East Point College of Pharmacy

East Point Campus, Jnana Prabha, Virgo
Nagar PostBengaluru – 560049, Karnataka

Approved
by
Pharmacy Council of India, New Delhi

Affiliated
to
Rajiv Gandhi University of Health SciencesKarnataka
Bengaluru – 560041 India

LAB MANUAL

INDUSTRIAL PHARMACY-I

B. PHARM 5th SEMESTER

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

B Pharmacy

Program Outcomes (PO's)

PO 1- Pharmacy Knowledge

Possess knowledge and comprehension of the core and basic knowledge associated with theprofession of pharmacy, including biomedical sciences; pharmaceutical sciences; behavioral, social, and administrative pharmacy sciences; and manufacturing practices.

PO 2- Planning Abilities

Demonstrate effective planning abilities including time management, resource management,delegation skills and organizational skills. Develop and implement plans and organize workto meet deadlines.

PO 3- Problem analysis

Utilize the principles of scientific enquiry, thinking analytically, clearly and critically, whilesolving problems and making decisions during daily practice. Find, analyze, evaluate and apply information systematically and shall make defensible decisions

PO 4- Modern tool usage

Learn, select, and apply appropriate methods and procedures, resources, and modernpharmacy-related computing tools with an understanding of the limitations.

PO 5- Leadership skills

Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles when appropriate to facilitate improvement in health and wellbeing.

PO 6- Professional Identity

Understand, analyse and communicate the value of their professional roles in society (e.g.health care professionals, promoters of health, educators, managers, employers, employees).

PO 7- Pharmaceutical Ethics

Honor personal values and apply ethical principles in professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values,communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions and take responsibility for the outcomes associated with the decisions

PO 8- Communication

Communicate effectively with the pharmacy community and with society at large, such as,being able to comprehend and write effective reports, make effective presentations and documentation, and give and receive clear instructions

PO 9- The Pharmacist and society

Apply reasoning informed by the contextual knowledge to assess societal, health, safety andlegal issues and the consequent responsibilities relevant to the professional pharmacy practice.

PO 10- Environment and sustainability

Understand the impact of the professional pharmacy solutions in societal and environmentalcontexts, and demonstrate the knowledge of, and need for sustainable development.

PO 11- Life-long learning

Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

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Programme Specific Outcomes (PSO's)	
PSO 1	Acquire a thorough foundational knowledge in pharmaceutical sciences, including pharmacology, pharmaceutics, medicinal chemistry, and pharmacognosy, to excel in further academic pursuits
PSO 2	Gain expertise in the application of contemporary pharmaceutical techniques and technologies, enhancing employability across various sectors including the pharmaceutical industry, academia, and research institutions.
PSO 3	Equip with entrepreneurial skills and knowledge of pharmaceutical business management, including market analysis, product development, regulatory affairs, and financial planning, to initiate and run successful ventures in the pharmacy sector

Course Outcomes (CO's)	
Code: BP506P Industrial Pharmacy-I	
CO 1	Relate the physicochemical properties of various dosage form and their manufacturing techniques
CO 2	Prepare formulations of solid, semisolid, and liquid dosage forms as per the batch formula
CO 3	To perform pre-formulation studies and prepare simple solutions and cosmetics
CO 4	To understand the knowledge through oral assessment

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GENERAL LABORATORY INSTRUCTIONS

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(A) Personal Hygiene:

1. Personal hygiene is enormously important during work in a pharmaceutical laboratory because people engaging in the preparation of medicinal products are working for patients who may already be ill.
2. Personnel should be well aware, trained, and should practice good health habits.
3. Smoking, eating, drinking, chewing, and the storage of food should be restricted in the laboratory areas.
4. Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should not engage in laboratory activities.

(B) Personal Protective Equipment (PPE):

1. A clean white coat (apron) should be worn to protect the person from the product, and conversely, the product should be protected from contamination by the person.
2. During the preparation and/or manufacturing process, safety equipment such as mouth masks, head caps, gloves, goggles, etc. must be used. Similarly, long hair should be tied back and properly covered with a head cap to ensure that any open cuts are covered.
3. It is the responsibility of the individual to ensure that the correct safety equipment is used and avoid direct contact with chemicals and APIs.

(C) Clean Work Area:

1. The cleanliness of the work area and equipment used during the compounding/preparation of medicaments is of paramount importance.
2. The risk of contaminating the final product with either dust, dirt, or microorganisms from the surroundings or from other ingredients from a previous preparation can be considerable if attention is not paid to the cleanliness of the work area and equipment.
3. Before starting to compound a product, the work area and equipment should be cleaned with a suitable solution, which must be allowed to dry fully.
4. Never use the apron outside the laboratory.

(D) Equipment Cleaning:

1. Equipment and utensils should be cleaned, stored, and where appropriate, sterilized to prevent contamination or carry-over of a material that would affect the quality of the intermediate or API beyond the official or other established specifications.
2. In cases where equipment is assigned to the continuous preparation of successive batches of the same intermediate or API, equipment should be cleaned at appropriate intervals to prevent the build-up and carry-over of contaminants (e.g., degradants or objectionable levels of microorganisms) that would alter the product quality

(E) Label Preparation:

The label for any pharmaceutical intermediate or finished product must be prepared before starting the compounding/preparation procedure. This will enable the product to be labelled as soon as it has been manufactured and packaged, eliminating the risk of the product being mislabelled and given to the wrong patient.

(F) Weighing and Measuring Procedure:

1. During weighing, using a clean balance pan as well as a spatula helps to prevent the mixing of different pharmaceutical ingredients, as many ingredients resemble each other.
2. After weighing or measuring each ingredient, label it using a paper piece or tag as soon as it has been weighed or measured.
3. Close the bottles/containers tightly after weighing and place them on the respective shelf/place after completing the weighing process.

Experiment No: 01

PREFORMULATION STUDIES ON PARACETAMOL/ASPIRIN/ OTHER DRUG

AIM: To perform different preformulation studies of prepared granules.

REQUIREMENTS: Measuring cylinder, Funnel, Sieves, Mortar & pestle, Spatula.

PRINCIPLE: Preformulation is defined as the phase of research and development in which preformulation studies characterize physical and chemical properties of a drug molecule in order to develop safe, effective and stable dosage form. The objective of preformulation study is to develop the elegant, stable, effective and safe dosage form by establishing kinetic rate profile, compatibility with the other ingredients and establish Physico-chemical parameter of new drug substances. The major preformulation studies/parameters of granules are as follows:

1. **Bulk density:** It is defined as ratio of total mass of the powder to the bulk volume of powder. It gives an idea about tablet porosity and its relationship with disintegration time and hardness of a tablet. It is measured by pouring weighed powder into a measuring cylinder and the volume is noted down. It is expressed in gm/ml and is given by

$$D_b = M/V_o$$

Where,

M= Mass of powder,

V_o = Bulk volume of powder

2. **Tapped density:** It is defined as ratio of total mass of the powder to the tapped volume of powder. Tapped volume is measured by tapping the powder to constant volume. It is expressed in gm/ml and is given by:

$$D_t = M/V_t$$

Where,

M= Mass of powder,

V_t = Tapped volume of powder

3. **Angle of repose (Θ):** It is the maximum angle possible between surface of pile of powder and the horizontal plane, can be used to measure frictional forces in a powder.

$$\Theta = \tan^{-1}(h/r)$$

Where, Θ= angle of repose, H height of the powder in cm, R is the radius of heap of powder

Relationship between Angle of reposes and flow property

Angle of repose(θ)	Type of flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

1. **Carr's Compressibility Index:** It indicates the ease with which a material can be induced to flow; it is expressed as a percentage and is given by

$$I=(Dt-Db)/Dt \times 100$$

Where, D is the tapped density of the powder. Db is the bulk density of the powder.

Relationship between Carr's index and flow property

Carr's index	Type of flow
5-15	Excellent
12-15	Good
15-22	Fair
23-30	Poor
33-38	Very poor
>40	Extremely poor

1. **Hausner's ratio:** It indicates the flow properties of the powder and is measured by the ratio of tapped density to the bulk density.

Hausner's ratio = (Tapped density)/ (Bulk density) ×100

Values of Hausner's ratio :< 1.25: good flow and > 1.25: poor flow

If Hausner's ratio is between 1.25-1.5, flow property can be improved by addition of glidants.

2. **Size and Size Distribution Analysis:** The particle-size distribution (PSD) of a powder, or granular material, is a list of values or a mathematical function that defines the relative amount, (typically by mass) of particles present according to size.

The size and shape distribution of the metal particles impacts powder behavior during die filling, compaction, and sintering, and therefore influences the physical properties of the parts created. In the pharmaceutical industry the size of active ingredients influences critical characteristics including content uniformity, dissolution and absorption rates.

Measurement Techniques:

1. Sieve Analysis
2. Air elutriation analysis
3. Photo analysis
4. Optical counting methods
5. Electro resistance counting methods
6. Sedimentation techniques
7. Laser diffraction methods

The way PSD is usually defined by the method by which it is determined. The most easily understood method of determination is sieve analysis, where powder is separated on sieves of different sizes. Thus, the PSD is defined in terms of discrete size ranges: e.g. "% of sample between 45 μm and 53 μm", when sieves of these sizes are used. The PSD is usually determined over a list of size ranges that covers nearly all the sizes present in the sample. However, the idea of the notional "sieve", that "retains" particles above a certain size, and "passes" particles below that size, is universally used in presenting PSD data of all kinds.

The PSD may be expressed as a "range" analysis, in which the amount in each size range is listed in order. It may also be presented in "cumulative" form, in which the total of all sizes "retained" or "passed" by a single notional "sieve" is given for a range of sizes. Range analysis is suitable when a particular ideal mid-range particle size is being sought, while cumulative analysis is used where the amount of "under-size" or "over-size" must be controlled.

PROCEDURE:

Bulk density and tapped density: Pass a quantity of sample sufficient to complete the test through a sieve, if necessary, to break up agglomerates. Into a measuring cylinder of 100 ml, gently introduce, without compacting, approximately 15g of the test sample and weighed. Carefully level the powder without compacting, if necessary, and read the unsettled apparent

volume to the nearest graduated unit. Calculate the bulk density by applying the above formula. The tapped volume is obtained by mechanically tapping the measuring cylinder containing the sample of 15 gm with a fixed drop of 14±2 mm at a nominal rate of 300 drops per mins until a

constant volume is observed. Then calculate the tapped density by using the above formula.

After getting the value of bulk density and tapped density, **Carr's Compressibility Index and Hausner's ratio** is calculated by using the formula.

Angle of repose: The static angle of repose was measured according to the fixed funnel and free standing cone method. A funnel was clamped with its tip 2cm above a graph paper placed on a flat horizontal surface. The powders were carefully poured through the funnel. Block the orifice of the funnel by thumb. Fill the powder in the funnel and remove the thumb immediately. After emptying the powder from the funnel, measure the height of the pile and diameter.

Size and Size Distribution Analysis: Arrange all the sieves on the shaker one above the other in increasing opening order i.e. decreasing sieve number, the one with powder sample occupying the upper most position. Weigh about 50g (W) of given sample and place it over the top sieve(Lowest sieve number).Shake the sieve either mechanically or electrically for a period of half an hour.

The powder retained on each sieve is collected and weighed separately. The percentage weight retained on each sieve is calculated by,

Percentage powder retained= $\frac{weight\ of\ powdere\ that\ have\ retained\ over\ the\ sieve}{weight\ of\ total\ powder\ taken\ for\ experiment} x100$

OBSERVATIONS:

Sl.No	Sieve number passed or retained	Arthematic mean size of opening (µm)	Average size of the particle	Weight retained on a sieve (gm)	% weight retained	Cumulative percentage of oversized particles	Cumulative percentage of undersized
1	10/16	1350		W_1			
2	16/22	855		W_2			
3	22/40	517.5		W_3			
4	40/60	287.5		W_4			
5	60/85	142.5		W_5			
6	85/100	27.5		W6			

REPORT: The preformulation parameters of the given sample were found to be:

Bulk density:

Tapped density:

Carr's Compressibility Index:

Hausner's ratio:

Angle of repose:

Size distribution analysis: The given sample is size separated by the sieves.

Their frequency distribution curve of the particle was plotted.

The average particle size----µm were found to be maximum of ---%

The average particle size----- µm were found to be minimum of ----%

The cumulative size distribution curve were also plotted and the total average particle size is found to be-- µm

VIVA QUESTIONS:

- What is preformulation?
- What are true density and bulk density and tapped density? What is porosity?
- What is the role of bulkiness and compressibility of powder in the manufacturing of the dosage forms?
- What is void volume?
- What is the importance of angle of repose?
- What are the different methods used to determine size distribution analysis?

INTRODUCTION TO TABLETS

Tablets may be defined as the solid unit dosage forms containing one or more medicaments and excipients, prepared either by molding or compression. It comprises a mixture of active substances and excipients in powder or granule form. The excipients include diluents, binders or granulating agents , glidants and lubricants to ensure efficient tablet compression, disintegrants to promote tablet break-up in the digestive tract , sweeteners or flavors to enhance taste and pigments to make tablets visually attractive.

ADVANTAGES:

1. Tablets offer the greatest compatibilities of all oral dosage forms for the greatest dose precision and the least content variability.
2. Their cost is lowest of all oral dosage form.
3. They are lightest and compact.
4. Easiest and cheapest to package and ship.
5. They have better physical and chemical stability and exert physiological activity of drug.
6. Special forms to facilitate patient compliance eg: - sustained release, extended release formulations.
7. Suitable for large scale economical production.

DISADVANTAGES:

1. Unsuitable for infants and children and patients who cannot swallow.
2. Delayed onset of action compared to liquid orals and parenterals.
3. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT or combination of above features make tablet manufacturing difficult.
4. Bitter tasting drugs, drugs with objectionable odor or drugs that are sensitive to oxygen or atmospheric moisture may require encapsulation or entrapment prior to compression.

DIFFERENT TYPES OF TABLETS

They are generally divided as

A. Compressed tablets
B. Moulded tablets/ Tablets triturates.

CLASSIFICATION OF TABLETS ACCORDING TO USAGE:

(A) Tablets ingested orally:

1. Compressed tablet, e.g. Paracetamol tablet
2. Multiple compressed tablet
    a. Layered tablets
    b. Press coated/Dry coated Tablets
3. Repeat action tablet
4. Delayed release tablet, e.g. Enteric coated Bisacodyl tablet
5. Sugar coated tablet, e.g. Multivitamin tablet
6. Film coated tablet, e.g. Metronidazole tablet
7. Chewable tablet, e.g. Antacid tablet

(B) Tablets used in oral cavity:

1. Buccal tablet, e.g. Vitamin-C tablet
2. Sublingual tablet, e.g. Nitroglycerin tablet
3. Troches or lozenges
4. Dental cone

(C) Tablets used to prepare solution:

1. Effervescent tablet, e.g. Dispirin tablet (Aspirin)
2. Dispensing tablet, e.g. Enzyme tablet (Digiplex)
3. Hypodermic tablet
4. Tablet triturates e.g. Enzyme tablet

(D) Tablets administered by other Routes

1. Implantation tablets

2. Vaginal tablets

FORMULATION OF TABLETS:

In addition to active ingredient, tablet contains a number of inert materials known as additives or excipients.

Different excipients are:

1. Diluents
2. Binders and adhesives

3. Disintegrants
4. Lubricants and glidants
5. Colouring agents
6. Flavoring agents
7. Sweetening agents

1. Diluents (Fillers)

Diluents are used to make required bulk of the tablet when the drug dosage is inadequate to produce the bulk. Secondary reason is to provide better tablet properties such as improve cohesion, to permit use of direct compression manufacturing or to promote flow.

a. Diluents for wet granulation
    i. Lactose (hydrous): Most widely used. Lactose reacts with certain amine drugs / proteins in the presence of metal stearates (lubricants) resulting in the tablet discoloration with time. Such a reaction is known as *Millard reaction(Browning reaction)*
    ii. Anhydrous lactose
    iii. Dicalcium phosphate and calcium sulfate: Excellent for water sensitive drugs because they contain appreciable water content and have low affinity to atmospheric moisture.
    iv. Bentonite and kaolin
b. Diluents for dry granulation and direct compression
    i. Spray dried lactose
    ii. Directly compressible starches (corn, wheat or potato). They act as lubricant, binder and disintegrants
    iii. Colloidal silica
    iv. Sodium chloride used for dental cones
    v. Mannitol, sorbitol, sucrose, dextrose (These agents can also be used as binder in solution form or for wet granulation)

2. Binders and Adhesives: These materials are added to hold powders together to form granules to promote cohesive compacts for directly compressed tablet.

Example: Acacia, tragacanth- Solution for 10-25% Conc. Cellulose derivatives- Methyl cellulose, Hydroxy propyl methyl cellulose, Polyvinylpyrrolidone (PVP)- 2% conc. Starch paste- 5-15% solution.

3. Disintegrants: Added to a tablet formulation to facilitate its breaking or disintegration when it comes in contact with water in GIT. Disintegrants acts by three mechanisms

a. Swelling e.g., alginates, starch, PVP ect Improving penetration of aqueous liquids (wetting agents) e.g., SLS, clays
b. Liberation of gas from effervescent base, e.g., $NaHCO_3$ and citric acid.

   Superdisintegrants: Swells up to ten fold within 30 seconds when contact water. Example: Crosscarmellose- cross-linked cellulose, Crosspovidone- cross-linked povidone (polymer), Sodium starch glycolate- cross-linked starch.

4. Lubricants: These are added for the following reasons

- Prevents adhesion of the tablet material to the surface of dies and punches.
- Reduce inter-particular friction; improve the rate of flow of tablet granulation.
- Facilitate ejection of the tablets from the die cavity.

Example: Lubricants- Stearic acid, Stearic acid salt – Stearic acid, Magnesium stearate, Talc, PEG (Polyethylene glycols).Glidants- Corn Starch – 5-10% conc, Talc-5% conc., Silica derivative – Colloidal silicas such as Cab-O-Sil, Syloid, Aerosil in 0.25-3% conc.

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

5. Coloring agent: The use of colors and dyes in a tablet has three purposes:

(i) It makes the tablet more esthetic in appearance.

(ii) Colour helps the manufacturer to identify the product during its preparation.

All colorants used in pharmaceuticals *must be approved and certified by the FDA (food & Drug Administration*). Dyes are generally listed as FD&C (food, Drug & Cosmetic Dyes) dyes and D&C (Drug & Cosmetic Dyes).

Example: FD & C yellow 6-sunset yellow FD & C yellow 5- Tartrazine FD & C green 3- Fast Green FD & C blue 1- Brilliant Blue FD & C blue 2 – Indigo carmine D & C red 3- Erythrosine. D & C red 22 – Eosin Y

6. Flavoring agents: Flavors are usually limited to chewable tablets or other tablets intended to dissolve in the mouth. Flavor oils are added to tablet granulations in solvents, are dispersed on clays and other adsorbents or are emulsified in aqueous granulating agents (i.e. binder).Usually, the maximum amount of oil that can be incorporated to a granulation without influencing its tableting characteristics is 0.5 to 0.75% w/v.

6. Sweetening agents: The use of sweeteners is primarily limited to chewable tablets.

e.g - Sugar.

Mannitol-72% as sweet as sugar, cooling & mouth filling effect

Saccharin- Artificial sweetener, 500 times sweeter than sucrose. *Disadvantages*: it has a bitter after taste and carcinogenic

Aspartame (Searle) - widely replacing saccharin. *Disadvantage* – lack of stability in presence of moisture

MANUFACTURING METHODS OF TABLETS: In the tablet-pressing process, it is important that all ingredients be dry, powdered, and of uniform grain size as much as possible. The main guideline in manufacture is to ensure that the appropriate amount of active ingredient is equal in each tablet so ingredients should be well-mixed. Compressed tablets are exerted to great pressure in order to compact the material. If a sufficiently homogenous mix of the components cannot be obtained with simple mixing, the ingredients must be granulated prior to compression to assure an even distribution of the active compound in the final tablet. Two basic techniques are used to prepare powders for granulation into a tablet: wet granulation and dry granulation.

Powders that can be mixed well do not require granulation and can be compressed into tablets through Direct Compression.

The manufacturing of tablet dosage form is basically done by two methods, such as

1) Wet Granulation (most products)
2) Direct Compression

WET GRANULATION: Wet Granulation is a process of size enlargement whereby small particles are gathered into larger permanent aggregates in which the original particles can still be identified. Granulation usually refers to processes whereby agglomerates with sizes ranging from 0.1 to 2.0 mm are produced. The most important reasons for a granulation step prior to tableting are to:

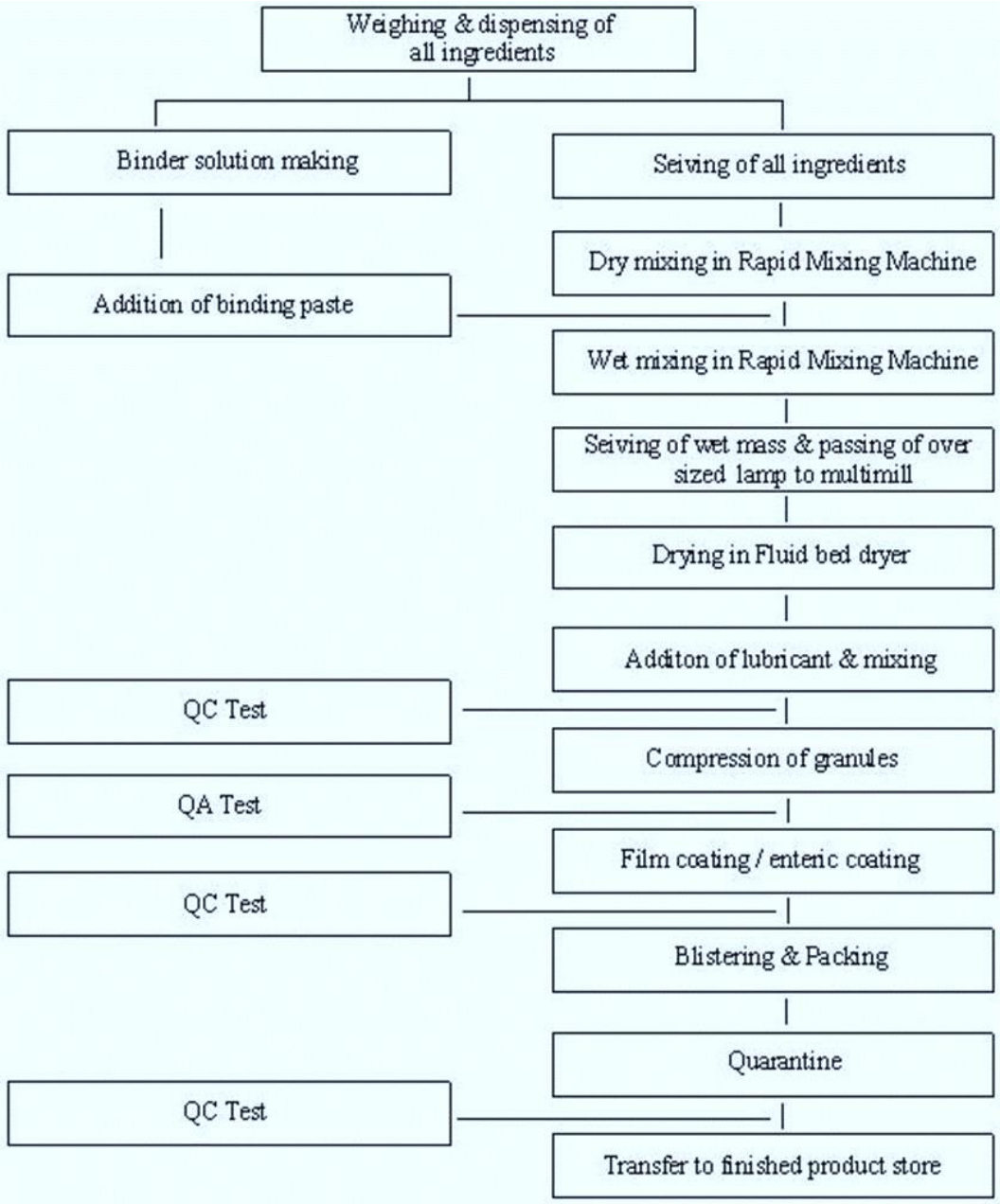
- Improve the flow properties of the mix and hence the uniformity of the dose.
- Prevent segregation of the ingredients.
- Improve the compression characteristics of the tablet mixture.
- Reduce dust during handling

The flow ability of the tablet mixture improves because the granules are larger and more spherical than the primary particles. Larger particles usually flow better than small particles (e.g. compare the flow ability of crystal sugar with powder sugar). In the hopper of tablet machines, small particles tend to segregate from the larger ones because of the vibration of the machine.

This causes higher concentrations of small particles at the bottom of the hopper. After granulation all particles are bound tight in the right amount in the granules, which prevents segregation of the small particles

Process Flow Chart

(Wet granulation method)



Equipment's used in wet granulation method:

1. Electronic Balance
2. Sieve
3. Rapid Mass Granulator (RMG)
4. Multimill
5. Fluid Bed Dryer
6. Double Cone Blender
7. Vat for the preparation of granulating fluid

DIRECT COMPRESSION: In the direct compression method, directly compressible filler (also called a filler-binder) is blended with the active(s), a lubricant and a disintegrating agent. Such free flowing directly compressible fillers make direct compression possible and practical. These include anhydrous lactose, unmilled dicalcium phosphate dihydrate, microcrystalline cellulose (e.g., Avicel PH 101), and modified (spray processed) lactose (e.g., Ludipress). Modified starch, e.g. Starch 1500 flows better and compresses better than original starch, but are not as effective as other materials as the sole filler-binder. Generally, Starch 1500 is used as a component of a direct compression filler system, most likely for its disintegrating property, i.e., as a more compactible and better flowing substitute for starch. Certain materials like mannitol, sorbitol and modified sucrose are particularly useful in formulating direct compression chewable tablets.

Direct compression method can be classified as

a) Direct Compression with direct compressible materials and

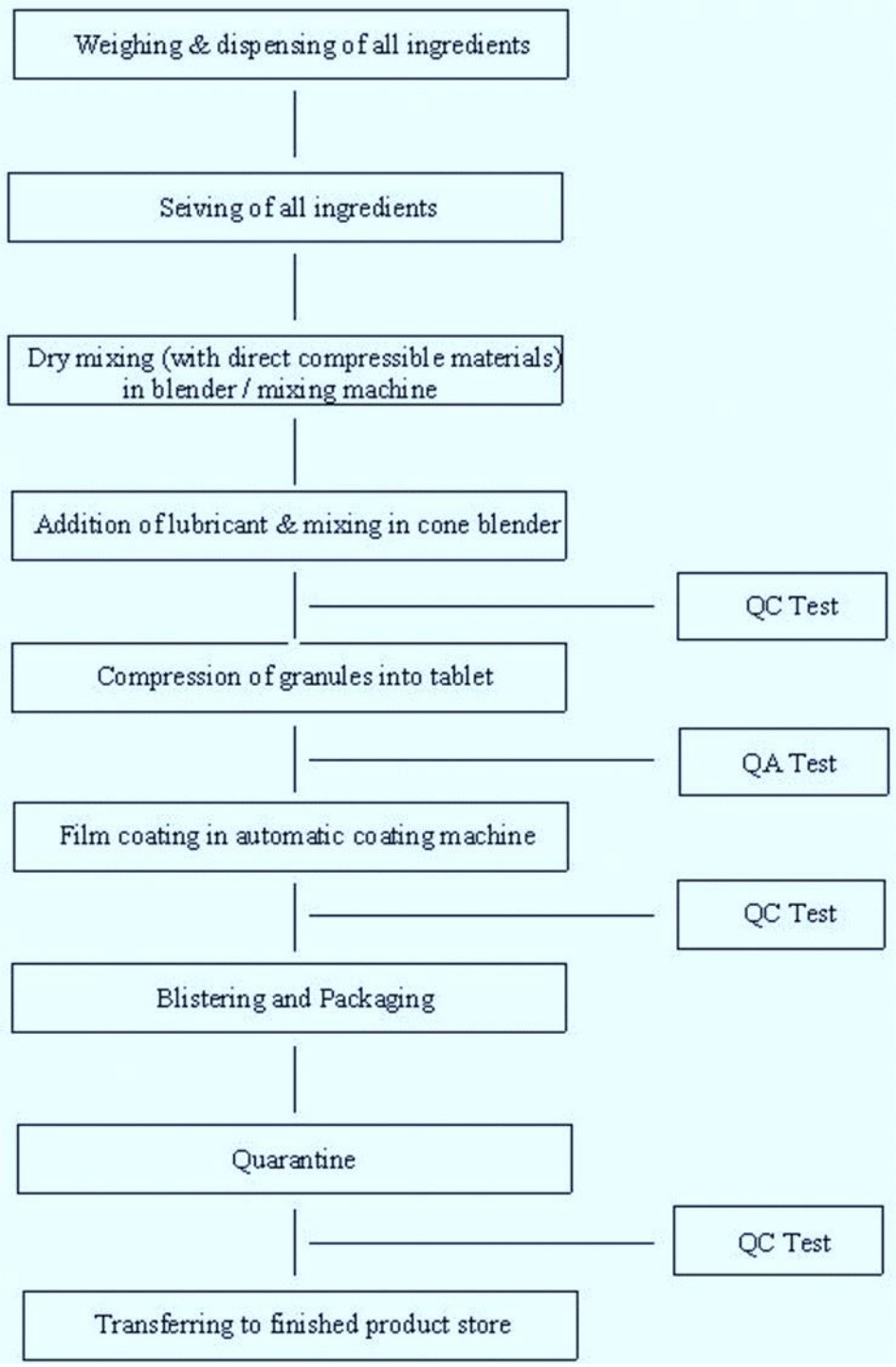
b) Direct Compression by Slugging method

Equipment's used in direct compression method:

1. Electronic Balance
2. Sieve
3. Double cone blender
4. Rotary Press

Process flow chart

(Direct Compression with direct compressible materials)



Experiment No: 02

PREPARATION OF PARACETOMOL TABLETS

AIM: To prepare and submit 10 paracetamol (100 mg) tablets by wet granulation method.

REQUIREMENTS: Mortar and pestle, spatula, beaker, Sieve

PRINCIPLE: Tablet is an important solid dosage form which is usually prepared with the aid of suitable pharmaceutical excipients. Tablets may vary with size, shape, cut, hardness, thickness. Their disintegration and dissolution characteristics and other aspects change depending on their intended use and method of manufacturing.

Compressed tablets are mainly prepared by 3 basic methods

- Wet granulation
- Dry granulation
- Direct compression

Wet granulation is the widely used method for the production of compressed tablets. Steps involved in wet granulation method are

a) Weighing and blending of ingredients

b) Preparing a damp mass by adding wet binder

c) Converting the damp mass into wet granules

d) Drying of granules

e) Sizing the granules by dry screening

f) Addition of lubricants

g) Formation of tablets by compression

During the preparation process each step may influence the quality of tablet produced. In this preparation paracetamol used as API (antipyretic), lactose as adjuvant, starch (purified) as binding agent, starch monohydrate as disintegrant, magnesium stearate as lubricant and talc as Glidant.

Ingredients table (Formula):

Sl. No	INGREDIENTS	1-TABLET	10-TABLETS	PURPOSE
1	Paracetamol(Api)			Analgesic & Antipyretic
2	Starch (Purified)			Binding agent
3	Lactose Monohydrate			Diluent
4	Strarch Monohydrate			Disintegrant
5	Talc			Glidant
6	Mg.Stearate			Lubricant

PROCEDURE:

a) **Preparation of starch mucilage**: Dissolve 5mg of starch in 100ml of distilled water then resulting mixture is heated on a water bath until the starch is gelatinized by the formation of mucilage.

b) Divide disintegrating agent (starch monohydrate) into 2 portions to incorporate during wet granulation and after drying of granules to act as an intragranular and extra granular disintegrant.

c) **Wet Granulation**: Accurately weigh and mix the specified amount of paracetamol and other excipients (except half of the disintegrating agent and lubricant) until uniform powder is formed by geometric mixing.

d) A damp mass of the mixture is prepared by adding appropriate amount of the 5% starch mucilage and kneading by hand.

e) Wet mass is subsequently passes through a 6/10 mesh sieve/screen to form wet granules. Resulted granules are spread evenly on a large piece of paper in a tray and dried at 40°C-60°C for 30min in an oven.

f) Dried granules are passed through a sieve 16 or 20 # and mixed with remaining half of the disintegrating agent and lubricant.

g) Resulting granules mixture is compressed in a tablet compression machine to obtain tablets.

h) Prepared tablets are stored properly for further evaluation.

REPORT: Paracetamol tablets were prepared by wet granulation method and submitted.

VIVA QUESTIONS:

- What is tablet?
- What are the advantages and disadvantages of tablet? What are the different types of tablet?
- What are the different methods of preparation of tablet?
- What are the basic ingredients used in wet granulation method? Give examples. What is the use of paracetamol?
- What are the steps involved in wet granulation method?

Experiment No: 03

EVALUATION OF PARACETOMOL TABLETS

AIM: To evaluate prepared paracetamol tablets.

REQUIREMENTS: Beaker, Test tubes, Test apparatuses

PRINCIPLE:

Evaluation parameters of tablets:

APPEARANCE:

Tablet from each formulation were randomly selected and organoleptic properties such as color, taste, and shape were evaluated.

HARDNESS TEST:

The tablet hardness is defined as the force required to break a tablet in a diametric direction. A tablet was placed between two anvils. Force was applied to anvils and crushing strength that causes the tablet to break was recorded. The hardness was measured using Monsanto hardness tester.

THICKNESS:

The thickness of tablets was determined using a Vernier calliper. Three tablets from each batch were used, and average values were calculated.

FRIABILITY TEST:

The friability of tablets was determined using Roche Friabilator. It is express in percentage (%). Ten or twenty tablets were initially weighed and revolved at 25 rpm for 4 min. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated. The % friability was then calculated by,

$F = (W_{initial} - W_{fiinal}) \times 100 / W_{initial}$

Acceptance criteria for % friability % weight loss should be less than 1%.

WEIGHT VARIATION TEST:

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual weighed is then compared with average weight for the weight variations. The following percentage deviation in weight variation is allowed (U.S.P).

Average weight	% Difference
130 mg or less	10
130 – 324 mg	7.5
More than 324 mg	5

DISINTEGRATION TIME TESTING:

It was determine using USP tablet disintegration test apparatus, using 900 ml of distilled water without disk at room temperature. Test was performed on 6 tablets. One tablet each is kept in all six tubes. The tubes travel upward and downward in water at 37°C±2°C. The time taken for all the six tablets to break down and pass through the mesh at the bottom of the tube is noted. The tablets pass the test if all the six tablets disintegrate within the prescribed time (Less than 30 mins for uncoated tablets as per U.S.P).

IN VITRO DRUG RELEASE STUDY:

The release rate of paracetamol from tablets was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus Type-II. The dissolution test was performed using 900ml of 5.8pH phosphate buffer, at 37°C±0.5°C and 50 rpm. A sample (10ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. The samples were filtered through a 0.45µ membrane filter. Absorbance of these solutions was measured at 243 nm using a Thermospectronic-1 UV/V double-beam spectrophotometer. Cumulative percentage drug release was calculated using an equation obtained from a standard curve.

REPORT: The evaluation tests are performed and all the tablets are found to be in the acceptable limits.

VIVA QUESTIONS:

- What are the different evaluation tests of tablet?
- What are the equipment's used to test hardness and friability of tablet? What is the disintegration time of uncoated tablet?
- What is the use of Vernier calliper?
- What is the range of acceptance of weight variation test of tablet as per U.S.P?

Experiment No: 04

PREPARATION OF ASPIRIN TABLETS

AIM: To prepare and submit 10 Aspirin (100 mg) tablets by wet granulation method.

REQUIREMENTS: Mortar and pestle, spatula, beaker, Sieve

PRINCIPLE: Tablet is an important solid dosage form which is usually prepared with the aid of suitable pharmaceutical excipients. Tablets may vary with size, shape, cut, hardness, thickness. Their disintegration and dissolution characteristics and other aspects change depending on their intended use and method of manufacturing.

Compressed tablets are mainly prepared by 3 basic methods

- Wet granulation
- Dry granulation
- Direct compression

Wet granulation is the widely used method for the production of compressed tablets. Steps involved in wet granulation method are

h) Weighing and blending of ingredients

i) Preparing a damp mass by adding wet binder

j) Converting the damp mass into wet granules

k) Drying of granules

l) Sizing the granules by dry screening

m) Addition of lubricants

n) Formation of tablets by compression

During the preparation process each step may influence the quality of tablet produced. In this preparation Aspirin used as API (Aspirin, also known as acetylsalicylic acid, is a medication used to treat pain, fever, or inflammation), lactose as adjuvant, acacia as binding agent, starch monohydrate as disintegrant, magnesium stearate as lubricant and talc as Glidant.

Ingredients table (Formula):

Sl. No	INGREDIENTS	1 TABLET	10 TABLETS	PURPOSE
1	Aspirin (Api)			Treat Pain, Fever, Or Inflammation
2	Acacia			Binding agent
3	Lactose Monohydrate			Diluent
4	Strarch Monohydrate			Disintegrant
5	Talc			Glidant
6	Mg.Stearate			Lubricant

PROCEDURE:

a) Divide disintegrating agent (starch monohydrate) into 2 portions to incorporate during wet granulation and after drying of granules to act as an intragranular and extra granular disintegrant.

b) **Wet Granulation**: Accurately weigh and mix the specified amount of Aspirin and other excipients (except half of the disintegrating agent and lubricant) until uniform powder is formed by geometric mixing.

c) A damp mass of the mixture is prepared by adding appropriate amount of the acacia and drop wise addition of water.

d) Wet mass is subsequently passes through a 6/10 mesh sieve/screen to form wet granules. Resulted granules are spread evenly on a large piece of paper in a tray and dried at 40°C-60°C for 30min in an oven.

e) Dried granules are passed through a sieve 16 or 20 # and mixed with remaining half of the disintegrating agent and lubricant.

f) Resulting granules mixture is compressed in a tablet compression machine to obtain tablets.

g) Prepared tablets are stored properly for further evaluation.

REPORT: Aspirin tablets were prepared by wet granulation method and submitted.

VIVA QUESTIONS:

- What is the use of aspirin tablet?
- What is the use of diluent and Glidant in tablet formulation? Give examples.

  Give some examples of binders used in tablet formulation.
- Why disintegrating agents are used in 2 portions in tablet preparation?

Experiment No: 05

EVALUATION OF ASPIRIN TABLETS

AIM: To evaluate prepared Aspirin tablets.

REQUIREMENTS: Beaker, Test tubes, Test apparatuses

Evaluation parameters of tablets:

APPEARANCE:

Tablet from each formulation were randomly selected and organoleptic properties such as color, taste, and shape were evaluated.

HARDNESS TEST:

The tablet hardness is defined as the force required to break a tablet in a diametric direction. A tablet was placed between two anvils. Force was applied to anvils and crushing strength that causes the tablet to break was recorded. The hardness was measured using Monsanto hardness tester.

THICKNESS:

The thickness of tablets was determined using a Vernier caliper. Three tablets from each batch were used, and average values were calculated.

FRIABILITY TEST:

The friability of tablets was determined using Roche Friabilator. It is express in percentage (%). Ten or twenty tablets were initially weighed and revolved at 25 rpm for 4 min. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated. The % friability was then calculated by,

$$F = (W_{initial} - W_{fiinal}) \times 100 / W_{initial}$$

Acceptance criteria for % friability % weight loss should be less than 1%.

WEIGHT VARIATION TEST:

Twenty tablets were selected randomly from each batch and weighed individually on electronic balance. The individual weighed is then compared with average weight for the weight variations. The following percentage deviation in weight variation is allowed (U.S.P).

Average weight	% Difference
130 mg or less	10
130 – 324 mg	7.5
More than 324 mg	5

DISINTEGRATION TIME TESTING:

It was determine using USP tablet disintegration test apparatus, using 900 ml of distilled water without disk at room temperature. Test was performed on 6 tablets. One tablet each is kept in all six tubes. The tubes travel upward and downward in water at 37°C±2°C. The time taken for all the six tablets to break down and pass through the mesh at the bottom of the tube is noted. The tablets pass the test if all the six tablets disintegrate within the prescribed time (Less than 30 mins for uncoated tablets as per U.S.P).

IN VITRO DRUG RELEASE STUDY:

The release rate of Aspirin from tablets was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus Type-II. The dissolution test was performed using 900ml of 5.8pH phosphate buffer, at 37°C±0.5°C and 50 rpm. A sample (10ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium. The samples were filtered through a 0.45µ membrane filter. Absorbance of these solutions was measured at 265 nm using a Thermospectronic-1 UV/V double-beam spectrophotometer. Cumulative percentage drug release was calculated using an equation obtained from a standard curve.

REPORT: The evaluation tests are performed and all the tablets are found to be in the acceptable limits.

VIVA QUESTIONS:

- How can we calculate friability of uncoated tablet?
- Which test apparatus is used for invitro drug release study?
- What are the different organoleptic properties are tested for tablet?

Experiment No: 06

FORMULATION OF FILM COATED TABLETS OF PARACETAMOL

AIM: To prepare 10 tablets of paracetamol film coated tablets.

REQUIREMENTS: Mortar and pestle, Sieve, Beaker, Glass rod

PRINCIPLE: All drugs have their own characteristic, like some drugs are bitter in taste or have an unpleasant odor, some are sensitive to light or oxides, some are hygroscopic in nature. Because of this reasons, tablet coating is the choice of option to solve such problems in conventional dosage form. Tablet film coating is performed by two types, one is aqueous film coating (generally water is used as a solvent) and non-aqueous film coating (generally organic solvents are used). Some problems are associated with the non-aqueous film coating like safety of employees (as most of the solvents are dangerous, smell, and they are not good to breathe), atmospheric pollution etc. But key problem is with the approval of the regulatory authority. High quality aqueous film coating must be smooth, uniform and adhere satisfactorily to the tablet surface and ensure chemical stability of a drug. Coating may be applied to a wide range of oral solid dosage forms, including tablets, capsules, and multiparticulate and drug crystals. When coating composition is applied to a batch of tablets in a coating pan, the tablet surfaces become covered with a tacky polymeric film. Before the tablet surface dries, the applied coating changes from a sticky liquid to tacky semisolid and eventually to a non-stick dry surface. The entire coating process is conducted in a series of mechanically operated acorn-shaped coating pans of galvanized iron stainless steel or copper. The smaller pans are used for experimental, developmental, and pilot plant operations, while the larger pans for industrial production.

Necessity of Tablet Coating:

- A number of reasons can be suggested, like: The core contains a material which has a bitter taste in the mouth or has an unpleasant odour. Coating will protect the drug from the surroundings with a view to improve its stability.
- Coating will increase the ease by which a tablet can be ingested by the patient.

- Coating will develop the mechanical integrity; means coated products are more resistant to mishandling (abrasion, attrition, etc.)
- The core contains a substance which is incompatible in the presence of light and subject to atmospheric oxidation, i.e. a coating is added to improve stability.
- The coated tablets are packed on high-speed packaging machine. Coating reduces friction and increases packaging rate.
- Coating can modify the drug release profile, e.g., enteric coating, osmotic pump, pulsatile delivery.

Ingredients table (Formula):

Name of the ingredient	Quantity (%w/w)
Cellulose acetate	6.3
PEG 400	0.7
Acetone	89
Deionized water	4

PROCEDURE: Paracetamol uncoated tablets are prepared by wet granulation method. The prepared tablets are then coated with film coating solution prepared as below.

Film coating solution preparation: The coating solution was prepared by dissolving PEG in water followed by addition of this solution to acetone. Cellulose acetate was then added to the above mixture and stirred to achieve a clear solution.

The coating process was performed in a Vector Hi-Coater LDCS (batch size, 1.5 kg, with inclusion of placebo tablets) at a product temperature of 28ºC. Coated tablets were dried in a vacuum drying oven at 40ºC for 24 hours to remove residual solvent and moisture.

REPORT: 10 tablets of paracetamol film coated tablets are prepared and submitted.

VIVA QUESTIONS:

- Why tablets are coated?
- What are the different types of tablet coating? What are the types of film coating?
- What are the different polymers used in tablet coating? Which equipment is used for tablet coating?

Experiment No: 07

PREPARATION AND EVALUATION OF HARD GELATIN CAPSULES OF TETRACYCLINE HYDROCHLORIDE

AIM: To prepare and evaluate hard gelatin capsules of tetracycline hydrochloride.

REQUIREMENTS: Mortar and pestle, beaker, test tubes, spatula, glass rod, Test apparatuses

PRINCIPLE: Hard gelatin capsule shells are used in most commercial medicated capsules. The community pharmacist also uses hard gelatin capsules in the extemporaneous compounding of prescriptions. The empty capsule shells are made of gelatin, sugar, and water. As such, they can be clear, colourless, and essentially tasteless; or they may be colored with various dyes and made opaque by adding agents such as titanium dioxide. Most commercially available medicated capsules contain combinations of colorants and opaquants to make them distinctive, many with caps and bodies of different colors. Gelatin is obtained by the partial hydrolysis of collagen obtained from the skin, white connective tissue, and bones of animals. In commerce, it is available in the form of a fine powder, a coarse powder, shreds, flakes, or sheets. Gelatin is soluble in hot water and in warm gastric fluid; a gelatin capsule rapidly dissolves and exposes its contents. Gelatin, being a protein, is digested by proteolytic enzymes and absorbed. Advantages of hard gelatin capsule are rapid drug release possible, flexibility of formulation and sealed HGCs are good barriers to atmospheric oxygen. Disadvantages of this dosage form are very bulky materials are a problem, filling equipment process is slower than tablets, generally more costly than tablets, but must judge on a case-by-case basis; concern over maintaining proper shell moisture content.

Tetracycline is used to treat a wide variety of infections, including acne. It is an antibiotic that works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for viral infections (e.g., common cold, flu). First Tetracycline hydrochloride granules are prepared by using wet granulation technique by using required ingredients. Then these granules are filled in the hard gelatin capsule shell

FORMULA:

Name of the ingredient	Quantity (mg)
Tetracycline hydrochloride	100
Microcrystalline cellulose	38
PVPK30	6
Magnesium stearate	4
Talc	2
Alcohol	q.s

PROCEDURE:

Formulation of Granules of Tetracycline hydrochloride:

Tetracycline hydrochloride granules were prepared by wet granulation method. Specified quantity of tetracycline hydrochloride, micro crystalline cellulose and PVP K30 will be weighed and mixed uniformly. Required quantity of alcohol drop wise incorporated to the blend. Wet granules will be passed through sieve #10 & air dried for 15 minutes. The dried granules will then be passed through sieve #22. Required quantity of magnesium stearate & talc were added to the granules. The prepared granules were then added to the Size #3 empty hard gelatin capsule.

Evaluation of prepared capsule of tetracycline hydrochloride:

Weight Variation Test: Twenty capsules were selected randomly from each batch and weighed individually on electronic balance. The individual weighed is then compared with average weight for the weight variations. The % difference should be 10%.

Disintegration time Testing: It was determine using disintegration test apparatus, using 900 ml of distilled water with disk (in case capsule floats) at room temperature. Test was performed on 6 capsules. One capsule each is kept in all six tubes. The tubes travel upward and downward in water at 37°C±2°C. The capsules pass the test if no drug or particles other than capsule fragments remained on the mesh or tube. The time taken for that is considered as disintegration time.

In vitro drug release study: The release rate of Tetracycline hydrochloride from capsule was determined using United States Pharmacopeia (USP) Dissolution Testing Apparatus Type-II. The dissolution test was performed using 900ml of 5.8pH phosphate buffer, at 37°C±0.5°C and 50 rpm. A sample (10ml) of the solution was withdrawn from the dissolution apparatus hourly and the samples were replaced with fresh dissolution medium.

The samples were filtered through a 0.45µ membrane filter. Absorbance of these solutions was measured at 344 nm using a Thermospectronic-1 UV/V double-beam spectrophotometer. Cumulative percentage drug release was calculated using an equation obtained from a standard curve.

REPORT: Tetracycline hydrochloride hard gelatin capsules were prepared and evaluated.

VIVA QUESTIONS:

- Define capsule?
- What are the types of capsule?
- What are the advantages and disadvantages of hard gelatin capsules? What is the source and properties of gelatin?
- What is the use of tetracycline?
- What is the use of PVPK30 in the above formulation? What are the evaluation tests of capsules?

Experiment No: 08

PREPARATION OF CALCIUM GLUCONATE INJECTION

AIM: To prepare and submit 10 ml Calcium gluconate injection.

REQUIREMENTS: Beaker, Glass rod, Funnel, Filter paper, Ampoule

PRINCIPLE: Injections are sterile solutions, emulsions or suspensions. They are prepared by dissolving, emulsifying or suspending an active ingredient and any other substances in water for injection. Injecting is the act of giving medication by use of syringe and needle to obtain the desired therapeutic effect taking into account the patient's safety and comfort. It is suitable for those drugs that are altered or not absorbed by other methods of administration.

Calcium gluconate is a mineral supplement and medication. As a medication it is used by injection into a vein to treat low blood calcium, high blood potassium, and magnesium toxicity. Supplementation is generally only required when there is not enough calcium in the diet. Calcium Gluconate is the calcium salt of gluconic acid, an oxidation product of glucose, and contains 9.3% calcium, which is about one-third of the calcium in strength of calcium chloride USP. Since it is soluble to the extent of only one part in 30 parts of cold water, the 10% solution is supersaturated and is stabilized by the addition of calcium saccharate tetrahydrate 0.46% w/v.

FORMULA:

Ingredients	1 ml injection	10 ml injection
calcium gluconate monohydrate	98 mg	
calcium saccharate tetrahydrate	4.6 mg	
Water for injection upto	1 ml	

PROCEDURE: calcium gluconate monohydrate and calcium saccharate tetrahydrate are dissolved in water for injection in a beaker and makes upto required volume. Filter it and take 1 ml of the filtrate. Then it is transferred into previously sterilized ampoules, sealed properly and sterilized by autoclaving.

USES: It is used as mineral supplement and medication.

REPORT: Calcium gluconate injection were prepared and submitted

VIVA QUESTIONS:

- What is the use of calcium gluconate?
- What are the general methods to prepare injections?
- What is the use of calcium saccharate tetrahydrate?

Experiment No: 09

PREPARATION OF ASCORBIC ACID INJECTION

AIM: To prepare and submit 2 ml ascorbic acid injection.

REQUIREMENTS: Beaker, Glass rod, Funnel, Filter paper, Ampoule

PRINCIPLE: Injections are sterile solutions, emulsions or suspensions. They are prepared by dissolving, emulsifying or suspending an active ingredient and any other substances in water for injection. Injecting is the act of giving medication by use of syringe and needle to obtain the desired therapeutic effect taking into account the patient's safety and comfort. It is suitable for those drugs that are altered or not absorbed by other methods of administration. Ascorbic Acid (vitamin C) is a water-soluble vitamin. It occurs as a white or slightly yellow crystal or powder with a light acidic taste. It is an antiscorbutic product. Ascorbic Acid injection is a clear, colourless to slightly yellow sterile solution of Ascorbic Acid in Water for Injection, for intravenous, intramuscular or subcutaneous use.

FORMULA:

Ingredients	1 Ampoule	2 Ampoules
Ascorbic Acid	0.5 gm	1 gm
Water for injection upto	2 ml	4 ml

PROCEDURE: Ascorbic acid is dissolved in water for injection in a beaker and makes upto required volume. Filter it and take 2 ml of the filtrate. Then it is transferred into previously sterilized ampoules, sealed properly and sterilized by autoclaving.

USE: It is used as anti-scurvy.

REPORT: Ascorbic acid injection were prepared and submitted

VIVA QUESTIONS:

- What is injection?
- Why drugs give in injection form? What is the use of ascorbic acid?
- What are the routes of administration of ascorbic acid injection

Experiment No: 10

QUALITY CONTROL TEST OF (AS PER IP) MARKETED TABLETS AND CAPSULES

Aim: Quality control test of marketed tablets and capsules as per I.P.

REQUIREMENTS: Volumetric flask, Mortar and pestle, Pipette, Beaker, Stop watch, Measuring cylinder, Whatman filter paper, UV spectrophotometer, Dissolution apparatus.

PRINCIPLE: Quality control is a procedure or set of procedures intended to ensure that a manufactured product or performed service adhere to a defined set of quality criteria or meets the requirement of the client or costumer. Quality is not an accident this is the result of intelligent effort. The quality in the pharmaceutical industry has become a very important and sensitive issue. In the pharmaceutical industry, it is essential for controlling the errors during the every stage in production process since total quality of the product must be ensured according to compendia of drugs. In order to determine the specifications of the finished product, the quality characteristics related to the manufacturing process should be taken into account. An appropriate specification for each aspect of quality studied during the phase of development and during the validation of the manufacturing process should be determined. At least those aspects considered to be critical should be the object of specifications routinely verified.

Content of active ingredients (Tablets/Capsules): For this test according to IP determine the amount of active ingredient(s) by the method described in the assay and calculate the amount of active ingredient(s) per tablet/ capsule. The result lies within the range for the content of active ingredient(s) stated in the monograph. This range is based on the requirement that 20 tablets/ capsules, or such other number as may be indicated in the monograph, are used in the assay. Where 20 tablets/ capsules cannot be obtained, a smaller number, which must not be less than 5, may be used, but to allow for sampling errors the tolerances are widened in accordance with Table 1. As specified by the IP requirements Table1 apply when the stated limits are between 90 and 110 percent. For limits other than 90 to 110 percent, proportionately smaller or larger allowances should be made.

Content of active ingredients test

weight ofactive ingredients in each tablet/capsule	**Subtract from lower limit for samples of**			**Add to the upper limit for samples of**		
	15	**10**	**5**	**15**	**10**	**5**
0.12 g or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 0.12 g But less than 0.3 g	0.2	0.5	1.2	0.3	0.6	1.5
0.3 g or more	0.1	0.2	0.8	0.2	0.4	1.0

Uniformity of content for tablets: The content uniformity test is to ensure that every dosage form contains equal amount of drug substance i.e. active pharmaceutical ingredient within a batch. Mainly it is used for testing the consistency of bulk powders before or after compression, liquid orals before filling, also during filling of powders into capsules or liquids into vials or ampoules and amount of active pharmaceutical ingredient within individual unitsof tablets or capsules.

Normally testing is confirmed by performing specific assay to determine the content of drug material contained in particular dosage form. The content uniformity test is used to ensure that every tablet contains the amount of drug substance intended with little variation among tablets within a batch. Due to increase awareness of physiological availability, the content uniformity test has been included in the monographs of all coated and uncoated tablets and al capsules intended for oral administration. Randomly select 30 tablets. 10 of these assayed individually. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% andnot more than 115% of the labeled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablets assayed individually and none may fall outside of the 85 to 115% range.

Uniformity of content for capsules:

This test is applicable to capsules that contain less than 10 mg or less than 10 per cent w/w of active ingredient. For capsules containing more than one active ingredient carry out 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 ingredient(s) in a pooled sample of the capsules has been shown to be within accepted limits of the stated content. Determine the content of active ingredient in each of 10 capsules taken at random using the method given in the monograph or by any other suitable analytical method of equivalent accuracy and precision.

The capsules comply with the test if not more than one of the individual values thus obtained is outside the limits 85 to 115per cent of the average value and none is outside the limits 75 to125per cent. if maximum of three individual values are outside the limits 85 to 115 per cent of the average value repeat the determination using another 20 capsules. The capsules complywith the test if in the total sample of 30 capsules not more than three individual values are outside the limits 85 to 115 per cent and none is outside the limits 75 to 125per cent of the average value.

Dissolution Test:

Dissolution is the process by which a solid solute enters a solution. Dissolution is pharmaceutically defined as the rate of mass transfer from a drug substance into the dissolution medium or solvent under standardized conditions of liquid/solid interface, temperature and solvent composition. Dissolution is considered one of the most important quality control tests performed on pharmaceutical dosage forms and is now developing into a tool for predicting bioavailability, and in some cases, replacing clinical studies to determine bioequivalence. Two types of apparatus are generally used to carry out dissolution. Usually apparatus Type I (Paddle type) is employed in the evaluation of tablets (or capsule) containing poorly water soluble drugs while apparatus Type II (basket type) is used for partially water soluble drugs. This test is designed to determine compliance with the dissolution requirements for solid dosage administered orally. The test is intended for a: apside or tablet. This test is provided to determine compliance with the dissolution equirements for solid dosage forms administered orally.

Dissolution Medium: Use the dissolution medium specified in the individual monograph. if the medium is a buffered solution, adjust the solution so that its pH is within 0.05 units of the pH specified in the monograph.

Method: Place the stated volume of the dissolution medium, free from dissolved air, into the vessel of the apparatus. Assemble the apparatus and warm the dissolution medium to 36.5° to 37.5°. Unless otherwise stated, place one dosage unit simultaneously and in a reproducible way in the apparatus, taking care to exclude air bubbles from the surface of the dosage unit. When Apparatus 1 is used, allow the tablet or capsule to sink to the bottom of the vessel priorto the rotation of the paddle.

A suitable device such as a sinker made up of stainless steel maybe used to keep the dosage unit horizontal at the bottom of the vessel for tablets or capsules that would otherwise float. When Apparatus II is used, place the tablet or capsule in a dry basket at the beginning of each test. Lower the basket into position before rotation. Operate the apparatus immediately at the speed of rotation specified in the individual monograph. Within the time interval specified, or at each of the times stated, withdraw a specimen from a zone midway between the surface of the dissolution medium and the top of the rotating blade or basket, not less than 10 mm from the waft of the vessel. Specimen withdrawal at each sampling time point should be from the same location either manually or automatically. Measure media temperature at each sampling time point, the inter-vessel temperature should agree within a range of 0.4°C. Except in the case of single sampling, add a volume of dissolution medium equal to the volume of the samples withdrawn. Filter the sample solution promptly through a membrane filter disc with an average pore diameter not greater than LORI. Discard the first few ml of the filtrate. Perform the analysis as directed In the individual monograph Repeat the whole operation five times. Where two or more tablets or capsules are directed to be placed together in the apparatus, carry out six replicate tests. The results are plotted as concentration versus time.

OBSERVATIONS:

Content of active ingredients of tablets

Tablet no	Drug content in each tablet (T1)	Average drug content (T2)	Difference in drug content (T1-T2)	% Difference	More than Less than official limit

Uniformity of drug content

Tablet no	Drug content in each tablet (T1)	Average drug content (T2)	Difference in drug content (T1-T2)	% Difference	More than less than official limit

DISSOLUTION TEST

Test tube	Time(min)	Filtrate(ml)	Dilution fluid(ml)	Absorbance

Results:

I. Tablet compliance on the specification of I.P. for content of active= Passes/Fails

II. Tablets compliance on the specification of I.P. for uniformity of content = Passes/Fails

III. The percentage of drug present in tablet dissolved in 30 min =

IV. Capsule compliance on the specification of I.P. for content of active =Passes/Fails

V. Capsules compliance on the specification of I.P. for uniformity of content = Passes/Fails

VI. The percentage of drug present in capsule dissolved in 30 min= -------- %

Experiment No: 11

PREPARATION OF EYE OINTMENT

AIM: To Prepare and submit 3 tubes each containing 4gm of eye ointment.

REQUIREMENTS: Beaker, glass rod, measuring cylinder, water bath, spatula.

PRINCIPLE: Antibiotics are popularly used in solution or in ointment for the ophthalmic route. Conventional ocular formulations such as emulsions, suspensions, and ointments are developed to improve solubility, precorneal residence time and ocular bioavailability of drugs. Along with drops, ointments are the most common way to treat many eye problems. Because the go right into eyes, they can start to work much faster than a medicine taken by mouth. Eye ointments are drugs in a greasy, semisolid form. Once ointment applied to eyes, itbreaks into tiny drops. These hang out between eyeball and eyelid for a while. Ophthalmic ointments are another class of carrier systems developed for topical application. Ocularointment comprises of mixture of semisolid and a solid hydrocarbon (paraffin). At has a melting point at physiological ocular temperature (34°C). The choice of hydrocarbon is dependent on biocompatibility. Ointments help to improve ocular bioavailability and sustain

FORMULA:

Ingredients	For 100 gm	For 10 ml
White soft paraffin	80gm	
Wool fat	10gm	
Liquid paraffin	10ml	

PROCEDURE:

1. Weigh and measure all the required ingredients of cold cream properly and keep them separately
2. Add white soft paraffin and wool fat in 100m1 beaker and melt them in order of melting point.

3. Add liquid paraffin to the main preparation with continuous stirring.
4. Transfer the prepared ointment to the suitable container

PRECAUTION: Avoid contamination during use.

Uses:

1. Eye ointment use in acute or long – term problems.
2. Eye infections.
3. Inflammation condition.
4. Soreness, with dry-eye syndrome.

Examples of eye ointments: Chloramphenicol ointment, Tetracycline ointment, Hydrocortisone ointment

REPORT: Eye ointment were prepared and submitted

VIVA QUESTIONS:

- What are eye ointments?
- What are the different types of drugs it may contain?
- What are the formulation parameter

Evaluation of Glass containers (As per IP)

Experiment No: 12

PREPARATION OF ATROPINE EYE DROPS

AIM: To prepare and submit 10 ml of Atropine eye drop.

REQUIREMENTS: Beaker, Glass rod, Measuring cylinder, Conical flask

PRINCIPLE: Eye drops are saline-containing drops used as an ocular route to administer. Depending on the condition being treated, they may contain steroids, antihistamines, sympathomimetics, nonsteroidal anti-inflammatory drugs (NSAIDs), antibiotics, antifungal, or topical anesthetics. Eye drops sometimes do not have medications in them and are only lubricating and tear-replacing solutions. Eye drops are also used for stopping itching and redness of the eyes. Atropine eye drop is used before eye examinations (e.g., refraction) and to treat certain eye conditions (e.g., uveitis). It belongs to a class of drugs known as anticholinergic. Atropine works by widening (dilating) the pupil of the eye.

FORMULA:

Ingredients	For 100 ml	For 10 ml
Atropine sulphate	1 gm	
Phenyl mercuric nitrate solution, 0.004% w/v	50 ml	
Purified water upto	100 ml	

PROCEDURE: Weigh the medicament and dissolve it in the bactericidal solution in a small conical flask. Transfer it to a 10 ml measure, rinse the flask, and adjust the final volume with purified water. Sterilize it by autoclaving at 115°C for 30 mins.

PRECAUTION: Avoid contamination during use.

REPORT: Atropine eye drops were prepared and submitted

VIVA QUESTIONS:

- What is the use of Atropine sulphate eye drops?
- What is the use of Phenyl mercuric nitrate?
- Give some example of antibacterial agents used in eye drops
- How we can sterilize Atropine sulphate eye drops

Experiment No: 13

PREPARATION OF COLD CREAM

AIM: To prepare and submit 10gms of cold cream (w/o type of emulsion)

APPARATUS: Beaker, glass rod, china dish, mortar and pestle, thermometer.

PRINCIPLE: Cold cream is w/o type of emulsion, which when applied to the skin, a cooling effect is produced, due to the slow evaporation of water, present in emulsion. Cold cream is prepared by saponification reaction between and alkali-borax; i.e borax reacts with free fatty acids of bees wax and produce borax soap in-situ (ester of fatty acid). This soap acts as emulsifying agent.

In cold cream, the internal phase is oil and external phase is water, hence it forms o/w type of emulsion. But after application on the skin, water evaporates and leads to phase inversion from o/w type to w/o type emulsion. Therefore oily phase, which is remaining (left) on the skin, gives emollient nature. Liquid paraffin is used as emollient and rose oil is used as perfume, to give a pleasant flavour to the cream.

Ingredients table (Formula):

Ingredients	Official formula	Working formula
White Bees Wax		
Liquid paraffin(emollient)		
Borax		
Water		
Perfume		

PROCEDURE:

Since there will be little wastage ((loss) during weighing and preparing, to manipulate these practical losses, calculate the ingredients for at least one or two grams extra, than prescribed.

1) Grate the white beeswax in to small pieces. Weigh the required quantity of white beeswax and liquid paraffin and melt in china dish, by heating on a water bath up to 70°C.

2) In a glass beaker, dissolve borax in water and heat up to 70°C

3) When both oily and aqueous phases reach the same temperature (70°C), gradually add borax solution to the melt of beeswax, with constant stirring.

4) Stir continuously until it becomes cool. When the temperature lowers to 40-45°C, incorporate rose oil and mix uniformly, until a homogenous semi solid mass is obtained.

Dispensing: weigh the prescribed quantity of cream on a butter paper and transfer to an ointment jar or metallic/plastic collapsible tube, close it thoroughly and label.

DIRECTION: Apply to skin.

USES: Cold cream is used as an emollient for the treatment of dry skin. Hence this becomes quite popular in winter season.

STORAGE: Store in a cool place but do not allow to freeze.

Auxiliary label: FOR EXTERNAL USE ONLY

REPORT: 10gms of cold cream were prepared and submitted.

VIVA QUESTIONS:

- What are creams?
- How is cold cream prepared?
- What is the difference between ointments and creams? What is the use of liquid paraffin in cold cream?
- What is saponification?

Experiment No: 14
PREPARATION OF VANISHING CREAM

AIM: - To prepare and submit 10gms of vanishing cream (o/w type).

APPARATUS: China dish, glass rod, beaker, Bunsen burner, thermometer

PRINCIPLE: Vanishing cream is o/w type of emulsion, which when applied to the skin, it vanishes and leaves an almost invisible layer on it. Hence it is called as 'vanishing cream'. The layer left behind after application, acts as a base or foundation, for facial make up. Hence vanishing creams are also called as 'foundation creams'. Since water is an external phase, it will be quickly washed off with water.

The main ingredients of vanishing creams are stearic acid, alkali and water. Stearic acid gives a pearly white shining appearance to the cream, which on application gives a thin white film of free stearic acid. Soap is prepared in-situ by the chemical reaction between alkali and stearic acid, which is used as emulsifying agent.

Vanishing creams are o/w type emulsion; there is a possibility of evaporation of water from the external phase of emulsion. Therefore, glycerine, polyethylene glycol or alcohol are incorporated as humectants, to prevent the drying out of cream, since external phase of vanishing cream is aqueous, it should be protected from the contamination, from microorganisms by adding suitable preservatives, like methyl paraben or propyl paraben. These creams are also be scented pleasantly, using suitable perfumes in small quantities.

Ingredients table (Formula):

Ingredients	Official Formula(100 gm)	Working Formula
Stearic acid		
Potassium hydroxide		
Glycerine(humectants)		
Methyl paraben		
Water		
Perfume		

PROCEDURE:

- Melt stearic acid in china dish on water bath by heating up to 70^0C.
- In a beaker, Dissolve KOH, and methyl paraben (methyl parahydroxybenzoate) in water, add glycerin to it.
- Heat this aqueous solution up to 70^0C on water bath.

- When both aqueous and oil phases reaches the same temperature 70^0C, add aqueous phase to the melted stearic acid with continuous stirring.
- Remove the dish from heat and continue the stirring and when temperature reaches 40^0C, add perfume.
- Mix uniformly until it becomes cool and homogenous cream is obtained.

DISPENSING: Weigh the prescribed quantity of cream on the butter paper and transfer to a wide mouthed, small, screw capped plastic or glass bottle or to collapsible tube, seal and label.
DIRECTION: Used for external application. Apply to skin where ever necessary.

STORAGE: store in a cool place.

AUXILIARY LABEL: FOR EXTERNAL USE ONLY

USES: vanishing cream is used as foundation for holding the makeup preparation for longer period.

REPORT: 10gms of vanishing cream were prepared and submitted.

VIVA QUESTION:

1. What is vanishing cream?
2. What is the use of vanishing cream?
3. Why it is also called foundation cream?
4. What is the use of stearic acid and methyl paraben in vanishing cream?
5. What is humectant?

Experiment No: 15

EVALUATION OF GLASS CONTAINERS (AS PER IP)

AIM: To carryout different evaluate tests of glass container as per I.P.

REQUIREMENTS: Class container, Beaker, Conical flask, Burette, Mortar and pestle, Sieve

PRINCIPLE: Glass containers may be colourless or coloured. Neutral glass is a borosilicate glass containing significant amounts of boric oxide, aluminum oxide, alkali and/or alkaline earth oxides. It has a high hydrolytic resistance and a high thermal shock resistance. Soda-lime-silica glass is a silica glass containing alkali metal oxides, mainly sodium oxide and alkaline earth oxides, mainly calcium oxide. It has only a moderate hydrolytic resistance.

According to their hydrolytic resistance, glass containers are classified as:

- Type I glass containers which are of neutral glass, with a high hydrolytic resistance, suitable for most preparations whether or not for parenteral use.
- Type II glass containers which are usually of soda-lime- silica glass with high hydrolytic resistance resulting from suitable treatment of the surface. They are suitable for most acidic and neutral, aqueous preparations whether or not for parenteral use.
- Type III glass containers which are usually of soda- lime-silica glass with only moderate hydrolytic resistance. They are generally suitable for non-aqueous preparations for parenteral use, for powders for parenteral use and for preparations not for parenteral use.Glass containers intended for parenteral preparations may be ampoules, vials or bottles. Glass is a common material to be used in either non sterile or sterile liquid dosage forms. It leaches alkali from its surface. Hence, a limit test for alkalinity is to be performed before using it for a particular product. USP and IP provide two tests to determine the chemical resistance of glass containers.

1. Powdered Glass Test

From the glass containers, alkaline constituents (oxides of sodium, potassium, calcium, aluminum, etc.) are leached into purified water under conditions of elevated temperatures. When the glass is powdered the leaching of alkali can be enhanced in the powdered is critical. The principle involved in the powdered glass test in estimate the amount of alkali leached form the glass powder. The amount of acid that is necessary to neutralize the released alkali (a specified limit) is specified in the pharmacopoeia. The basic analysis is acid-base titration using methyl red indicator.

2. Water Attack Test

This is only for treated soda lime glass containers under the controlled humidity conditions which neutralize the surface alkali and glass will become chemically more resistant. The principle involved in the water attack test is to determine whether the alkali leached form the surface of a container is within the specified limits or not. Since the inner surface is under test entire container (ampoule) has to be used. The amount of acid that is necessary to neutralize the released alkali from the surface is estimated, the leaching of alkali is accelerated using elevated temperature for a specified time. Methyl red indicator is used to determine the end point. The basic is acid-base titration.

PROCEDURE:

Powdered glass test:

Step-1: **Preparation of glass specimen**: Few containers are rinsed thoroughly with purified water and dried with stream of clean air. Grind the containers in a mortar to a fine powder and pass through sieve no.20 and 50.

Step-2: **Washing the specimen**: 10gm of the above specimen is taken into 250 ml conical flask and wash it with 30 ml acetone. Repeat the washing, decant the acetone and dried ate specimen after which it is used within 48hr.

Step-3: 10gm sample is added with 50ml of high purity water in a 250ml flask. Place it in an autoclave at 121°C±2°C for 30min.Cool it under running water. Decant the solution into another flask, wash again with 15ml high purity water and again decant. Titrate immediately with 0.02N sulphuric acid using methyl red as an indicator and record the volume.

Water attack test:

Rinse thoroughly with high purity water. Fill each container to 90%of its overflow capacity with water and is autoclaved at 121°C for 30min then it is cooled and the liquid is decanted which is titrated with 0.02N sulphuric acid using methyl red as an indicator. The volume of sulfuric acid consumed is the measure of the amount of alkaline oxides present in the glass containers.

Limits of alkalinity for glass containers

TESTS	CONTAINER	VOL.OF 0.02N H_2SO_4
Powdered glass test	Type I	1.0
	Type II	8.5
	Type III	15.0
Water attack test	Type II(100ml or below)	0.07
	Type II(above 100ml)	0.02

REPORT: Evaluation test for glass containers were performed.

VIVA QUESTIONS:

- What are the different types of glass container? What are the major components of glass?
- What type of substances can be packed in type-III glass container? What is type – IV glass container? What is the use?
- Which indicator is used in powder glass test?
- What is the main principle involved in water attack

Vision and Mission of the Institution

Vision

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

Mission

M1 Create pharmacy graduates through **quality education**

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

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

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