

M.D. Goyal

Regd No. 15557.

Handling of Prescription:

1. *Receiving*

The prescription should be received by the pharmacist and read carefully. If there is any doubt regarding the prescription he must consult the prescriber. There should not be any guess work regarding the spelling etc. because this may lead to serious consequences. Therefore doubts must be cleared before compounding any prescription.

2. *Collecting the Materials*

Read the label on the bottle of the ingredient at the time of removing from the shelf, taking out the ingredients from the container and again at the time of replacing the container back on the shelf to avoid any mistake.

3. *Compounding*

Compounding is the most important phase in handling the prescription. In this case proper drug is dispensed in a suitable form. This can be achieved only if accuracy, cleanliness and if proper techniques are observed in the preparation of any medication. Only one prescription should be compounded at one time.

The finished product should be transferred to a suitable container depending on the nature and quantity of the medicament to be dispensed and the method of its use. Various types of containers used for different types of formulations are described below:

- (i) Round Vials: for tablets and capsules
- (ii) Oval prescription bottles: for liquids of low viscosity e.g. mixtures, emulsions etc.
- (iii) Wide mouth bottles: for filling liquids of high viscosity, large quantities of tablets, capsules and bulk powders.
- (iv) Coloured fluted bottles: for preparations meant for external use e.g. liniments and lotions.
- (v) Ointment Jars and collapsible tubes: for ointments, creams or any other semi-solid dosage form.
- (vi) Paper wrapper and envelopes: for oral powders dispensed as individual doses.
- (vii) Dropper bottles: for eye drops, ear drops or other liquids to be administered by drops.
- (viii) Sifter top containers: for dusting powders.

The container should be selected approximately of the same volume as that of medication to be dispensed.

4. *Labelling*

The filled containers should be suitably labelled. A good quality of paper and adhesive should be used for labelling the containers. The size of the label should be proportional to the size of the container and should be hand written in capital letters or typed. The label should be affixed on the smooth surface (in the case of dispensing bottles) and in the centre of the bottle leaving sufficient margin towards the top and bottom of the bottle. The following information should be written on all the labels:

- (i) Type of the preparation: The mixture, The Emulsion, The powder etc. Its quantity should also be mentioned.
- (ii) For: Name of the patient, age and sex.
- (iii) Registration no.
- (iv) Date of dispensing.
- (v) Expiry date if any.
- (vi) Direction for its use.
- (vii) Storage conditions.
- (viii) Name and address of the pharmacy.
- (ix) In case of liquid preparations which require previous shaking e.g. emulsions, suspensions, liniments, lotions etc. must be attached with secondary label "Shake the bottle before use".
- (x) The prescriptions meant for external use e.g. liniments, lotions, ointments, eye drops, ear drops etc. must be attached with secondary label "for external use only".

The sample labels are given below:

| <i>THE POWDER</i> |
|--|
| (5 × 250 mg) |
| For: Mrs X.Y.Z. Age: 25 yrs (F) |
| Regd. no. 47 |
| Date of dispensing: |
| Directions: One to be taken when the pain is severe. |
| Dispensed by: |
| Name and address of pharmacy. |

| <i>THE MIXTURE</i> |
|---|
| (90 ml) |
| For: Mr X.Y.Z. Age: 40 yrs (M) |
| Regd. no. 267 |
| Date of dispensing |
| shake the bottle before use. |
| Directions: One tablespoonfull to be taken three times a day. |
| Dispensed by: |
| Name and address of Pharmacy. |

| <i>THE OINTMENT</i> |
|--|
| (40 gm) |
| For: Miss. A.B.C. Age: 20 yrs (F) |
| Regd: No: 307 |
| For external use only. |
| Date of dispensing: |
| Directions: To be applied to the skin as directed. |
| Dispensed by: |
| Name and address of Pharmacy. |

| <i>THE LINIMENT</i> |
|--|
| (60 ml) |
| For: Mr. X.Y.Z. Age: 28 yrs (M) |
| Ragd no: 327 |
| For external use only |
| Date of dispensing |
| Shake the bottle before use. |
| Directions: To be applied to the affected part with rubbing. |
| Dispensed by: |
| Name and address of Pharmacy. |

5. Marking the Dose:

A dose marking should be applied to all the multidose containers of liquid preparations e.g. mixtures and emulsions for the convenience of the patient while taking a dose. After filling the container a piece of paper is cut upto the level of the liquid from the centre of the curvature of the bottle. This paper is then divided into equal parts according to the number of doses to be administered which should be given a deep cut to clearly indicate the level of the dose. This paper should be fixed to the bottle.

6. Finishing

After filling and labelling, the container should be corked, thoroughly polished to remove the finger prints and then dispensed.

Latin Terms and Abbreviations Commonly Used in Prescription Writing.

| <i>Latin term or phrase</i> | <i>Abbreviation</i> | <i>English meaning</i> |
|--|----------------------------|-------------------------|
| Ad | ad | to, up to |
| Ad libitum | ad. lib | at pleasure, as desired |
| Admove | admove | apply |
| Agita | agit | shake, stir |
| Alter | alt | the other, alternate |
| Alternis horis | alt. hrs. | alternate hours |
| Ana | aa. | of each |
| Ante | a. | before |
| Ante cibos | a. c. | before meals |
| Applicandus | applicand | to be applied |
| Aqua | aq. | water |
| Aqua bulliens | aq. bull. | boiling water |
| Aqua destillata | aq. dest | distilled water |
| Auris dextra | a. d. | right ear |
| Auris laeva | a. l. | left ear |
| Bis in die | b. i. d. | twice a day |
| Capsula | caps | capsule |
| Capiendus | capiend | to be taken |
| Cataplasma | cataplasma | poultice |
| Charta | chart | powder paper |
| Cibos | cibos | food, meals. |
| Cochleare— amplum magnum | coch— amp mag | one table spoonful |
| Cochleare— maximum medium modicum | coch— max med mod | one desert spoonful |
| Cochlear— minimum parvum | coch— min parv. | one teaspoonful |
| Collunarium | collunar | a nose wash |
| Collutorium | collut | a mouth wash |
| Collyrium | collyr | an eye wash |
| Congius | cong | a gallon |
| Cum | c | with |

| | | |
|---------------------|----------------|--------------------------|
| Cum duplo | c.dup. | with twice as much. |
| Cum parte aequale | c. pt. aeq. | with an equal quantity |
| Cyathus | cyath | a glass |
| Dexter | dext | right |
| Divide | div. | divide. |
| Dolore urgente | dol. urg. | when the pain is severe |
| Emulsio | emul | an emulsion |
| E | — | with |
| Ex | — | out of |
| E. lacte | e. lact | with milk |
| Ex. aqua | ex. aq. | with water |
| Ex. modo prescripto | e. m. p. | in the manner prescribed |
| Fiat, fiant | ft. | make, let it be made |
| Granum, grana | gr. | a grain |
| Gutta, guttae | gtt. | a drop, drops. |
| Hora | h. | an hour |
| Hora somni | h. s. | at bed time |
| In dies | In. d. | daily |
| Inter cibos | i. c. | during meals |
| Injectio | Inj. | an injection |
| Laevo | l. | left |
| Levis | lev. | light |
| Linimentum | lin. | a liniment |
| Liquor | liq. | solution |
| Mane | m. | morning |
| Minimum | min. | a minim |
| Misce | m. | mix, let (it) be mixed. |
| Mistura | mist | a mixture |
| Mitte | mitt | send |
| Mitte tales | mitt tal | send such |
| Modo dicto | m. dict | as directed, as stated |
| Modo prescripto | m. pres | as prescribed |
| More dicto | m. dict | as directed |
| Nebula | nebul | a spray |
| Nocte maneque | noct. maneq | night and morning |
| Non repetatur | non rep, n. r. | do not repeat |
| Octarius | o. | a pint |
| Oculo utro | o.u. | each eye |
| Oculus dexter | o.d. | right eye |
| Oculus laevus | o.l. | left eye |
| Oculus sinister | o.s. | left eye |
| Omni | omn. | every |
| Omni hora | omn. hor, o.h. | every hour |

Weights and Measures

There are two systems of weights and measures (a) the imperial system (b) the metric system, with which the pharmacist must be familiar. The imperial system is an old system based on arbitrary and unrelated units e.g. grains, drachms, ounces and gallons whereas the metric system or decimal system is based on related and rationally derived units e.g. milligrams, grams, centimeters, meters, millilitres, litres etc. Because of its easier calculations, greater accuracy and flexibility and use in other sciences, now a days this is the most widely used system by official agencies.

At present still a large number of physicians trained to use the imperial system prescribe the drugs in the old system and some hospitals still retain it as the local standard. Some drugs are prescribed in fractional doses (1/200, 1/150, 1/100 gr.). The bottles for liquids are still manufactured to contain ounce measurements rather than milliliters.

Due to the above mentioned reasons, it is still necessary to be familiar with both the systems which are described in detail as follows:

(a) Imperial System:

Imperial system is divided into two systems.

- (i) Avoirdupois system.
- (ii) Apothecaries system.

Avoirdupois system:

According to this system the standard unit for weighing is pound and all other measures of mass are derived from pound. It is represented by lb.

$$1 \text{ lb} = 16 \text{ oz (avoir)}$$

$$1 \text{ lb} = 7000 \text{ grains}$$

$$1 \text{ oz} = 7000/16 = 437.5 \text{ grains.}$$

Apothecaries System:

It is also known as troy system. The standard weight in this system is grain.

$$20 \text{ grain} = 1 \text{ scruple}$$

$$60 \text{ grain} = 1 \text{ drachm}$$

$$480 \text{ grain} = 1 \text{ ounce (Apothe)}$$

$$8 \text{ drachm} = 1 \text{ ounce (Apothe)}$$

$$12 \text{ ounces (Apothe)} = 1 \text{ pound (Apothe)}$$

$$5760 \text{ grain} = 1 \text{ pound (Apothe)}$$

Abbreviations Commonly Used in Weighing

| <i>Latin name</i> | <i>Symbol</i> | <i>English name</i> | <i>Equal to</i> |
|-------------------|---------------|---------------------|-----------------|
| Gramm | gr | grain | 1 grain |
| Scrupulus | ♃ | Scruple | 20 grain |
| Drachma | | drachm | 60 grain |

| | | | |
|-------|----|----------------|-------------|
| Uncia | oz | ounce (Avoir) | 437.5 grain |
| Uncia | | ounce (Apothe) | 480 grains |
| Libra | lb | pound (Avoir) | 7000 grains |
| Libra | !b | pound (Apothe) | 5760 grains |

Measures of Capacity

Standard units for capacity are same in avoirdupois as well as apothecaries system. The standard unit is gallon and all other measures of capacity are derived from gallon.

1 gallon = 160 fluid ounces.

1/4th of a gallon = 1 quart = 40 fl. ounce.

1/8th of a gallon = 1 pint = 20 fl. ounce.

1/160th of a gallon = 1 fl. ounce.

1/8th of one fl. ounce = 1 fl. drachm.

1/60th of one fl. drachm = 1 minim.

1 fluid ounce = 480 minim.

1 fluid drachm = $480/8 = 60$ minim.

Abbreviations Commonly Used in Measures of Capacity

| <i>Latin name</i> | <i>Symbol</i> | <i>English name</i> | <i>Equal to</i> |
|-------------------|---------------|---------------------|-----------------|
| Minimum | m | minim | 1 minim |
| Fluidrachma | | fl. drachm | 60 minim |
| Fluiduncia | | fl. ounce | 480 minim |
| Octarius | O | pint | 20 fl. ounces |
| Congius | C | gallon | 160 fl. ounces |

Metric System

Standard unit of measures of mass (weight) is kilogram and all other measures of mass are derived from kilogram

1 Kilogram (kg) = 1000 gm

1 Hectogram (hg) = 100 gm

1 Decagram (dag) = 10 gm

1 Gram (gm) = 1 gm

1 Decigram (dg) = 0.1 gm = 100 mg

1 Centigram (cg) = 0.01 gm = 10 mg

1 Milligram (mg) = 0.001 gm = 1 mg

1 Microgram (μ g, mcg) = 1/1000 mg

Powders

Powders are the solid dosage form of medicament in which the drug or drugs are dispensed in a finely divided state. They are available in crystalline or amorphous form. Whenever crystalline substances are to be dispensed in powder form, they must be reduced to a fine powder before mixing them with other substances. Powders may be dispensed as divided powders (single doses) by wrapping individually in suitable size papers or as bulk powders in suitable containers.

Classification

Powders may be classified as follows.

1. Simple powders
2. Compound powders
3. Powders enclosed in capsules
4. Compressed powders (Tablets)
5. Granular effervescent powders
6. Powders for external use.

1. Simple Powders

Simple powders are those powders when only one ingredient is present. They are generally wrapped in individual papers and dispensed.

2. Compound Powders

In compound powders more than one ingredients are mixed together in the ascending order of their weight. Whenever crystalline substances are to be incorporated they must be reduced to a fine powder, mixed and divided into required number of powders. They are dispensed as individual doses by wrapping the powder in suitable size paper or it may be dispensed as bulk powder in a suitable sized screw capped wide mouthed bottle with specific instructions for its use. For hygroscopic powders double wrapping should be done in which inner wrapper should be waxed paper.

Since the wastage of powders during weighing, mixing and dividing is unavoidable so calculate for one extra powder than required. If this produces quantities in which fractions are involved, calculate for sufficient number of extra powders to produce directly weighable quantities.

Since the dispensing balances are not very sensitive so quantities less than 100 mg cannot be weighed accurately on such balances, therefore when very small quantities of drugs are to be used they must first be diluted with an inert substance to increase the quantity of the drug so as to make it a weighable quantity. Potent substances like Codeine phosphate, Arsenic trioxide, Hyoscine hydrobromide etc. are dispensed in this way.

Potent Substances

Substances having a maximum dose of less than 60 mg should be regarded as potent substances. They should be weighed either on a chemical balance or upon a delicate pair of dispensing balance specially reserved for the purpose. In no case quantities less than 60 mg be weighed on such balances. When quantities less than 60 mg are required, triturations should be prepared and then weighed.

Bulk Powders

When large quantities of powders are dispensed in a container and the patient is asked to use a measured quantity of the drug as a dose. Generally these powders are dispensed in wide mouth containers with a suitable measure for easy removal of the contents.

Effervescent Granules

These are the powders made in the form of granules which when added to water produce effervescence through the evolution of carbon dioxide. Generally these powders are used as antacids.

Effervescent granules usually contain Sodium bicarbonate, Citric acid and Tartaric acid. They must contain certain medicament and sweetening agent like sucrose or saccharin.

Powders for External Use

They are generally known as dusting powders and are meant for external application to the skin for antiseptic, antiperspirant, lubricant, protective, absorbent and astringent purposes. The dusting powder must be passed through a very fine sieve to remove gritty particles. They may be packed in sifter containers or wide mouthed containers.

Capsules

Capsules are the solid unit dosage form of medicament in which drug(s) is enclosed in a practically tasteless, hard or soft soluble container or shell made up of a suitable form of gelatin. A preservative and colouring agent may be included in the formation of shells.

There are two types of capsules (i) Hard gelatin capsules which are generally used for filling the solid substances and (ii) soft gelatin or flexible capsules which are used for filling liquid and semi-solid prepa-

The hard gelatin capsules are made up of two cylindrical halves (i) longer and narrow half is called the base and (ii) shorter and wider half is called cap. The drug is filled into the base and cap is placed over it.

Hard gelatin capsules differ from soft gelatin capsules that they are hard in nature, used for filling the solid substances and are manufactured in two stages where the shells are prepared at one stage and filling is done in the second stage. The hard gelatin capsules can be extemporaneously filled and cost of production is less. Whereas soft gelatin capsules are elastic in nature due to the presence of a plasticizer in the shell, are used for filling the liquid and semi-solid preparations and filling is done in one stage only. Soft gelatin capsules cannot be prepared in the dispensary because it requires heavy machinery, hence the cost of production is more.

Enteric Coated Capsules

Enteric coated capsules disintegrate only in the intestine i.e. in the alkaline medium and not in the stomach where the medium is acidic in nature.

For enteric coating the filled capsules are treated with cellulose acetate phthalate or a mixture of stearic acid and butyl acetate. Now a days enteric coated capsules have been largely superseded by enteric coated tablets.

Although extemporaneous filling of capsules is rare in the dispensaries but in large hospitals it is necessary to fill such capsules for clinical trials and in cases where a particular combination of drugs is required. Hence for practice, only a few exercises are given where a small number of capsules are to be filled.

Mixtures

A mixture is a liquid preparation intended for oral administration in which drug or drugs are dissolved, suspended or dispersed in a suitable vehicle and generally several doses are contained in a bottle. When only one dose is dispensed it is known as draught.

Mixtures differ from solutions that the mixtures may be homogeneous or heterogeneous and are for oral administration whereas solutions are homogeneous and are for external or internal use. Mixtures are extemporaneously prepared and they are supplied in such doses that whole of the mixture is used up within a few days. If need arises then fresh mixture is prepared.

Advantages of mixtures

1. They are more quickly effective than solid dosage forms which require previous disintegration in the body before absorption can take place.
2. Certain substances can only be given in liquid form because they are inconvenient to administer in any other form due to their liquid nature and large dose e.g. castor oil, liquid paraffin, aromatic waters etc.
3. Certain substances like potassium iodide and potassium bromide may cause pain in the stomach if given in the solid form as a powder or a tablet.
4. Certain substances are useful when they are administered in a suspension form e.g. light kaolin and bismuth salts, because in suspension form they afford large surface area for the absorption of toxic substances in the gut.
5. Mixtures are easy to administer and economical as compared to other oral preparations.

Disadvantages

1. They are comparatively less stable than solid dosage forms.
2. Incompatibility is more in liquid preparations as compared to solid ones.
3. They are more bulky and difficult to carry.

Classification

Mixtures may be classified as follows:

1. Simple mixtures
2. Mixtures containing diffusible solids.
3. Mixtures containing indiffusible solids.
4. Mixtures containing precipitate forming liquids.
5. Mixtures containing slightly soluble liquids.
6. Miscellaneous mixtures.

1. Simple mixtures

A simple mixture is one which contains only soluble ingredients e.g. carminative mixture, diaphoretic mixture, cough expectorant etc.

Method of Dispensing

- (a) Dissolve the solid substances in $\frac{3}{4}$ th of the vehicle. The reasons for this is that (i) the volume occupied by the other ingredients rarely exceeds the remaining $\frac{1}{4}$ th, but if this volume exceeds, the $\frac{3}{4}$ th quantity of vehicle used must be reduced. (ii) Solution formation is hastened by using as much of the solvent as convenient.

- (b) Examine the solution critically by holding the container against light. If foreign particles are visible pass the solution through cotton wool, further pour little more vehicle over cotton wool so that the solution therein is removed.
- (c) Add any liquid ingredients. Volatile liquids are added at the end just before adjusting the final volume with vehicle.
- (d) Add more of vehicle to produce the final volume.
- (e) Transfer the mixture to a bottle, cork, and thoroughly polish the bottle to remove finger prints. Attach the label, wrap the bottle and dispense.

2. *Mixtures containing diffusible solids*

Diffusible solids are those substances which do not dissolve in water, but on shaking they can be mixed with it and remain evenly distributed throughout the liquid for sufficient long time allowing uniform distribution of the drug in each dose. However, on standing, the insoluble solids settle at the bottom of the bottle which require re-shaking of the bottle each time whenever a dose is to be measured. Hence the bottle containing the diffusible mixture must be labelled "Shake the bottle before use". Diffusible solids include: aromatic chalk powder, bismuth carbonate, light kaolin, magnesium oxide, magnesium carbonate, magnesium trisilicate, phenolphthalein and rhubarb powder.

Method of Dispensing

Finely powder the diffusible and other substances (if they are already not in fine powder) in a mortar. Mix them thoroughly. Add a small amount of vehicle out of $\frac{3}{4}$ th measured out vehicle and triturate to make a smooth cream (Due to the presence of air in the interstices of many powders, they float at the surface of water and do not mix with the vehicle. To prevent this tendency, a smooth cream is prepared by adding a small amount of vehicle at first and then diluted); add the remainder of vehicle. If foreign particles are visible pass the mixture through a piece of muslin but if one or two foreign particles are visible, remove them with a glass rod. Add liquid ingredients and make up the required volume by adding more of vehicle. Transfer the mixture to a bottle, cork, polish, label and dispense. "Shake the bottle before use" label must be attached.

3. *Mixtures containing indiffusible solids*

Indiffusible solids are those substances which do not dissolve in water and they do not remain evenly distributed throughout the vehicle, even after shaking they immediately settle at the bottom therefore it becomes difficult to measure the dose. The indiffusible substances are made diffusible by increasing the viscosity of the vehicle by adding suitable suspending agent i.e. compound tragacanth powder or tragacanth mucilage. The former is used at the rate of 2 gm/100 ml and later at the rate of $\frac{1}{4}$ th of the volume of mixture to be prepared.

Compound tragacanth powder must be used as suspending agent when the vehicle is medicinally active because tragacanth mucilage is prepared by using chloroform water as vehicle which may replace certain amount of medicinally active vehicle thereby decreasing its medicinal and flavouring properties.

Method of Dispensing

Finely powder the indiffusible solid in a mortar (if it is already not in a fine powder). Add any diffusible or soluble substances and the calculated amount of suspending agent. Mix thoroughly. **Triturate** the powder with a small amount of vehicle (out of $\frac{3}{4}$ th measured vehicle) to form a smooth cream then add the remainder of the measured out vehicle.

If foreign particles are present strain through muslin, add liquid ingredients and make up the required volume by adding more of the vehicle. Transfer the mixture to a bottle, label and dispense. "Shake the bottle before use" label must be attached.

Emulsions

Emulsions are the biphasic liquid dosage form of medicament in which two immiscible liquids (generally one of which is water and the other is some lipid or oil) are made miscible by the addition of a third substance known as emulsifying agent or emulgent. Milk is an example of natural emulsion.

An emulsion may also be defined as a mixture of two immiscible liquids in which one liquid is dispersed as minute globules into the other. The liquid that is broken up into globules is called dispersed phase or internal phase and the liquid in which the globules are dispersed is known as continuous phase, external phase or dispersion medium. The globules remain dispersed only for a short time, separation takes place quickly upon standing. Therefore a third substance known as emulsifying agent is added to the system which forms a film around the globules of the dispersed phase thereby the globules remain scattered indefinitely in the continuous phase and a uniform, stable product is formed.

Purpose of Emulsification

1. Certain medicinal agents having an unpleasant taste and odour can be made more palatable for oral administration in the form of emulsions which are otherwise difficult to take e.g. cod liver oil, shark liver oil, castor oil etc.
2. To prepare a homogeneous product containing immiscible liquids (oil and water).
3. The activity of certain drugs can be increased and action prolonged by emulsifying the drug in a suitable vehicle.
4. Sterile, stable intravenous emulsions containing fats, carbohydrates and vitamins all in one preparation can be administered to the patients who are unable to take these vital substances by oral route.
5. Dermatological preparations like liniments, lotions and creams help in quick absorption of drugs from skin surfaces when applied externally.

Types of emulsions:

There are two types of emulsions.

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

In oil in water type emulsions the oil is in the dispersed phase whereas water is in the continuous phase. These types of emulsions are prepared by using emulsifying agents generally obtained from natural sources like gum acacia, tragacanth, methyl cellulose, saponins and soaps formed from monovalent bases like Na^+ , K^+ and NH_4^+ , oil in water type emulsions are preferred for internal use because the unpleasant taste and odour is masked by emulsification and oil being in a finely dispersed state is more quickly assimilated in the body. Some of the o/w type emulsions can also be used externally.

In water in oil type emulsions, the water is in the dispersed phase whereas oil is in the continuous phase. These types of emulsions are mainly used externally. Emulsifying agents like wool fat, resins, bees wax, synthetic compounds and soaps formed from divalent bases like Ca^{++} , Mg^{++} and Zn^{++} are used for the preparation of water in oil emulsions.

Tests to Identify the Type of Emulsions

Since both types (o/w) and (w/o) of emulsions are similar in appearance therefore it is very difficult to differentiate them with naked eye. They can be identified with the help of following tests.

(a) Dilution test

Take a few drops of emulsion in a test tube and dilute it with 2-3 drops of water and shake. If the emulsion remains uniform, it is o/w emulsion but if the water forms a separate layer it is w/o emulsion. Reverse will be the case if the emulsion is diluted with oil.

(b) Dyesolubility test

Mix an oil soluble dye like scarlet red with an emulsion. Place a drop of it on microscope slide and see under the microscope, if the continuous phase appears to be red, it is w/o emulsion but if scattered globules appears red and continuous phase colourless, it is o/w emulsion. The test can be repeated by using amaranth, a water soluble dye. If the continuous phase appears red it is o/w emulsion but if scattered globules appears red and continuous phase colourless it is w/o emulsion.

(c) Conductivity test

Take emulsion in a beaker and dip a pair of electrodes in it which are connected through a low voltage lamp. Pass the current through the electrodes. If the bulb glows, it is o/w emulsion but if it does not glow then the emulsion is w/o because in the first case water is in the continuous phase which has allowed the current to pass through but in the second case oil is in the continuous phase through which the current has not passed because water is good conductor of electricity whereas oil is a bad conductor of electricity.

Emulsifying Agents

Emulsifying agents or emulgents are the substances which reduce the interfacial tension between the two phases i.e. aqueous phase and oily phase thus make them miscible with each other and form a stable emulsion.

No single emulsifying agent possess all the properties required for the preparation of stable emulsion therefore sometimes it becomes necessary to use two or more than two emulsifying agents instead of one to get a product of desired qualities. Emulsifying agents commonly used include:

1. Natural emulsifying agents from vegetable sources: Acacia, tragacanth, agar, chondrus, pectin and starch.
2. Natural emulsifying agents from animal sources: Gelatin, egg yolk and wool fat.
3. Semi-synthetic polysaccharides; Methyl cellulose and sodium carboxymethyl cellulose.
4. Synthetic emulsifying agents: Anionic, cationic and non-ionic.
5. Inorganic emulsifying agents: Milk of magnesia, magnesium oxide, magnesium trisilicate, magnesium aluminium trisilicate, bentonite etc.

Preparation of Emulsions:

Emulsions can be prepared by the following methods:

1. Dry gum method.
2. Wet gum method
3. Bottle method.

In dry gum method the oil is triturated with gum and then water is added to make a primary emulsion whereas in wet gum method the gum is triturated with water to form a mucilage first and then oil is added for the preparation of primary emulsion.

For extemporaneous compounding of emulsions by dry gum method and wet gum method the most efficient apparatus used is mortar and pestle. Wedge wood or porcelain mortar and pestle is used which should be flat bottomed and rough on the inner surface so as to produce fine particles of the dispersed glo-

bules. Glass mortars should not be used because of their smooth surface which will not produce a good emulsion.

The quantities of oil, gum and water required for primary emulsion are as follows:

| Proportion of | oil : | Water : | Gum |
|---------------|-------|---------|-----|
| Fixed oils | 4 : | 2 : | 1 |
| Volatile oils | 4 : | 4 : | 2 |

The most commonly used fixed oils include castor oil, cod liver oil, shark liver oil, olive oil, almond oil and liquid paraffin (mineral oil).

The volatile oils include turpentine oil, sandal wood oil, cinnamon oil and peppermint oil.

1. Dry Gum Method

This method is also known as 4 : 2 : 1 method because these figures represent the proportions of oil, water and gum acacia required for the preparation of primary emulsion.

Measure the given quantity of oil with a clean and dry measure and transfer it to a dry mortar. To this add the calculated quantity of acacia and triturate rapidly so as to mix them. To this incorporate water required for primary emulsion and triturate rapidly without ceasing till a clicking sound is produced and the product becomes white or nearly white. At this stage the emulsion is known as primary emulsion. Then add more of water to produce the required volume. If any soluble ingredient is also to be incorporated that must be dissolved in the second part of water to be added after making the primary emulsion and to produce the final volume.

2. Wet Gum Method

The proportion of oil, water and gum are same as for dry gum method. In this method the calculated quantity of gum is triturated with water required for primary emulsion, to form a mucilage. Then the given amount of oil is incorporated in small portions with rapid trituration until a clicking sound is produced and the product becomes white or nearly white. Add more of vehicle to produce the final volume.

3. Bottle Method

The bottle method is used for the preparation of emulsions of volatile and other non-viscous oils. The emulsions can be prepared by both dry gum and wet gum methods. Because of low viscosity the volatile oils require greater amount of gum for emulsification than fixed oils.

In the preparation of majority of emulsions it is necessary to prepare first the primary emulsion which is diluted afterwards with more of vehicle. It is very difficult to mix whole of the oil with whole of water all at once because the volume of the liquid becomes quite large and the shearing force required to cut the dispersed phase into suitable size of globules is difficult to obtain. However, if the oil is first emulsified with only a small portion of water and emulsifying agent, a primary emulsion is formed by suitably reducing the size of oil globules, which can be diluted afterwards with more of water. The entire process of emulsion formation depends on the proper preparation of primary emulsion. Better the primary emulsion formed better will be the emulsion.

Creaming of Emulsion:

In creaming of emulsion the dispersed globules of oily phase collect at the surface of emulsion and form a thick layer over there whereas in sedimentation the dispersed globules move downward towards the bottom and form a layer over there. Creaming is a temporary phase because it can be re-distributed by mild shaking or stirring to get a homogeneous product. At the same time creaming is undesirable because a badly

creamed emulsion may lead to cracking with complete separation of two phases. The rate of creaming is governed by Stoke's law which states:

$$V \propto \frac{r^2 (d_1 - d_2) g}{9\eta}$$

The factors which lead to creaming include radius of globules, difference between the densities of dispersed phase and continuous phase, gravitational constant and viscosity of the dispersion medium.

Cracking of Emulsion

In cracking of emulsions the coalescence of the dispersed globules take place and two separate layers of the dispersed phase and continuous phase are formed which are difficult to redispense by shaking or stirring to get the original product. Hence cracking is more serious than creaming. The factors which lead of cracking include: addition of emulsifying agent of opposite type, decomposition or precipitation of emulsifying agent, addition of common solvent, micro-organisms, high temperature and creaming.

Semisolid Dosage forms

OINTMENTS

Ointments are the soft semisolid preparations meant for external application to the skin or mucous membrane. They usually contain a medicament or medicaments dissolved, suspended or emulsified in the base. Ointments are used for their emollient and protective action to the skin. They may also be used as vehicles or bases for the topical application of medicinal substances. An ointment for use in the eyes is known as ophthalmic ointment.

Ointment bases

An ointment base is that substance or part of an ointment which serves as a carrier or vehicle for the medicament. An ideal ointment base should be inert, stable, smooth, compatible with skin, non-irritating and should release the incorporated medicament readily. Since there is no single ointment base available which possess all these qualities therefore it becomes necessary to use more than one ointment base in the preparation of ointments.

Classification of bases

1. *Oleaginous bases*

These bases are insoluble in water, non washable and greasy in nature. Examples are Petrolatum (yellow soft paraffin and white soft paraffin), liquid paraffin and hard paraffin which are obtained from petrol. The animal fat includes lard.

2. *Absorption bases*

They are generally anhydrous bases which can absorb a large amount of water but still retain their ointment like consistency. These are also greasy in nature but can be easily removed from the skin. e.g. wool fat (lanolin), wool alcohols, bees wax, cholesterol etc.

3. *Emulsion bases*

These are semisolid o/w and w/o emulsions. Some additional amount of water can be incorporated in both the types and still retain soft cream like consistency e.g. hydrophilic ointment etc.

4. *Water soluble basis*

These bases contain only the water soluble ingredients and not fats or greasy substances that is why sometimes they are known as greaseless bases e.g. carbowaxes.

Preparation of ointments

Ointments can be prepared by two methods:

- (i) Trituration method.
- (ii) Fusion method.

(i) *Trituration method*

Powder the medicament if already not in fine powder. Triturate it with a small amount of base on an ointment slab with a stainless steel spatula with long blade. Incorporate this to the rest of the base with

thorough trituration until uniform. If liquids are also to be incorporated, pestle and mortar should be used for the purpose.

(ii) *Fusion method*

When an ointment base contains a number of solid substances, melt them in decreasing order of their melting points to avoid over-heating of low melting point substances. Add the medicament to the melted bases and stir thoroughly until the mass cools down and a homogeneous product is formed.

If any liquid or aqueous substance is also to be incorporated, that must be heated to about the same temperature as the melted bases. After mixing the two portions they should be stirred uniformly and thoroughly until a homogeneous mass is obtained. Rapid cooling should be avoided.

Creams

Creams are thought of as ointments but usually contain a water soluble base due to which they can be easily removed from the skin. They are of softer consistency and have a lighter body than true ointments. When applied to the skin, creams leave no visible evidence of their presence on the skin.

Pastes

Pastes are the semi-solid preparations meant for external application to the skin. They differ from ointments that they generally contain a large amount of finely powdered solids such as starch, zinc oxide, calcium carbonate etc. They are quite thick and stiff than ointments but are less greasy than ointments.

Packing

Ointments, creams and pastes should be packed in ointment jars or collapsible tubes. They should be labelled with good quality of paper and adhesive. The label should be attached to the collapsible tubes towards the top because during use the tube is rolled up and this will prevent the spoilage of the label until the tube is practically empty. A secondary label "for external use only" must be attached.

Monophasic Liquid Dosage Forms

Syrups

Syrups are sweet, viscous, concentrated aqueous solutions of sucrose or other sugars in water or any other suitable aqueous vehicle. When purified water alone is used in making the solution of sucrose, the preparation is known as simple syrup. When the preparation contains some medicinal substance it is known as medicated syrup. When the syrup does not contain any medicament but contains various aromatic or pleasantly flavoured substances are known as flavouring syrups. They are used for masking the disagreeable taste of bitter or saline drugs. They are also used as vehicles or flavours for extemporaneous preparations.

Simple syrup is prepared by dissolving 66.7 gm sugar in sufficient amount of water to produce 100 gm. Recently prepared syrups should be used. If the syrup is to be stored for sometime it must be preserved by adding suitable preservative.

Gargles

Gargles are aqueous solutions used for the treatment of an infection of the throat. Usually they are concentrated solutions and must be diluted with water before use. In using the gargles they are brought into intimate contact with the mucous membrane of the throat and are allowed to remain there for a few moments after which they are thrown out of the mouth.

Mouth Washes

A mouth wash is an aqueous solution with a pleasant taste and odour used for rinsing, deodorant, refreshing or antiseptic action. The medicated mouth washes should not be indiscriminately used by a normal person, the continuous use may prove harmful.

Enemas

Enemas are aqueous or oily solutions or suspensions intended for introduction into the rectum for their purgative; sedative, anthelmintic, anti-inflammatory or nutritive effects. They may also be used for X-ray examination of the lower bowel.

Inhalations

Inhalations are the liquid preparations containing volatile ingredients and are meant for local or systemic action on the nasal or respiratory tract. They are used to relieve nasal congestion and inflammation of the respiratory tract. If the ingredients are volatile at room temperature, they may be placed on an absorbent pad and inhaled therefrom. In other cases they may be added to warm water, but not boiling water and the vapours are inhaled for five to ten minutes.

Ear Drops

Ear drops are the liquid preparations in which the drugs are dissolved or suspended in a suitable vehicle like water, dilute alcohol, glycerin, propylene glycol or any other suitable solvent and are intended for instillation into the ear with a dropper.

Ear drops are generally used for cleaning the ear, drying weeping surfaces, softening the wax and for treating the mild infections.

Ear drops are dispensed in coloured fluted bottles attached with a dropper or in suitable plastic containers. The containers should be labelled "for external use only".

Liniments

Liniments are the liquid preparations meant for external application to the skin. They are applied with friction and rubbing of the skin. They should not be applied to the broken skin. Liniments should be dispensed in coloured fluted bottles in order to distinguish from preparations meant for internal use. The bottle should be labelled "for external use only" and "shake the bottle before use".

Lotions

Lotions are usually liquid suspensions or dispersions intended for external application to the skin without rubbing. Lotions are used for local cooling, soothing or protective purposes.

Lotions should be dispensed in coloured fluted bottles in order to distinguish from preparations meant for internal use. The container should be labelled "for external use only". On long standing lotions have a tendency to separate out therefore the container must be labelled "shake before use".

Pharmaceutical Incompatibilities

A pharmaceutical incompatibility may be defined as the result of prescribing or mixing the substances which are antagonistic in nature and an undesirable product is formed which may affect the safety, purpose or appearance of the preparation. These incompatibilities are of three types i.e. therapeutic, physical and chemical.

1. Therapeutic Incompatibility

Therapeutic incompatibility may be the result of prescribing certain drugs to the patient with the intention to produce a specific degree of action but the nature or the intensity produced is different from that intended by the prescriber. It may be due to the administration of (i) over dose or improper dose of a single drug (ii) wrong dose or dosage form (iii) contra-indicated drugs (iv) synergistic and antagonistic drugs. For example tetracycline hydrochloride administered with milk makes tetracycline inactive due to calcium present in milk. Therefore water should be used instead of milk for the oral administration of tetracycline hydrochloride preparations.

Sometimes haste or error in the case of prescribing a wrong drug e.g. mercuric chloride in place of mercurous chloride, barium carbonate in place of barium sulphate, labelling of skin ointment as eye ointment may be the cause of prescribing wrong drugs or mode of administration. Although for all these matters prescriber is responsible but it is the duty of the pharmacist to bring these errors to the notice of the prescriber for the instructions to be changed.

2. Physical Incompatibility

Physical incompatibility is due to immiscibility, insolubility, precipitate formation or liquefaction of solid materials. This usually causes nonuniform, unsightly or unpalatable mixture e.g. oils and water are immiscible with each other, which can be made miscible by the addition of an emulsifying agent. Indiffusible solids can be made diffusible by adding a suitable suspending agent. Eutectic substances can be dispensed by adding certain absorbent.

3. Chemical Incompatibility

Chemical incompatibility may be the result of chemical reactions between the ingredients of a prescription and a harmful or even dangerous product may be formed. Therefore, precautions should be taken either to prevent the formation of harmful product or to correct them by addition or substitution of troublesome ingredient.

Chemical incompatibility may be

(a) Tolerated

In which the reaction is minimised by adopting some suitable order of mixing or mixing the solutions in dilute form but no alteration is made in the active ingredients of the preparation.

(b) Adjusted Incompatibility

In such incompatibilities the reaction is prevented by addition or substitution of one of the reacting substances with another of equal therapeutic value but does not affect the medicinal action of the preparation (e.g. substitution of caffeine citrate with caffeine in sodium salicylate and caffeine citrate mixture).

In some of the chemical reactions precipitates are formed which may be diffusible or indiffusible in nature.

If the precipitates formed are diffusible in nature then method A is followed in which the vehicle is divided in two parts, to one part one of the reacting substances is dissolved and to the other part other reacting substances are dissolved and then these two solutions are mixed together slowly with continuous stirring.

If the precipitates formed are indiffusible in nature then method B is followed in which the vehicle is divided into two parts, to one part one of the reacting substance is dissolved and to the other part a suspending agent like compound tragacanth powder in the ratio of 2 gm/100 ml or tragacanth mucilage in the ratio of 1/4th of the total volume of mixture to be prepared is triturated with troublesome ingredient, then the first and second solutions are combined together slowly with continuous stirring.

Whether method A or method B has been used in dispensing the prescription, it is very important to fix a "Shake the bottle" label to the container and ensure that the patient follows and realizes the importance of these directions.

SUPPOSITORIES

Suppositories are special shaped solid dosage form of medicament for insertion into body cavities other than mouth. They may be inserted into rectum, vagina or urethra. These products are so formulated that after insertion, they will either melt or dissolve in the cavity fluids to release the medicament. Suppositories varies in shapes, sizes and weights. Generally suppositories weighing 1 to 2 gm are prepared. The bases used for the preparation of suppositories include cocoa butter, glycerol galatin and soap glycerin.

Cocoa butter also known as theobroma oil is obtained from the crushed and roasted seeds of *Theobroma cacao*. It has butter like consistency and chocolate like odour. It has a melting point of 30 to 35 °C.

Uses

Suppositories are used for any one of the three different purposes.

1. To produce local action.
2. To produce systemic action.
3. To produce mechanical action on the lower bowel and facilitate evacuation in the treatment of haemorrhoids, anal irritation, constipation etc.

Types of Suppositories

1. Rectal Suppositories

They are meant for introduction into the rectum for their systemic action. They are tapered at one or both ends and usually weigh about 2 gm. Rectal suppositories meant for children are smaller in size and weight than the adult suppositories. They usually weigh about 1 gm.

2. Vaginal Suppositories

They are also known as pessaries and are meant for introduction into the vagina. Now a days a few special tablets or capsules, oval or suppository shaped are prepared for use in the vagina and are known as vaginal tablets or vaginal capsules respectively.

3. Urethral Suppositories

They are also known as urethral bougies and are meant for introduction in the urethra. They are very rarely used.

4. Nasal Suppositories

They are also known as nasal bougies or buginaria and are meant for introduction into the nasal cavity. They are always prepared with glycerol-gelatin base. Nasal suppositories are very rarely used.

5. Ear Cones

They are also known as aurinaria and are meant for introduction into the ear. They are seldom used.

Suppository Bases

Since suppositories are special solid dosage form of medicament they must retain its shape, solidity and firmness during storage and administration but must melt or dissolve in the cavity fluids when inserted into

the body cavity. Therefore the materials used as suppository bases must impart these properties and also fulfil other formulation requirements. There are a large number of bases used but theobroma oil, glycerogelatin and polyethylene glycols fulfil the above mentioned requirements.

1. *Theobroma Oil*

It is also known as cocoa butter. It is obtained from the crushed and roasted seeds of *Theobroma cocoa*. It is a yellowish white solid which becomes brittle on storage. It has butter like consistency and chocolate like odour. It has a melting point of 30 to 35 °C. It is a mixture of the glyceryl esters of stearic, palmitic, oleic and other fatty acids.

2. *Glycerogelatin*

Glycerogelatin base is a mixture of glycerin and water which is made stiff by the addition of gelatin. The stiffness of the mass depends upon the proportion of gelatin used. Glycerogelatin base is well suited for suppositories containing belladonna extract, boric acid, chloral hydrate, bromides, iodides, iodoform etc. This base may be used to prepare all types of suppositories but it is particularly used in vaginal suppositories.

3. *Soap-Glycerin Suppositories*

In glycerogelatin base the gelatin is replaced with either curd soap or sodium stearate which makes the glycerin sufficiently hard for suppositories and a large quantity of glycerin upto 95% of the mass can be incorporated, further the soap helps in the evacuation action of glycerin whereas the gelatin does not. Soap-glycerin suppositories are very hygroscopic therefore must be wrapped in waxed paper or tin foil.

4. *Emulsifying Bases*

They are synthetic bases and a number of proprietary bases of good quality are available e.g. *massa esterinum*, *witepsol* and **massuppol**.

Preparation of Suppositories

Suppositories are prepared by hot process and cold compression. On laboratory scale they are prepared by hot process or fusion method. In this method a suppository mould made up of stainless steel, nickel-copper alloy, brass, aluminium or plastic having 6 to 12 cavities with desired shape and size is used. Unless otherwise stated a standard mould of 1 gm capacity is used.

For cleaning, lubrication and removal of suppositories the mould can be opened longitudinally by removing the screws in the centre of the plates. For cleaning the opened plates are cleaned with detergent and hot water, and dried thoroughly. During cleaning the mould should never be scrapped.

The thoroughly cleaned and dried mould is then lubricated with opposite type of lubricant e.g. a lubricant containing soft soap 10 gm, glycerol 10 gm and alcohol (90%) 50 ml is most suitable for oily bases and liquid paraffin or arachis oil for glycerogelatin suppositories respectively.

Before melting the base, keep the lubricated mould in the inverted position over ice to cool and drain any excess of the lubricant. Taking into consideration the displacement value of the medicament, place the calculated quantities of the base in a dish heated over water bath. To this add the weighed amount of drug and mix to melt. Pour the melted mass into the cavities of the mould already kept on ice. Fill the required number of cavities to overflowing, this is done to prevent the formation of hollows in the top of finished suppositories because cocoa butter contracts on cooling due to which hollows are formed. Allow to remain

the mould on ice for about 15 minutes or till the mass solidifies. Remove the mould from ice and trim off excess of the mass with the help of a sharp blade or knife. Open the mould and remove the suppositories. If any lubricant is there, wipe it off with filter paper or clean cloth. Wrap the suppositories individually in wax paper and then pack them in shallow, partitioned card board boxes.

Displacement Value

Since the volume of a suppository from a particular mould remains same but its weight varies due to the variation in densities of medicaments and the base with which the mould was calibrated. To get a product of uniform and accurate weight, allowance must be made for the change in density of the mass due to added drugs. For this purpose the displacement value of the medicament is taken into consideration.

Displacement value may be defined as the quantity of the drug which displaces one part of the medication.

Displacement values of some medicaments used in suppositories with reference to cocoa butter are given below:

| <i>Medicament</i> | <i>Displacement value</i> | <i>Medicament</i> | <i>Displacement value</i> |
|------------------------|---------------------------|------------------------|---------------------------|
| Aminophylline | 1.5 | Morphine hydrochloride | 1.5 |
| Boric acid | 1.5 | | |
| Chloral hydrate | 1.5 | Phenobarbitone | 1.0 |
| Cocaine hydrochloride | 1.5 | Tannic acid | 1.0 |
| Hamamelis dry extract | 1.5 | Zinc oxide | 5.0 |
| Hydrocortisone acetate | 1.5 | Castor oil | 1.0 |
| Iodoform | 4.0 | Liquid medicaments | 1.0 |

To calculate the actual quantity of base required the following procedure is used.

Prepare 8 suppositories each containing 300 mg of bismuth subgallate. The displacement value of bismuth subgallate is 3.

To take into consideration wastage, calculate for two extra suppositories i.e. for 10.

Since 1 gm weight suppository mould is used so total weight of theobroma oil (alone) required for 10 suppositories

$$= 1 \times 10 = 10 \text{ gm}$$

Total weight of bismuth subgallate required for 10 suppositories

$$= 300 \times 10$$

$$= 3000 \text{ mg} = 3 \text{ gm}$$

Displacement value of bismuth subgallate = 3

i.e. 3 gm of bismuth subgallate displaces

$$= 1 \text{ gm of cocoa butter}$$

1 gm of bismuth subgallate displaces

$$= \frac{1}{3} \text{ gm of cocoa butter}$$

3000 mg or 3 gm of bismuth subgallate displaces

$$= \frac{1}{3} \times 3 = 1 \text{ gm of cocoa butter}$$

Using 1 gm mould actual amount of cocoa butter required

$$= (1 \times 10) - 1 = 9 \text{ gm.}$$

The total weight of 10 suppositories will be $9 + 3 = 12$ gm. Therefore although made in a 1 gm mould each suppository weighs 1.2 gm. Using standard mould it is impracticable to make suppositories each containing 300 mg of the drug and weighing 1 gm. Therefore in prescriptions 1 gm indicates the standard size of the mould and necessary calculations according to displacement value of the medicament must be made for correct quantity of base to be used in the preparation of suppositories.