Vidya Siri College of Pharmacy

#67/4, Off Sarjapur Road, Bangalore East Taluk, Chikkakannalli, Bengaluru – 560 035

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VIDYA SIRI
COLLEGE OF PHARMACY

PHARMACEUTICS-1
LABORATORY RECORD

Name of the Student : .....

Reg. No. : .....

Class :.....

Batch : .....

Vidya Siri College of Pharmacy
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VIDYA SIRI
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CERTIFICATE

This is to certify that Mr./Ms.

_____

is a student of ***D.Pharm PART-I (ER 2020)****and has satisfactorily completed the Practical prescribed by Board of Examination Authority, Bangalore in* ***PHARMACEUTICS-1****during the academic year*

……..

*Reg. No.*_____*Date:*___

Signature of the Subject Teacher

S.NO	DATE	EXPERIMENTS	PAGE.NO
1		Handling And Refering Official References: Pharmacopoeias And Formularies	
2		Syrups - General Principles Simple Syrup IP	
3		Piperazine Citrate Elixir IP	
4		Aqueous Iodine Solution IP	
5		Emulsions - General Principles Castor Oil Emulsion	
6		Cod Liver Oil Emulsion	
7		Suspensions - General Principles Calamine Lotion IP	
8		Magnesium Hydroxide Mixture BP	
9		Semi Solid Dosage Form- Ointment Simple Ointment Bases	
10		Sulphur Ointment	
11		Cetrimide Cream	
12		Liniments - General Principles Turpentine Liniment IP	
13		White Liniment IP	
14		Powders - General Principles Effervescent Compound Powder BPC	
15		Dusting Powder	
16		Parenteral Products - General Principles Sodium Chloride Intravenous Infusion IP	
17		Calcium Gluconate Injection IP	
18		Hard Gelatin Capsules - Introduction Tetracycline Capsules	
18		Tablets - Introduction, Method Of Calculation , Paracetamol Tablets IP	
19		Cosmetics – Introduction Lotion -Vanishing Cream	
20		Cold Cream	
21		Tooth Paste	
22		Shampoo	
23		Demonstration Of Various Stages Of Tablet Manufacturing Processes	
24		Appropriate Methods Of Usage And Storage Of Inhalers, Spacers, Insulin Pen	
25		Demonstration Of Quality Control Test Of Tablets	

26		Official Quality Control Tests Of Hard Gelatin Capsules	
27		Quality Control Tests For Parenteral Products	

Experiment No: **Date:**

HANDLING AND REFERING OFFICIAL REFERENCES: Pharmacopoeias and Formularies.

Aim: To study in detail handling and referring official references - Pharmacopoeia and Indian National Formulary to retrieve the formulations.

Theory:

Indian Pharmacopoeia (IP) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India in fulfillment of the requirements of the Drug and Cosmetics Act, 1940 and Rules 1945 there under.

IP is recognized as the official book of standards for the drugs being manufactured and/or marketed in India. IP contains a collection of authoritative procedures of analysis and specifications of drugs for their identity, purity and strength. The standards of the IP are authoritative in nature and are enforced by the regulatory authorities for ensuring the quality of the drugs in India.

During quality assurance and at the time of dispute in the court of law the IP standards are legally acceptable. The standards prescribed in the IP are to establish the compliance with regulatory requirements on an article.

The criteria to be adhered are: a) The interpretation of a monograph must be in accordance with all the general requirements, testing methods, texts and notices pertaining to t, in the IP. A product is not of standard quality unless it complies with all the requirements of monograph.

Objectives:

- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, pharmaceutical aids and dosage forms as well as medical devices, and to keep them updated by revision on a regular basis.
- To develop monographs for herbal drugs, both raw drugs and extracts/formulations there from.
- To accord priority to monographs of drugs included in the National Essential Drugs List and their dosage forms.
- To take note of the different levels of sophistication in analytical testing/ instrumentation available while framing the monographs
- To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products.
- To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP and International Pharmacopoeia with a view to harmonizing with global standards.
- To review existing monographs periodically with a view to deleting obsolete ones and amending those requiring upgradation / revision.
- To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles / materials

Volume 1 is devoted mainly to test methods that are applicable to all the articles of the pharmacopoeia and general information pertaining to the quality requirements of medicinal substances. It also includes reference data such as reference spectra, typical chromatograms etc. The test methods reflect the sophistication of analytical methodology and instrumentation**.**

The General Monographs for dosage forms of active pharmaceutical ingredients (APIs) are grouped together at the beginning of **Volume 2.**

Monographs for other articles of a special nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and veterinary products are given in separate sections in **Volume 3.**

Contents of the Pharmacopoeia: The technical part of the pharmacopoeia shall be broadly divided into the following sections:

1. Introduction
2. General Notices
3. Monographs
4. Test methods
5. Reagents and Solutions
6. General Texts
7. Index

1. Introduction:

The Scientific Director of the Indian Pharmacopoeia Commission (IPC) shall write this part after all the contents of the pharmacopoeia have been finalised. It shall briefly give the background to the edition and describe the salient features including the additions to and deletions from the previous edition.

2. General Notices:

The purpose of the General Notices is to provide the basic guidelines to the interpretation and application of the standards, tests, assays and other specifications of the pharmacopoeia, as well as to the statements made in the monographs, test methods and appendices. Included, among other things, is the system of nomenclature of chemical compounds that is to be adopted. Recommendations on storage of drugs and specific labelling requirements may also be given.

3. Monographs

A monograph states the quality or test parameters, the acceptance criteria and details of the tests that are to be performed to determine compliance with the criteria.

A) Active Pharmaceutical Ingredients (APIs) (Bulk Drug Substances) Chemical Excipients

a. **Title of the monograph:** The main title for a drug substance is the International Non-proprietary Name (INN) approved by the World Health Organization. Subsidiary names and synonyms have also been given in some cases; where included, they have the same significance as the main title. The main titles of drug products are the ones commonly recognised in practice.

Synonyms drawn from the full nonproprietary name of the active ingredient or ingredients have also been given. Where, however, a product contains one or the other of different salts of an active molecule, the main title is based on the full name of the active ingredient. For example, Chloroquine Phosphate Tablets and Chloroquine SulphateTablets

b. **Chemical Formula:** When the chemical structure of an official substance is known or generally accepted, the graphic and molecular formulae are normally given at the beginning of the monograph for information. This information refers to the chemically pure substance and is not to be regarded as an indication of the purity of the official material. Elsewhere, in statement of purity and strength and in descriptions of processes of assay, it will be evident from the context that the formulae denote the chemically pure substances.

c. **Atomic and Molecular Weights.** The atomic weight or molecular weight is shown , as and when appropriate at the top right hand corner of the monograph.

d. **Statement of purity:** A definitive statement of the purity of the article, two spaces below Chemical name, and expressed in the following manner: AB contains not less than X per cent and not more than Y per cent of the chemical entity expressed as the molecular formula, calculated on the dried basis (where a test for loss on drying is specified), or on the anhydrous basis (where a test for water is specified), where AB is the pharmacopoeial name of the article, X and Y are the lower and higher percentage figures, respectively, expressed to one decimal place only.

e. **Description:** A brief description of the physical form of the material, including colour, texture, whether hygroscopic, odour, if readily apparent, and any other characteristic. The statements under the heading Description are not to be interpreted in a strict sense and are not to be regarded as official requirements

f. **Solubility:** Statements on solubility are given in Chapter 2.4.26 of the pharmacopoeia and are intended as information on the approximate solubility at a temperature between 15º and 30º, unless otherwise stated, and are not to be considered as official requirements. However, a test for solubility stated in a monograph constitutes part of the standards for the substance that is the subject of that monograph.

g. **Identification**: At least two or three identification tests, starting with physical and instrumental tests and ending with general chemical reactions shall be given.

h. Appearance
i. pH
j. specific optical rotation
k. light absorbing impurities

l. Related substances, iron, chlorides, non volatile substances, residual solvents.
m. Microbial contamination, sterility, pyrogen, sulphated ash, Loss of drying
n. Assay

o. **Storage:** Specific directions are given in some monographs with respect to the temperatures at which Pharmacopoeial articles should be stored, where it is considered that usage at a lower or higher temperature may produce undesirable results. The storage conditions are defined by the following terms:
— Store in a dry, well-ventilated place at a temperature not exceeding 30º
— Store in a refrigerator (2º to 8º). Do not freeze
— Store in a freezer (-2º to -18º)
— Store in a deep freezer (Below -18º)

Storage conditions not related to temperature are indicated in the following terms:
— Store protected from light
— Store protected from light and moisture

m. **Labelling:** The labelling of drugs and pharmaceuticals is governed by the Drugs and Cosmetics Rules, 1945. The statements that are given in the monographs under the sideheading 'Labelling' are not comprehensive. Only those that are necessary to demonstrate compliance or otherwise with the monograph have been given and they are mandatory. For example, in the monograph on Betamethasone Sodium Tablets the labelling statement is "The label states the strength in terms of the equivalent amount of betamethasone". Any other statements are included as recommendations

B) Inactive Ingredients other than Chemicals Drugs of Plant Origin

Title of the Monograph, Description, Identification and other tests, including Assay, Relative density, Weight per ml, Refractive index, Melting point, Freezing point, Viscosity, Peroxide value, Acid value, Ester value, Unsaponifiable matter, Acetyl value, Hydroxyl value, Saponification value, Iodine value, Acidity, Foreign matter, Total ash, Ash insoluble in hydrochloric acid, Storage and Labelling.

C) Dosage Forms

Title of the Monograph, Definiti,on/ Description, Content statement, Identification, Related substances/ Impurities, Specific tests, Disintegration, Dissolution, Other tests, Assay, Storage and Labelling.

4. Test Methods: Test Methods shall be broadly divided into the following sections.
a. Apparatus
b. Physical and physicochemical methods
c. Identification tests
d. **Limit tests:** The limits given are based on data obtained in normal analytical practice. They take into account normal analytical errors, of acceptable variations in manufacture and of deterioration to an extent that is acceptable. No further tolerances are to be applied to the

limits for determining whether or not the article under examination complies with the requirements of the monograph
e. Chemical assays
f. Biological tests
g. Pharmaceutical tests

5. Reagents and Solutions:

This section shall provide details of the quality and of preparation of reagents and solutions that are to be used in the tests and assays of the pharmacopoeia. It shall also include information on Reference Substances that are required for specific tests.

6. General Texts:

These shall consist of general information, not specific to any product, but pertaining to aspects of production and testing of pharmaceuticals impacting on quality, such as sterilisation, the quality of water for pharmaceutical use, containers (including closures) for packing drugs and drug products etc.

7. Index:

The Index shall be in alphabetical order of the titles of monographs, titles and sub-titles of test methods and of general texts, as well as of reagents and special solutions mentioned in any of the pages of the Pharmacopoeia except the cover page. The Annexures that follow show specimens of monographs in different formats for APIs, excipients, dosage forms etc.

SYRUPS - General Principles

According to IP, s*yrups* are defined as oral liquids, which are sweet and viscid and often contain added flavouring and colouring agents and into which medicaments are incorporated.

The concentration of sugar in syrup is 66.7% w/w. At this concentration sucrose has a high tendency to crystallise. To prevent this, co-solvents such as glycerin, sorbitol, and propylene glycol are added. Sometimes, artificial sweetening agents such as saccharin and viscosity builders such as cellulosic gums (tragacanth) are also added to the preparation of syrups. Syrups may contain a small concentration of alcohol as a preservative or co-solvent to incorporate flavouring agents. Syrups as such do not require any preservative. Due to high concentration of sucrose, syrups possess high osmotic pressure. When the osmotic pressure is high, bacteria, fungi, and moulds cannot grow in the preparation. However, antimicrobial agents may be sometimes added to prevent the growth of bacteria, yeasts, and moulds.

Advantages

1. Syrups retard oxidation of drugs, because sucrose itself gets hydrolysed to lavulose and dextrose, which are reducing sugars.
2. Syrups are sweet in taste. Therefore, bitter taste of drugs can be reduced, example is ephedrine hydrochloride syrup.
3. Syrups prevent microbial decomposition of many vegetable drugs.

Disadvantages

1. On continuous intake, syrup promotes dental decay and causes gingivitis, because it is a very good supplement for bacterial growth.
2. Syrup is not preferred by diabetic patients and patients on a restricted calorie intake.
3. Aluminium salts are not added to syrups, as these are incompatible with sucrose. Similarly acidic drugs are not added as these promote crystallization of sucrose.

Classification

Syrups as such do not have any medicinal value, but used as vehicles for dispensing the drugs. Syrups are classified into two types.

- **Medicated syrups:** Pure drugs and extracts (of medicinal plants) are added to the syrup. Examples are paracetamol syrup IP, salbutamol sulfate syrup IP, promethazine hydrochloride syrup IP, ephedrine hydrochloride syrup NF etc.
- **Flavoured syrups:** Aromatic or flavoured substances are added to the syrups. Examples are orange syrup BP, lemon syrup BPC.

Formulation: The following ingredients can be added for the preparation of syrups.

Sl. No.	*Ingredients type*	*Examples*
1	Vehicles	Water, glycerin
2	Sweetening agents	Sucrose, saccharin
3	Colouring agents	Amaranth (red), tartrazine (yellow)
4	Flavouring agents	Tincture of lemon, tincture of ginger
5	Preservatives	Sodium benzoate, methyl paraben + propyl paraben
6	Stabilizers	Glycerin, sorbitol

Storage

Syrups should be stored in well dried, completely filled, and well-stoppered bottles in a cool dark place (25 ^{o}C). The bottles may be colourless or amber coloured (light-resistant). Syrups should not be exposed to unnecessary fluctuations in temperature.

Experiment No. **Date:**

SIMPLE SYRUP IP

AIM: To prepare and submit 20 g of simple syrup IP.

FORMULA

Ingredients	Official Formula	Working formula
Sucrose (sugar)	667 g	
Purified water, quantity sufficient to produce (qs)	1000 g	

THEORY

Simple syrup IP is a concentrated or nearly saturated solution of sucrose in purified water. 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. It possesses high osmotic pressure. Therefore, microorganisms cannot grow in syrups. Methyl paraben in a concentration not higher than 0.15% may be used as a preservative, if necessary. Simple syrup is sweet in taste and used as a vehicle in formulations containing nauseous and bitter substances. Normally pharma-grade powdered sugar is used for this preparation. Simple syrup as such does not have any medicinal value, but used as vehicle for dispensing the medication.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Hundred ml empty beaker is weighed and the weight is noted.
2. Calculated quantity of sucrose is weighed in the same beaker.
3. 3/4th quantity of water is placed into the beaker.
4. Sucrose is dissolved by heating with occasional stirring.
   Precaution: Over heating of sugar solution should be avoided because it leads to caramellization of sugar. This is indicated by black colour of the solution.
5. After cooling, purified water is added to make up to the required weight.
6. The syrup is filtered through muslin cloth if necessary.
7. The simple syrup is transferred into a light-resistant container (amber coloured container).
8. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Sweetening agent, vehicle.

STORAGE: Store in a tightly closed container in a cool place.

CALCULATIONS

1. 1000 g of simple syrup requires 667 g of sucrose

   $$\text{20 g of simple syrup requires} = \frac{667 \times 20}{1000} = 13.34 \text{ g}$$

2. Purified water quantity sufficient to produce = 20 g

SIMPLE SYRUP IP
20 g

COMPOSITION: Sucrose 66.7% w/w

CATEGORY: Sweetening agent, vehicle

STORAGE: Store in a tightly closed container in a cool place

MFG. LIC. NO.: 16 - A

MFG. DATE: 05.09.2003

BATCH NO.: 27

EXPIRY DATE: Six months from the date of manufacture. If the container is opened, syrup should be used within 15 days from the date of opening.

MANUFACTURED BY: ROLL NO.:50

EVALUATION

The product is evaluated by the following tests.

1. The product should not contain dark (black to brown) coloured particles.
2. Insoluble particles must be absent.
3. The weight of the syrup must be checked to ensure that the desired weight is prepared.
4. Simple syrup IP should be sweet in taste, but should not possess any flavour.
5. Simple syrup IP should possess high viscosity, but should be easily pourable.
6. The label must be checked for correct size and complete details must be written with no corrections.

Experiment No. **Date:**

PIPERAZINE CITRATE ELIXIR IP

AIM: To prepare and submit 20 ml of Piperazine citrate elixir IP.

FORMULA

Ingredients	Official Formula	Working formula
Piperazine citrate	18.00 g	
Chloroform spirit	00.50 ml	
Glycerin	10.00 ml	
Orange oil	0.025 ml	
Simple syrup	50.00 ml	
Purified water qs	100.00 ml	

THEORY

Piperazine citrate elixir is used as anthelmintic to expel the worms from the intestine. The medicinal agent, piperazine citrate is a salt form and is soluble in the vehicle, purified water. Glycerin acts as a co-solvent to enhance the solubility of drug. Chloroform spirit acts as a preservative. Orange oil acts as flavouring agent.

Piperazine citrate possesses unpleasant taste (acid taste). Therefore sweetening agent like simple syrup is used to mask the taste of the drug. However, chloroform spirit, glycerin, and orange oil also help in masking the taste of the drug.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated. Simple syrup is prepared using the procedure mentioned in page no. 3.

1. Weighed quantity of piperazine citrate is dissolved in little quantity of water.
2. Orange oil is mixed with chloroform spirit and poured into piperazine citrate solution.
3. Syrup and glycerin are added to the above solution and mixed well.
4. Finally the volume is made up to required level with purified water in a measuring cylinder.
5. The contents are mixed well and kept aside for some time.
6. The preparation is filtered, if necessary.
7. The preparation is then transferred into a light-resistant container.
8. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Anthelmintic.

DOSE: 4 - 15 ml is required for thread worms daily in divided dose, up to 30 ml for treating round worms, a single dose is administered according to the age of the patient, as given below.

For children	9 to 12 months	2.5 ml
	2 to 3 years	5.0 ml
	4 to 6 years	7.5 ml

7 to 12 years 10.0 ml

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

EVALUATION:

The product is evaluated by the following tests.

1. Insoluble particles must be absent.
2. The volume of the elixir must be checked to ensure that the desired volume is prepared.
3. Piperazine citrate elixir IP should be sweet in taste and orange in flavour.
4. Piperazine citrate elixir IP should possess high viscosity, but should be easily pourable.
5. The label must be checked for correct size and complete details must be written with no corrections.

Experiment No: **Date:**

AQUEOUS IODINE SOLUTION IP

AIM: To prepare and submit 20 ml of aqueous iodine solution IP.

SYNONYM: Lugol's solution.

FORMULA

Ingredients	Official Formula	Working Formula
Iodine	50 g	
Potassium iodide	100 g	
Purified water qs	1000 ml	

THEORY

Aqueous iodine solution is used to supplement iodine in iodine deficiency conditions like goitre. To treat the patient, iodine is supplied in solution form in a concentration of 50 mg/ml.

Iodine is very slightly soluble in water. Hence, potassium iodide is added to increase the solubility of iodine. Complexation reaction between potassium iodide and iodine takes place to form polyiodide complexes as shown below.

$$KI + nI_2 \longrightarrow \underset{\text{Polyiodides}}{KI.I_2 + KI.2I_2 + KI.3I_2 + ...+ KI.nI_2}$$

Polyiodides are easily soluble in water by ion induced dipolar interaction. Higher polyiodides are more soluble than lower polyiodides. Higher polyiodides are produced in a concentrated solution. Therefore, iodine and potassium iodide are dissolved first in small quantity of water. Then, the preparation can be easily diluted to required volume. In making iodine solutions, potassium iodide may be replaced by sodium iodide.

Since iodine (present in iodine solutions) reacts with some ingredients of ordinary glass container, iodine resistant container like amber coloured container is used to store iodine solutions.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Weighed quantity of potassium iodide is dissolved in small quantity of purified water.
2. Weighed quantity of iodine is dissolved in the above solution.
3. Sufficient purified water is added to produce the required volume.
4. The preparation is then transferred into a well-closed amber coloured container.
5. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Iodine supplement in iodine deficiency conditions like goitre.

DOSE: 0.3 - 1 ml.

STORAGE: Store in a tightly closed container in a cool place.

ADVICE FOR PATIENTS: The solution should be taken by mixing the contents with water or milk. When used prior to thyroidectomy, the prescribed course (i.e., number of doses) should be completed.

PRECAUTION: Iodine preparations should not be administered during pregnancy and lactation. These interfere with tests for thyroid function. Some patients show skin sensitivity to iodine.

EVALUATION

The product is evaluated by the following tests.

1. Insoluble particles must be absent.
2. The volume of the solution must be checked to ensure that the desired volume is prepared.
3. Aqueous iodine solution IP should be a clear liquid having a deep brown colour and the odour of iodine.
4. The label must be checked for correct size and complete details must be written with no corrections.

EMULSIONS - General Principles

Emulsions are biphasic systems containing two immiscible liquids, one of which is dispersed as minute globules in the other with the help of emulsifying agent.

Figure 1 represents an emulsion with its phases. The liquid which is converted into minute globules is called *dispersed phase* and the liquid in which the globules are dispersed is called *continuous phase*. Normally two immiscible liquids cannot remain dispersed for a longer period, so an emulsifying agent is added to the system. It forms a flexible and strong film around globules and distributes them uniformly in the continuous phase, so that a stable emulsion is formed.

The globules' size (diameter) in emulsion varies from 0.1 to 100 μm. Emulsions having globule size more than 25 μm are called as *coarse emulsions*. Emulsions having a globule diameter between 0.25 and 25 μm are called as *fine emulsions*. Fine emulsions are milky in appearance.

Emulsions having globules' size about 0.01 μm are known as *micro emulsions*. These emulsions appear transparent.

Advantages

1. Medicines having unpleasant taste and odour can be made more acceptable for oral administration in the form of an emulsion. Examples are castor oil and cod liver oil.
2. Emulsions provide protection to drugs, which are prone to oxidation and hydrolysis. Example is vitamin A.
3. Various external preparations such as creams, lotions, and aerosols can be formulated in emulsion form.
4. Sterile stable intravenous emulsions containing fats, carbohydrates, and vitamins can be administered to the patients who are unable to swallow them orally.
5. Emulsions improve the absorption of oil when taken internally.
6. Radio-opaque emulsions are used as diagnostic agents in X-ray examination.

Disadvantages

1. Emulsions have a short shelf life. These are unstable and the insoluble phase separates slowly.
2. Being liquid dosage forms, these are packed in glass or plastic containers. Thus care should be taken in handling and storage.

Types of emulsions: The emulsions are of 2 types

a) Oil-in-water emulsion (*o/w*): In *o/w* emulsion, oil is the dispersed phase and water is the continuous phase. The *o/w* type of emulsion is preferred for internal use. In these emulsions, gum acacia, tragacanth, and soaps of monovalent bases like Na^+, NH_4^+, K^+ are used as emulsifying agents.

b) Water-in-oil emulsion (*w/o*): In *w/o* type of emulsion, water is the dispersed phase and oil is the continuous phase. In these emulsions, wool fat, resins, bees wax, and soaps of divalent bases like Ca^{++}, Mg^{++}, Zn^{++} are used as emulsifying agents.

Tests for identification of emulsions: Following tests are used to distinguish *o/w* and *w/o* emulsions.

1. *Dilution test*: The emulsion is diluted with water. If emulsion remains miscible, then it is *o/w* type. If emulsion breaks then it is *w/o* type.

2. *Dye solubility test*: A water-soluble dye powder (amaranth) is sprinkled on emulsion. If a drop of emulsion under microscope shows red colour throughout, then it is *o/w* type. In other words, if only dispersed particles show colour, then it is *w/o* type.

3. *Conductivity test*: A pair of electrodes connected through a low voltage bulb is dipped in emulsion. If electricity is conducted, bulb glows. Then the emulsion contains water as continuous phase and the emulsion is *o/w* type. If bulb does not glow then it is *w/o* type.

Other tests such as fluorescence test, creaming test, cobalt chloride test, and filter paper test can also be used, but of least importance.

Methods of preparation

Mortar and pestle can be used to prepare emulsions in small scale using the following methods.

Dry gum method: Example is arachis oil emulsion (*o/w* type) using acacia as emulsifying agent.

Wet gum method: Example is castor oil emulsion (*w/o* type) using acacia as emulsifying agent.

Bottle method: For example, turpentine liniment IP (*o/w* type) is prepared using soft soap as emulsifying agent.

On large-scale, equipment such as colloid mill, Silverson emulsifier is used.

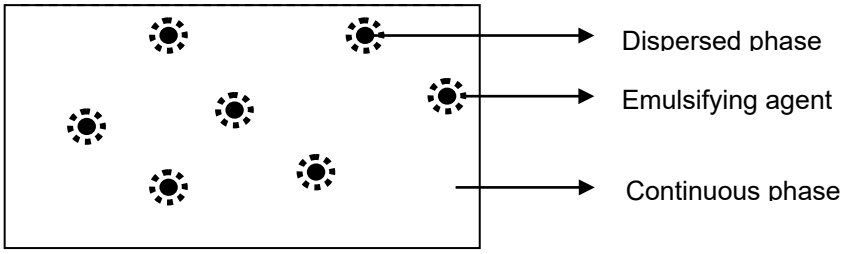


Figure 1: Emulsion with phases

Primary emulsion: Emulsions for internal use are prepared using acacia gum as emulsifying agent. To prepare emulsions with acacia in a laboratory scale, first primary emulsion must be prepared. (Later primary emulsion is diluted easily with continuous phase). For preparing primary emulsion, the following ratios of oil, water, and emulsifying agents are taken based on the nature of oil.

Nature of oil	***Example***	***Ratios of ingredients for preparation of primary emulsion***		
		Oil	***Water***	***Acacia***
Fixed oil	Castor oil	4	2	1
Mineral oil	Liquid paraffin	3	2	1
Volatile oil	Turpentine oil	2	2	1
Oleo-resin	Male fern extract	1	2	1

Experiment No. **Date:**

CASTOR OIL EMULSION

AIM: To prepare and submit 25 ml of the Castor oil Emulsion.

Ingredients	Official formula	Working formula
Castor oil	20 ml	
Cinnamon water up to	50 ml	

THEORY

Castor oil emulsion is used as a laxative, to empty the GI tract, while the patient is prepared for the colon x-ray, proctoscopy, and endoscopic examination. Castor oil is best taken on an empty stomach, followed with one full glass of water. On oral administration, castor oil emulsion produces one or more copious stools within 2 to 6 hr after ingestion. The purgative action is due to ricinoleic acid that is produced on the hydrolysis of ricinolein (present in castor oil) in the intestine. Ricinoleic acid stimulates water secretion in the intestine while decreasing glucose absorption. Chronic use of castor oil emulsion is not recommended, since absorption of nutrients may be reduced.

Precautions for administration

Castor oil, and other laxatives, should not be used regularly or excessively as they can lead to dependence for bowel movement. Laxatives should not be used when nausea, vomiting, or abdominal pain is present since these symptoms may indicate appendicitis. Use of a laxative in this instance could promote rupturing of the appendix. Castor oil emulsion should not be given in the therapy of acute constipation.

Principle

The amount of castor oil in commercial castor oil emulsions varies from about 35 to 67%. The amount of oil present influences the dose of the emulsion required. Castor oil is obtained from the seeds of *Ricinus communis* (Euphorbiaceae). Castor oil possesses bland taste at first, but afterwards slightly acrid. Hence it cannot be taken orally as it is. It is supplied in the form of emulsion using acacia as an emulsifying agent.

Castor oil is a fixed oil. Therefore, primary emulsion formula is oil:water:acacia = 4:2:1. The emulsion is prepared by wet gum method and emulsion formed will be *o/w* type in which castor oil is a dispersed phase and cinnamon water is a continuous phase.

PROCEDURE

Using the prescription formula, the working formula is calculated. The quantities of acacia, cinnamon water, and castor oil are calculated using the primary emulsion formula.

1. Weighed quantity of acacia is placed in a mortar.
2. Measured quantity of cinnamon water at once (calculated for primary emulsion formula) is added into the mortar.
3. The contents in the mortar are triturated to form mucilage.

4. Measured quantity of castor oil is added in small quantities, with constant, rapid, and light trituration to produce a thick cream. Trituration is continued for three minutes, to obtain a white, stable emulsion. It is indicated by click sound.
5. Some more quantity of cinnamon water is added gradually, with continuous trituration.
6. The contents are transferred into a measuring cylinder.
7. The pestle and mortar are rinsed with cinnamon water and rinsings are transferred into the measuring cylinder.
8. The quantity is adjusted to the required volume using cinnamon water and the contents are stirred well.
9. The castor oil emulsion is then transferred into a wide mouthed light resistant container.
10. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Laxative.

DOSE: 4 to 16 ml

STORAGE: Store in a tightly-closed container in a cool place.

DIRECTION: Take on an empty stomach, followed with one full glass of water.

AUXILIARY LABEL: SHAKE WELL BEFORE USE

EVALUATION

The product is evaluated by the following tests.

1. The volume of the preparation must be checked to ensure that the prescribed volume is prepared.
2. Castor oil emulsion should possess high viscosity, but should be easily pourable.
3. Dilution test must confirm the *o/w* type of emulsion.
4. The label of the container must be verified for correct size and complete details must be written with no corrections.

Experiment No. **Date:**

COD LIVER OIL EMULSION

AIM: To prepare and submit 30 ml of Cod liver oil emulsion.

FORMULA

Ingredients	Official Formula	Working formula
Cod liver oil	30 ml	
Egg yolk	4 ml	
Purified water qs	60 ml	

THEORY

Cod liver oil is a rich source of vitamin D and is therefore used as an anti-rachitic agent. Cod liver oil is a fixed oil obtained from fresh liver of the cod fish, *Gadus morrhua* and other species of the family *Gadidae*. Cod liver oil possesses unpleasant odour and taste, and is insoluble in water. Therefore, it must be supplied in an emulsion form of *o/w* type. Here, cod liver oil is a dispersed phase and water is a continuous phase. Egg yolk is used as an emulsifying agent. The absorption of cod liver oil is faster and better from emulsion dosage form.

PROCEDURE

Using the prescription formula, the working formula is calculated.

1. Egg yolk is separated from the broken egg and placed in a measurer. Equal volume of water is added and mixed thoroughly.
2. The calculated volume of the above egg yolk is placed in a mortar.
3. The calculated volume of cod liver oil is added to the mortar and mixed with constant stirring.
4. Purified water (1/3rd the total quantity) is gradually added with constant trituration.
5. The mixture is strained through a muslin cloth.
6. Mortar and pestle are rinsed with little volume of water and transferred through the muslin cloth.
7. The volume is adjusted to the required level with water in a measuring cylinder.
8. The contents are mixed well and transferred into a narrow mouthed container.
9. The container is capped, polished, labelled, and dispensed.

CATEGORY: Anti-rachitic (in deficiency of vitamin D).

DOSE: Not more than 10 ml daily.

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

AUXILIARY LABEL: SHAKE WELL BEFORE USE.

EVALUATION

The product is evaluated by the following tests.

1. The volume of the emulsion must be checked to ensure that the prescribed volume is prepared.
2. Cod liver oil emulsion should possess high viscosity, but should be easily pourable.
3. Cod liver oil emulsion should not show any signs of separation even after standing for a long period. The separation of layers indicates improper emulsification.
4. Dilution test must confirm the *o/w* type of emulsion.
5. The label must be checked for correct size and complete details must be written with no corrections.

SUSPENSIONS - General Principles

Suspensions are biphasic liquid dosage forms in which finely divided solid particles are dispersed in a liquid vehicle. The solid particles are known as dispersed phase whereas liquid vehicle is known as continuous phase. Figure 3 represents suspension with its phases. Suspensions are usually administered orally, parenterally, and externally.

Ideal properties of suspensions

1. Finely divided solid particles should not settle rapidly and should be readily re-dispersed on gentle shaking of the container if particles settle.
2. The suspended particles should not form a hard cake.
3. Its viscosity should be in such a way so as to allow easy withdrawal of the contents.
4. The suspension should be free from gritty particles.

Classification of suspensions

Based on type of application

Suspension type	***Examples***
Oral suspensions	Magnesium hydroxide suspension
Parenteral suspensions	Streptomycin suspension
Ophthalmic suspensions	Indomethacin suspension
External application	Calamine suspension

Based on the nature of solids

Suspension type	***Examples***
Flocculated suspensions	Tetanus toxoid suspension
De-flocculated suspensions	Procaine penicillin G suspension

Formulation of suspensions: The following ingredients can be added for the preparation of suspensions.

Sl. No.	***Type of ingredient***	***Examples***
1	Drug	Aluminium hydroxide gel, paracetamol.
2	Flocculating agents	Electrolytes (aluminium chloride), hydrocolloids (bentonite).
3	Thickening agents	Tragacanth, sodium CMC.
4	Wetting agents	Glycerin, Tweens.
5	Preservatives	Sodium benzoate, methyl paraben + propyl paraben
6	Colouring agents	Tartrazine (yellow), amaranth (red).
7	Sweetening agents	Sucrose, saccharin.
8	Flavouring agents	Orange oil, lemon oil, banana flavour.

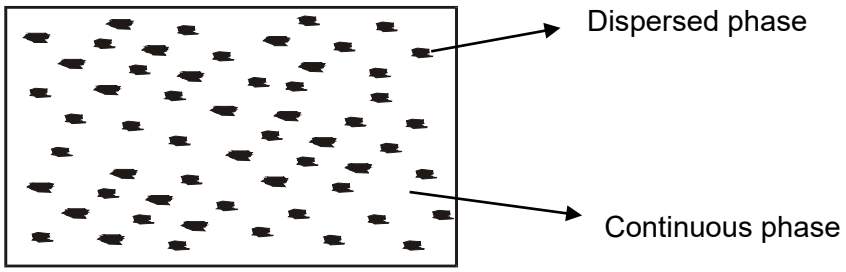


Figure 3 : Suspension with its phases

AUXILIARY LABEL: SHAKE WELL BEFORE USE

STORAGE: Store in tightly closed container. Do not keep in cold place.

Experiment No. **Date:**

CALAMINE LOTION IP

AIM: To prepare and submit 20 ml of calamine lotion IP.

FORMULA

Ingredients	Official formula	Working formula
Calamine	150 g	
Zinc oxide	50 g	
Bentonite	30 g	
Sodium citrate	5 g	
Liquefied phenol	5 ml	
Glycerin	50 ml	
Rose water qs	1,000 ml	

THEORY

Lotions are usually liquid suspensions or dispersions meant for application to the skin without friction.

Lotions are applied to the skin using absorbent material such as cotton. Calamine lotion is used as a topical protectant. Calamine is a zinc oxide with a small amount of ferric oxide. The powder has pink colour. It is used as astringent and protective for obtaining relief from sunburn, insect bite, and other similar irritations. The pink colour helps to disguise the presence of lotion on skin. Zinc oxide is used as an astringent and produces weak antimicrobial action. The antimicrobial and astringent actions of zinc oxide are due to the release of zinc. Zinc is released from zinc oxide on hydrolysis in the acidic moisture of the skin.

Bentonite is a natural colloidal hydrated aluminium silicate. It is pale buff coloured powder. It is insoluble in water, swells nearly 12 times of its bulk and forms magma with desirable rheological characters. Hence, it is used as a suspending agent. Sodium citrate acts as a buffer and maintains the pH within limits appropriate to skin application. It also helps in the suspending action of bentonite and prevents frothing on shaking the preparation. Liquefied phenol acts as an antiseptic, preservative, and local anaesthetic. Glycerin is used for its soothing action and makes the preparation more viscous for the proper application of skin. It is also used as emollient and humectant. Rose water gives a good odour (smell) to the preparation.

The functions of the ingredients of calamine lotion are tabulated as follows;

Ingredient	***Chemical name***	***Functions***
Calamine	Zinc oxide and ferric oxide	Astringent, protective
Zinc oxide	Zinc oxide	Astringent, weak antimicrobial agent
Bentonite	Colloidal hydrated aluminium silicate	Suspending agent (increases the bulk and viscosity)
Sodium	Sodium citrate	Buffer and maintains the pH of the

citrate		preparation, supports the suspending property, prevents froth
Liquefied phenol	Phenol	Antiseptic, preservative, local anaesthetic
Glycerin	Glycerin	Soothing agent, viscolizer, emollient, humectant
Rose water	Rose water	Vehicle, odouring agent

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Calamine, zinc oxide, and bentonite are triturated with a solution of sodium citrate in about 3/4th quantity of rose water.
2. Liquefied phenol and glycerin are added to the above mixture, mixed well.
3. Sufficient rose water is added to produce the required volume.
4. The preparation is shaken to ensure uniform distribution.
5. The preparation is then transferred to a bottle.
6. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Topical protectant.

STORAGE: Store in a well-closed container in a cool place. Do not freeze.

AUXILIARY LABELS: FOR EXTERNAL USE ONLY.
SHAKE WELL BEFORE USE.

ADVICE FOR PATIENTS: The lotion should be applied to the skin as required and allowed to dry.

EVALUATION

The product is evaluated by the following tests.

1. Calamine lotion IP must be free from grittiness when rubbed on the skin. i.e., it must have good spreadability.
2. The volume of the suspension must be checked to ensure that the desired volume is prepared.
3. It should possess moderate viscosity.
4. Calamine lotion IP must possess aromatic odour due to rose water and should possess pink colour.
5. The label must be checked for correct size and complete details must be written with no corrections.

Experiment No. **Date:**

MAGNESIUM HYDROXIDE MIXTURE BP

AIM: To prepare and submit 20 ml of magnesium hydroxide mixture BP.

SYNONYMS: Cream of magnesia, milk of magnesia.

FORMULA

Ingredients	Official formula	Working formula
Light magnesium oxide	52.5 g	
Sodium hydroxide	15.0 g	
Magnesium sulphate	47.5 g	
Chloroform	2.5 ml	
Purified water, freshly boiled & cooled qs	1000 ml	

THEORY

Milk of magnesia is used as antacid and laxative. According to its usage, the dose changes. It is a suspension of magnesium hydroxide in water. It is also sometimes called as a mixture. Mixture is a general term used to indicate the preparations for oral administration.

Magnesium hydroxide mixture BP contains an aqueous suspension of hydrated magnesium oxide containing not less than 7.0% w/w and not more than 8.5% w/w of magnesium hydroxide. It cannot be directly prepared by suspending magnesium hydroxide in water. Magnesium hydroxide is prepared *in situ* using magnesium sulphate, sodium hydroxide, and light magnesium oxide. These are exothermic reactions (heat is liberated) and are explained as follows;

Double decomposition reaction

$MgSO_4$ + $2NaOH$ ⟶ $Mg(OH)_2$ + Na_2S0_4

Magnesium sulphate — Sodium hydroxide — Magnesium hydroxide Translucent gelatinous precipitate — Sodium sulphate

Hydration reaction

MgO + H_2O ⟶ $Mg(OH)_2$

Magnesium oxide — Water — Magnesium hydroxide creamy precipitate, heavy

Magnesium hydroxide prepared from magnesium sulphate is gelatinous in nature, where as magnesium hydroxide prepared from magnesium oxide is heavy and settles fast. Therefore, magnesium hydroxide is prepared from both magnesium sulphate and light magnesium oxide. The prepared magnesium hydroxide will remain in colloidal condition for a longer time, without formation of clumps. Thus, the magnesium hydroxide preparation is neither too viscous to obstruct pouring from the container nor too thin to allow undue settling.

After filtration, the precipitate of magnesium hydroxide is washed several times with water to remove sulphate ions ($Na_2SO_4 \rightarrow 2Na^+ + SO_4^{2-}$). Sodium sulphate is soluble in water. The mixture must be made free from sulphate ions, otherwise purgative action of sodium sulphate precipitates. Further it also causes constipation problem at a later period. After thorough washing of the filter cake, the pH of the final product is nearly 10.

Chloroform acts as a preservative. In place of chloroform, 0.2% w/v methyl paraben or 0.125% w/v sodium benzoate or a similar preservative can also be used.

If glass containers are to be used for supplying this formulation, 0.1% w/v citric acid may be added to minimize the leaching of alkali from the glass containers into milk of magnesia. In case of plastic containers, citric acid is not added.

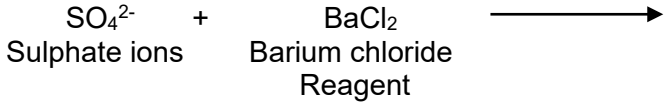
Magnesium hydroxide mixture should not be stored in a cold place because freezing produces a coarsening of the particles.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Sodium hydroxide is dissolved in purified water (15% of the total volume) in a mortar.
2. Light magnesium oxide is added to the above. This is triturated to form a smooth cream. Sufficient purified water is added to produce 25% volume of the preparation.
3. Magnesium sulphate is dissolved in another 25% volume of purified water and is placed into another mortar.
4. Suspension of step (2) is transferred in a thin stream into solution of step (3), with continuous trituration.
5. The precipitate is allowed to settle, then the clear liquid is decanted and the precipitate is transferred through a calico strainer.
6. The precipitate is washed with purified water several times, until the precipitate is free from sulphate ions, which can be confirmed by sulphate test.

Sulphate Test: A few drops of washings are treated with a few drops of barium chloride solution. If sulphate ions are present, the following reaction takes place;



Sulphate test reaction, observation, and inferences are given in the following table.

Test	***Observation***	***Inference***	***Test***	***Observation***	***Inference***
A few drops of washings + a few drops of barium chloride reagent	No precipitate formed or doubt of forming a precipitate	No reaction takes place	Add a few drops of dilute hydrochloric acid to the above mixture	Traces of precipitate dissolve or clear solution	Sulphate ions absent, stop washing
	White precipitate formed	Reaction takes place		Precipitate insoluble	Sulphate ions present, continue washing

7. The washed precipitate is mixed with purified water.
8. Chloroform is dissolved in the above mixture.
9. The volume is made up to the required quantity with purified water.
10. The suspension is transferred into a tightly closed container.
11. The container is capped, polished, labelled, and submitted.

CATEGORY: Antacid, laxative.

DOSE: 5 - 10 ml as an antacid.
15 - 30 ml as a laxative.

STORAGE: Store in a tightly closed container. Do not keep in a cold place.

AUXILIARY LABEL: SHAKE WELL BEFORE USE.

EVALUATION

The product is evaluated by the following tests.

1. Magnesium hydroxide mixture must pass for the test for absence of sulphates.
2. The volume of the suspension must be checked to ensure that the desired volume is prepared.
3. It should possess moderate viscosity.
4. The preparation is observed for milky white appearance. On standing clear supernatant liquid appears above the flocs sediment.
5. Before submitting, the preparation is shaken to observe for redispersibility.
6. The label must be checked for correct size and complete details must be written with no corrections.

SEMI SOLID DOSAGE FORM- Ointment

Semi solid dosage forms are mainly meant for external application e.g. ointment, pastes, creams, jellies and pastes etc. The suppositories are also included in this category although these are unit dosage form.

Ointment: Ointment are semi-solid dosage form for external application to the skin and the mucous membrane. They usually contain medicament or medicaments dissolved, suspended or emulsified in an ointment base. They may contain a suitable antimicrobial preservative. The ointments are suitable as protective and emollient

Ointment base: The ointment base is that substance or part of an ointment which serves as a carrier or vehicle for the medicament. While selecting a suitable ointment base, the factors such as the action desire, nature of the medicament to be incorporated and the stability of an ointment are to be considered.

Classification of ointment bases:

1) Oleaginous base:
   a) Petrolatum (soft paraffin)
   b) Hard paraffin
   c) Liquid paraffin
2) Absorption bases.
   a) Wool fat
   b) Hydrous wool fat
   c) Wool alcohol
   d) Beeswax
3) Emulsion bases
4) Water soluble bases

Preparation of ointment: The ointments are prepared by any one of the following method:

1. Trituration method:
2. Fusion method
3. Chemical reaction method
4. Emulsification method

1. **Trituration method:** This method is used when base is soft and the medicament is insoluble in the base.

2. **Fusion method:** This method is used when ointment base has number of ingredients of different melting point such as white bees wax, Stearic acid, hard paraffin and cetyl alcohol, it is necessary to melt them in decreasing order to their melting point.

3. **Chemical reaction method:** Chemical reactions are involved in the preparation of several ointments. For example, iodine ointment. Iodine may be present in free form or in combined form with the ointment base.

4. **Emulsification method:** This method is used to melt fats, oils and waxes together on a water bath at the temperature of 70ºC. The aquesous solution is also heated at same temperature and added to the melted bases with continuous stirring.

Experiment No: **Date:**

SIMPLE OINTMENT

AIM: To prepare and submit 10 g of simple ointment base.

FORMULA:

Ingredients	Official formula	Working formula
Wool fat	50 g	
Hard paraffin	50 g	
Cetostearyl alcohol	50 g	
White soft paraffin	850 g	

*Note: Calculate for 2 g extra so as to nullify the losses.

THEORY

Simple ointment is a semisolid dosage form. Simple ointment does not contain any active ingredients. Therefore it is used as an ointment base to prepare medicated ointments.

Wool fat absorbs about 50 % of its weight of water. It ensures satisfactory emulsification of the aqueous solution of medicament. It helps in absorbing the active ingredients. Hard paraffin is used to stiffen the ointment base. Cetostearyl alcohol improves the stability and emollient property of the ointment. White soft paraffin is used as a protective and emollient base. It is used when the medicament is colorless or pale or white colour.

Simple ointment absorbs about 15% of its weight of water forming a W/O emulsion.

Following measurers should be taken while preparing ointment.

- All the ingredients should be melted together, by this the maximum temperature needed for melting and the melting point can be reduced. This happens due to the solvent action of the substance which lowers the melting point of others.
- Melting point can also be reduced by stirring during melting and by lowering the china dish as much as possible.
- After melting, the ingredients should be stirred until the ointment is cold to prevent the formation of hard lumps.
- If granular product is obtained after cooling, then it should be melted again using minimum heat. Again it is stirred until cold.

PROCEDURE

1. Wool fat and hard paraffin are weighed and transferred in to a china dish.
2. Cetostearyl alcohol is weighed and transferred in to the china dish.
3. White soft paraffin is weighed on a butter paper and transferred in to the china dish.
4. The dish is placed on water bath and the dish is lowered as far as possible.
5. The ingredients are stirred well during melting.
6. After melting all the ingredients, the china dish is removed from the water bath.
7. The mixture is decanted into other hot china dish so as to remove any foreign matter if present.
8. The mixture is stirred until the ointment is cooled and is allowed to settle.
9. Required quantity of ointment is weighed on butter paper and is transferred into an ointment pot.
10. The container is polished, labeled, and dispensed.

CATEGORY: Ointment base.

AUXILARY LABEL: FOR EXTERNAL USE ONLY

STORAGE: Store in cool place

EVALUATION

The product is evaluated by the following tests.

1. The weight must be checked to ensure that the prescribed quantity is prepared.
2. Simple ointment should be white in colour and free from foreign particles.
3. The label must be checked for correct size and complete details must be written with no corrections.

EXPERIMENT NO: **DATE:**

SULPHUR OINTMENT

AIM: To prepare and submit 10 G of the Sulphur ointment.

FORMULA

Ingredients	Official formula	Working formula
Sublimed sulphur, finely sifted	100 g	
Simple ointment prepared with white soft paraffin	990 g	

THEORY

Sulphur ointment is a semi solid dosage form. Sulphur ointment is pale colored substance and hence the simple ointment is used as base which contains white soft paraffin. Sulphur ointment is prepared by mixing sulphur in simple ointment. Sulphur is mixed with about three times of its weight of the base. Mixing the drug with small quantity of base gives homogenous and smooth dispersion with minimal effort.

Sulphur is used in treatment of scabicide.

PROCEDURE

1. Sublimed sulphur is weighed and triturated to a fine powder.
2. The fine sulphur powder is passed through sieve no.180.
3. From this, required quantity of sublimed sulphur is weighed and placed on a cleaned ointment slab.
4. Small quantity of simple ointment is weighed in a butter paper and transferred on to the ointment slab.
5. Sublimed sulphur is mixed with little quantity of simple ointment by levigation using an ointment spatula, until mixture is homogenous and smooth without any gritty particles.
6. The remaining paraffin ointment is also incorporated and smooth mixture is obtained.
7. Required quantity of ointment is weighed and transferred in to a collapsible tube (or in a wide mouthed screw capped bottle).
8. The container is polished, labelled and dispensed.

CATEGORY: Scabicide.

AUXILLARY LABEL: FOR EXTERNAL USE ONLY

STORAGE: Store in cool place

EVALUATION

The product is evaluated by the following tests.

1. The weight must be checked to ensure that the prescribed quantity is prepared.
2. Sulphur ointment should be pale yellow in colour.
3. Sulphur ointment should be free from gritty particles, foreign particles.
4. The label must be checked for correct size and complete details must be written with no corrections.

EXPERIMENT NO: **DATE:**

CETRIMIDE CREAM

AIM: To prepare and submit 10 G of Cetrimide cream.

FORMULA

Ingredients	Official formula	Working formula
Cetrimide	3 g	
Cetostearyl alcohol	50 g	
Liquid Paraffin	500 mL	
Purified water	q.s 1000 mL	

THEORY

Cetrimide cream is a semi solid dosage form. The drug is mixed with small quantity of base gives homogenous and smooth dispersion with minimal effort.

Cetrimide is an antiseptic agent used in the treatment of wound infection and burns. It helps to prevent infection by killing the bacteria, fungi and viruses on the skin and cleaning up the wounds, cuts and minor burns.

PROCEDURE

1. Cetostearyl alcohol is weighed and transferred into a beaker.
2. Cetostearyl alcohol is dissolved in liquid paraffin with help of hot water.
3. Weighed quantity of Cetrimide is dissolved in purified water at same temperature.
4. Then the oily solution is poured into the aqueous solution and stirred vigorously until emulsion is formed and cooled.
5. Required quantity of cream is weighed and transferred in to a container or a collapsible tube.
6. The container is polished, labelled and dispensed.

CATEGORY: Antibacterial.

AUXILLARY LABEL: FOR EXTERNAL USE ONLY

STORAGE: Store in cool place

EVALUATION

The product is evaluated by the following tests.

1. The weight must be checked to ensure that the prescribed quantity is prepared.
2. Cetrimide cream should be white in colour.
3. Cetrimide cream should be free from gritty particles, foreign particles.
4. The label must be checked for correct size and complete details must be written with no corrections.

LINIMENTS - General Principles

Liniments are liquid or viscous preparations meant for application to the unbroken skin with friction and rubbing.

Liniments may be alcoholic or oily solutions or emulsions. Liquid preparations are convenient to apply on the skin. In alcoholic liniments, alcohol helps in penetrating the medicament into the skin and increases its counter-irritant and rubefacient actions. In oily liniments, groundnut oil is commonly used which spreads more easily on the skin. Liniments should not be applied on broken skin because a) the ingredients of liniment may cause excessive irritation, b) liniment need to apply by rubbing, which is not possible with broken skin.

Liniments should be dispensed in coloured bottles.

Label: Label must state the following

'FOR EXTERNAL USE ONLY'
'SHAKE WELL BEFORE USE'
'SHOULD NOT BE APPLIED ON BROKEN SKIN'

Storage: Liniments should be stored in tightly closed containers in a cool place.

Experiment No. **Date:**

TURPENTINE LINIMENT IP

AIM: To prepare and submit 20 ml of turpentine liniment IP.

FORMULA

Ingredients	Official formula	Working formula
Soft soap	90 g	
Camphor	50 g	
Turpentine oil (freshly rectified)	650 ml	
Purified water, qs	1000 ml	

THEORY

Turpentine liniment is used as counter irritant and rubefacient. Camphor is soluble in turpentine oil, but not in water. At the same time, turpentine oil is immiscible with water. Hence two-phase system like emulsion can be prepared. Here *o/w* type emulsion is formed using soft soap as emulsifying agent. Turpentine oil remains as dispersed phase and water acts as continuous phase. Emulsion type of turpentine liniment is viscous preparation, therefore it is easy to rub on the skin. It must be noted that the turpentine oil used should be freshly distilled, otherwise good emulsion cannot be obtained or becomes discoloured on storage.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Weighed quantity of soft soap is mixed with little quantity of purified water in a mortar.
2. Weighed quantity of camphor is dissolved in turpentine oil in a 50 ml beaker.
3. The camphor solution is gradually added to the soap mixture with trituration and continued until a thick creamy emulsion is formed.
4. Sufficient purified water is added to produce the required volume.
5. The preparation is shaken to ensure uniform distribution of phases.
6. The preparation is then transferred to a light-resistant container.
7. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Counter irritant, rubefacient.

STORAGE: Store in a tightly closed container in a cool place.

AUXILIARY LABELS: FOR EXTERNAL USE ONLY
SHAKE WELL BEFORE USE
NOT TO BE APPLIED TO WOUNDS AND BROKEN SKIN.

EVALUATION

The product is evaluated by the following tests.

1. The volume of the liniment must be checked to ensure that the desired volume is prepared.
2. It should possess high viscosity.
3. Turpentine liniment IP must possess aromatic odour due to camphor and turpentine.
4. Turpentine liniment IP on dilution with purified water remains miscible.
5. Turpentine liniment must appear as a milky preparation but not as a brown or dark colour.
6. The label must be checked for correct size and complete details must be written with no corrections.

Experiment No. **Date:**

WHITE LINIMENT IP

AIM: To prepare and submit 20 ml of White liniment IP.

FORMULA

Ingredients	Official formula	Working formula
Ammonium chloride	12.5 g	
Dilute ammonia solution	45 ml	
Oleic acid	83.3 ml	
Turpentine oil	250 ml	
Purified water, qs	625 ml	

THEORY

White liniment is used as counter irritant and rubefacient. Turpentine oil is immiscible with water. Hence two-phase system like emulsion can be prepared. Here *o/w* type emulsion is formed using soft ammonium oleate as emulsifying agent. Ammonium oleate is produced from oleic acid and dilute ammonium solution. Ammonium oleate is oil in water emulsifying agent. But the preparation contains ammonium chloride which due to common ion effect depresses the ionization of the soap and decreases its solubility in water. This and with high percentage of turpentine oil, it will lead to phase inversion producing water in oil emulsion. Turpentine oil remains as dispersed phase and water acts as continuous phase. Emulsion type of white liniment is viscous preparation, therefore it is easy to rub on the skin. It must be noted that the turpentine oil used should be freshly distilled, otherwise good emulsion cannot be obtained or becomes discoloured on storage.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. The bottle is cleaned and calibrated at 30 mL.
2. Measured turpentine oil and oleic acid is mixed in the bottle.
3. Ammonia solution is diluted with equal volume of warm water.
4. Then diluted ammonia solution is added into the oily solution, shake the bottle vigorously after each addition.
5. Ammonium chloride is weighed and dissolved in water and is added to the bottle.
6. Sufficient purified water is added to produce the required volume.
7. The preparation is shaken to ensure uniform distribution of phases.
8. The preparation is then transferred to a light-resistant container.
9. The bottle is capped, labelled, polished, and submitted.

CATEGORY: Counter irritant, rubefacient.

STORAGE: Store in a tightly closed container in a cool place.

AUXILIARY LABELS: FOR EXTERNAL USE ONLY
SHAKE WELL BEFORE USE
NOT TO BE APPLIED TO WOUNDS AND BROKEN SKIN.

EVALUATION

The product is evaluated by the following tests.

1. The volume of the liniment must be checked to ensure that the desired volume is prepared.
2. It should possess high viscosity.
3. Turpentine liniment IP must possess aromatic odour due to camphor and turpentine.
4. Turpentine liniment IP on dilution with purified water remains miscible.
5. Turpentine liniment must appear as a milky preparation but not as a brown or dark colour.
6. The label must be checked for correct size and complete details must be written with no corrections.

POWDERS - General Principles

Pharmaceutical powder is a homogeneous mixture of finely divided drugs or chemicals in a solid form.

Pharmaceutical powders are meant for internal and external use. The solid drugs are available in crystalline and amorphous forms. The particle size of the powder plays an important role in physical, chemical, and biological properties of dosage form. As the particle size of powder decreases, the dissolution, absorption, and therapeutic efficacy of drugs increases.

Advantages

1. Powders are more stable than liquid dosage forms against hydrolysis and oxidation.
2. Chances of incompatibility are less in powders compared to liquid dosage forms.
3. Large quantities of powder drugs can be easily administered to the patient by dissolving or mixing drugs in a suitable liquid.
4. Children and elderly patients cannot swallow dosage forms such as capsules and tablets. They can easily take powder drugs.
5. The onset of action of powdered drug is rapid as compared to other solid dosage forms, for example tablets.
6. It is convenient for physician to prescribe the dose of powder medicament depending upon the need of the patient.
7. Powders are more economical and can be prepared extemporaneously as compared to other solid dosage forms, since no special machinery or techniques are required.
8. Powders can be used both internally and externally.

Disadvantages

1. Drugs having bitter, nauseous, and unpleasant taste cannot be dispensed in powder form.
2. Deliquescent (tendency to loose water) and hygroscopic substances (tendency to absorb water) cannot be dispensed in powder form.
3. Quantity less than 100 mg cannot be weighed conveniently by dispensing balance.

Methods of preparation

Powders can be prepared by the methods such as spatulation, trituration, geometric dilution, sifting, and tumbling.

Packing

If powders are required to be packed in individual doses (example camphor-menthol mixture), the steps involved in packing are shown in Figure 4 using paper. In case of volatile oils, hygroscopic powders, efflorescent powders and eutectic mixtures, double wrapping is used. In this case, an inner wax-paper and a slightly bigger-sized outer bond paper are jointly used. If powders are required to be packed in bulk (example, dusting powder), the powder is packed in a screw-capped wide-mouthed glass bottle or self dispensing plastic container.

Classification of powders

Sl. No.	*Type/use*	*Example*
1	Bulk powder for internal use	Rhubarb powder
2	Bulk powder for external use	Dusting powder
3	Simple powder for internal use	Aspirin powder
4	Compound powder for internal use	Oral rehydration salt (ORS)
5	Powders enclosed in catchets	Sodium aminosalicylate

Experiment No. **Date:**

EFFERVESCENT COMPOUND POWDER BPC

AIM: To prepare and submit 2 doses of Effervescent compound powder BPC.

SYNONYM: Seidlitz powder.

FORMULA

Ingredients	Official Formula	Working Formula
Sodium potassium tartrate	7.5 g	
Sodium bicarbonate	2.5 g	
Tartaric acid	2.5 g	
Send 2 doses		

THEORY

Sodium potassium tartrate effervescent powder is used as a saline purgative. It causes watery evacuation of bowels without irritation.

This is an effervescent formulation in powder form. Effervescence is produced because of the reaction between the acidic and alkaline ingredients, when placed in water;

$$\underset{\text{Tartaric acid}}{H_2C_4H_4O_6} + \underset{\text{Sodium bicarbonate}}{2\ NaHCO_3} \rightarrow \underset{\text{Sodium tartrate}}{Na_2C_4H_4O_6} + \underset{\text{Water}}{2\ H_2O} + \underset{\text{Carbon dioxide}}{2\ CO_2}\uparrow$$

In this formulation, the powder is supplied in two packets. *Blue paper packet* (Powder no.1) contains sodium potassium tartrate and sodium bicarbonate. *White paper packet* (powder no. 2) contains tartaric acid. The no. 1 powder is dissolved in about 250 ml of water, which may be cold or warm, and no. 2 powder is added. The mixture is stirred, and the liquid is taken, while the liquid is effervescing.

Usually effervescent salts are supplied in granular form rather than powder form, in order to decrease the rate of dissolution of the substances upon addition to water. A retarded effervescence means a greater degree of carbonation of water. If the powders were in state of fine powders, there may be violent and uncontrollable effervescence with consequent loss of solution and the medicament due to their overflowing from the glass of water. Further, the carbonation of the solution will be much reduced. Therefore, care should be taken, while placing the powder in a glass of water.

PROCEDURE

Using the prescription formula, the working formula is calculated.

1. All the powdered ingredients are passed through sieve no. 60.
2. Weighed quantity of sodium potassium tartrate and sodium bicarbonate are mixed thoroughly on wax-paper using spatula.
3. The powder on wax-paper is enclosed as per the procedure explained in page no. 40. This powder requires double wrapping and therefore blue paper is used as outer paper.

4. Required quantity of tartaric acid is weighed and enclosed in a double wrapper consisting of outer white paper.
5. The two powder packets are tied with a paper-band and dispensed in a neatly labelled envelope.

CATEGORY: Saline purgative.

DOSE: 1 packet of each powder.

STORAGE: Store in a cool and dry place.

DIRECTION: The blue packet powder is dissolved in 250 ml of water. The white paper packet is added and the mixture is stirred. The liquid is consumed during effervescing.

EVALUATION

The product is evaluated by the following tests.

1. Once the paper packet is opened, the powder must not spill into the foldings. The powder should not contain any lumps.
2. The weight of the powder must be equal to one dose.
3. Powder must not produce any odour.
4. The packing must be double wrapping.
5. One paper packet should be blue in colour and other should be white in colour.
6. Two paper packets containing ingredients must be kept together using paper-band.
7. The label of the package must be verified for correct size and complete details must be written with no corrections.

Experiment No. **Date:**

DUSTING POWDER

AIM: Prepare and submit 10 g of the Dusting powder.

FORMULA

Ingredients	Official formula	Working formula
Zinc oxide	20 g	
Salicylic acid	5 g	
Starch powder	75 g	

THEORY

Zinc oxide acts as an astringent and salicylic acid acts as a local-antiseptic. The dusting powder should flow easily, spread uniformly, possesses good covering capability, have good absorptivity, and adhere to the skin on application. Starch powder is used to impart these properties to the dusting powder.

Dusting powder is defined as a homogeneous powder meant for external application to the skin and is generally applied in a very fine state of subdivision to avoid local irritation.

This prescription is a medicated dusting powder and applied to open wounds. The powder protects the wound from chaffing and irritation caused by friction, moisture, or chemical irritants. Dusting powders are generally dispensed in sifter-topped cans. It may be applied with a powder-puff, a soft brush, or a sterile gauze pad. Care must be taken to avoid mechanical irritation of damaged skin surfaces.

Small particles are less likely to irritate the sensitive tissue, hence it is necessary to pass the powder through sieve no. 80.

Allowance should be given for loss of powder during dispensing. About 20% excess should be considered for calculation.

PROCEDURE

Using the prescription formula, the working formula is calculated.

1. The required quantities of fine powders of zinc oxide, salicylic acid, and starch are weighed.
2. Salicylic acid is mixed with zinc oxide followed by starch in a geometric ratio by light trituration (using mortar and pestle).
3. The above powder is mixed and passed through sieve no 80.
4. The required quantity of powder is weighed and filled into a screw cap wide mouthed glass bottle or self-dispensing plastic container.
5. The container is capped, labelled, polished, and submitted.

CATEGORY: Astringent, local-antiseptic.

STORAGE: Store in a well-closed container.

AUXILIARY LABEL: FOR EXTERNAL USE ONLY.

EVALUATION

The product is evaluated by the following tests.

1. The powder must be in fine powder form without any lumps.
2. The weight of the powder must be equal to the prescribed weight.
3. Powder must not possess any odour.
4. The powder must be placed in wide mouthed bottle or self-dispensing plastic container.
5. The label must be checked for correct size, complete details must be written with no corrections.

PARENTERAL PRODUCTS - GENERAL PRINCIPLES

Parenteral products are those preparations, which are injected into the body with the help of a needle. The term has its derivation from Greek word *para* and *enteran* meaning outside intestine. These preparations are also called *injections*. Normally, they are injected under or through one or more layers of the skin or mucous membranes. Since these tissues are delicate, care should be exercised during their preparation in order to prevent contamination with microorganisms and foreign material, as they produce several toxic effects. Parental products of necessity should be sterile and therefore called *sterile products*. They include injection dosage forms, irrigated solutions, ophthalmic products and implants.

NOMENCLATURE (USP 1996): The following nomenclature pertains to five general types of preparations for parental administration. They may contain buffers, preservatives or other added substances.

1. [Drug] Injections: Liquid preparations that are solutions.
   E.g.: Insulin injection, Normal saline injection.

2. [Drug] for Injections: Dry solids that, upon addition of suitable vehicle, yield solutions.
   E.g.: Penicillin G potassium for injection.

3. [Drug] Injectable Emulsions: Liquid preparations of drug substances dissolved or dispersed in a suitable emulsion.
   E.g.: Sterile phytomenadione (Vit. K) emulsion.

4. [Drug] Injectable suspensions: Liquid preparations of solid suspended in a suitable liquid medium.
   E.g.: Sterile hydrocortisone suspension.

5. [Drug] for Injectable suspensions: Dry solids that, upon the additions of suitable vehicle, yield preparations confirming in all respects to the requirements for injectable suspension. E.g.: Sterile chloramphenicol for suspension.

CLASSIFICATION: Based on the volume of a preparation that is placed in a container, parental products are classified as

1. Large volume parenterals (LVPs)
2. Small volume parenterals (SVPs)

Large Volume Parenterals (LVPs): Aqueous drug solutions intended for infusion and hermetically sealed in a container of greater than 100 ml volume. LVPs intended to be administered are frequently called *intravenous* (I.V) *fluids* or infusion fluids. A few examples of LVPs are as follows:

Infusion fluids: E.g.: 1. Normal saline injection (NaCl 0.9%). A volume of 540 ml is packed in a glass bottle. 2. Dextrose 5% injection. A volume of 540 ml is packed in a glass bottle.

Irrigation solutions: E.g.: Surgical irrigating solutions. Volume > 1000 ml

Hemofiltration or dialysis: E.g.: Peritoneal dialysis solutions (> 1000 ml)

Parenteral nutrition: As a rule, preservatives are not added to the large volume parenterals. This is to avoid the possible toxicity of the preservatives. Infect, the total amount of preservative, that may be required for 1,000 ml is quite high. If such high volumes are introduced into the body as a single dose infusion, high amount of preservatives accumulates in the body, which subsequently leads to toxicity.

These are used when dilution of drugs is to be carried out. Two or more sterile products are added to an I.V. fluid for administration. These combinations are called as *intravenous admixture*.

Small Volume Parenterals (SVPs): It applies to an injection that is hermetically sealed in a container of 100 ml or less volume. These injections are either solutions or suspensions. A few examples are:

Insulin injection – solution
Cimetidine hydrochloride injection – solution
Procaine penicillin G for injection – suspension

SVPs can be packed in containers, such as ampoules vials as single dose SVPs. These are formulated in volumes of convenient amount of solution, 0.5 to 2 ml, which is the usual dose of the drug. A maximum of 5 ml can be packed in ampoules.

SVPs can be packed in multidose containers, which are usually vials. It should be stressed that unless otherwise indicated in the monograph, multiple-injection container are not permitted to allow the withdrawal of greater than 30 ml. It is necessary to limit the penetrations made into the closure and thus protect against loss of sterility. Each rubber closure can be punctured about 6 times. Considering a dose of 5 ml, a total 6 doses (total 30 ml) can be dispensed. Usually, preservatives are added to the multidose container in order to maintain sterility through the use of 6 doses. Any accidental contamination during the withdrawal of doses will be taken care by preservatives.

GENERAL QUALITY CONTROL TESTS:
Parenteral products should be free from

- All types of living microorganisms
- Microbial products such as toxins and pyrogens
- Particles such as dust, fibre, and insoluble substances.

They should be isotonic with body fluids. Therefore, utmost care should be taken in the preparation of injectables to avoid all types of physical, chemical and microbial contaminations. In order to ensure these characteristics, parenteral products are evaluated as follows;

1. *Pyrogen test*: Product should be free from pyrogens.
2. *Sterility test*: Product should pass this test regarding the absence of aerobic, anaerobic, and fungi organisms.
3. *Clarity test*: Product should be free from particles and fibres.
4. *Leakage test*: This will ensure physical integrity. The container should be perfectly sealed.

Recommended overfill volume for official parenteral products:

Labeled size, ml	Excess volume for mobile liquids, ml	Excess volume for viscous liquids, ml
0.5	**0.10**	**0.12**
1	**0.10**	**0.15**
2	**0.15**	**0.25**
5	**0.30**	**0.50**
10	**0.50**	**0.75**
20	**0.60**	**0.90**
30	**0.80**	**1.20**
50 or more	**2 %**	**3%**

EXPERIMENT NO: **DATE:**

SODIUM CHLORIDE INTRAVENOUS INFUSION IP

AIM: To prepare and submit 100 ml of 0.9% w/v sodium chloride intravenous infusion IP.

SYNONYM: Saline infusion

FORMULA: As per IP

Ingredients	Official formula	Working formula
Sodium chloride	0.9 g	
Water for injection q.s.	100 ml	

THEORY

Sodium chloride is a strong electrolyte and therefore easily soluble in water. Sodium chloride injection is more closely approximates to the composition of extracellular fluids of the body than the solution of any other single salt. Further more, the fluid sodium chloride exerts approximately the same osmotic pressure on the body as that of the body fluids. The pH of the solution is approximately 5 with a range from 4.5 to 7.

Saline infusion is introduced into the body through a sterile infusion set. The lumen of this set occupies a minimum of 40 ml of the solution. In view of this fact, an extra volume of 40 ml is added to the formulation as an overfill volume. Now the patient is assured of the labeled amount of solution, i.e., 100 ml.

No preservative is added because of the possible toxicity of preservative, when large volumes are introduced into the body at a time.

Sodium chloride injection is compatible with dextrose, ringer solution, cimetidine HCl, and ciprofloxacin. However, it is incompatible with mannitol 25% solution.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated. The manufacturing operations are done in clean rooms.

Cleaning of Infusion Bottles

Infusion bottles are cleaned thoroughly with detergent solution and then with tap water. Finally, cleaned with distilled water. The bottles are kept in an inverted position in a tray and dried in hot air oven.

Preparation of Sodium Chloride Solution

The desired amount of sodium chloride is accurately weighed and dissolved in the desired amount of water for injection. The drug solution is filtered through G-4 filter to remove any foreign particles.

Filling of Bottles

Some infusion bottles have markings indicating their capacity. However, the exact volume has to be measured and transferred into the bottle.

Sealing of Bottles

The rubber closure is placed to the neck of the bottle and sealed with aluminium caps.

Sterilization

In general, sodium chloride injection is subjected to terminal sterilization. This can be achieved by autoclaving at $121^{O}C$ for 30 minutes at 15 $lbs/inch^2$.

Labelling

Appropriate label is fixed to the bottle.

COMPOSITION: Each ml contains 9 mg of sodium chloride.

CATEGORY: Electrolyte and fluid replenisher

DOSE: 500 to 1000 ml
(further quantity varies depending upon clinical conditions and size of the patient)

STORAGE: Sodium chloride solution should be stored at room temperature and protected from excessive heat and freezing.

AUXILIARY LABEL: Discard if any particulate matter is present.

ROUTE OF ADMINISTRATION: Intravenous route

DATE OF EXPIRY: 5 years from the date of manufacture

QUALITY CONTROL:

1. Particulate matter: absent/present
2. Leaking: no/yes

REPORT:

Example: Prepare and submit 100 bottles of 0.9% sodium chloride IV infusion each containing 100 ml. Give the necessary calculations and the working formula.

Volume of contents present in each bottle = 100 ml
Excess volume in each bottle (overfill volume) = 40 ml
Total volume required for each bottle = 140 ml
Number of bottles to be submitted = 100 ml
Number of extra bottles required (1%) = 01
Total number of bottles required = 100 + 1 = 101
Total volume of drug solution required for 101 bottles = 140 x 101 = 14,140 ml ≈ 14.2 litres
Sodium chloride required = 9 %
Overages required 4% = (4/100) x 9 = 0.036%
Total sodium chloride required = 0.9 + 0.036 = 0.936 %
Total sodium chloride required for 14.2 litres = (0.936/100) x 14,200 = 132.92 g

The composition obtained from the above calculation is reported in the table.

Ingredient	**Working Formula***
Sodium chloride	132.92 g
Water for injection	14,200 ml

* for 101 bottles

Experiment No: **Date:**

CALCIUM GLUCONATE INJECTION IP

AIM: To prepare and submit 2 ampoules, each containing 10 ml of calcium gluconate injection IP.

FORMULA

Ingredients	Official formula	Working formula
Calcium gluconate	9.65 g	
Calcium D-saccharate	0.35 g	
Water for injection q.s.	100 ml	

MANUFACTURER'S DEFINITION: Calcium gluconate injection is a sterile solution of calcium gluconate in water for injection. Not more than 5.0% of the calcium gluconate may be replaced with a suitable calcium salt as a stabilising agent.

STANDARDS: Calcium gluconate injection contains a quantity of calcium equivalent to not less than 8.5 percent and not more than 9.4 percent of the stated amount of calcium gluconate, $C_{12}H_{22}O_{14}Ca.H_2O$.

USUAL STRENGTHS: The equivalent of 500 mg and 1 g of calcium gluconate in 5 ml; the equivalent of 1 g of calcium gluconate in 10 ml (A 10% w/v solution of calcium gluconate contains approximately 0.45 mmol of Ca^{++} per ml).

10% w/v solution of calcium gluconate is also available in 10, 50, and 100 ml vials.

TYPE: Monophasic liquid dosage form - solution

THEORY: Calcium gluconate is slowly soluble in about 30 parts of water and soluble in about 5 parts of boiling water. Calcium in the form of calcium gluconate is used in the strength of 10%. In fact ten percent solution of calcium gluconate in water gives a saturated solution. Any temperature fluctuations during storage yield crystallization of calcium gluconate. Therefore, I.P prescribes to replace a part of calcium gluconate (not more than 5% of the total) by an equal amount of more soluble calcium salt, such as calcium D-saccharate or calcium lactobionate. These more soluble calcium salts are called stabilizing agents. The pH of the calcium gluconate injection can be adjusted from 6.0 to 8.2 using sodium hydroxide and/or hydrochloric acid. It is prepared in a single dose container, preferably Type I glass container.

Calcium gluconate is usually administered intravenously as a 10% solution, slowly by direct intravenous injection, or by continuous or intermittent intravenous injection. Maximum administration rates of 1.5 and 2 ml/min have been recommended for direct intravenous injection. By intermittent infusion a maximum of 200 mg/min has bees suggested. Calcium gluconate has been given by intramuscular or, rarely, subcutaneous injection to adults, but these routes are not recommended because of possible tissue necrosis, sloughing, and abscess formation.

Calcium gluconate is compatible with substance such as dextrose 5%, sodium chloride 0.9%m aminophylline, amphotericin B, ascorbic acid injection, chloramphenicol sodium succinate, furosemide, heparin sodium, and penicillin G sodium. Calcium gluconate is incompatible with

substance such as metoclopramide HCl, indomethacin sodium trihydrate, citrates, soluble carbonates, phosphates, and sulfates.

REQUIREMENTS:

Ampoules, 10 ml	2	Calcium gluconate
Beaker, 250 ml	1	Calcium D-saccharate
Beaker, 100 ml	1	G - 4 filter
Measuring cylinder, 10 ml	1	Autoclave
Syringe with needle, 10 ml	1	Water for injection

PROCEDURE: Depending on the quantity of preparation to be submitted, the working formula is calculated. The manufacturing operations are done in clean rooms.

Cleaning of Ampoules: Cleaning of type I ampoules is carried out by following the usual procedure.

Preparation of Calcium Gluconate Solution:

1. The desired amount of calcium gluconate and calcium D-saccharate are accurately weighed.
2. On account of solubility problems, calcium gluconate is first dissolved in water for injection in beaker with the aid of heat.
3. Then calcium D-saccharate is dissolved in the above solution.
4. The solution is allowed to cool.
5. After cooling, filter the drug solution is filtered through G-4 filter (or Whatmann filter paper) to remove any foreign particles.

Filling into Ampoules: Filling of ampoules is done following the usual procedure.

Sealing of Ampoules: The ampoules can be sealed by using pull-sealing technique.

Sterilization: In general, calcium gluconate injection is subjected to terminal sterilization. This can be achieved by autoclaving at 121^{o}C at 15 lbs/inch^{2} for 30 minutes.

Packing: Ampoules are packed in a suitable ampoule box and labeled.

COMPOSITION: Each ml contains 100 mg of total calcium

CATEGORY: Calcium replenisher (Calcium gluconate injection is supplemented where dietary calcium intake is deficient and in impaired absorption, due to old age and in case of osteoporosis. This injection is indicated in case of hypocalcaemic tetany and also in cardiac resuscitation.)

DOSE: 1 to 2 g (500 mg of calcium gluconate is approximately equivalent to 2.3 mmol of Ca^{++}).

STORAGE: Store in a cool place.

AUXILIARY LABELS: 1) Discard, if any particulate matter is present.
2) If crystallization has occurred during storage, warming may dissolve the precipitate. The injection must be clear at the time of use.

SCHEDULE:

ROUTE OF ADMINISTRATION: Intramuscular or slow intravenous route

DATE OF EXPIRY: 3 years, from the date of manufacture.

QUALITY CONTROL:

1. Particulate matter: absent/present
2. Leaking: no/yes
3. Tip: sharp/round
4. Charring: absent/present

REPORT:

Example: Prepare and submit 100 ampoules of calcium gluconate injection IP each containing 10 ml. Give the necessary calculations and the working formula.

Volume of contents in each ampoule = 10 ml
Excess volume in each ampoule (overfill volume) = 0.5 ml
Total volume required for each ampoule = 10.5 ml
Number of ampoules to be submitted = 100
Number of extra ampoules required = 10
Total number of ampoules required = 100 + 10 = 110
Total volume of drug solution required for ampoules= 10.5x110 = 1115 ml
= 1.2 litres
Calcium gluconate required = 9.65%
Overages added = 4%, i.e., (4/100) x 9.65 = 0.386%
Total calcium gluconate required = 9.65 + 0.386 = 10.036%
Total calcium gluconate required for 1.2 litres = 10.036/100 x 1200
= 120.43 g
Overages added = 4%, i.e., (4 x 100) x 0.35 = 0.0149%
Total calcium D-saccharate required = 0.35 + 0.014 = 0.365%
Total calcium D-saccharate required for 1.2 litres = (0.365/100) x 1200
= 4.368 g
The composition obtained from the above calculation is reported in table.

Ingredients	Official Formula	Working Formula*
Calcium gluconate	9.65 g	120.43 g
Calcium D-saccharate	0.35 g	4.368 g
Water for injection q.s.	100 ml	1200 ml

* for 110 ampoules

HARD GELATIN CAPSULES - INTRODUCTION

Hard gelatin capsule consists of two parts namely 'cap' and 'body'. The diameter of cap is slightly larger than body. But the length of cap is smaller than body. The drug is filled in body and is inserted into cap to give final form - capsule.

Storage: The moisture content of the capsules will be in the range of 12-15% w/w. Improper storage results in change in moisture content leading to damaged capsules as given below.

Moisture content	Damage
Less than 10%	Brittle, shrink, and dimensional changes
More than 16%	Soft, tacky, loss of mechanical strength, and deformation

Further such capsules cause problems during filling. Therefore hard gelatin capsules are stored in closed containers at temperatures less than 100 ^{o}F and 40 - 60% RH. To maintain these conditions air-conditioned facilities are used.

Sizes: Hard gelatin capsules are manufactured and sold in different sizes. Cap length of any capsule is exactly half of the total length of the capsule after closing. Different sizes and their filling capacities are shown in the Table . Filling capacity of capsule varies depending upon the density of the powder and degree of pressure used in filling.

Capacities of Empty Capsules

Sizes	*Quinine sulfate, mg*	*Sodium bicarbonate, mg*	*Bismuth subnitrate, mg*
000	*600*	*1320*	*1680*
00	*360*	*900*	*1200*
0	*300*	*660*	*840*
1	*210*	*480*	*600*
2	*180*	*360*	*480*
3	*120*	*300*	*360*
4	*90*	*240*	*240*
5	*60*	*120*	*120*

FORMULATION OF CAPSULE CONTENTS

The hard gelatin capsules often contain only the active ingredient(s). However the following ingredients are also used in the manufacture of capsules.

Sl. No.	Ingredients	Examples
1	Fillers (Diluents)	Starch, lactose, dicalcium phosphate, microcrystalline cellulose
2	Glidants	Colloidal silica, corn starch, talc, silicones magnesium stearate, glycol esters,
3	Lubricants	Magnesium stearate, stearic acid
4	Disintegrating agents (super disintegrants)	Sodium starch glycolate, croscarmellose sodium, crospovidone
5	Surfactants	Sodium lauryl sulphate
6	Protective sorbents	Calcium oxide, magnesium oxide, calcium carbonate, magnesium carbonate
7	Anti dusting agents	Edible oils

EXPERIMENT NO: **DATE:**

TETRACYCLINE CAPSULES

AIM: To prepare and submit 100 Tetracycline capsules USP, each containing ___ mg of Tetracycline.

FORMULA AS PER USP:

Ingredients	Official formula	Working formula
Tetracycline		

Note: The working formula is calculated for 110 capsules. Extra 10 capsules are required to account for the production losses.

SELECTION OF EMPTY HARD GELATIN CAPSULES: Commonly employed empty capsules for human use range from size 000 to size 5. The filling capacity of empty capsules for aspirin is as follows.

Capsule size	Approximate quantity of drug (g)
000	0.96
00	0.60
0	0.55
1	0.33
2	0.25
3	0.20
4	0.15
5	0.10

As the dose of the aspirin required to be filled in capsules is 0.3 g, the size 1 empty capsules are selected for this formulation.

FILLING MACHINE: Capsule filling machine consists of the following parts as shown in Figure 6.

1. Bed having 100 holes.
2. Loading tray having 100 holes.
3. Powder tray
4. Pin plate having 100 pins
5. Sealing plate having a rubber top
6. Lever
7. Cam handle
8. Discharging handle

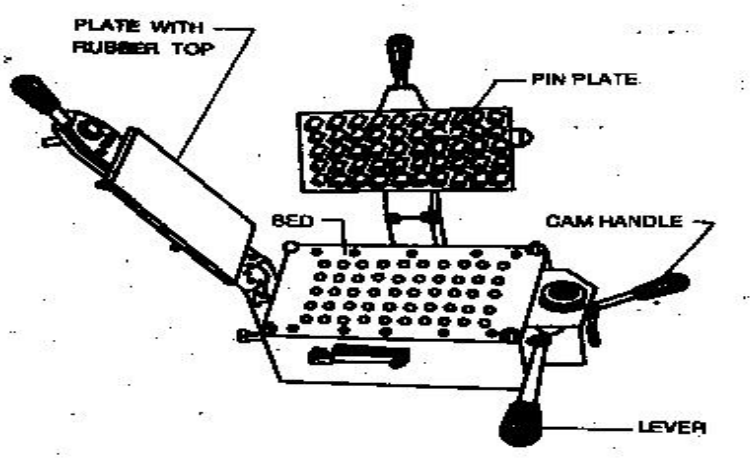


Figure :Hand operated capsule filling machine

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Empty capsules of required size, size __, are selected. Capsules are filled into the loading tray of the filling machine.
2. The cam handle is operated to hold the bodies of capsules.
3. The loading tray is lifted to separate caps from bodies.
4. Then the powder tray is placed in position and the Tetracycline powder is spread uniformly.
5. The excess powder is scrapped towards platform of the powder tray.
6. The pin-plate is brought into the position to press the powder uniformly.
7. The pin-plate is raised and the remaining powder is filled into the bodies of the capsules. (Steps 6 and 7 are repeated, until powder is completely filled).
8. The powder tray is removed.
9. The cap holding tray is placed into the position.
10. Then the plate with rubber top is lowered and the lever is locked to join caps and bodies firmly.
11. The lever is unlocked and the plate with rubber top is lifted.
12. The discharge handle is operated to push the filled capsules out. The capsules are collected.
13. The filled capsules are subjected to dusting in cloth.
14. The capsules are polished by rubbing them with gloves containing muslin cloth.
15. Capsules are subjected to quality control tests and the remaining capsules are placed in wide-mouthed, air-tight container.
16. The container is labeled and submitted.

COMPOSITION:

CATEGORY:

DOSE:

STORAGE: Store in a tightly-closed container in a cool and dry place.

AUXILIARY LABEL:

DATE OF EXPIRY: 12 months from the date of manufacture

REPORT:

TABLETS - INTRODUCTION

According to IP, *tablets* are solid dosage forms, each containing a unit dose of one or more medicaments.

They are generally intended for oral administration. Tablets can be manufactured in a variety of sizes, shapes, and surface markings. Compressed tablets are flat or convex and may have lines or break marks, a symbol or any other markings.

- some tablets are swallowed (Eg. Ibuprofen, paracetamol),
- some are swallowed after being chewed (Eg. Sodium bicarbonate antacid tablets),
- some are dissolved or dispersed before administration (Eg. Aspirin effervescent tablets, amoxycillin dispersible tablets),
- some are retained in the mouth where the medicament is released (Eg. isosorbide mononitrate sublingual tablets).

A majority of tablets are manufactured by compression of uniform volume of powdered mass or granules by applying high pressures (psi) and utilising steel punches and dies. Tablets are prepared by

- Direct compression of powders or granular mass.
- Compression of granules obtained by dry granulation.
- Compression of granules obtained by wet granulation.

Different additives such as diluents, binders, disintegrating agents, moistening agents, adsorbents, lubricants and other substances (sweetening agents, colouring agents, flavouring agents, etc.,) are included in the formulation. These are capable of modifying the behaviour of dosage form in the digestive tract

METHOD OF CALCULATION – TABLETS

Granulating mass

Initial weight of granulating mass taken in a watch glass = A g
Weight of granulating mass left in the watch glass after granulation = B g
Amount of granulating mass consumed = A - B = C g
This is applicable for wet granulation process

Weight of granulating agent in the granules

Let the percent of granulating agent in the granulating mass = D%
100 g of granulating mass contains D g of granulating agent
C g of granulating mass contains $\frac{C \times D}{100}$ = E g of granulating agent

Weight of granulating agent in each tablet

Total 'n' number of tablets consume E g of granulating agent
Each tablet contains ? granulating agent
$\frac{E}{n}$ = F g of granulating agent
(This value has to be included in the working formula)

Further calculations in tablets

This calculation is applicable for both dry and wet granulations

Total weight of dry granules = G g
Weight of granules retained on # 44 = H g
Weight of fines = I g
% fines obtained in the granulation = $\frac{I}{G} \times 100$
Amount of fines added (normally 15 %) = $\frac{15 \times H}{100}$ = J g
(based on the coarse granules)

Total weight of granules = Weight of granules retained on # 44
+ Weight of 15% fines = H + J = K g
Theoretical weight of the tablet
= (weight of drug + weight of diluent + wt. of binding agent if any + wt. of granulating agent, F) = L grams

Number of compressible tablets planned = $\frac{K}{L}$ = M

Weight of talc (lubricant) to be taken = 2% of K, i.e., $\frac{2 \times K}{100}$ g = P grams

Practical weight of each tablet = $\frac{(K+P)}{M}$ g

The granular mass corresponding to each tablet is weighed for three tablets separately and used for setting the machine for the desired parameters.

The following points are considered while undertaking calculations

1. If the % of fines formed is less than 15%, then the entire amount of fines are added to the coarse granules.
2. If the % of fines is more than 15%, only 15% of them are taken and the rest of fines are rejected.
3. Actually, the % of fines is calculated based on the total weight of granules.
4. The 15% fines that are needed for compression are calculated based on the weight of coarse granules (i.e., wt. of granules retained on # 44).
5. Weight of lubricant (2%) is calculated based on the total weight of coarse granules and fine granules (K).
6. Dimensions and hardness of each tablet are adjusted using 3 samples of the calculated weight of each tablet.

EXPERIMENT NO: **DATE:**

PARACETAMOL TABLETS IP

AIM: To prepare and submit 50 paracetamol tablets IP, each containing 500 mg of paracetamol.

SYNONYM: Acetaminophen tablets

FORMULA AS PER IP:

Ingredients	Official formula	Working formula
Paracetamol	0.500 g	
Starch powder, 5%	0.010 g	
Starch paste, 10%	q.s.	
Talc, 2%	q.s.	

Note: The working formula is calculated for 60 tablets. Extra 10 tablets are required to account for the production losses.

THEORY

Paracetamol tablets are commonly used as analgesics and antipyretics. Starch powder acts as a disintegration agent. Starch paste acts as binding agent. Talc is used as glidant. The dose (bulk) of paracetamol is sufficiently high to compress in the die. Hence diluent is not required. Paracetamol is not susceptible to moisture and temperature. Therefore wet granulation method is suitable for granulation.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated. A flow sheet for the manufacture of paracetamol tablets is prepared.

Preparation of Granulating Medium (10% starch paste)

Ten g of starch is weighed and transferred into a beaker (250 ml). Fifty ml of water is added into the beaker and slurry is prepared by stirring with a glass rod. Twenty-five ml of water is added and the beaker is placed on a wire gauge. The slurry is heated with Bunsen burner to obtain a thick paste. Remaining 25 ml of water is added and stirred well. Heating is stopped and the starch paste is cooled.

Sifting of Powders

Desired quantities of paracetamol and starch powders are weighed as per the working formula. These powders are passed through 60-mesh sieve.

Blending of Powders

The sifted powders are mixed thoroughly in mortar with pestle until uniform blend is obtained.

Wet Granulation (Screening)

A small quantity of granulating medium is taken into a watch glass and weighed (A g). From this, little quantities of granulating medium are transferred to the mortar containing powders and triturated. This procedure is continued until smooth dough is formed. The end point to stop adding granulating medium is decided by the following test.

Test	Observation	Inference
The wet mass is taken into hand and a round ball is made. It is pressed in the palm with the thumb.	The ball crumbles under moderate pressure without giving fines.	Stop adding granulating medium. The mass is ready for wet screening.
	The ball breaks forming many fines	Continue adding granulating medium

The wet mass is passed through 10-mesh sieve in a tray. This process breaks wet mass forming wet granules. Wet granules surface area is more so drying will be effective. Wet granules are spread in the tray.

Drying

The granulating medium left in the watch glass is weighed (B g). The tray containing granules is placed in a hot-air oven and the temperature is adjusted at 70^{o}C. Drying is continued until the moisture content of granules is reduced to about 6%. (This can be done by taking a sample of granules and measuring the moisture content using Cenco Moisture Balance consisting of IR lamp). The oven is switched off and the granules are allowed to reach room temperature.

Dry Screening

The total granules are weighed (G g). The dry granules are passed through 22/44-mesh sieves completely. The granules that are retained on 44-mesh sieve are weighed (H g). These are coarse granules. The granules that are passed through 44-mesh sieve (and collected in a tray) are weighed (I g). These are termed as fines. Percentage fines formed are calculated.

Dry Blending

Fifteen percent fines are calculated and weighed (J or I g). These fines are added to the coarse granules. The required quantity of talc is added. The ingredients are blended in order to get a uniform distribution of ingredients. Now the granules are ready for compression.

Compression

Three packets of granules, containing the practical weight of one tablet, are prepared. These are used to adjust the pressure of the punches in order to get tablets of sufficient hardness. The remaining granules are compressed to obtain tablets. The production yield is calculated using the formula.

Packing

Compressed tablets are placed in wide-mouthed, light-resistant container. The container is capped and cleaned.

Labelling

Appropriate label is prepared and fixed to the container.

COMPOSITION: Each tablet contains 500 mg of paracetamol

CATEGORY: Analgesic, antipyretic

DOSE: 500 mg to 1 g every 4 to 6 hours, up to 4 g daily, in divided doses.

STORAGE: Store in a well-closed container.

AUXILIARY LABEL: Swallow a tablet with a glass of drinking water.

DATE OF EXPIRY: 24 months from the date of manufacture.

PRODUCTION YIELD:

IN-PROCESS QUALITY CONTROL:

1. Diameter
2. Thickness
3. Weight variation
4. Hardness
5. Friability
6. Disintegration time

REPORT: _____ (number) paracetamol tablets are prepared and submitted.

COSMETICS – INTRODUCTION

According to Drugs and Cosmetics Act, 1940, Cosmetic can be defined as an article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

Cosmetics are classified in many ways. Since cosmetics are for different organs of the body, classification based on the organ to which cosmetic is applied, is selected.

Cosmetics for the skin
- Powders
- Creams
- Lotions
- Deodorants
- Bath and Cleansing preparations
- Make-up preparations
- Suntan preparations

Cosmetics for the hair
- Shampoos
- Tonics
- Hair dressings and Brilliantines
- Hair waving preparations
- Beard softeners
- Shaving media
- Depilatories

Cosmetics for the nails
- Nail polishes and polish removers
- Manicure preparations

Cosmetics for the teeth and mouth
- Dentifrices
- Mouthwashes

Borderline and kindred products
- Eye preparations
- Foot powders and applications
- Insect repellants
- Miscellaneous products

But in this section selected formulations are studied namely vanishing cream, cold cream, tooth paste, tooth powder, and shampoo.

EXPERIMENT NO: **DATE:**

LOTION -VANISHING CREAM

AIM: To prepare and submit 20 g of vanishing cream.

SYNONYMS: Foundation cream, snow, fairness cream

FORMULA

Ingredients	Given formula	Working formula
Stearic acid	24.00 g	
Deionized water	64.00 g	
Glycerin	10.50 g	
Potassium hydroxide	0.99 g	
Rose oil	0.50 g	

Note: The working formula is calculated for 22 g. Extra 2 g is required to nullify production losses.

THEORY

Vanishing cream is *o/w* type emulsion in semisolid form containing large percentage of water as continuous phase and oil or fatty constituents as dispersed phase.

When vanishing creams are applied and well spread on the skin, they do not leave any visible or greasy film or residue. Therefore they are called as vanishing creams.

In this preparation part of stearic acid (20 – 30%) reacts with potassium hydroxide to form a soap, which acts as an emulsifying agent. (The unreacted stearic acid acts as a dispersed phase). Stearic acid melts above body temperature (when rubbed) and crystallizes in a form so as to be invisible providing a non-greasy film. Stearic acid also imparts attractive appearance to the cream. With stearic acid white creams are produced and sometimes because of this whiteness these creams are called 'snow'. Stearic acid of fine quality should be used and total proportion should not exceed 25%. The texture of cream also depends on amount of stearic acid saponified and alkali used.

Glycerin in the preparation acts as emollient and humectant. Rose oil in the formulation acts as a flavoring agent. Rose oil is added when the mixture is cool, to avoid the excessive loss of perfume by evaporation.

Vanishing creams are used to provide an adherent base for the subsequent application of face powder and other make up cosmetics. They are non-greasy in nature.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Weighed quantity of potassium hydroxide is dissolved in water (75%) in a china dish.
2. Weighed quantity of stearic acid is melted in another china dish.
3. The temperature of two phases is maintained between 60 and 70^{o}C.
4. The melted fatty phase is poured into hot aqueous phase with continuous stirring.
5. Glycerin is mixed with the remaining quantity of water and the temperature is raised to 60 – 70^{o}C.
6. Contents of (5) are poured into (4) slowly with continuous and vigorous stirring for 20 minutes. 3-5% excess of water is used to compensate the loss of water due to evaporation during manufacture.
7. When cream starts thickening (because of cooling) during stirring, rose oil is added. Slow stirring is continued to avoid air entrapment.
8. The cream is placed on a wax-paper (butter-paper) and transferred into a container (or collapsible tube).
9. The container is capped, polished, labeled, and submitted.

CATEGORY: Base for subsequently applied cosmetics (foundation cream)

STORAGE: Store in air-tight container in a cool place.

AUXILIARY LABEL: For external use only

DATE OF EXPIRY: Best use before 18 months from the date of manufacture

REPORT:

EXPERIMENT NO: **DATE:**

COLD CREAM

AIM: To prepare and submit 20 g of cold cream.

SYNONYMS: Ointment of rose water, antiquated cream, non-emollient cream, winter cream.

FORMULA

Ingredients	Given formula	Working formula
White bees wax	10.0 g	
Liquid paraffin	30.0 g	
Borax (Di Sodium Tetra Borate Deca Hydrate)	0.5 g	
Rose oil	0.1 ml	
Water	9.5 ml	

Note: The working formula is calculated for 22 g. Extra 2 g is required to nullify production losses.

THEORY

Cold cream is *w/o* type of emulsion in semisolid form containing liquid paraffin as continuous phase and water as dispersed phase.

The term cold in conjunction with cold cream is originated due to cooling sensation caused by evaporation of the water in cream after it is applied to the skin.

Borax (sodium borate) reacts with free fatty acids of beeswax (cerotic acid) to produce borax soap. It acts as an emulsifying agent. Usually sodium soap produces o/w emulsion, but in this formulation, phase inversion occurs and w/o emulsion is produced. Because of this reason oily phase is poured into aqueous phase during manufacture. Rose oil acts as a flavoring agent.

Borax solution is heated to the same temperature of melted fat and mixed to prevent the formation of lumps. Liquid paraffin acts as an emollient and unreacted borax acts as bacteriostatic, if necessary preservatives like methyl paraben (0.12%) and propyl paraben (0.02) can be used.

Cold creams are applied only on dry skin and for the persons whose natural supply of oily exudation from the sebaceous glands is insufficient to keep the skin soft. Cold creams are in great demand during cold seasons.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Weighed quantity of white bees wax is placed in a measured quantity of liquid paraffin in a china dish.
2. The contents are melted on a water bath and temperature is maintained at 70^{o}C.
3. Weighed quantity of borax is dissolved in measured quantity of water in another china dish. This aqueous solution is also heated to 70^{o}C.
4. Gradually oily solution is poured into borax solution with continuous and rapid stirring.
5. When the cream starts thickening, rose oil is added and stirred slowly to prevent air entrapment.
6. The cream is placed on a wax-paper (butter-paper) and transferred into a wide mouthed bottle (or collapsible tube).
7. The container is capped, polished, labeled, and submitted.

CATEGORY: Emollient, bacteriostatic, protective

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

AUXILIARY LABEL: For external use only

DATE OF EXPIRY: Best use before 24 months from the date of manufacture

REPORT:

EXPERIMENT NO: **DATE:**

TOOTH PASTE

AIM: To prepare and submit 20 g of toothpaste.

SYNONYMS: Dental cream, dentifrice-paste

FORMULA

Ingredients	Given formula	Working formula
Calcium carbonate	50.0 g	
Sodium lauryl sulphate	2.0 g	
Glycerin	15.0 g	
Sodium CMC	1.0 g	
Sodium saccharin	0.5 g	
Peppermint oil	1.0 ml	
Water up to	100 ml	

Note: The working formula is calculated for 22 g. Extra 2 g is required to nullify production losses.

THEORY

Toothpaste is white or creamy white, peppermint oil flavoured, sweet tasted, foaming, opaque, semisolid preparation in which abrasive is suspended in the aqueous mucilage base.

Toothpaste is a most popular form of dentifrice. Food debris and plaque seem to be the causes for tooth problems. The primary function of toothpaste is the maintenance of oral hygiene. The major requirement of toothpaste is to clean the teeth and to remove the adhering layers as much as possible, without causing damage to the surface. Secondary results of this cleaning affect the incidence of tooth decay, gingival health and mouth odours.

In this formulation, calcium carbonate (precipitated chalk) is used as an abrasive agent. The main use of abrasive agent is to remove any adhered layer on the teeth. Sodium lauryl sulphate is used as the surfactant. Surfactant is mainly used for penetration of the surface film on the tooth by lowering the surface tension and also to remove the debris from the teeth. Glycerin acts as a humectant, which would be used to prevent the paste from drying out and hardening to an unacceptable level. Sodium CMC is used as the gelling agent. It maintains the integral stability of the paste and also prevents the separation of components. Sodium saccharin is used as sweetening agent and peppermint oil is used as flavoring agent.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Calcium carbonate and sodium saccharin are blended in mortar.
2. Glycerin is mixed with water in a beaker and sodium CMC is dissolved in this mixture.
3. The liquid components mixture of step 2 is added into the mortar containing powder ingredients of step 1. Contents are triturated to mix.
4. Mixing is continued slowly to form paste. Care must be taken during mixing to avoid air entrapment.
5. Finally peppermint oil and sodium lauryl sulphate are added. Mixed properly. (These ingredients can be added as late as possible because mixing of the sodium lauryl sulphate creates foaming and air entrapment if care is not taken).
6. Thoroughly mixed homogenous paste is packed in collapsible tube.
7. The tube is capped, polished, labeled, and submitted.

CATEGORY: Abrasive

STORAGE: The toothpaste is stored in collapsible tube in a cool place.

AUXILIARY LABEL: For external use only

DATE OF EXPIRY: Best use before 3 years from the date of manufacture

REPORT:

EXPERIMENT NO: **DATE:**

SHAMPOO

AIM: To prepare and submit 20 ml of shampoo.

SYNONYM: Hair cleanser

FORMULA

Ingredients	Given formula	Working formula
Coconut oil	10.00 g	
Potassium hydroxide	5.38 g	
Sodium hydroxide	0.50 g	
Glycerin	12.65 g	
Oleic acid	14.00 g	
Water	56.72 g	
Perfume	0.75 g	

Note: The working formula is calculated for 22 ml. Extra 2 ml is required to nullify production losses.

THEORY

Shampoo is pleasantly odoured detergent liquid preparation for the washing of hair, packed in a form convenient for use.

Shampoo is a cosmetic of hair. The primary function of shampoo is cleansing the hair of accumulated sebum, scalp debris and residues of hair-grooming preparations. Although any efficient detergent can do this job, cleansing should be selective and should preserve a quantity of the natural oil that coats the hair and the scalp.

In this preparation, soap is formed by the saponification reaction between potassium hydroxide, sodium hydroxide and coconut oil, oleic acid. Glycerin increases the viscosity of the preparation. Perfume is a flavoring agent and water is a vehicle.

PROCEDURE

Depending on the quantity of preparation to be submitted, the working formula is calculated.

1. Weighed quantity of potassium hydroxide is dissolved in 1/3rd the volume of water in a beaker.
2. Measured quantity of coconut oil is added into another beaker.
3. The alkali solution is added in a thin stream into heated oil with continuous stirring until saponified.
4. The glycerin is mixed with another 1/3rd the volume of water, boiled to the same temperature.
5. Then cocoanut soap solution is added in small portions into glycerin solution, and stirred until dissolved.

6. Sodium hydroxide is dissolved in the rest of the water and added to the soap solution immediately after the cocoanut soap has dissolved.
7. Oleic acid is added and stirred slowly until completely saponified.
8. Solution is allowed to cool. Perfume is added and mixed well.
9. Shampoo is filtered at room temperature, if necessary.
10. 20 ml of shampoo is transferred into a narrow-mouthed, tightly-closed container.
11. The container is capped, polished, labeled, and submitted.

CATEGORY: To clean and condition the hair

STORAGE: Store in a cool place

AUXILIARY LABEL: For external use only

DATE OF EXPIRY: Best use before 3 years from the date of manufacture

REPORT:

Experiment No: Date:

DEMONSTRATION OF VARIOUS STAGES OF TABLET MANUFACTURING PROCESSES

AIM: Demonstration of various stages of tablet manufacturing processes.

THEORY

This experiment consists of demonstration of various stages of tablet manufacturing process like particle size reduction, weighing of active ingredient and excipients, mixing, granulation, drying, compression and coating.

1. Particle size reduction
2. Weighing of active ingredient and excipients
3. Mixing
4. Granulation
5. Drying
6. Compression
7. Coating

1**. PARTICLE SIZE REDUCTION:**

Sizing (size reduction, milling, crushing, grinding, pulverization) is an important step in the process of tablet manufacturing.

In manufacturing of compressed tablets, the mixing or blending of several solid pharmaceutical ingredients is easier and more uniform if the ingredients are about the same size. This provides a greater uniformity of dose. A fine particle size is essential in the case of lubricant mixing with granules for its proper function.

Advantages of smaller tablets are as follows:

- Increased surface area, which may enhance an active ingredient's dissolution rate and hence bioavailability
- Improved tablet-to-tablet content uniformity due to a larger number of particles per unit weight
- Controlled particle size distribution of dry granulation or mix to promote better flow of mixture in tablet machine
- Improved flow properties of raw materials
- Improved colour and/or active ingredient dispersion in tablet excipients
- Uniformly sized wet granulation to promote uniform drying

The following problems may arise if the process is not controlled properly:

- A possible change in polymorphic form of the active ingredient, rendering it less or totally inactive, or unstable
- A decrease in bulk density of active compound and/or excipients, which may cause flow problem and segregation in the mix
- An increase in surface area from size reduction may promote the adsorption of air, which may inhibit wettability of the drug to the extent that it becomes the limiting factor in dissolution rate

Various types of machine may be used for the dry sizing or milling process, depending on whether gentle screening or particle milling is needed. The range of equipment employed for this process includes:

- Fluid energy mill
- Colloidal mill
- Ball mill

- Hammer mill
- Cutting mill
- Roller mill

POWDER BLENDING:

The successful mixing of powder is more difficult than mixing liquid, as perfect homogeneity is difficult to achieve. Another problem is the inherent cohesiveness and resistance to movement between the individual particles. The process is further complicated in many systems by the presence of substantial segregation influencing the powder mix. This arises from the difference in size, shape, and density of the component particles. The powder/granules may be blended at the pre-granulation and/or post-granulation stage of tablet manufacturing. Each process of mixing has an optimum mixing time, and longer mixing may result in an undesired product. The optimum mixing time and speed must be evaluated. Blending prior to compression is normally achieved in a simple tumble blender. This be a fixed blender into which the powders are charged, blended and discharged. It is now common to use a bin blender from which the container (bin) can be removed and brought directly to other processing steps.[1] In special cases of mixing a lubricant, overmixing should be particularly monitored. The various blenders used include the "V" blender, oblicone blender, container blender, tumbling blender, and agitated powder blender.

Nowadays, to optimize the manufacturing process, particularly in wet granulation, various improved pieces of equipment which combines several processing steps (mixing, granulation and/or drying) are used. These are the mixer granulator and high shear mixing machine.

GRANULATION : Refer experiment (paracetamol granules)

DRYING:

Drying is an important step in the formulation and development of a pharmaceutical product. It is important to keep the residual moisture low enough to prevent product deterioration and ensure free flowing properties. The commonly used dryers include the fluidized-bed dryer, vacuum tray dryer, microwave dryer, spray dryer, freeze dryer, turbo-tray dryer, and pan dryer.

TABLET COMPRESSION:

After the preparation of granules (in wet granulation) or sized slugs (in dry granulation) or mixing of ingredients (in direct compression), they are compressed to get the final product. The compression is done either by a single-punch machine (stamping press) or by a multi-station machine (rotary press). The tablet press is a high-speed mechanical device. It squeezes the ingredients into the required tablet shape with extreme precision. It can make the tablet in many shapes, although they are usually round or oval. Also, it can press the name of the manufacturer or the product into the top of the tablet.

Stage 1: Top punch is withdrawn from the die by the upper cam. Bottom punch is low in the die so powder falls in through the hole and fills the die.

Stage 2: Bottom punch moves up to adjust the powder weight. It raises and expels some powder.

Stage 3: Top punch is driven into the die by upper cam. Bottom punch is raised by lower cam. Both punch heads pass between heavy rollers to compress the powder.

Stage 4: Top punch is withdrawn by the upper cam. Lower punch is pushed up and expels the tablet, which is removed from the die surface by surface plate.

Stage 5: Return to stage 1.

Tablet testing: will be discussed in next experiment.

PACKAGING:

Tablets must be packaged before they can be sent out for distribution. The type of packaging depends on the formulation of the medicine.

Blister packs are a common form of packaging. They are safe and easy to use, and the user can see the contents without opening the pack. Many pharmaceutical companies use a standard size of blister pack. This saves the cost of different tools and changing the production machinery between products. Sometimes the pack may be perforated so that individual tablets can be detached. This means that the expiry date and the drug's name must be printed on each part of the package. The blister pack itself must remain absolutely flat as it travels through the packaging processes, especially when it is inserted into a carton. Extra ribs are added to the blister pack to improve its stiffness.

8.
Experiment No: **Date:**

APPROPRIATE METHODS OF USAGE AND STORAGE OF INHALERS, SPACERS, INSULIN PEN

AIM: Study in detail the appropriate methods of usage and storage of special dosage forms including different types of Inhalers, Spacers and Inhalers.

THEORY: The methods of usage and storage of special dosage forms depends on the formulation. Usage methods and storage of Inhalers, spacers and insulin pens will be discussed in detail.

Inhaler: These are the medical device where the powdered medicament is measured and administered in the body through a metered dose inhaler. There are different types of inhaler that serve different purposes and required different techniques.

Usage: Using a metered-dose inhaler: Instructions should be read before using it.

i) Getting Ready:

- Take the cap off, look inside the mouthpiece and make sure there is nothing in it. Shake the inhaler hard 10-15 times before each use. Breathe out all the way and try to push out as much as air you can.

ii) Breathe in slowly:

- Hold the inhaler with the mouthpiece down and place your lips around the mouthpiece so that you form a tight seal. Keep breathing in slowly, as deeply as you can.

iii) Hold your breath:

- Take the inhaler out of the mouth. If the patient can holds breath as slowly till count of 10. This lets the medicine reach deep into the lungs.
- Lips should be puckered and breathe out slowly through the mouth.
- If you are using inhaler, quick-relief medicine (beta-agonists), wait about 1 minute before you take your next puff. You do not need to wait a minute between puffs for other medicines.
- Put the cap back on the mouthpiece and make sure it is firmly closed.
- After using your inhaler, rinse your mouth with water, gargle, and spit. Do not swallow the water. This helps reduce side effects from your medicine.

Keep inhaler clean

Look at the hole where the medicine sprays out of your inhaler. If you see powder in or around the hole, clean your inhaler.

- Remove the metal canister from the L-shaped plastic mouthpiece.
- Rinse only the mouthpiece and cap in warm water.
- Let them air-dry overnight.
- In the morning, put the canister back inside. Put the cap on.
- DO NOT rinse any other parts.

Replacing inhaler

Most inhalers come with counters on the canister. Keep an eye on the counter and replace the inhaler before you run out of medicine.

DO NOT put your canister in water to see if it is empty. This does not work.

Bring your inhaler to your clinic appointments. Your provider can make sure you are using it the right way.

Storing inhaler

Store your inhaler at room temperature. It may not work well if it is too cold. The medicine in the canister is under pressure. So make sure you do not get it too hot or puncture it.

SPACERS:

Inhaler with a spacer

- Put the inhaler into the spacer.
- Shake it for 5 seconds.
- Hold the inhaler up with your index finger on top and your thumb underneath to support it. Use the other hand to hold the spacer if you need to.
- Breathe out.
- Put the mouthpiece between your teeth, and close your lips tightly around the spacer. (Make sure your tongue doesn't block the opening.)
- Press the top down and breathe in until your lungs fill completely -- about 3-5 seconds.
- Hold the medicine in your lungs as long as you can (5-10 seconds is good), then breathe out.
- If you don't get enough air in the first breath, wait 15-30 seconds and try again. Shake the inhaler again before the second puff. Don't fill the chamber with two puffs of medicine at once.
- Recap the mouthpiece.
- If your medicine has a steroid in it, rinse your mouth and gargle with water after you use the inhaler. Spit out the water.

How to Use a Dry Powder Inhaler

- Remove the cap.
- For a single-use device, load a capsule.
- Breathe out slowly (not into the mouthpiece).
- Put the mouthpiece between your front teeth and close your lips around it.
- Breathe in through your mouth deeply for 2-3 seconds.
- Remove the inhaler. Hold your breath for as long as you can. (Between 4 and 10 seconds is good.)
- Breathe out slowly.

How to Clean the Inhaler

You have to clean them about once a week so the medication doesn't build up and block the mouthpiece.

Metered Dose Inhaler:

- Remove the canister and cap from the mouthpiece.
- Don't wash the canister or put it in water.
- Run warm tap water through the top and bottom of the mouthpiece for 30-60 seconds.
- Use a soft cloth to remove any medication buildup.
- Shake off the water.
- Let the mouthpiece dry completely. Overnight is best.
- If you need to use the inhaler before the mouthpiece dries, shake off the extra water, replace the canister, point it away from your face, and test-spray it twice before you use it.

DPI: Don't wash it with soap and water. Clean the mouthpiece with a dry cloth. Check the instructions for more information.

INSULIN PEN

An insulin pen is an injection device with a needle that delivers insulin into the subcutaneous tissue (the tissue between your skin and muscle)
The pens allow more simple, accurate, and convenient delivery than using a vial and syringe.
Not every person with diabetes will need to take insulin. However, those that do sometimes find that sticking to an insulin schedule can be demanding, disruptive, and draining.
Some people prefer insulin pens as a way to make taking insulin less intrusive and inconvenient.

In this article, we look at the types of insulin pen, how to use them, and the benefits and disadvantages of choosing an insulin pen over a vial and syringe.

People with diabetes use insulin pens to inject insulin, a vital hormone for people who have diabetes. They contain a cartridge, a dial to measure dosage, and a disposable needle.
Insulin pens are growing in popularity, and many people with diabetes nowadays use a pen to administer insulin.

Types

Insulin pens are mostly disposable or reusable.
Different brands and models of insulin pen are available. Most fall into two distinct categories: disposable and reusable.

- **A disposable pen:** This contains a prefilled insulin cartridge. Once used, the entire pen unit is thrown away.
- **A reusable pen:** This contains a replaceable insulin cartridge. Once empty, a person discards the cartridge and installs a new one.

A person must replace the disposable needle after each injection of insulin. With proper care, reusable insulin pens can last for several years.

When to use an insulin pen?

To determine when a person should inject, pay attention to the times you check the blood sugar, when to eat and what of insulin to be taken.

- The patient should check their blood sugar no more than 30 minutes before a meal.
- If rapid-acting insulin are given before meals, the insulin is injected when patient sits to have a meal.
- If regular insulin is taken before meals, the insulin should be injected by no more than 30 minutes before the meal.
- If intermediate- or long-acting insulin is to be injected, then insulin should be injected at the same time each day of the meal.

How to use?

Follow the instructions for using an insulin pen closely, as they vary slightly in use between manufacturers.

People who have never used an insulin pen before may need to seek advice from their doctor before first use.

Here is a general guide for insulin pen use. However, you may find that some steps are different on purchasing a particular brand. Clarify how to use any specific insulin pen with a doctor.
The overall steps are as follows:

1. If using a new pen, the insulin pen is removed from the refrigerator 30 minutes before use.
2. The expiration date, correct type and strength should be checked.
3. If necessary, a new cartridge should be inserted into a reusable pen and insulin is mixed by gently rolling the pen between the palms of the hands.

4. The pen should be tilted up and down, until the insulin is clear and smooth.
5. Hands to be washed thoroughly.
6. The pen cap is removed, and the top is cleaned with alcohol.
7. Firmly a new needle is attached to the pen.
8. Remove the needle caps while retaining the outer cap.
9. Turn the dial to the correct dose.
10. Double-check the dose before injecting.
11. Clean the chosen injection site with alcohol, and allow the area to dry.
12. Do not inject into areas that have wounds or bruising.
13. If possible, vary the injection site to avoid lumps or swelling.
14. Hold the pen to the injection site, being sure to following any instructions on the packaging.
15. Press the injection button and wait for 10 seconds before removing the needle from the skin.
16. Press on the injection site for 5 to 10 seconds, but do not rub the skin.
17. Remove and safely dispose of the needle.
18. Replace the cap on the pen.

Storage

- Unopened insulin and new insulin pens require storage in the refrigerator.
- However, once a person has opened insulin, they must keep the hormone at room temperature and out of direct sunlight.
- According to the American Diabetes Association, when a person stores insulin at room temperature, it lasts for around 28 days.
- Expiry date depends on the type of insulin that the pen contains. It is always important to check the date and follow any instructions for storage and use.
- Expired or improperly stored insulin may not be as effective as it should be.
- Insulin pens should never be stored with the needle attached, even if it is a new needle. This can affect the cleanliness and sterility of the needle, interfere with the insulin dose given, and increase the risk of infection

Experiment No: **Date:**

DEMONSTRATION OF QUALITY CONTROL TEST OF TABLETS

AIM: The aim of the experiment is demonstration of uncoated tablets for in-process quality control tests.

THEORY: A variety of tests are conducted on tablets in order to make sure that the manufactured tablets are of the best possible quality. From the point of production of tablets, quality control tests are classified into two categories.

In-process quality control tests	**Finished product quality control tests**
Appearance	Dissolution rate
Dimensions	Uniformity of content
Uniformity of weight (Weight variation)	Content of active ingredient and confirmation of all the tests reported in in-process quality control
Hardness	
Friability	
Disintegration	

In-Process Quality Control Tests

In-process quality control tests are the tests conducted when the tabletting is under process. These tests should be completed quickly, without halting the process for long time. In this experiment, in-process quality control tests are performed on uncoated tablets.

Finished product quality control tests are performed after completion of punching. They are not performed here. However theory related to these tests is explained.

Appearance (Unofficial test): The tablets should be free from cracks, depressions, pinholes, etc. The colour and polish of the tablet should be same on whole surface. There should be no signs of coating. The surface of the tablets should be smooth.

Dimensions (Unofficial test): The dimensions of the tablets are thickness and diameter. The tablets should have uniform thickness and diameter. Thickness and diameter of a tablet are measured using a Vernier calipers or screw gauge. These values are checked and are used to adjust the initial stages of compression. These dimensions are related to hardness and friability.

Uniformity of weight (Weight variation test) (Official test): This is an important in-process quality control test, which has to be checked frequently (every half hour). Corrections are made during the punching of tablets if necessary. Any variation in the weight of tablet (for any reason) leads to either

under medication or overdose. This is particularly true when the drugs are potentor low-dose drugs. All tablet machines have provision to receive a known quantity (volume which is correlated to weight) of granules. Improper flow of granules from hopper into the die is responsible for weight variation.

The tolerance values of weight variation for uncoated tablets as per I.P.are as shown in the table.

Average weight (mg)	Percentage deviation
80 or less	10.0
More than 80 and less than 250	7.5
250 or more	5.0

Lubricants (magnesium stearate), glidants (corn starch, talc), and antiadherants (talc, corn starch) are added for the proper flow of granules. Optimum amount of fines also improves the flow and helps to maintain uniform weight of tablet.

Hardness (Unofficial test): *Hardness* (diametral crushing strength) is a force required to break a tablet across the diameter.

The hardness of a tablet is an indication of its strength. This is a valuable test, which might influence tablet disintegration and dissolution rate. Depending on the type and concentration of the binding agent (for example, acacia mucilage, starch paste, sugar syrup, methyl cellulose dispersion etc), the hardness of the tablet varies. The tablet should be stable to mechanical stress during handling and transportation. The degree of hardness varies with the different manufacturers and with the different types of tablets. The force is measured in kilograms and the hardness of about 4 kg is considered to be satisfactory for uncoated tablet. It is tested by using hardness testers such as Monsanto tester, Pfizer tester, Erweka tester, Schleuniger tester, and Strong- Cobb tester. Unfortunately, different testers do not produce the same results for the tablet.

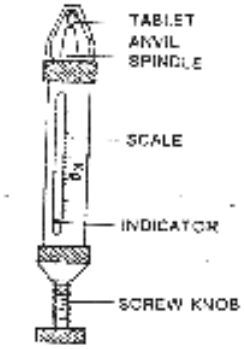


Figure 1: Monsanto Hardness tester

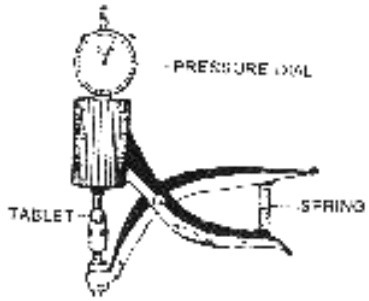
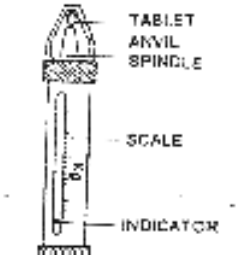
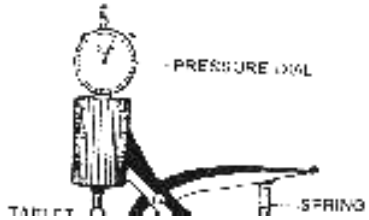


Figure 2: Pfizer Hardness tester





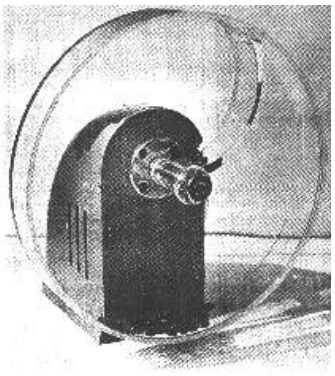
Friability (Unofficial test): *Friability* is the loss of weight of tablet in the container/package, due to removal of fine particles from the surface.

This in-process quality control test is performed to ensure the ability of tablets to withstand the shocks during processing (coating and strip-packing), handling, transportation, and shipment. The friability of tablets is indicated by chipping, capping, or breaking.

The extent of friability is estimated using Roche friabilator. It is expressed as percentage w/w. The allowable friability is less than 0.8%. This limit is strictly adhered when the tablets are further processed for coating.

Friability problems are encountered with thin-tablets, large-diameter tablets, granules having excessive fines (due to entrapped air), or excessively dried granules.

Figure 3: Roche Friabilator



Disintegration (Official test): *Disintegration* is defined as that state in which anyresidue of tablet, except fragments of insoluble coating, remaining on the screen of the test apparatus consisting of a soft mass having no palpably firm, unmoistened core.

This test can be determined quickly with greater ease. This is the only in- process quality control test that is more related to the performance of the tablet.

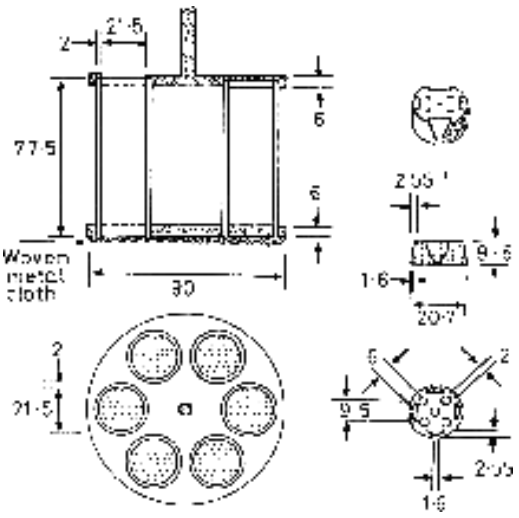
Disintegration process involves the breaking of tablet into small particles. The quicker the disintegration, the faster could be the action. Disintegration roughly indicates the possible pattern of dissolution of active substance. Hence, the experimental conditions closely mimic the situations that a tablet encounters in gastrointestinal tract, in terms of temperature, pH and mechanics. For this purpose, the pharmacopoeia prescribed specifications and standards for equipment and procedures. The disintegration time should be as less as possible unless otherwise specified as in case of special type of controlledrelease products. I.P. specifications are given in the table.

Specifications for disintegration

Type of Dosage Form	Vehicle	Time of disintegration	State of disintegration	Remarks
Uncoated tablets	Water	15 min.	Complete	Passes
Coated tablets	Water	One hour	Complete	Passes
	if failed, 0.1 N HCl	Our hour	Complete	Passes
Enteric coated tablets	0.1 N HCl mixed phosphate	2 hours	No complete disintegration	Passes
	Buffer, pH 6.8	60 min.	Complete	Passes
Soluble tablets	Water (19 to 21^{O}C)	3 min.	Complete	Passes
Hard gelatin capsules	Water	30 min.	Complete	Passes
Soft gelatin capsules	Water	60 min.	Complete	Passes

This test is not applicable to sustained release tablets, chewable tablets, and sublingual tablets. Disintegration time of tablets can be reduced (or disintegration rate can be enhanced) by including disintegrating agents such as starch, methylcellulose, etc., in the formulation

Figure: Disintegration test apparatus



Finished Product Quality Control Tests

Dissolution rate (Official test): The results of this test depend on the solubility of the active substance. This test involves kinetic method. For highly aqueous soluble drugs, dissolution test may not be required. This test is obligatory for all tablets and capsules. It is conducted only on the finished products, as the procedure involved is time consuming. Dissolution rate has direct relevance in the performance of dosage specially to predict rate and extent of drug absorption or bioavailability. Hence I.P. prescribes specifications for equipment and methods. Usually apparatus Type II (basket type) is used for partially water-soluble drugs, while apparatus Type I (paddle type) is employed in the evaluation of tablets (or capsules) containing poorly water-soluble drugs. The experimental conditions closely simulate the situations that a dosage form encounters in the gastrointestinal tract.

The results are plotted as concentration versus time. Values for $t_{50\%}$, $t_{90\%}$, and percent dissolved in 30 min are used as guides. T_{50} is defined as length of time required for 50% of the drug to go into solution. A t_{90} for 30 min. is most satisfactory.

This test has great importance in the evaluation of sustained and controlled release products.

Content of active ingredients (Official test): Determine the amount of active ingredient(s) and calculate the amount of active ingredient(s) stated in the monograph. 20 tablets are used for assay. All the tablets should fall with in 90 to 110%.

Uniformity of content (Official test): This test is applicable to tablets that contain less than 10 mg or less than 10% w/w of active ingredient. For tablets containing more than one active ingredient carry out test for each active ingredient that corresponds to the aforementioned conditions.

This should be carried out only after the content of active ingredient(s) in a pooled sample of the tablets has been shown to be within accepted limits of the stated content. This test is not applicable to tablets containing multivitamins and trace elements.

	Test	***Observation***		***Inference***
I part	Determine the content of active ingredient(s) in each of 10 tablets. Calculate the average value. Take the difference and percentage difference.	All tablets contents are within 15% difference.		Passes
		One tablet content is out of 15% difference	But less than 25%	Passes
		Two or three values are out of 15% difference	But less than 25%	Go to the II part of the test
II part	Determine the content of active ingredient in each of 20 more tablets. Calculate the average value of 30 tablets. Take the difference and percentage difference.	Not more than three individual values are out of 15%	But less than 25%	Passes

PROCEDURE: The procedures for in-process quality control tests are explained below.

Appearance: The tablets are examined externally under a biconvex lens for surface, colour, polish, etc. The tablets should be free from cracks, depressions, pinholes, etc.

Test	Observation	Inference
Surface roughness	Smooth / Irregular	Passes / Does not pass
Cracks	Absent / Present	Passes / Does not pass
Depressions	Absent / Present	Passes / Does not pass
Pinholes	Absent / Present	Passes / Does not pass
Colour	Uniform / Ununiform	Passes / Does not pass
Polish	Uniform / Ununiform	Passes / Does not pass

Uniformity of weight (Weight variation): Every tablet in each batch shouldhave a uniform weight. 20 tablets are weighed individually. Average weight is calculated from the total weight of all tablets. The individual weights are compared with the average weight. The percentage difference in the weight variation should be within the permissible limits.

The percentage deviation is calculated by using the following formula.

$$\% \text{ deviation} = \frac{\text{individual weight} - \text{average weight}}{\text{average weight}} \times 100$$

Tablet No.	Weight of individual tablet, mg	Average weight, mg	Difference in the weights, mg	% difference	More / less than official limit
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					

15					
16					
17					
18					
19					
20					

Number of tablets falling beyond the official limit :.....
Batch of tablets passes / does not pass for weight variation test.

Hardness: The hardness of tablet is tested using the hardness tester. The tablet is placed across the diameter in between the spindle and the anvil. The knob is adjusted to hold the tablet in position. The reading of the pointer is adjusted to zero. The pressure is increased slowly to break the tablet. "Hardness factor" - the average of the several determinations is determined and reported.

Tablet no.	Hardness in kg/cm^2
1	
2	
3	
4	
5	

Average hardness of tablets: .....kg / cm^2.
Batch of tablets passes / does not pass for hardness test.

Friability: Roche friabilator is used to measure the friability of the tablets. It rotates at a rate of 25 rpm. 10 tablets are weighed collectively and placed in the chamber of the friabilator. In the friabilator, the tablets are exposed to rolling, resulting from free fall of tablets within the chamber of the friabilator. After 100 rotations (4 minutes), the tablets are taken out from the friabilator and intact tablets are again weighed collectively. Percentage friability is determined by using the following formula.

$$\text{Friability} = \frac{(W1 - W2)}{W1} \times 100$$

Where as, W1 = Weight of the tablets before test
W2 = Weight of the tablets after test

Weight of 10 tablets		Difference in the weights (W1 - W2) g	% friability
Before test W1 g	After test W2 g		

Permitted % friability = 0.8
Batch of tablets passes / does not pass for friability test.

Disintegration: The disintegration test apparatus consists of a basket-rack assembly containing six open-ended glass tubes. They are held vertically and the bottom of the tube is covered with 10-mesh screen. By the use of a motor

the basket raises and lowers in the immersion fluid at a frequency of 29 to 32 cycles per minute. The wire screen is always maintained below the level of the fluid. The fluid temperature is maintained at 37 ± 2^{o}C throughout the test.

The disintegration time is noted when all tablets pass through the sieve. This time should comply with the time stated in the monograph for that tablet.

Test	Observation	Inference
Water (or specified medium) is placed in the disintegration apparatus. The temperature of the medium is maintained 37^{o}C. A tablet is placed in each of the six tubes of the basket. Then the plastic weights are placed over each tablet to prevent the tablet coming outside of the tubes of the basket. The basket is allowed to operate.	Time required for complete disintegration of all the six tabletsis ..... min	Batch of tablets passes / does not pass for disintegration test.

Disintegration time for uncoated tablets (unless stated in IP) is 15 minutes.Batch of tablets passes / does not pass for disintegration test.

SUMMARY OF OBSERVATIONS

Sl. No.	Test	Observation	Inference
1	Appearance		
2	Tablet thickness		
3	Tablet diameter		
4	Uniformity of weight		
5	Hardness		
6	Friability		
7	Disintegration		

Experiment no: **Date:**

OFFICIAL QUALITY CONTROL TESTS OF HARD GELATIN CAPSULES

AIM: To carryout official quality control tests for filled hard gelatin capsules.

THEORY: Pharmacopoeial standards control the quality of capsules in relation to their medicinal use, i.e., to ensure that they contain the correct drug in the correctdosage and that is available for absorption. IP specifies the following quality control tests for capsules.

1) **Content of active ingredients**: Determine the amount of active ingredients of 10 capsules. Calculate the amount in each capsule. The result lies with in the range of 89.8 – 110.4 for the capsules weighing 300 mg or more.

2) **Uniformity of weight (Weight variation)**: This is an important in-process quality control test, which has to be checked frequently. Corrections are made during the filling operation, if necessary. Any variation in the weight of capsule (for any reason) leads to either under medication or over medication. This is particularly true when the drugs are potent or low dose drugs. All capsule filling machines have provision to receive a known quantity of granules. Improper flow of granules from hopper is responsible for weight variation.

   The tolerance values of weight variation for capsules as per IP 1996 are as shown in the table.

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

3) **Uniformity of content**: This test is applicable to capsules that contain < 10 mg or < 10% w/w of active ingredient. For capsules containing > one active ingredient carryout the test for each active ingredient that corresponds to the afore-mentioned conditions.

   The test should be carried out only after the content of active ingredients in a pooled sample of the capsules has been shown to be within accepted limits of the stated content.

   Note: The test is not applicable for capsules containing multivitamins and trace elements.

	Test	***Observation***		***Inference***
I part	Determine the content of active ingredient in each of 10 capsules. Calculate the average value. Take the difference and percentage difference.	All capsules contents are within 15% difference.		Passes
		One capsule content is out of ±15% the limit.	But less than ± 25%	Passes
		Two or more values are out of ±15%	But less than ± 25%	Go to the II part of the test
II part	Determine the content of active ingredient in each of 20 more capsules. Calculate the average value of 30 capsules. Take the difference and percentage difference.	Not more than three individual values are out of ± 15%	But less than ± 25%	Passes

4) Disintegration: Introduce one capsule into each of 6 tubes. If the capsules float on the surface of the medium, a disc may be added. Suspend the assembly in the beaker containing water (unless otherwise stated in the individual monograph) and operate the apparatus. Remove the assembly from the liquid. The hard gelatin capsules pass the test if all of them have disintegrated with in 30 minutes in case of hard gelatin capsules (for soft gelatin capsules the limit is 60 minutes).

If 1 or 2 capsules fail to disintegrate, repeat the test on 12 additional capsules. Not less than 16 of 18 capsules tested disintegrate.

Note: This is not applicable to modified release capsules. If dissolution test is mentioned in the individual monograph, then disintegration test is not required.

PROCEDURE:

1. **Content of active ingredients**: The amount of active ingredients present in each of 10 capsules is determined. Average weight, difference in the weightsand percentage difference in the weights of content is determined. The resultlies with in the range of 89.8 – 110.4 for the capsules weighing 300 mg or more.

Capsule no.	Amount of drug in each capsule, g W1	Average amount of drug of all capsules, g W2	Difference in the quantity, g (W1 – W2)	% Difference	More than 110.4 / less than 89.8 %
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Number of capsules falling beyond the official limit: ……..
Batch of capsules passes / does not pass for weight variation test.

2. **Uniformity of weight (Weight variation):** Every capsule in each batchshould have uniform weight. 20 capsules are weighed individually. Average weight is calculated from the total weight of all capsules. The individual weights are compared with the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage deviation shown in table and none deviates by more than twice that percentage.

	Test	***Observation***	***Inference***
I part	Weigh 20 intact capsules individually. Take average weight	All weights of capsules are within 7.5 % difference.	Passes
		One or more than one capsule weight is out of the limit.	Go to the II part of the test

II part	Weigh an intact capsule. Open the capsule without losing any part of the shell and remove the contents as completely as possible. Weigh the shell. The weight of the contents is the difference between the weighings. Repeat the procedure with a further 19 capsules. Determine the average weight. Differences are determined between individual net content and the average.	All weights of capsules are within 7.5 % difference.		Passes
		One capsule weight is more than 7.5 %	But less Than 15%	Passes
		Two capsules weights are more than 7.5 %	But less Than 15%	Passes

Observations:

Capsule No.	Weight of individual capsule, mg	Average weight, mg	Difference in the weights, mg	% difference	More / less than official limit
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Number of capsules falling beyond the official limit:.....

Batch of capsules passes / does not pass for weight variation test

3. **Uniformity of content**: This test is not performed for aspirin capsules because the weight of capsules is more than 10 mg.

4. **Disintegration**:

Test	Observation	Inference
Water is placed in the disintegration apparatus. The temperature of the medium is maintained $37^{o}C$. Capsules are placed, one ineach of the six tubes of the basket. Then the plastic weights are placed over each capsule to prevent the capsule coming outside of the tubes of the basket. The basket is allowed to operate.	Complete disintegration of all the six capsules	Time required is ..... min

Number of capsules disintegrated within 30 minutes: ……..
Batch of capsules passes / does not pass for weight variation test

SUMMARY OF OBSERVATION

A. Content of active ingredients: Passes / fails
B. Uniformity of weight: Passes / fails
C. Disintegration: Passes / fails

REPORT

Experiment no: **Date:**

QUALITY CONTROL TESTS FOR PARENTERAL PRODUCTS

AIM: To carryout quality control tests for ampoules.

THEORY: Drug products administered by injection are characterized by four qualities: sterility, freedom from pyrogenicity, freedom from particulate matter, and freedom from leakage. The achievement of sterile, nonpyrogenic, particulate-free, and leak free parenteral products provides a significant challenge to the originality and creativity of parenteral scientists and technologists. As per Indian Pharmacopoeia 2014, test for sterility, test for pyrogens, test for particulate matter, test for uniformity of content, and test for extractable volume should be performed on injections. While impressive technological advances have been made in the production of parenteral products, the testing for the quality of these products involves relatively simple procedures.

Quality control tests performed on incoming stock, stock during processing, and finished products are given in the following table.

Table: Details of quality control tests

	Type of material		
	Incoming stock	**Stock during processing**	**Finished products**
Types of tests performed	1) Glass tests on containers 2) Identity tests on rubber closures 3) Microbial load tests	1) Conductivity measurement of water 2) Volume of fill 3) Temperature during autoclaving 4) Time of autoclaving 5) Count of labels 6) Identity of labels	1) Uniformity of content 2) Leaker test 3) Clarity test 4) Pyrogen test 5) Sterility test 6) Extractable volume

Leaker Test

This test is performed only on ampoules. Ampoules are hermatically sealed containers. Hermatically sealed containers don't allow transfer of ampoules content outside and also don't allow anything inside the ampoules. If any pore or crack is present in the ampoules, such ampoules are called as leakers. Leakers may allow microorganisms or any dangerous material to enter inside. Leakers may also allow the leaking of contents from inside to outside resulting in spoilage of labels. Changes in temperature during storage cause expansion and contraction of the ampoule and contents, which results in further interchange.

The leaker test is performed on each and every ampoule as it is a non-destructive test. It detects the leakers. Leakers are formed due to incomplete sealing of ampoules. More leakers are formed from tip sealing technique than from pull sealing technique. In addition, leakers are formed at the tip of the seal or at the base due to improper handling.

Clarity Test

This test is performed on ampoules, vials, and infusion bottles. All the units prepared in the batch are subjected to this test as it is a non destructive testand less time consuming. Clarity test is performed to ensure that every filled andsealed container is free from visible particulate matter measuring more than 30 microns in size. USP established limits as mentioned below;

50 particles measuring 10 microns size or more can be present per ml.5 particles measuring 25 microns size or more can be present per ml. 0 particles measuring 50 microns size or more can be present per ml.

With the available technology, it is possible to prepare parenterals without any particulate matter. However, clarity test is performed to remove the containers having particulate matter if accidentally enters.

Alternatively, instrumental techniques are used to detect the presence of particles. The methods are light scattering, light absorption, and electrical resistance. But these are destructive tests.

Pyrogen Test

Pyrogen test is conducted on parenterals to determine the presence of pyrogens. Pyrogens are unwanted substances and may accidentally enter in parenterals. The characteristics of pyrogens are enumerated below;

Pyrogens are excretory products of bacteria and virus.
Pyrogens are lipopolysacharides chemically.
Pyrogens are fever producing substances.
Pyrogens produce febrile reaction on parenteral administration.

Presence of pyrogens can be determined by two methods namely rabbit test and LAL test.

Rabbit test : Rabbits are used as the test animals because they show a physiologic response to pyrogens similar to that of human beings. This is an official test used to determine the presence of pyrogens. The principle involved in the test is “increase in the temperature of rabbits on administration of pyrogenated injection.

Three healthy and adult rabbits are used for the test. The animals are housed at suitable conditions of temperature and humidity. The animals are given *ad libitum* water and food. The animal is conditioned by conducting a training exercise as described under the recommended procedure, omitting the injection.

The food is stopped for 2 hours before the test and during the test. Accessto water may be allowed. The animals should be placed under the conditions of the test at least 1 hour before the injection. An accurate thermometer graduated in 0.1 °C is inserted into rectum of the rabbit to a depth of about 6 cm. Prior to thetest determine the temperature of animal by taking 2 measurements at an interval of 30 minutes. The mean of the 2 temperatures is called as the "control temperature" of the animal.

The syringes, needles, and glassware are made free from pyrogens by heating at 250 °C for not less than 30 minutes. Warm the solution to approximately 38 °C. Into a marginal vein of the ear of each of 3 rabbits, 10 ml ofthe solution per kg of body weight is injected. The injection should be administered in less than 4 minutes.

When the injection has been completed, the temperature of the animal is recorded for every 30 minutes upto 3 hours. The maximum temperature recorded for each rabbit is considered to be its response.

If no rabbit shows an individual rise in temperature of 0.6 °C or moreabove its respective control temperature, and if the sum of the 3 temperaturerises does not exceed 1.4 °C, the tested material meets the requirements for the absence of pyrogens. If 1 or 2 rabbits show a temperature rise of 0.6 °C or more, or if the sum of the temperature rises exceeds 1.4 °C, continue the test using 5 other rabbits. If not more than 3 of the 8 rabbits show individual rises intemperature of 0.6 °C or more, and if the sum of the 8 temperature rises does not exceed 3.7 °C, the tested material meets the requirements for the absence of pyrogens.

LAL test (Limulus Amoebocyte Lysate test): This test is used to detect or quantify pyrogens from Gram-negative bacteria using lysate reagent. Lysate reagent is a freeze dried product obtained from the lysate of amoebocytes (white blood cells) from the horseshoe crab (*Limulus polyphemus* or *Tachypleus tridentatus*).

Prepare sample solutions by dissolving or diluting the pharmaceutical substance or the finished preparation using water. Adjust the pH of the solution to 6.0–8.0. The pH may be adjusted by the use of acid or base. Mix a volume of the Lysate solution with an equal volume of the sample solution (parenteral preparation) in one tube. Similarly, mix a volume of the Lysate solution with an equal volume of the standard solution (solution containing known amount of pyrogens) in another tube. Incubate both the tubes at 37±1°C for 60 ± 2 minutes, avoiding vibration. Test the integrity of the gel for tests carried out in tubes. Take each tube from the incubator and invert it in smooth motion. If a firm gel has formed that remains in place upon inversion, record the result as positive. Aresult is negative if an intact gel is not formed. Intact gel definitely forms in the tube containing pyrogens.

LAL test possesses certain **advantages**. LAL test has been found to be 5 to 10 times more sensitive than the rabbit test. It can be used to quantify the pyrogens. The time required to get the results in this test is short. This test is more economical.

Sterility Test

All the parenteral products must pass the sterility test as they are subjected to an effective process of sterilization. Sterility test is conducted using fluid thioglycollate medium for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria.

Sterility test is conducted using Soya-bean casein digest medium for the culture of both fungi and aerobic bacteria.

After preparation of media, portions of the media are incubated for 14 days. No growth of microorganisms should occur. At the same time, microorganisms are inoculated in to another set of media and incubated. Growthof microorganisms should occur in the media, which indicates the correctness of media.

Method: The sterility test may be carried out using the technique of membrane filtration or by direct inoculation of the culture media with the product to be examined. Appropriate negative controls are included. Transfer the contents of the container to be tested to the culture medium. Add an inoculum of a small number of viable microorganisms (aerobes, anaerobes and fungi) to the medium. Incubate the media for not less than 14 days. If the product to be examined has antimicrobial activity, carry out the test after neutralizing this with a suitable neutralizing substance or by dilution in a sufficient quantity of culture medium. Incubate the inoculated media for not less than 14 days.

Observation and interpretation of results : Examine the media for macroscopic evidence of microbial growth at intervals during the incubation period and also at the end of the test. If the Lmaterial being tested renders the medium turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination 14 days after the beginning of incubation transfer portions (each not less than 1mL) of the medium to fresh vessels of the same medium and then incubate the original and transfer vessels for not less than 4 days.

If no evidence of microbial growth is found, the product to be examined complies with the test for sterility. If evidence of microbial growth is found the product to be examined does not comply with the test for sterility.

If the test is declared to be invalid for any reasons, the test is repeatedwith the same number of units as in the original test.

If no evidence of microbial growth is found in the repeat test, the product examined complies with the test for sterility. If microbial growth is found in the repeat test, the product examined does not comply with the test for sterility.

If parenteral products comply with all the tests conducted by quality controldepartment, then the products are said to be of standard quality and the productscan be released into the market.

Extractable Volume

Where the nominal volume does not exceed 5 ml, the containers comply with the requirements of Method 1 and where the nominal volume exceeds 5 ml, the containers comply with the requirements of Method 2. Suspension should be shaken before the contents are withdrawn; oily injections may be warmed but should be cooled to 25 ^{O}C before carrying out the test.

Method 1: Use 6 containers, 5 for the test and 1 for rinsing the syringe used. Inspect the 5 containers to be used in the test visually and ensure that each contains approximately the same volume of the preparation.

Using a syringe with a capacity not exceeding twice the volume to be measured and fitted with a suitable needle, take up a small quantity of the liquid under examination from the container reserved for rinsing the syringe, and discharge it from the syringe whilst the needle is pointing upwards so as to expel any air. Withdraw as much as possible the contents of one of the containers reserved for the test and transfer, without emptying the needle, to a dry graduated cylinder of such occupies not less than 40 per cent of the nominal volume of the cylinder. Repeat the procedure until the contents

the 5 containers have been transferred and measure the volume. The content of each container is not more than the nominal volume and the average content of 5 containers is not morethan 115 per cent of the nominal volume.

Method 2: Transfer the contents of not less than 3 containers separately to dry graduated cylinders such that the volume to be measured occupies not less than 40 percent of the nominal volume of the cylinder and measure the volume transferred. The contents of each container are not less than the nominal volumeand not more than 110 per cent of the nominal volume.

Multiple dose containers labeled to yield a specific number of doses shall contain a sufficient excess to permit the withdrawal of the designated number of doses.

PROCEDURE: Leaker test and clarity test are performed in this experiment.

Leaker Test

The ampoules prepared in the laboratory (or purchased from the market) are used for this test. This test can be conducted using vacuum chamber only for leaker test or can be conducted in an autoclave to complete both sterilization as well as leaker test.

1. Methylene blue solution is prepared by dissolving 5 g in 1000 ml of water.
2. The blue coloured solution is placed in a wide mouthed container (bin).
3. All the ampoules are submerged in the dye solution by their inverted positionas shown in Figure

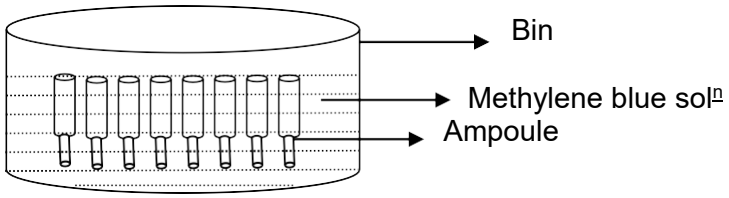


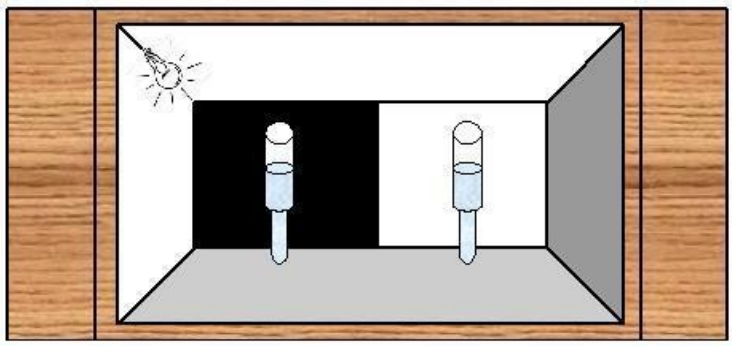
Figure: Inverted ampoules submerged in methylene blue solution

1. The entire container is placed in an autoclave in which water is placed earlieruntil the entire heating coil is immersed.
2. The ampoules are autoclaved for 30 min.
3. After 30 min., allow the pressure to come down to atmospheric pressure.
4. The lid of an autoclave is carefully removed.
5. The container with ampoules (bin) is taken out.
6. All the ampoules are removed from the bin and washed with water.
7. All the ampoules are checked for the appearance of blue colour.

CLARITY TEST:

1. The clarity tester is connected to the mains.
2. The bulb is checked for its correctness of the function.
3. An ampoule from the batch is placed against dark background in itsinverted position after mild shaking to see for the presence of light particles. Care is taken to prevent the formation of air bubbles which otherwise may interfere with the observation.
4. The same ampoule is placed against light background in its inverted position after mild shaking to see for the presence of dark particles.
5. The procedure is repeated on every ampoule of the batch.
6.

Ampoule No	Observation	Inference
1	Particles are absent / Particles are present	Passes / does not pass
2	Particles are absent / Particles are present	Passes / does not pass
3	Particles are absent / Particles are present	Passes / does not pass



Assignments

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

  1. Various systems of measures commonly used in prescribing, compounding and dispensing practices

  2. Market preparations (including Fixed Dose Combinations) of each type of dosage forms, their generic name, minimum three brand names and label contents of the dosage forms mentioned in theory/practical

  3. Overview of various machines / equipments / instruments involved in the formulation and quality control of various dosage forms / pharmaceutical formulations.

  4. Overview of extemporaneous preparations at community / hospital pharmacy vs. manufacturing of dosage forms at industrial level

  5. Basic pharmaceutical calculations: ratios, conversion to percentage fraction, alligation, proof spirit, isotonicity

A TYPICAL FORMAT FOR THE ASSESSMENT OF AN ASSIGNMENT

Name of the College:

Name of the Student:	
Academic Year of the Student	
Name of the Subject	
Title of the Assignment:	
Date on which the Assignment was given:	
Date on which the Assignment was submitted:	
Name & Designation of the Evaluator:	
Signature of the Evaluator with Date:	

Directions: For evaluation, enter rating of the student utilizing the following scale: **5 – Excellent; 4 - Very Good; 3 – Good; 2 – Satisfactory; 1 - Poor**

Assessment criteria	**Score**	**Comments, if any**
a. Relevance with the content		
b. Use of the resource material		
c. Organization & mechanical accuracy		
d. Cohesion and Coherence		
e. Language proficiency & Timely submission		
Total Score		

Signature of the Student with Date:

Note: Subject teacher should try to cover all assignments mentioned in the list for each practical subject by assigning the topics to the students. Students should be encouraged to submit an assignment (in a format decided by the Institute) and encouraged to present assignments (at least any one assignment per subject) in the class.

A typical format for the assessment of a Field visit Report

Name of the College:

Name of the Student:	
Academic Year of the Student:	
Name of the Subject:	
Name & full address of the organization visited:	
Date and duration of Visit:	
Name & Designation of the Evaluator:	
Signature of the Evaluator with Date:	

Objectives set for the field visit: (give 2 – 4 objectives one by one)
Prior preparation of the student for the field visit: (minimum 100 words)
Describe the general experiences during the field visit: (minimum 100 words)
Learning points: Describe what theoretical concept that is correlated during the field visit: (minimum 300 words)

Definitions of categories of the formulations

Abrasive: It is a rough substance used to clean a surface.

Analgesic: A drug that selectively relieves pain by acting on the CNS or peripheral pain mechanisms, without significantly altering consciousness.

Antacid: An alkaline substance that neutralises gastric acidity and increases the pH of the gastric contents.

Antipyretic: An agent that reduces the increased body temperature.

Antirheumatic: An agent that prevents or lessens rheumatism symptoms like stiffness or swelling of muscles and joints with pain.

Antiscorbutic: It is an agent that prevents or cures scurvy (a disease due to lack of vitamin C).

Antiseptic: An agent that destroys or inhibits the growth of pathogenic microorganisms when applied on wound thereby preventing infection.

Antithrombotic: It is an agent that prevents or cures thrombosis (intra vascular formation of a blood clot).

Bacteriostatic: It is an agent that hinders or arrests the bacterial growth.

Calcium replenisher: An ingredient that is administered to replenish the deficient calcium in the body.

Carminative: An agent that expels gases formed in the stomach or intestine.

Demulcent: An agent that produces soothing effect.

Diaphoretic: An agent that increases sweating.

Disinfectant: An agent that kills microorganisms when applied to non-living objects.

Diuretic: An agent that promotes a net loss of sodium ions (Na^+) and water from the body.

Electrolyte replenisher: It is an ingredient that is administered to replenish the deficient electrolytes in the body.

Emollient: It is a substance that softens and sooths skin or mucous membrane.

Expectorant: An agent that promotes the expulsion of mucous from the respiratory tract by decreasing its viscosity.

Flavouring agent: An ingredient that induces aroma to the preparation.

Fluid replenisher: It is an ingredient that is administered to replenish the deficient fluid in the body.

Laryngitis: Inflammation of larynx (The organ of voice situated below and in front of the pharynx and at the upper end of the trachea).

Nutrient replenisher: It is an ingredient that is administered to supply nutrient in deficient conditions.

Preservative: It is a substance that prevents or inhibits microbial growth and may be added to pharmaceutical preparation to prevent spoilage of the preparations.

Sweetening agent: An ingredient that provides sweetness to the dosage form.

Vehicle: A solid/liquid substance that is used as a medium for the administration of drugs.

Definitions and meanings of some important terms

1% v/v: 1 ml of liquid solute present in 100 ml of a vehicle or solvent.

1% w/v: 1 gram of solid solute dissolved in 100 ml of solvent or vehicle.

1% w/w: 1 gram of liquid or solid in 100 gram of vehicle or solvent.

Acute condition: A situation in which the symptoms are severe and exhibits for a short period.

Amber coloured container: A container having brown colour, which prevents the passage of light (light-resistant container).

Ampoule: All-glass hermetically sealed container used for a parenteral or other sterile product.

Antiadherants: These are the agents, which reduce sticking or adhesion of tablet granulation (or powder) to the faces of the punches or die wall.

Antioxidants: It is a substance capable of inhibiting oxidation and that may be added for this purpose to pharmaceutical products, which undergo deterioration by oxidative processes.

Aseptic filling: It is a process of filling sterile products into sterile containers under controlled conditions.

Aseptic transfer: It is used to designate the transfer of medicament under the conditions in which every reasonable means has been used to destroy or eliminate viable microorganisms, but with the recognition that an absolute condition has not been achieved.

Bactericide: It is an agent causing the death of bacteria.

Binders: These are used to provide cohesiveness to the tablet, particularly when the powders are very fine and not free flowing.

BP: British Pharmacopoeia.

BPC: British Pharmaceutical Codex.

Bubble formation (Bulbing): It is the process of formation of fragile bubbles at the tip due to excessive heating of air and gases in the neck resulting in expansion against the soft glass. Wet glass at the neck increases the frequency of bubble formation.

Capping: It is a term used to describe the partial or complete separation of the top or bottom crowns from the main body of the tablet.

Category: Use.

Charring: While sealing of ampoules, drug (or additive largely organic) combustion products may be formed leaving tip/neck charring.

Chipping: Refers to the defect in which pieces are broken and chipped out of the tablets.

Chronic condition: A situation in which the symptoms persist for a long time.

Coarse powder: (# 20): All particles pass through a 20-mesh sieve and not more than 40% through 60-mesh sieve.

Cold place: It is a storage place (for drugs) that maintains any temperature not exceeding 8 ^{o}C (normally between 2 and 8 ^{o}C) according to IP.

Compactability: It is defined as the ability of a powder to be compressed into a tablet of a certain strength or hardness.

Compressibility: It is defined as the ability of a powder to decrease in volume under pressure.

Container: The container is one that holds or retains the articles (contents) and may be in direct contact with the article.

Cool place: It is a storage place (for drugs) that maintains any temperature between 8 ^{o} and 25 ^{o}C according to IP.

Cosolvency: Weak electrolytes and nonpolar molecules frequently have poor water solubility. Their solubility usually can be increased by the addition of a water miscible solvent in which the drug has good stability. This process is known as co-solvency.

Co-solvent: A second solvent used to increase the solubility of solute in a solvent, normally water.

Diluents: Diluents are fillers designed to make up the required bulk of the tablet when the drug dosage itself is inadequate to produce this bulk.

Direct compression: Some granular chemicals such as potassium chloride and methenamine possess free flowing as well as adhesive properties that enable them to be compressed directly in a tablet machine without the need of either wet or dry granulation.

Disintegrants: These are used to cause the tablets to disintegrate, when exposed to a liquid environment (may be acidic environment as in stomach, or alkaline environment as in intestine, or in any solvent *in vitro*).

Disintegration: It is defined as that state in which no residue of the tablet or capsule remains on the screen of the apparatus or if a residue remains, it consists of fragments of insoluble coating of the tablets or of capsule shells or is a soft mass with no palpable core.

Dissolution: It is a process in which the drug is released from the dosage forms (example, tablets) and immediately goes into molecular solution.

Dosage form: The drug, vehicle, and/or excipients are put in a suitable form for conveying the drug for administration to the patient.

Doughy mass: A mass formed during wet granulation having a consistency of semisolid that crumbles under moderate pressure without giving fines.

Dry granulation: The process of compacting large masses of the mixture and subsequent crushing and sizing of pieces to obtain smaller particles called granules.

Elixirs: These are clear, sweet, and aromatic hydro-alcoholic solutions intended for oral use.

Emollient: Emollient is an agent that softens or soothes the skin or an irritated internal surface.

Emulsions: These are biphasic systems containing two immiscible liquids, one of which is dispersed as minute globules in the other with the help of an emulsifying agent.

Enema: An enema is a solution or suspension that is introduced into the rectum or colon to cause evacuation or for local or systemic therapeutic action or for diagnostic purposes.

Eutectic powder: It is defined as a mixture of powdered ingredients, which melt when mixed with one another.

Evacuation enema: It is a type of enema that is used to cleanse the bowel either in constipation or before an operation either by stimulating peristalsis or by lubricating impacted faeces.

Fines (# 60): All particles pass through 60-mesh sieve and not more than 40% through a 100-mesh sieve.

Flowability: It means the capacity of material to flow freely from hopper into the feed frame and dies.

Freezer: A place in which the temperature is maintained thermostatically between 20 and -10 ^{o}C.

Gargle: Gargle is an aqueous pleasantly flavoured solution, usually prepared in concentrated form, intended for use, after dilution with warm water, to prevent or to treat throat infections.

Geometric dilution: A sequence of mixing of ingredients with gradually increasing amounts in a ratio of 2, 4, 8, 16,……..

Glidants: These are intended to promote flow of the tablet granulation or powder materials by reducing friction between the particles.

Granulation: A process of converting mixture of powders into free flowing particles.

Hardness test: It is a test to measure the applied force required to break a tablet across the diameter.

Incompatibility: It occurs as a result of mixing of two or more antagonistic substances and produces an undesirable product that may affect the safety, efficacy, and appearance of the pharmaceutical preparation.

IP: Indian Pharmacopoeia.

Lamination: Lamination is the separation of a tablet into two or more distinct layers.

Large volume parenterals: Aqueous drug solutions intended for infusion and hermetically sealed in a container of greater than 100 ml volume.

Levigation: It is a process of converting ingredients into a paste with the vehicle or by rubbing with a large spatula, on a warm tile.

Light-resistant container: A container that protects the contents from the effects of actinic light (rays of light beyond the violet end of the spectrum that produce chemical effects) by virtue of the specific properties of the material of which it is made.

Linctuses: Linctuses are viscous liquid oral preparations that are used for the relief of cough.

Liniments: Liniments are liquid or viscous preparations, applied to the unbroken skin with friction and rubbing meant for counter irritant and rubefacient actions.

Lotions: Lotions are usually liquid suspensions or dispersions meant for application to the skin without friction.

Lubricants: These are intended to reduce the friction (during tablet ejection) between the walls of the tablet and the walls of die cavity in which the tablet formed.

Masking agent: An agent that suppresses the colour, flavour, taste etc.

Mixing: Mixing is a process of preparing a homogeneous mass of dissimilar particles.

Mottling: Mottling is an unequal distribution of colour on tablets, with light or dark areas appearing on the surface.

Mouthwash: Mouthwash is an aqueous solution with a pleasant taste and odour generally regarded as a medicated liquid for cleansing the mouth or treating diseased states of the oral mucous membrane or also used to clean and deodorize the buccal cavity.

Multiple dose vial: A container, usually of glass, having a relatively large opening closed by means of a rubber stopper, which permits the insertion of a sharp needle and the withdrawing of a part of the contents. The stopper reseals when the needle is withdrawn to maintain the integrity of the package.

Nauseous substance: A substance that induces the sensation of vomiting.

Necrosis: It is a condition of morphological changes indicative of cell death.

NF: National Formulary.

Normal saline: It is a solution containing 0.9% w/v sodium chloride in water, which is normally small volume such as 10 ml.

Orange flower water: A saturated solution consisting of odoriferous principles of the flowers of *Citrus aurantium* prepared by distilling the fresh flowers with water and separating the excess volatile oil from the clear water portion of the distillate.

Overages: It is the excess amount of drug that must be added to the preparation to maintain percent labeled amount of drug during the expected shelf life period.

Overfill volume: It is the excess volume of the solution to be added to ampoules, vials etc, in order to account for the volume that sticks to the container. The intention is to facilitate the withdrawal of actual dose from the container without difficulty.

Oxidation: Oxidation is a process of addition of oxygen or removal of hydrogen or removal of electrons from the molecule.

Paediatric: Meant for children.

Powder: Powder is a homogeneous mixture of finely divided solids (drugs or chemicals).

Preservative: A substance that prevents the growth of microorganisms.

Preservative: In the common pharmaceutical sense, preservative is a substance that prevents or inhibits microbial growth and may be added to pharmaceutical preparation to prevent spoilage of the preparations by microorganisms.

Purified water: Purified water is the water produced by deionization (DI) followed by distillation or reverse osmosis (RO) or ultrafiltration (UF). Purified water IP must not contain any added substances. Hence microbial control of this water is difficult. Purified water is kept (or stored) at 80 ^{o}C from the time of production till it is used for manufacture.

Purified water is used in the preparation of dosage formulations like solids, oral liquids and creams. But it is not used in the preparation of parenterals.

Pyrogens: Pyrogen is high molecular weight lipid associated with a lipopolysaccharide and is an endotoxin produced by *Bacillus microorganisms,* which cause transient fever and in the worst cases death due to shock, if introduced into the human body

qs: Quantity sufficient to produce, to, up to.

Room temperature: The temperature prevailing in a working environment.

Shelf life (expiry date): By convention, it is the time required for the drug to reduce its concentration to 90 percent of the initial labeled concentration.

Slugging: When the initial blend of powders is forced into the dies of a large capacity tablet press and is compacted by means of flat faced punches, the compacted masses are called slugs and the process is referred to as slugging.

Small volume parenterals: This is the category of parenterals including ampoules of 1 ml, 2 ml, 3 ml, 5 ml, 20 ml, and vials of 2 ml, 5 ml, 10 ml, 15 ml, 20 ml, and 30 ml.

Solute: A solute is the smaller component present in the solution and is usually non-volatile in nature.

Solutions: Solutions are liquid preparations containing one or more chemical substances dissolved in a solvent, usually water.

Solvent: A liquid having the ability to dissolve the solute and constitute a major proportion in solution.

Spatulation: A mild mixing process of ingredients using spatula.

Sterilization: A process designed to eliminate or destroy living microorganisms to a high level of probability. Normally, there should be no greater than 1 x 10^{-6} probability of a survivor.

Stirring: A mixing process of liquids/semisolids using a glass rod or a mixer.

Suspensions: Suspensions are biphasic liquid dosage forms in which a solid phase is dispersed in a liquid medium.

Syrups: Syrups are sweet, viscous, concentrated or nearly saturated solutions of sucrose in purified water.

Tightly-closed container: It is a container that protects the contents, a) from contamination by extraneous liquids, solids, and vapours b) from loss or deterioration of the article from effervescence, deliquescence, and evaporation under normal conditions of handling, shipment, storage, and distribution. A tightly-closed container must be capable of being tightly re-closed after use.

Trituration: A process of mixing using mortar and pestle/mixing equipment like planetary mixer.

Vehicle: A solid/liquid substance that is used as a medium for the administration of drugs.

Well-closed container: It is a container that protects the contents a) from extraneous solids and liquids b) from loss of the material under normal conditions of handling, shipment, storage, and distribution.