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Review Article

Formulation Development

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ABSTRACT

Formulation development is the process of changing a drug into a suitable form like tablets, capsules, liquids, creams, or injections so it can be used safely and effectively. Since some drugs have problems like poor solubility, instability, or bad taste, they are mixed with excipients to improve their quality and patient acceptance. Preformulation studies help in selecting the right dosage form and manufacturing method. cGMP, evaluation tests, SOPs, and stability studies ensure the product is safe, stable, and of good quality for patient use.

INTRODUCTION

Formulation development refers to the scientific process of designing and producing a pharmaceutical product (tablet, capsule, injection, cream, etc.) In a form that is stable, effective, safe, and acceptable to the patient. Formulation development is a core part of pharmaceutical product design. It involves transforming a pure drug substance (active pharmaceutical ingredient — API) into a safe, effective, stable, and easy-to-administer dosage form such as tablets, capsules, liquids, semisolids, or injectables. This process ensures that the patient receives the correct dose of the drug in a form that delivers the desired therapeutic action with maximum safety and reliability.

A drug by itself cannot always be administered directly because it may have limitations such as poor solubility, instability, unpleasant taste, hygroscopicity, or low bioavailability. Therefore, formulation development combines the API with appropriate excipients (inactive but essential

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ingredients) to overcome these limitations. These excipients help improve drug stability, manufacturability, absorption, palatability, and patient acceptability. The formulation development process is scientific and systematic. It begins with preformulation studies that characterize the physical and chemical properties of the drug. Based on these results, a suitable dosage form and appropriate excipients are selected. Prototype formulations are prepared and optimized through laboratory trials. Manufacturing processes such as mixing, granulation, drying, compression, coating, filling, or sterilization are developed and standardized to ensure consistent product quality.

Objectives:

1. Ensure drug stability – chemical, physical, and microbiological.
2. Optimize drug delivery – bioavailability and therapeutic effects.
3. Enhance patient compliance -minimum side effects .
4. Meet regulatory standards – pharmacopeia and ICH guidelines.

2. CONCEPT OF cGMP:

cGMP= current good manufacturing practices → ensures product quality & patient safety.

Purpose: prevent contamination, ensure consistency, maintain quality.

Facilities of cGMP:

1. Personnel – Trained staff, QC unit
2. Buildings & facilities – Clean, safe, proper layout
3. Equipment – Correct design, maintained, clean
4. Control of materials – Proper receipt, storage, testing
5. Process controls – written procedures for all steps
6. Packaging & labeling – controlled, approved
7. Holding & distribution – quarantine until qc release
8. Laboratory controls – specifications, tests, standards
9. Records – maintain batch & cleaning records
10. Returned goods – test and decide reprocessing or rejection

3. Steps In Formulation Development:

A. Drug Identification & Characterization :

Drug identification and characterization involve studying the identity, purity, and essential physical–chemical properties of a drug before formulation.

1. Identification Of Drug :

- Physical tests (colour, odour, solubility)
- Chemical tests
- Chromatography (TLC, HPLC)
- Spectroscopy (UV, IR, NMR,MS)

2. Characterization of drug:

Used to study the properties that affect formulation performance.

- Physical (crystalline / amorphous)
- Chemical properties
- Purity tests
- Stability (ICH)
- Microbial limits

B. Excipient Compatibility Study:

Excipient compatibility study is done to check whether the drug and excipients are chemically and physically compatible when mixed together in a formulation.

- **Method of Excipients Study:-**

1. Select excipients
2. Prepare 1:1 drug–excipient mixture
3. Store at 40°c/75% RH (ICH)
4. Check by visual, DSC, HPLC
5. No change = compatible

C. Formulation Development :

Formulation development is the process of designing and preparing a safe, effective, stable, and acceptable dosage form of a drug using suitable excipients and manufacturing methods.

1. Preformulation (solubility, stability, pka, compatibility)
2. Select dosage form (tablet, capsule, syrup, ointment, etc.)
3. Select excipients
4. Prepare prototype batches
5. Evaluate (pre-compression & post-compression tests)
6. Stability studies (ICH)

D. Formulation Optimization:

Formulation optimization is the process of adjusting and improving the formulation to achieve the best quality, stability, safety, and effectiveness of a dosage form.

Purpose: To get best quality, stability, patient acceptance & low cost.

Steps in formulation optimization:

1. Define TPP(e.g., 12-hr release)
2. Identify CQAs (dissolution, hardness, assay)
3. Identify variables (CMA,CPP)
4. Use doe/statistics
5. Select optimized formula
6. Validate + stability test

E. Evaluation Of Formulations:

Evaluation of formulations involves testing the quality, safety, stability, and performance of a prepared dosage form to ensure it meets standard requirements.

1. **Pre-compression:-** angle of repose, bulk density, Carr's index
2. **Tablets/capsules:-** appearance, weight variation, hardness, friability, disintegration, dissolution, assay
3. **Liquids:-** appearance, pH, viscosity, sedimentation, assay
4. **Semisolids:-** colour, spreadability, viscosity, drug content
5. **Parenterals:-** sterility, pyrogens, pH, clarity, isotonicity

F. Stability Studies (ICH):

Stability study is the process of testing how a drug product maintains its quality, safety, and effectiveness over time under different environmental conditions.

Purpose: determine shelf life & storage conditions.

Types Of Stability Study:

1. **Long-term:-** 25°c / 60% RH (12–24 months)
2. **Intermediate:-**30°c / 65% RH (6–12 months)
3. **Accelerated:-** 40°c / 75% RH (6 months)

Parameters To Be Tested (IP):

- **Physical**:-colour, hardness, dissolution
- **Chemical:-** assay, degradation
- **Microbial:-** sterility, preservative efficacy

4. Requirement Listing And Procurement:

A. Procurement Of Drug And Excipients Require For Selected Formulation:

1. Common Drugs Used In Various Dosage Forms:

- **Tablets:** Paracetamol, ibuprofen, metformin
- **Capsules:** Amoxicillin, omeprazole
- **Liquids:** Paracetamol syrup, antacids
- **Ointments/creams:** Clotrimazole, diclofenac gel
- **Injections:** saline, ceftriaxone

2. Common excipients used in various dosage forms:

- **Diluents**-lactose,
- **Binders**-PVP,
- **Disintegrants**-ccs,
- **Lubricants**-mg stearate,
- **Preservatives**- parabens,
- **Gelling agents**-carbopol

B. Procurement Of Equipment And Instruments For Formulation And Analysis:

For Solid, Liquid Semisolid Forms:

Solid Dosage:- blender, RMG, FBD, tablet press, hardness tested liquids:- mixing tank, stirrers, filters, filling machine

Liquid:-beakers, measuring cylinders, volumetric flasks , magnetic stirrer, homogenizer,water bath ,PH meter, viscometer, filtration unit, autoclave, laminar airflow

Semisolids:- planetary mixer, triple roller mill, tube filler

Qc Instruments:- PH meter, UV-spectrophotometer, viscometer

BASIC TECHNIQUES:

1. SOP Handling:

A standard operating procedure (SOP) is a written, step-by-step instruction that explains how to perform a routine or repeated activity in an organization.

SOP Preparation:

1. The organization decides which activities need SOP'S.
2. Are written by people who understand the work (subject experts).
3. A team approach is used, especially for tasks involving many steps.
4. The team may include:-operators performing the task,engineers, technical experts, safety officers, equipment manufacturers

2. Various Equipment And Instruments Handling:

A. Tablet Compression Machine:

Objective:- To provide the standard operating procedure for tablet compression machine

Fig 1: Tablet Compression Machine

Procedure Of Tablet Compression Machine:

1. Ensure the machine is thoroughly cleaned.
2. Select the required die size and clean the dies.
3. Clean the upper and lower punches
4. Fix the dies, lower punches, upper punches, and feed frame.
5. Place the cleaned hopper in position.

6. Rotate the machine manually to check proper punch fitting.
7. Fill the hopper with granules.
8. Set the required tablet weight and compression pressure.
9. Check the weight of 20 tablets individual weights must be within limits.
10. Collect compressed tablets in a clean polythene bag placed in a labelled fibre drum.

B. Fluidized Bed Dryer:

Objective:- To provide the standard operating procedure for fluidized bed dryer

Fig 2: Fluidized Bed Dryer

Procedure Of Fluidized Bed Dryer:

1. Ensure the FBD, its parts, and the area are clean and have a "cleaned" label.
2. Check the integrity of the FBD bowl, sieve, and finger bags.
3. Ensure proper fixing of finger bags, retarding chamber, and bowl.
4. Obtain line clearance from QA and place the status label with product and batch details.
5. Adjust the FBD bowl properly under the retarding chamber.

C. Tablet Coater:

Objective: To provide the standard operating procedure for tablet coater

Fig 3: Tablet Coater

Procedure Of Tablet Coater:

1. The instrument has a metal body with a motor and hollow drive shaft. Connect the main cord to the 230 v ac power supply.
2. Switch on the mains and attach the required accessory directly or through the universal gearbox.
3. Use the emergency switch on the control panel to stop the machine in case of any issue.
4. Select and set the required parameters (temperature, rpm, and time) on the control panel.
5. If using a spray gun, insert the gun into the provided socket.

D. Capsule Filling Machine:

objective: to provide the standard operating procedure for capsule filling machine.

Fig 4: Capsule Filling Machine

Procedure of Capsule Filling Machine:

1. Load empty capsules into the loading tray and place it on the bed.
2. Operate the cam handle to separate caps from bodies.
3. Position the powder tray and fill it with the required powder using a scraper.
4. Collect excess powder from the tray platform.
5. Lower the pin plate and press the powder into the bodies.
6. Raise the pin plate and refill any remaining powder.
7. Remove the powder tray after filling is completed.
8. Place the cap-holding tray back in position.
9. Lower the rubber-top plate and lock the caps with the bodies.
10. Remove the loading tray and collect the filled capsules.

E. Extruder And Spheronizer:

A. Extruder:

Objective: To provide the standard operating procedure for extruder

Fig 5: Extruder

Procedure Of Extruder:

1. A standard-size billet/ingot is produced.
2. Heat the billet (for hot extrusion) and place it into the extrusion press.
3. A plugger applies high compression force to push the billet toward the die.
4. Metal flows through the die opening and takes the required shape.
5. The extruded part is removed and heat-treated for strength.

B. Spheronizer :

Objective: To provide the standard operating procedure for spheronizer.

Fig 6: spheronizer

Procedure Of Spheronizer:

1. A rotating friction plate is placed at the bottom of the cylindrical bowl.
2. Particles collide with the bowl wall and move in a rope-like motion for rounding.
3. Friction between particles and the grooved plate helps form spheres.
4. A cross-hatched grooved pattern increases friction for efficient spheronization.
5. Once spheres are formed, open the discharge valve; centrifugal force ejects the pellets.

F. Others:

Ball Mill :

Objective: To provide the standard operating procedure for ball mill.

Fig 7: ball mill

Procedure of Ball Mill:

1. Switch on the instrument
2. Remove the container of the ball mill from instrument
3. Clean the container and place the material to be ground in it.
4. Place the steel balls of different sizes in the container
5. Attach and fix the container to the instrument
6. Rotate the ball mill for the required period of time as per the protocol for grinding the material filled in it
7. After specified period of time, remove the container and the material from it.
8. Separate the steel balls from the material
9. Clean the ball mill container and switch off the instrument when not in use.

EXPERIMENTAL:

1. Preformulation Studies And Preparation Of Preformulation Data Sheet:

A. Introduction To Preformulation, Goals And Objectives, Study Of Physicochemical Characteristics Of Drug Substances:

Introduction:

Preformulation is a set of studies that evaluate the physicochemical properties of a new drug to understand how it will behave in a dosage form.

Before preparing tablets, capsules, or liquids, the drug and excipients are evaluated for their suitability. This evaluation process is called preformulation.

Objectives of Preformulation:

1. To collect information needed to design the best drug delivery system.
2. To check if the drug can be safely developed into a dosage form.
3. To help the formulator choose the right dosage form and excipients.
4. To study basic physical and chemical properties that affect drug performance.
5. To ensure the drug is stable, safe, and suitable for large-scale manufacturing.

Goals of Preformulation:

1. To find key physicochemical properties (solubility, crystal form).
2. To study drug release behaviour.
3. To identify physical characteristics (flow, particle size).
4. To confirm compatibility with excipients.

Study Of Physicochemical Characteristics Of Drug Substances: It involves testing the physical and chemical properties of a drug to understand how it will behave during formulation, storage, and in the body.

Physicochemical Characteristics:

- Solubility – how well the drug dissolves.
- Pka – ionization behaviour in different ph.
- Partition coefficient (log p) – lipid/water balance.
- Polymorphism – different crystal forms.
- Melting point / thermal behavior – heat stability.

- Particle size & shape – affects flow and dissolution.
- Density & flow properties – important for tablets/capsules.
- Hygroscopicity – moisture uptake.
- Stability – heat, light, humidity sensitivity.
- Compatibility – interaction with excipients.

B. Identification And Characterization Of Drug Using FTIR, DSC, And UV:

1. FTIR:- Used to identify functional groups in the drug. each group shows a characteristic peak (fingerprint).confirms drug identity and checks drug–excipient interaction.

FTIR Procedure :

1. Take a small amount of sample and place it on the ATR crystal (or prepare KBR pellet if required).
2. Collect a background scan (empty crystal).
3. Place sample and apply pressure (ATR).
4. Run the scan in the range 4000–400 cm^{-1}.
5. Save the spectrum and note major peaks.
6. Compare with standard spectrum for identification or compatibility.

2. DSC:- Studies thermal behavior of the drug. gives melting point, purity, crystallinity, and polymorphism.

Peak shift indicates incompatibility with excipients.

DSC Procedure:

1. Weigh 2–5 mg of sample and place it in an aluminium pan, then seal it.
2. Keep an empty pan as reference.
3. Set the temperature range (e.g., 25°c to 300°c) and heating rate (10°c/min).
4. Start the run under nitrogen purge.
5. Record the thermogram and note melting point, peaks, or thermal changes.

3. UV Spectroscopy:- UV spectroscopy is used to measure how much UV light a substance absorbs to determine its concentration and λmax.

UV Spectroscopy Procedure:

1. Prepare standard solution of the drug.
2. Scan between 200–400 nm to find λmax.
3. Prepare sample solution in the same solvent.
4. Measure absorbance at λmax.
5. Use beer–lambert's law (a = εbc) or calibration curve to find concentration.

C. Physical Properties: Physical Form (Crystal & Amorphous), Particle Size, Shape, Flow Properties, Solubility Profile Etc:

1. Physical Form (Crystal & Amorphous): Crystalline drugs have a fixed structure, stable, lower solubility.

Amorphous drugs are less stable but have higher solubility and faster dissolution.

2. Particle Size: Smaller particles → increased surface area, better dissolution and absorption larger particles → slower dissolution.

3. Particle Shape: Spherical particles → better flow needle or irregular shapes → poor flow, difficult to compress.

4. Flow Properties: Important for tablet/capsule manufacturing.

Measured by angle of repose, Carr's index, hausner ratio.

5. Solubility Profile: Determines how easily the drug dissolves in different solvents and pH. essential for predicting bioavailability and selecting dosage form.

D. Drug-Excipient Compatibility Study Using DSC, FTIR Etc:

To check if the drug and excipients interact so the formulation remains stable.

Methods Used Are Commonly:

DSC: detects changes in melting point.

FTIR: detects changes in functional-group peaks.

Procedure:

1. Mix drug + excipient (1:1 ratio).
2. Store samples at 40°c / 75% RH for 2–4 weeks.
3. Test using DSC and FTIR.
4. Compare with drug alone.

Interpretation:

No interaction: no major peak shifts or loss of peaks.

Possible interaction: melting point change (DSC) or peak shifts (FTIR).

E. Application Of Preformulation In Dosage Form Design:

1. Helps select the most suitable dosage form (tablet, capsule, suspension, injection).
2. Provides data on solubility, stability, and bioavailability to improve drug performance.
3. Helps choose compatible excipients (no interactions).
4. Guides formulation of stable products (proper pH, antioxidants, packaging).
5. Helps understand flow property, compressibility, needed for tablet manufacturing.
6. Assists in selecting storage conditions & packaging (light-sensitive, moisture-sensitive drugs)

2. Formulation Of Conventional Or Novel Drug Delivery Systems:

A. Formulation Of Conventional Drug Delivery System:

1. Tablet :- Made by mixing drug + excipients (diluent, binder, disintegrant, lubricant) → granulation → drying → compression.

2. Capsules :-Drug blend filled into hard/soft gelatin shells → sealed → packed.

3. Oral Liquids:-Drug dissolved or dispersed in water with sweeteners, preservatives, flavors → filtered → filled.

4. Semisolids (Ointments/Creams/Gels):-Drug mixed with base (petrolatum, paraffin) → phases heated → mixed → cooled → packed.

5. Parenteral (Injections):-Drug dissolved in sterile solvent → filtered → filled under aseptic conditions → sterilized → sealed.

B. Formulation Of Novel Drug Delivery System:

1. **Controlled Drug Delivery System:-** Drug + polymers (HPMC/EC) → releases drug slowly and steadily over long time.
2. **Nano-Carriers:-**Drug loaded into nanoparticles (PLGA/chitosan) → improves absorption, targeting, and reduces toxicity.
3. **Vesicular Drug Delivery System:-**Drug trapped in lipid/surfactant vesicles like liposomes/niosomes → better stability and targeted delivery.
4. **Gastro-Retentive Drug Delivery System:-** Formulated to stay longer in stomach using floating, swelling, or mucoadhesive polymers → improves gastric absorption.

5. **Nose-Brain Drug Delivery System:-**Drug delivered through nasal route using nano-gels/emulsions → direct transport to brain, bypassing BBB.

3. Evaluation:

A. Solid Dosage Forms:

1. **Dissolution:** Rate of drug release.
2. **Disintegration :** Time to break into particles.
3. **Hardness Test :** Tablet strength.
4. **Friability:** Resistance to chipping/ breaking. formulation.

B. Liquid Dosage Forms:

1. **Leakage & Clarity:** Check container integrity and solution clarity.
2. **Sterility**: Ensure no microbial contamination.
3. **Pyrogen Test:** Confirm absence of fever-causing substances.

C. Semisolid Dosage Forms:

1. **Viscosity:** Thickness of product; checked with viscometer.
2. **pH:** Ensures product is safe and non-irritant.

4. Labeling & Packaging:

A. Types Of Packaging: Primary, secondary, tertiary.

B. Packaging Materials: Glass, plastic, metal, paper/foil.

C. Evaluation Tests For Packaging Materials: Leak test, extractives test, hydrolytic resistance, self-seal test.

D. Labelling For Different Dosage Forms: Dose, directions, storage; “shake well” for liquids, “external use” for semisolids, sterility info for injections.

Formulation:

Object: To prepare cresol with soap solution (20ml as per IP)

Synonyms: Lysol.

Requirements:

A. Apparatus:- Beaker , water bath, tripod stand, measuring cylinder, stirrer, wire gauze, bunsen burner, pair of tongs, funnel , weighing balance , matchbox, pipette.

B. Chemicals:- Cresol, olive oil, sodium hydroxide, water.

Theory: Cresol, a mixture of o,m and p-cresol. It acts as disinfectant. It has low water solubility (about 3%), but the preparation requires a 50% concentration. A solubilizing agent is needed to dissolve this high proportion. This agent is a soap, formed when fatty acids in vegetable oil react with potassium hydroxide in a process called saponification. Cresol is added only after this reaction is complete.

Formulation Table:- 1

Sr. No	Ingredients	Quantity Given	Quantity Taken	Uses
1.	Cresol	50.0ml	10 ml	Main disinfectant
2.	Olive oil	18.0 gm	3.95 ml	Solubilizing agent
3.	Sodium hydroxide	4.20 gm	0.84gm	Alkali
4.	Purified water	Q.s upto 100ml	Q.s upto 20 ml	Vehicle

Procedure:

1. Dissolve sodium hydroxide in 5 ml in purified water.
2. Add vegetable oil and heat on a water-bath and mixing thoroughly.
3. Continue heating untill a small portion dissolve in water without separation of oily drops.
4. Add cresol and mix thoroughly.
5. Add sufficient purified water to produce the require volume.

Category: Disinfectant.

Storage: Store protected from moisture .

Uses: Disinfectant

Direction: For external use only.

Fig 8: Cresol With Soap Solution

3. Evaluation:

Liquid Dosage Form Testing Of As Per IP:

Cresol Soap Solution:

1. Physical Test:

Evaluation Table:- 2

Sr. No	Test	Inferences
1.	Volume	20ml
2.	Description	Reddish brown viscous liquid
3.	Insoluble particles	Absent
4.	Colour	Reddish brown
5.	Odour	Cresol/ phenol like
6.	Separation of solution	No separation

2. Chemical Test:

Category- Disinfectant

Test:

1. Appearance of Solution – 2.5ml mixed with 47.5ml of water forms a clear solution without producing any opalescence on standing for 3hrs.

2. Alkalinity- Dilute 2.5ml with 25ml of ethanol neutralised to phenol red solution and titrate with 1m sulphuric acid, using phenol red solution as indicator; not more than 0.6ml is required.

Fig 9: The Alkalinity Test Are Pass. Titred Are Required In 0.3ml And Solution Are Neutralised.

Category: Excipient

1. Identification-Suspend 1 gm in 10ml of water, add 0.1ml of 0.1m iodine, and shake for 30 sec . Add 1ml of starch solution and shake ; no blue colour develops.

Fig 10: Identification Test Are Pass No Blue Colour Develops

2. pH- 5.0 and 8.0 , determined in a 1.0 per cent w/v aqueous suspension.

Fig11: The pH Test Are Pass.

HANDS ON ACTIVITIES:

1. Identification And Characterization Of Drug By Melting Point, Solubility Study, UV Spectroscopy Etc:

Melting Point:-

Melting point is the temperature (or range of temperature) at which a substance changes from the solid state to the liquid state under specified conditions. The melting points of paracetamol where determined by capillary method observed value was compared with the reported value is 169- 172°c.

Fig 12: Set Up For Melting Point

Solubility Study:-

Solubility is defined in the IP as the extent to which a substance dissolves in a specified solvent to form a homogeneous solution under specified conditions.

According To IP, Solubility Of Paracetamol Is:

1. Sparingly soluble in water.
2. Freely soluble in alcohol.
3. Very slightly soluble in ether.
4. Soluble in 1 m sodium hydroxide.
5. Soluble in acetone.

UV Spectroscopy Of Paracetamol:-Paracetamol shows a characteristic UV absorption maximum (λmax) due to its aromatic ring and acetanilide structure.

Assay Of Paracetamol Tablet By UV Spectroscopy:

1. Weighed and powdered 20 tablets.
2. Weighed a quantity of powder containing about 0.15gm of paracetamol, added 50ml of 0.1m NaOH diluted with 100ml of water, shake for 15 min and added sufficient water to produce 200ml.

3. Mixed, filtered and diluted 10.0 ml of the filtrate to 100.0ml with water to 10.0ml of the resulting solution, added 10ml of 0.1 m NaOH, diluted to 100.0ml with water and mixed.
4. Measure the absorbance of the resulting solution of the maximum wavelength of about 257nm.
5. Calculated the content of c8h9no2 taking 715 as the specific absorbance at 257nm.

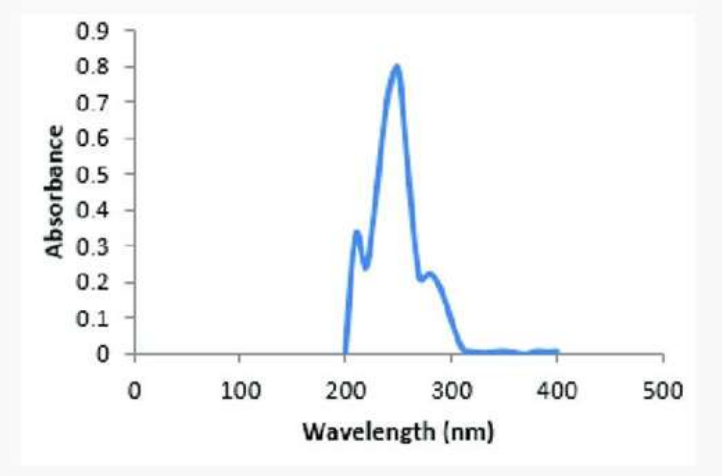

Fig 13: Absorbance Maxima Of Paracetamol (λ max)

2. To Study The Dissolution Of Given Solid Dosage Form:

Dissolution test is a test used to measure the rate and amount of drug that goes into solution from a solid dosage form in a given time, under specified conditions.

Method How To Perform In Dissolution Test:

1. Use dissolution apparatus (USP/ IP) with 900 ml medium (usually water or buffer).
2. Set paddle at 50–75 rpm.
3. Drop one tablet in each vessel.
4. Withdraw samples at fixed intervals (e.g., 5, 10, 15, 20, 30, 45, 60 min).
5. Measure absorbance using UV spectrophotometer.
6. Calculate % drug release at each time point.
7. Plot graph % drug release vs time for both brands.
8. Compare profiles using:f1 (difference factor), f2 (similarity factor) visual comparison of graph

3. Study Of Disintegration Time Of Different Marketed Tablets:

Disintegration time is the time required for a tablet or capsule to break down into small particles when placed in a specified liquid medium under standard test conditions.

Table No:-3

Sr. No	Brands	Disintegration time (min)
1.	Medamol 650 mg	1.31
2.	Paracip 650mg	1.13
3.	P-650mg	0.15
4.	Paracetamol 650 mg	1.00

4. Quality Control Of Different Dosage Forms As Per Pharmacopoeia:

A. Weight Variations :

According to the USP xxiv monograph, twenty tablets of each batch were used to evaluate weight variation among tablets. The mean and standard deviation were calculated based on these measurements.

B. Friability:-Friability testing was performed using a Roche friabilator. The test was carried out in triplicate for all batches as per the USP xxiv monograph.

C. Hardness:-hardness was determined using a digital force gauge (model: el=500n, electrolab).the test was carried out in triplicate for all batches as per the USP xxiv monograph for uncoated tablets.

4. Thickness:-The thickness of the matrix tablets was measured using a vernier caliper (mitutoyo dial thickness gauge, mitutoyo, japan).results were expressed as mean values of 10 determinations with standard deviations.

5. Tests For Evaluation Of Different Packaging Materials:

Packaging is an outer protective covering of a product,in which the product is enclosed in such a manner, that it becomes convenient to handle and open. Container and closure are the two main components of pharmaceutical packages.

Packaging Materials May Be Classified Into Three Categories:

1. Primary packaging which first covers the product and holds it – the parts that come into direct contact with the product. Examples – bottle, ampoule, ointment tube etc.
2. Secondary packaging which surrounds the primary packaging. Examples – box, carton, injection tray etc.
3. Tertiary packaging that is used for transportation in bulk. Examples – barrel, crate etc. Study of flow properties of the designed formulations

Tests For Evaluation of Packaging Materials:

1. **Leak Test:-** Checks if container is airtight and prevents leakage.
2. **Moisture Vapour Transmission Rate (MVTR):-** Measures how much moisture passes through the packaging.
3. **Compatibility Test:-** Ensures the packaging material does not react with the product.
4. **Chemical Resistance Test:-** Checks if material withstands drug, solvents, or chemicals.
5. **Light Transmission / Light Protection Test:-** Checks whether container protects contents from light (UV/visible).
6. **Drop Test / Impact Test:-** Tests mechanical strength and resistance to damage.
7. **Burst Test:-** Checks pressure resistance of packaging.
8. **Tensile Strength Test:-** Measures ability to stretch without breaking (films, foils).
9. **Seal Integrity Test:-** Ensures seals/closures are tight and strong.
10. **Dimensional check:-** Verifies size, thickness, and uniformity.

6. Study Of Flow Properties Of The Designed Formulations:

Flow properties help to check how well a powder or granules flow before tablet/ capsule manufacturing.

Important Flow Property Tests:

1. Angle Of Repose:-Measures flowability of powder.lower angle = better flow.

Formula: $\tan \theta = h / r$

2. Bulk Density:-Weight of powder / bulk volume. indicates packing ability.

3. Tapped Density:-Density after tapping the cylinder. shows how much the powder can settle.

4. Carr's Compressibility Index:-Shows compressibility and flow.

Formula:- ci = (tapped – bulk) / tapped × 100

Ci < 15% = good flow.

5. Hausner Ratio:- Another Flow Indicator:-

Formula:-hr = Tapped density / bulk density

Hr < 1.25 = good flow.

7. Determination Of Different Bulk Characteristics Like Bulk Density, Tapped Density:

1. Bulk Density:-Bulk density is the mass of powder divided by the bulk volume (before tapping).

Procedure:

1. Weigh the powder.
2. Transfer it into a measuring cylinder.
3. Note the initial volume (v_0).
4. Calculate:-bulk density = weight of powder / bulk volume (v_0)

2. Tapped Density: Tapped density is the mass of powder divided by the tapped volume after tapping.

Procedure:

1. Take the same measuring cylinder.
2. Tap it 100 times using a tapped density tester.
3. Note the final tapped volume (vt).
4. Calculate:- tapped density = weight of powder / tapped volume (vt)

8. Determination of Viscosity of Liquid And Semisolid Dosage Forms:

1. For Liquid Dosage Forms (Syrups, Suspensions):

Instrument:- Ostwald viscometer or brookfield viscometer

A. Using Ostwald Viscometer:

Principle: Time taken for a liquid to flow between two marks is proportional to viscosity.

Procedure:

1. Fill viscometer with test liquid.
2. Allow it to flow by suction.
3. Note the flow time between two marks.
4. Compare with flow time of water.

Viscosity = (density × flow time of liquid) / (density × flow time of water

B. Using Brookfield Viscometer:

Procedure:

1. Select appropriate spindle.
2. Immerse it in the liquid.
3. Set rpm (speed).
4. Read viscosity directly on the display.

2. For Semisolid Dosage Forms (Ointments, Creams, Gels):

Instrument: Brookfield viscometer (cone-and-plate spindle)

Procedure:

1. Place sample on plate.
2. Lower cone spindle until it touches the sample.
3. Set shear rate (rpm).
4. Instrument displays viscosity in CP or PA·S.

9. Partition Coefficient Determination:

Partition coefficient (p) is the ratio of a drug's concentration in oil phase (usually n-octanol) to its concentration in water phase at equilibrium.

It shows lipophilicity (fat solubility) of a drug.

10. Saturation Solubility Estimation:

Saturation solubility is the maximum amount of drug that can dissolve in a solvent at a specific temperature and pH. until the solution becomes saturated (equilibrium).

Purpose:

- To understand drug dissolution behavior
- Helps in formulation design
- Predicts bioavailability

CONCLUSION:

As the objective of this study was to attempt a formulation of the cresol soap solution using olive oil as a solubilizing agent and sodium hydroxide as an alkali, the cresol soap solution was successfully formulated and evaluated. The cresol soap solution was evaluated for physical tests such as volume, description, insoluble particles, colour, odour, and separation of solution, and for chemical tests such as appearance of solution, alkalinity, identification test, and ph. The results of the evaluation showed that the cresol soap solution prepared with olive oil as a solubilizing agent exhibited better alkalinity.

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