AmbujaNeotia

THE NEOTIA UNIVERSITY

ज्ञानम् आत्म प्रदीपाय

INDUSTRIAL PHARMACY - I

PRACTICAL LAB MANUAL

V SEMESTER (B.PHARM)

1. PREFORMULATION STUDIES ON PARACETAMOL

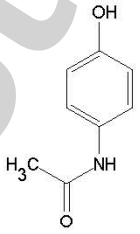
Aim:to evaluate the preformulation parameters of paracetamol

Principle:preformulation commences when a newly synthesized drug shows sufficient pharmacological promise in animal models to warrants evaluation in man. These studies should focus on properties of a new compound that could affect the drug performance in development of efficacious dosage form. A thorough understanding of these properties may ultimately provide a rationale for formulation design or support the need for molecular modification.

Defnition:preformulation involves the application of biopharmaceutical principles to physicochemical parameters of drug substance are characterized with a goal of designing optimum drug delivery system. Characterization of drug molecule is a very important step of preformulation stage of product development.

- **Name of the compound :**paracetamol
- **Chemical name:**n-acetyl-para-aminopheno.
- **Molecular formula:** $c_8h_9no_2$
- **Molecular weight:** 151.165 g·mol−1

molecularstructure



- **Description:** white powder.
- **Category:** pain and fever ,nonsteroidal anti-inflammatory drug.
- **dose:** 500 mg.
- **Storage:** store protected from light and moisture
- **Organoleptic characteristics:**

Bulk density:apparent bulk density (ρb) was determined by placing the granules into a graduated cylinder and measuring the volume (vb) and weight (m) "as it is".

pb = m/vb

Weight of sample =

Volume of sample =

Bulk density =

Tapped density: the measuring cylinder containing a known mass of granules was tapped for 100 times using a bulk density apparatus. The minimum volume (vt) occupied in the cylinder and the weight (m) of the granules was measured. The tapped density (pt) was calculated using the formula.

pb = m/vb

tapped volume =

tapped density =

Carr's index: it is the measure of potential strength that a power could build up in its arch in a hopper and also the ease with which such an arch could be broken. Compressibility index of the granules was determined by using the formula.

$$Ci\ (\%) = [(pt - pt/pt)] \times 100$$

Carr's index (%)	**Type of flow**
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
>40	Extremely poor

Bulk density =

Tapped density =

Ci =

Hausener's ratio: it is the measure of the flow property of the drug.

hausener's ratio = pt/pb

Angle of repose: it is the maximum angle possible between the surface of the pile of the powder and the horizontal plane. The angle of repose was measured by using funnel method, which indicates the flow ability of the granules.

Angle of repose is determined by the following formula.

$\tan \theta = h/r$

where θ = angle of repose

h and r are the height and radius of the powder cone.

$\theta = \tan^{-1} h/r$

$\theta =$

Angle of repose (θ)	**Type of flow**
<25	Excellent
25-30	Good
30-40	Fair/passable
>40	Very poor

Solubility analysis: The solubility of drug is an important physicochemical property because it effects the bioavailability of the drug, the rate of drug release into dissolution medium and consequently, the therapeutic efficiency of the pharmaceutical product.

This is a valuable step in developing a formulation. Solubility is usually determined in variety of commonly used solvents and some oils if the molecules are lipophilic. The solubility of material is usually determined by the saturated/ equilibrium solubility method, which employs a saturated solution of the material, where excess quantity of drug is taken in 10ml of each solvent and occasionally stirred for 24hrs at room temperature and sample was filtered and filtrate was suitably diluted and analyzedspectrophotometrically at 249nm.

Solubility	Parts of solvent required for 1 part of solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10000
Practically insoluble	10000 or more

The solvents used are distilled water, ethanol, chloroform and 0.1n hcl.

solubility of paracetamol in different solvents:

S.no	Solvent	Absorbance	Dilution factor	Concentration (mg/ml)	Solubility (parts required to dissolve 1g of drug)
1.	Water				
2.	Ethanol				
3.	0.1 n hcl				
4.	Chloroform				

Ph: a 50% w/v drug solution was analysed for its ph by using ph meter.

Report:

2. FORMULATION PARACETAMOL TABLETS

Aim: to formulate and evaluate the paracetamol tablets

Materials required apparatus:

Mortar and pestle, beaker, sieve # 10, tablet punching machine, hot air oven.

Chemicals:paracetamol, lactose, dry starch, magnesium stearate, talc.

Theory:

paracetamol has analgesic and antipyretic properties but it has no useful anti- inflammatory properties. Paracetamol is readily absorbed from the gastrointestinal tract. Paracetamol is categorized under bcs classification ii tablets are solid dosage forms containing one or more drugs with or without excipients, prepared by compression. It provides greatest dose precision and least content variability. Inert materials employed in addition to active ingredients are collectively called tablet additives. They include

1. **Diluents:** are fillers designed to make up the required weight of the tablet. Eg: lactose, inorganic dicalcium salts microcrystalline cellulose etc.

2. **Binding agents**: are added in dry or in liquid form to obtain cohesive mass for direct compression. Eg: cellulose derivatives, gelatin solution, glucose syrup, tragacanth mucilage etc.

3. **Disintegrating agents**: are added to facilitate breakup of the tablet when in contact with gastrointestinal fluids. Eg: dry starch, starch derivatives, clays, cellulose, cellulose derivatives, alginates

4. **Adsorbents:** included when formulation contains liquids, volatile oils etc.

5. **Antifrictional agents**: enhance flow properties. Eg : talc, corn starch, silica derivatives etc.

The usual methods of formulation include **wet granulation, dry granulation and direct compression.** The most widely used and most general method of tablet preparation is the **wet granulation method.** The active ingredient, diluent and disintegrents are mixed or blended well. Solutions of the binding agent are added to the mixed powder with stirring. The powder mass is wetted with the binding solution until the mass has the consistency of damp snow. If

the granulation is over wetted the granules will be hard, if not wetted sufficiently, the resulting granules will be too soft, breaking down during lubrication. The wet mass is forced through a 6 or 8 mesh (mesh no. Is the number of wires passing through an inch) screen or several mills can be used .moist materials from wet milling steps is placed on large trays and placed in drying chambers with a circulating air current and thermostable heat controller. Commonly used dryers are tray dryer, fluidized bed dryer. After drying, the granulation is reduced in particle size by passing smaller mesh screen. After drying granulation, the lubricant or glidants is added as fine powder to promote flow of granules. These granules then compressed to get tablet

3. **tablets are evaluated for their general appearance, hardness, friability, drug content, release, weight variation, dissolution and disintegration properties.**

Procedure Formula for Design ofParacetamol Tablets:

Ingredients for	1 tablet(mg)	For 40 tablets(g)
Paracetamol (drug)	125	5g
Lactose (diluent)	375	15g
Drystarch(binder &disintegrant)	48	1.92g
Talc (glidant)	40	1.6g
Magnesium stearate(lubricant)	12	0.48g
5%starch was used as the binding agent.	Qs	Qs

The tablets was granulated using wet granulation method as follows.

Paracetamol, lactose and half the quantity of starch were weighed and mixed thoroughly. It was granulated using 5% starch mucilage as binding agent and passed through no.10 mesh screen. The obtained the granules were dried at 55°c for 1 hr. After drying, dry screening was done using no.22 mesh screen. The rest of the starch powder along with talc

and magnesium stearate were added and mixed. These granules were compressed into tablets on a 16 station cadmach rotary tablet machine (12mm).

5. evaluation of tablets

1. Hardness test: tablet hardness was measured using monsanto hardness test apparatus.

2. Weight variation test: 20 tablets are weighed individually. Calculated the average weight and individual weight are compared with the average weight.

3. Friability test: friability is a measure of mechanical strength of the tablet. If a tablet has more friability it may not remain intact during packaging, transport or handling. Roche friabilator is used to determine the friability by following procedure. Pre weighed tablets are placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for at least 4 minutes. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as: % friability = 1- (loss in weight / initial weight) x 100

4. Assay: 20 tablets are powdered and weighed. A quantity of powder equivalent to about 0.15g of paracetamol are accurately weighed and added 50ml of 0.1m sodium hydroxide, diluted with 100ml of water, and shaked for 15 mins and added sufficient water to produce 250ml. They are mixed filtered and diluted 10ml of the filtrate to 100ml with water. To 10ml of resulting solution 10ml of 0.1m sodium hydroxide are added and diluted to 100ml with water and mixed. The absorbance of the resulting solution at the maximum at about 257nm were measured by using uv-visible spectroscopy.

5. Disintegration study experimental conditions were: medium: water speed: 30cycles/minute

temperature: 37±0.5°c one tablet was added into each of the 6 tubes of the apparatus and the assembly was suspended in a beaker containing water and time required to disintegrate each tablet was noted. From this average disintegration time was determined.

6. Dissolution study: the study was carried out using type-2 paddle type usp apparatus. The set condition was 900ml of 6.8ph phosphate buffer, at 50 rpm, 37°c for 45 minutes, 5ml of samples were withdrawn at time intervals of 5, 15, 30, 45 minutes, which was replaced by fresh equal volume of dissolution medium, the sample was diluted suitably, assayed at 249nm

by using uv-visible spectroscopy. The calibration curve was used to determine the drug concentration per ml. The amount of drug release was calculated using calibration curve method. Amount of drug release = $conc.\times vol.of.dissolutionmedium\times dilfactor$ 1000 percentage drug release = $amountofdrugreleasestrength$ x 100 report the formulation and comparative evaluation of marketed paracetamol tablets was performed.

3. FORMULATION ASPIRIN TABLETS

Aim: to formulate and evaluate the aspirin tablets

Materials required apparatus:

Mortar and pestle, beaker, sieve # 10, tablet punching machine, hot air oven.

Chemicals: aspirin, lactose, dry starch, magnesium stearate, and talc.

Theory:

Aspirin has analgesic and antipyretic properties but it has no useful anti-inflammatory properties. Aspirin is readily absorbed from the gastrointestinal tract. Aspirin is categorized under bcs classification ii tablets are solid dosage forms containing one or more drugs with or without excipients, prepared by compression. It provides greatest dose precision and least content variability. Inert materials employed in addition to active ingredients are collectively called tablet additives. They include

1. **Diluents:** are fillers designed to make up the required weight of the tablet. Eg: lactose, inorganic dicalcium salts microcrystalline cellulose etc.

2. **Binding agents**: are added in dry or in liquid form to obtain cohesive mass for direct compression. Eg: cellulose derivatives, gelatin solution, glucose syrup, tragacanth mucilage etc.

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4. **Adsorbents:** included when formulation contains liquids, volatile oils etc.

5. **Anti-frictional agents**: enhance flow properties. Eg : talc, corn starch, silica derivatives etc.

The usual methods of formulation include **wet granulation, dry granulation and direct compression.** The most widely used and most general method of tablet preparation is the **wet granulation method.** The active ingredient, diluent and disintegrents are mixed or blended well. Solutions of the binding agent are added to the mixed powder with stirring. The powder mass is wetted with the binding solution until the mass has the consistency of damp snow. If the granulation is over wetted the granules will be hard, if not wetted sufficiently, the resulting granules will be too soft, breaking down during lubrication. The wet mass is forced through a 6 or 8 mesh (mesh no. Is the number of wires passing through an inch) screen or several mills can be used .moist materials from wet milling steps is placed on large trays and placed in drying chambers with a circulating air current and thermostable heat controller. Commonly used dryers are tray dryer, fluidized bed dryer. After drying, the granulation is reduced in particle size by passing smaller mesh screen. After drying granulation, the lubricant or glidants is added as fine powder to promote flow of granules. These granules then compressed to get tablet

4. **tablets are evaluated for their general appearance, hardness, friability, drug content, release, weight variation, dissolution and disintegration properties.**

Procedure Formula for Design of Aspirin Tablets:

Ingredients for	**1 tablet(mg)**	**For 40 tablets(g)**
Aspirin (drug)	300	
Lactose (diluent)	375	
Drystarch(binder &disintegrant)	48	
Talc (glidant)	40	
Magnesium stearate(lubricant)	12	
5%starch was used as the binding agent.	Qs	

The tablets was granulated using wet granulation method as follows.

Aspirin, lactose and half the quantity of starch were weighed and mixed thoroughly. It was granulated using 5% starch mucilage as binding agent and passed through no.10 mesh screen. The obtained the granules were dried at 55°c for 1 hr. After drying, dry screening was

done using no.22 mesh screen. The rest of the starch powder along with talc and magnesium stearate were added and mixed. These granules were compressed into tablets on a 16 station cadmach rotary tablet machine (12mm).

5. evaluation of tablets

1. Hardness test: tablet hardness was measured using monsanto hardness test apparatus.

2. Weight variation test: 20 tablets are weighed individually. Calculated the average weight and individual weight are compared with the average weight.

3. Friability test: friability is a measure of mechanical strength of the tablet. If a tablet has more friability it may not remain intact during packaging, transport or handling. Roche friabilator is used to determine the friability by following procedure. Pre weighed tablets are placed in the friabilator. Friabilator consist of a plastic chamber that revolves at 25 rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets are rotated in the friabilator for at least 4 minutes. At the end of test tablets are dusted and reweighed; the loss in the weight of tablet is the measure of friability and is expressed in percentage as: % friability = 1- (loss in weight / initial weight) x 100

4. Assay: 20 tablets are powdered and weighed. A quantity of powder equivalent to about 0.15g of aspirin are accurately weighed and added 50ml of 0.1m sodium hydroxide, diluted with 100ml of water, and shake for 15 mins and added sufficient water to produce 250ml. They are mixed filtered and diluted 10ml of the filtrate to 100ml with water. To 10ml of resulting solution 10ml of 0.1m sodium hydroxide are added and diluted to 100ml with water and mixed. The absorbance of the resulting solution at the maximum at about 257nm were measured by using uv-visible spectroscopy.

5. Disintegration study experimental conditions were: medium: water speed: 30cycles/minute

temperature: 37±0.5°c one tablet was added into each of the 6 tubes of the apparatus and the assembly was suspended in a beaker containing water and time required to disintegrate each tablet was noted. From this average disintegration time was determined.

6. Dissolution study: the study was carried out using type-2 paddle type usp apparatus. The set condition was 900ml of 6.8ph phosphate buffer, at 50 rpm, 37°c for 45 minutes, 5ml of samples were withdrawn at time intervals of 5, 15, 30, 45 minutes, which was replaced by

fresh equal volume of dissolution medium, the sample was diluted suitably, assayed at 280nm by using uv-visible spectroscopy. The calibration curve was used to determine the drug concentration per ml. The amount of drug release was calculated using calibration curve method. Amount of drug release = $conc.\times vol.of.dissolutionmedium\times dilfactor$ 1000 percentage drug release = $amountofdrugreleasestrength$ x 100 report the formulation and comparative evaluation of marketed aspirin tablets was performed.

4. COATING OF TABLETS – FILM COATING OF TABLES / GRANULES

Aim: To perform coating of granules.

Theory:

Granulation is a technique of particle enlargement by agglomeration, is one of the significant unit operations in the production of pharmaceutical dosage forms, mostly and capsules. During the granulation process, small fine or coarse particles are convened into large agglomerates called granules.

Generally, granulation commences after initial dry mixing of the necessary powder ingredients along with the active pharmaceutical ingredient so that a uniform distribution of each ingredient throughout the powder mixture is achieved.

Formula for Film coating

Coating composition

Ingredients	**Qty Given**	**Qty Taken**
Hydroxy propyl methyl cellulose	4%	
Propylene glycol	1.2%	
Ethyl alcohol	45%	
Methylene chloride	q.s. ad 100%	

Apparatus:

Beaker, measuring cylinder, stirrer, coating pan, spray gun

Procedure:

1. Preparation of Coating Solution: Add the polymer gradually to the ethyl alcohol and agitate the solvent with continuous stirring.
2. Add the some portion of methylene chloride to this suspension so that polymer gets

solubilized.

3. Add the propylene glycol and remainder of methylene chloride to the above solution under constant stirring and the final mixture is mixed well by continuous stirring for 15-20 min.
4. Filter the prepared coating solution.

Granules Coating Operation:

1. Place 200 g of plain granules in the coating pan with three pieces of baffles installed.
2. The plain granules are heated to 4040°C by applying hot air.
3. Adjust the air pressure and the spraying speed of the spray gun to produce properly atomized coating liquid.
4. Turn on the coating pan and change the rotation speed to 20 rpm.
5. Spray the coating liquid onto the granules until a uniform film coating is formed.
6. Keep the distance of 25 inches of coating from the granule bed for efficient coating.
7. Stop spraying and keep the coating pan running for an additional few minutes to avoid sticking between the coated granules.
8. The granules were dried after coating by blowing air.

Observations:

Observations of film coated granules

Test	Observation	Inference
Coating	Uniform/Non uniform	Passes/Fail
Dark marks	Uniform/Non uniform	Passes/Fail

Precautions While Coating:

• During the coating process, the selection of the spraying rate of the coating liquid and the air blowing speed should be made with the aim not to over-wet the granules and to prevent sticking.

• The temperature should not be too high or too low. If the temperature is too high, the coating film formed will not be uniform; on the other hand, if the temperature is too low, drying will be very slow and the coated granules may stick to each other.

• Air bubbles should be avoided during the coating process.

• The coating materials should be passed through a 150-200-mesh sieve if particle agglomeration is present (or homogenized by using a homogenizer).

Results: Plain granules are uniformly film coated and submitted.

5. PREPARATION AND EVALUATION OF TETRACYCLINE CAPSULES

Aim: To Prepare and evaluate 250mg tetracycline capsules.

Theorv:

Capsules are solid dosage forms in which drug or mixture of drug is enclosed in hard gelatin capsule shell, in soft, soluble shell of gelatin, or in hard or soft shell of any other suitable material, of various shapes and capacities': They usually contain a single dose of active ingredient(s) and are intended for oral administration/ Tetracycline is a yellow, odorless, crystalline powder. Tetracycline is stable in air but exposure to strong sunlight causes it to darken. Tetracycline is very slightly soluble in water, freely soluble in dilute add and in alkali hydroxide solutions, sparingly soluble in alcohol, and practically insoluble in chloroform and in ethet. Tetracyclines are readily absorbed and are bound to plasma protein in varying degrees. They are concentrated by the liver in the bile and excreted in the urine and feces at high concentrations in a biologically active form. Tetracycline hydrochloride is a prescription antibiotic used to treat a wide range of infections. Its effective against a broad spectrum of bacteria, as well as other organisms, including some protozoan parasites. tetracycline has commonly been used to treat acne and other skin infections; respiratory tract infections such as pneumonia; genital and urinary infections; and Helicobacter pylori (the bacteria that can lead to stomach ulcers)) Ifs also sometimes used for treating Lyme disease and for preventing anthrax infections. The first drug in the tetracycline family, chlortetracycline was introduced in 1948. Overuse of tetracycline (and other antibiotics) in humans and farm animals have allowed some bacteria to build up a resistance to antibiotics. Doctors are now strongly advised to prescribe tetracycline only when there is proof, or a strong suspicion, that bacteria not a virus - is causing an infection. Since tetracycline does not work for colds, influenza (flu), or other viral infections, if you take it for these conditions, you may be promoting the development of drug-resistant diseases while doing nothing to help your illness.

Synonym: Tetracycline HC1, Achromycin.

Formulation of tetracycline capsules

Ingredients	Qty given/Capsule	Qty taken (No. of capsules x Quantity given)
Tetracycline hydrochloride	250mg	
Dried starch	25mg	
Dried talcum	25mg	

Apparatus:

Mortar and pestle, empty capsules, sieve, hand operated capsule filling machine, volumetric flask, pipette, beaker, stop watch, measuring cylinder, Whatinan filter paper, UV spectrophotometer, Disintegration test apparatus.

Procedure:

1. Weigh the required quantity of drug and other excipients.
2. Moisture content should be less than 1.5%.
3. Starch should be dried and sieved through 100*, moisture less than 1.5%.
4. Talcum should be dried and sieved through 100S, moisture less than 1%.
5. Mix all the ingredients uniformly using mortar and pestle.
6. Empty capsule shells of number "0" is selected and for filling the content in capsule shell.
7. Store capsules in air tight container.

Category: Antibiotic capsule.

Dose: Tetracycline is taken by mouth as a capsule or liquid, typically two to four times a day for seven to 14 days.

1. The usual dose of tetracycline for adults is 1-2 grams per day in two or four divided doses.
2. You should take tetracycline on an empty stomach tth a hill glass of water. Take the drug at least one hour before or two hours after meals or snacks.

Storage: Store in tightly closed container in cool and dry place.

Packing: In a plastic bottle.

EVALUATION OF TETRACYCLINE CAPSULES

Evaluation of Hard Gelatin Capsule

1. Disintegration Time : One capsule was placed in each of six tubes of assembly and assembly was suspended in water. Discs were added to each tube, temperature was maintained at 37±2°C and assembly was operated for 60 min.

2. Drug Content : Weigh an amount of the granules equivalent to 50 mg of losartan potassium was dissolved in 100 ml of phosphate buffer pH 6.8, filtered, diluted suitably and analyzed for the drug content at 246 nm using UV-visible spectrophotometer.

3. In-vitro Drug Release Study: The release rate of losartan potassium from granules was determined using IP Dissolution Test Apparatus Type II (basket type). Granules were first incorporated in empty hard gelatin capsule of size #3 and then placed in a dry basket at the beginning of each test. Lower the basket in the dissolution medium and apparatus was run at 50 rpm, The dissolution test was performed using 900 ml of phosphate buffer pH 6.8, at 37±0.5°C and 50 rpm. 5 ml were withdrawn at time intervals of five minute for 60 minutes. This was maintained at same temperature, was added to the bulk. The samples were filtered through Whatman filter paper no. 41. Absorbance of these solutions was measured using UV-Visible spectrophotometer. Cumulative percentage drug release was calculated using an equation obtained from a standard curve.

6. PREPARATION OF CALCIUM GLUCONATE INJECTION

Aim: To prepare and submit 3 ampoules each containing 10 ml calcium gluconate injection.

Theory:

Calcium is the most abundant cation and the fifth most common inorganic element in the human body. Calcium is essential for the maintenance of the nervous, muscular, and skeletal systems, and for cell membrane and capillary permeability. Its role in bone structure and muscle contraction is well known, but calcium is also important for blood coagulation, nerve conduction, and electrical conduction in the myocardium. Calcium gluconate is calcium salt of gluconic acid, an oxidation product of glucose) an element or mineral necessary for normal nerve, muscle, and cardiac function4alcium as the gluconate salt helps to maintain calcium balance and prevent bone loss when taken orallk)this agent may also be chemopreventive for colon and other cancers. Calcium gluconate injection is a sterile, preservative-free, nonpyrogenic, solution of calcium gluconate, a form of calcium, for intravenous u9 intravenous administration of calcium gluconate increases serum ionized calcium level.ciumgluconatedicearíates into ionized calcium in plasma. Ionized calcium and gluconate are normal constituents of body fluids.

Synonym: d-gluconic acid, calcium salt structure:

Standard IP: calcium gluconate injection contains a quantity of calcium equivalent to not less than 8.5% and not more than 9.4 % of stated amount of calcium gluconate.

Formulation of calcium gluconate injection

Ingredients	Quantity given/ampoule	Quantity taken (no. Of ampoule x quantity given)
calcium gluconate	lg	
calcium D saccharate	350mg	
water for injection (q.$)	10m1	

Apparatus: beaker, measuring cylinder, syringe, needle, ampoules,whatman filter paper/membrane filter, autoclave

Procedure:

1. Type I glass ampoules are selected and clean. The formulation is carried out in clean area.

2. Weigh accurately calcium gluconate and calcium d saccharate.

3. Dissolve calcium gluconate in water for injection in a beaker with application of heat then add calcium d saccharate to it.

4 adjust the ph in between 6-8 with 10% sodium hydroxide solution.

5. Keep the solution for cooling.

6. cooling filter the solution through whatman filter paper/ 0.45 pmmembrane filter to remove any particulate matter.

7. Fill the prepared injection in ampoules (type i) with the help of syringe.

8. Seal the ampoules by pull seal technique.

9. Sterilize the ampoules by autoclaving at 121°c for 30 minutes.

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

Storage: store below 40 °c, preferably between 15 and 30 °c, unless otherwise specified by manufacturer. No preservative added. Store in a well closed container and use only if solution is clear and seal intact.

Dosage: adults: 500 mg - 2 grams (5-20 inn children. 200-500 mg (2-5 ml) infants: not more than 200 mg (not more than 2 ml)

Dosage strengths:

Injectable solution: 100mg/m1 tablet: 50, 500, 650mg

Capsule: 500mg

Route of administration:

Calcium gluconate injection is for intravenous use only, it is not to be administered intramuscularly, intramyocardially, subcutaneously, or permitted to extravasate into any body tissue; may cause severe tissue necrosis and/or sloughing, and abscess formation

Method of administration:

The intravenous administration rate should not exceed 2 ml (0.45 mmol of calcium) per

minute.

The patient should be in the lying position and should be closely observed during injection-monitoring should include heart rate or ecg.

Category: this medication is used to prevent or treat low blood calcium levels in people who do not get enough calcium from their diets. It may be used to treat conditions caused by low calcium levels such as bone loss (osteoporosis).

side effects: constipation and upset stomach, dry mouth, increased thirst, increased urination. Allege reaction such as rash, itching, dizziness, trouble breathing. Precaution,: if you have any of the following health problems, consult your doctor or pharmacist beta° using this product high calcium levels (hypercalcomial, kidney disease, kidney stones link.

7. PREPARATION OF ASCORBIC ACID INJECTION

Ascorbic acid (vitamin c) is a water-soluble vitamin. It occurs as a white or slightly yellow

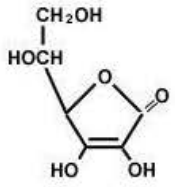
Crystal or powder with a slight acidic taste. It is an antiscorbutic product. On exposure to

Light, it gradually darkens. In the dry state, it is reasonably stable in air, but in solution it

Rapidly oxidizes. Ascorbic acid is freely soluble in water; sparingly soluble in alcohol;

Insoluble in chloroform, in ether, and in benzene. The chemical name of ascorbic acid is lascorbic acid. The empirical formula is c6h806, and the molecular weight is 176.13. The

Structure is as follows:



.Ascorbic acid injection is a sterile solution. Each ml contains: ascorbic acid 250 mg and

Edetate disodium 0.025% in water for injection qs. Prepared with the aid of sodium

Bicarbonate. Sodium hydroxide and/or hydrochloric acid may have been used to adjust ph.

Ingredients	Quantity given/Ampoule	Quantity taken(No.of ampoule x Quantity given)
Ascorbic acid		
Disodium edentate		
Sodium Hydroxide		
Sodium bicarbonate		
Water for injection q.s		

Apparatus: beaker, measuring cylinder, syringe, needle, ampoules, whatman filter paper/membrane filter, Ph meter.

Procedure:

1. Type I glass ampoules are selected and clean. The formulation is carried out in clean area.

2. Weigh accurately ascorbic acid.

3. Dissolve ascorbic acid in water for injection in a beaker with application of heat then add calcium d saccharate to it.

4 adjust the ph in between 6-8 with 10% sodium hydroxide solution.

5. Keep the solution for cooling.

6. cooling filter the solution through whatman filter paper/ 0.45 µmmembrane filter to remove any particulate matter.

7. Fill the prepared injection in ampoules (type i) with the help of syringe.

8. Seal the ampoules by pull seal technique.

9. Sterilize the ampoules by autoclaving at 121°c for 30 minutes.

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

Storage: store below 40 °c, preferably between 2◦ and 8 °c, unless otherwise specified by manufacturer. No preservative added. Store in a well closed container and use only if solution is clear and seal intact.

Uses:

Vitamin C is recommended for the prevention and treatment of scurvy

QUALITY CONTROL TEST:

1. Particulate test
2. Leaker test
3. Sterlity test
4. Content uniformity test
5. Pyrogen test

RESULT:

Ascorbic acid injection ampoules prepared and submitted.

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

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

Theory: 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.

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

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 Table 1 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 of active	**Subtract from lower limit for samples of**			**Add to the upper limit for samples of**		
ingredients in each tablet/capsule	**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 units of 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% and not 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 to 125per 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 comply with 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 prior to the rotation of the paddle. A suitable device such as a sinker made up of stainless steel may be 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=-------- %

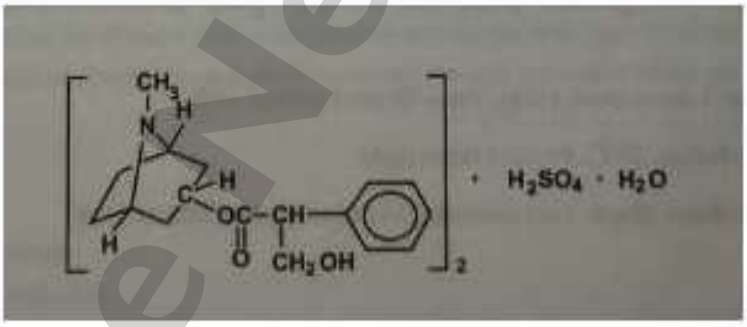
9. PREPARATION OF EYE DROPS

Aim: To Prepare and submit 15ml eye drops.

Theory: Ophthalmic preparations are sterile products, essentially free from foreign particles, suitably formulated and packaged in suitable container for either topical applicatiOlto the eyelids or instillation into the cu-de-sac between the eyeball and eye lids. Eye drops are sterile aqueous or oily solutions or suspension of one or, more medicaments intended for installation into the conjunctival sac for therapeutic purpose. Oily eye drops are less used but may nevertheless occasionally be requested. Certain eye drops may be supplied in a drug, sterile form to be reconstituted in an appropriate sterile liquid immediately before use. In such cases the label should state clearly on the container 'Powder for eye drop' and should include direction for the use of eye drops. Aqueous eye drops contain suitable antimicrobial preservatives at the appropriate concentrations because it is intended for use on more than one occasion: The antimicrobial preservatives should be compatible with the other ingredients of the preparation and should remain effective throughout the shelf life of the eye drops. Eyes drops sometimes do not have medications in them and are only lubricating and tear-replacing solutions. The most commonly employed ophthalmic dosage forms are solutions, suspensions and ointments.

Synonym: Oculumguttae

Structure:



Examples of eye drops; Zinc sulphate eye drop, Framycetin eye drop, Pilocarpine eye drop, Silver nitrate eye drop,

Ingredients	Qty given	Qty taken
Atropine sulphate		
Sodium chloride		
Sterile purified water		

Apparatus. Beaker. glass stirring rod, measuring cylinder, autoclave, spatula.

Procedure :

Weigh and measure all the required ingredients of eye drop properly and keep separately

Take 50rn1 beaker and dissolve sodium chloride in sterile purified water.

Add atropin sulphate and dissolve it by continuous shaking.

The eye drop is clarified by passing through membrane filter.

Sterilize the product by autoclaving at 121◦c for 30 minutes.

Packing: 15ml plastic dropper bottles.

Dose:

Storage condition:Store below 23•C Protect Inc light.

Eye drop. (Each I ml contains 10 mg atropine Sulfate (I %).

Uses:

To induce mydriasis and cvcloplegia.

It also acts on the blood vessels of the iris and ciliary body to restore natural permeability. Conditions which cause inflammation of the anterior segment e.g. iridocyclitis and anterior uveitis.

Observation:

Name of the test	**Specification**	**Observation**
Appearance	Clear, colourless	
pH	6-8	
Clarity test	Free from particulate matter	
Sterility test	sterile	

Result:

Eye drops is prepared and submitted.

10. PREPARATION OF EYE OINTMENT

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

Theory: 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, it breaks 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. Ocular ointment 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 the drug release. Ophthalmic ointment are used to the outside and edges of the eyelids, conjunctiva, cornea and iris. At contains sterilized ingredients packed under rigid aseptic conditions.

Synonym: Oculentum

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

Formula:

Ingredients	Qty given	Qty taken
White soft paraffin	80gm	
Wool fat	10gm	
Liquid paraffin	10ml	

Apparatus:

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

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.

Packing: Aluminium tube with cape or polyethylene screw cap and nozzle.
Dose: Apply eye ointment every three hours .

Storage: Stored below 25∘c and protected from light.

1. Keep the medicine out of children.
2. You are advised to dispose the tube once you have finished your 5 day course of treatment.

Category: Eye ointment

Uses:

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

OBSERVATIONS:

Test	Specification	Observation
Appearance	Pale yellow colour	
Leakage test	No leakage	
pH	6-8	
Homogeneity	Homogeneous and consistent	
Texture	Smooth	
Spread ability	Easily spreadable	

Result:

Eye ointment is prepared and submitted.

11. PREPARATION OF VANISHING CREAMS

Aim: Preparation of 20gm of vanishing cream.

Theory:

A cream is a preparation usually for application to the skin. Creams are semi-solid emulsions of oil and water. They are divided into two types: oil-in-water (0/W) creams which are composed of small droplets of oil dispersed in a continuous water phase, and water-in-oil (W/O) creams which are composed of small droplets of water dispersed in a continuous oily phase. Oil-in-water creams are more comfortable and cosmetically acceptable as they are less greasy and more easily washed off using water) Water-in-oil creams are more difficult to handle. Vanishing creams get their name from the fact that they seem to disappear when spread on the skin. It is also known as foundation cream which are applied to skin to provide a smooth emollient base before the application of face powder and other face make up. Vanishing creams also known for their smooth, dry feel on the skin and their pearly sheen. Chemically they are oil-in-water emulsions consisting of stearic acid, an alkali, a polyol and water. The cream helps the powder to adhere to the skin and also acts as skin protectant which prevents the damaging effect caused by the environmental factors.. One characteristic due to which these vanishing creams are preferred is the 'sheen effect'. Rather than giving a caked look to the face, they give a natural attractive sheen to the skin. Vanishing Creams has the advantage of being non-greasy which makes them suitable for use during the day. It is equally effective for normal and oily skin types. One important constituent of the cream is hydroquinone. This chemical is well known in dispelling sallowness and freckles. Four percent hydroquinone applied consistently is supposed to vanish all the age spots. The purpose of the vanishing cream is to lighten unnecessary dark spots or discoloration on the skin.

Synonym: Foundation cream, face cream

Formulation of vanishing cream

Ingredients	Quantity given	Quantity taken
Stearic acid	**18gm**	
Glycerin	**3gm**	
Lanoline	**2gm**	
Triethonalamine	**1gm**	
Methyl paraben	**0.18gm**	
Propyl paraben	**0.02gm**	
Rose water	**q.s**	
Purified water	**75.8 ml**	

Apparatus: Beaker, measuring cylinder, glass stirring rod, thermometer. water bath pipette,spatula.

Procedure:

1. Weigh all the required ingredients of vanishing cream properly and keep them separately.
2. Take stearic acid and lanoline in a beaker and melt them at 60C.
3. Take another beaker and add glycerin, tnethonalamine , water and heat up to 60C. Add the preparation of first beaker in a second beaker drop by drop with continuous stirring.
4. After cooling add methyl paraben, propyl paraben, rose oil and mix them thoroughly to obtain uniform product. Provide a professional finish.

Packing: In a suitable closed collapsible tube is packed and Labelled, make. Store in well closed container, in cool place. Do not freeze.

Uses:

1. It helps to keep the skin moisturized.
2. It is sometimes used as the base for cosmetics and make-up and evenjust plain foundation.
3. Vanishing creams are also helpful in keeping the skin afresh

OBSERVATION:

Name of the test	Specification	Observation
Appearance	White	
Odour	Rose type	
Ph	5-8	
Homogeneity	Homogeneous and consistent	
Texture	Smooth	
Spreadability	Easily spreadable	
Type of smear	Non- greasy	
Emolliency	No residue left	
Washability	Easily washable	

Result: Vanishing cream is prepared and submitted.