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The Brief Review on Formulation and Development

Ravindra Nanasaheb Dhokane, Mr. Dnyaneshwar S Vyavhare,
Dr. Megha T Salve.
Shivajirao Pawar College of pharmacy, Pachegaon-Newasa.414602.

Abstract:
Formulation development is a cornerstone of pharmaceutical development, ensuring the therapeutic efficacy, safety, and commercial viability of drug products. This review provides an overview of the essential stages involved, including compatibility studies with packaging, manufacturing vessels, filters, tubing, and other materials. It emphasizes the integration of pre-formulation studies, regulatory requirements, and process considerations into formulation strategies. A tailored approach is crucial for addressing drug-specific challenges, patient needs, and market demands. This article offers insights into the principles and methodologies driving formulation development, from discovery research to post-market phases.
Ensure no adverse interaction with containers or closures. Manufacturing Vessels and Aids: Assess compatibility with filters, tubing, gaskets, and other equipment. Include studies on sterility, moisture sensitivity, and temperature effects. Every drug molecule is unique, requiring a bespoke formulation strategy. Patient Demands: Develop dosage forms suitable for specific demographic. Stringent Regulatory Requirements: Need for extensive documentation and validation.

Keywords: *Pharmaceutical Development, Compatibility, Studies, Hold time.*

I. Introduction to Formulation Development

Pharmaceutical formulation is the process of combining different chemical substance It is obtained after in-depth study of physical, Chemical & mechanical properties of drug substance.

Objectives: To produce a final medicinal product that is stable and acceptable to the patient.
Definition:
It is the key Area of the product development that can determine Patient ability lifecycle of ultimately the success of pharmaceutical product that is the formulation and development.
In those physical, chemical & mechanical properties of drug Polymorphism, stability, pH & particle size of drug should be considered.

Concept of eGMP:
Overall concept-
• Quality should build into the product
• A product that is fits for its purpose.

Steps in formulation Development:
• Identification and Characterization:
1) Solubility melting point
2) Melting point
3) Assay
4) Stability
5) Microscopy
6) Powder flow of compression propertie
7)Excipient studies.
8)Spectroscopic character
9) Density and porosity

• **Drug-Excipient compatibility studies:**
It is most important part of Preformulation testing of proposed dosage form and it is necessary that it should be carried out before the development of formulation. This is required for following:
To find out the Excipient those are incompatible with the API.
To find out that Excipient that can stabilize the unstable API & impact on only the API
Analytical technique to detect Drug-Excipient compatibility-
i. Thermal method of analysis
ii. Differential scanning calorimeter.
iii. Differential thermal analysis.
iv. FT-IR spectroscopy
v. Diffuse reflectance spectroscopy
vi. Chromatography: - HPLC, HPTLC, etc.
vii. Fluorescence spectroscopy.

• Formulation Development:
1) Preformulation : characterization of API.
2) Formulation : choosing the quantitative formula & its process of fabrication.

• **Formulation optimization:**
The term optimization is to make perfect. It is used to pharmacy relative processing to formulation & processing. Optimization is an act of making design system perfect functional process or methodology or decision as fully perfect functional or as effective as possible.

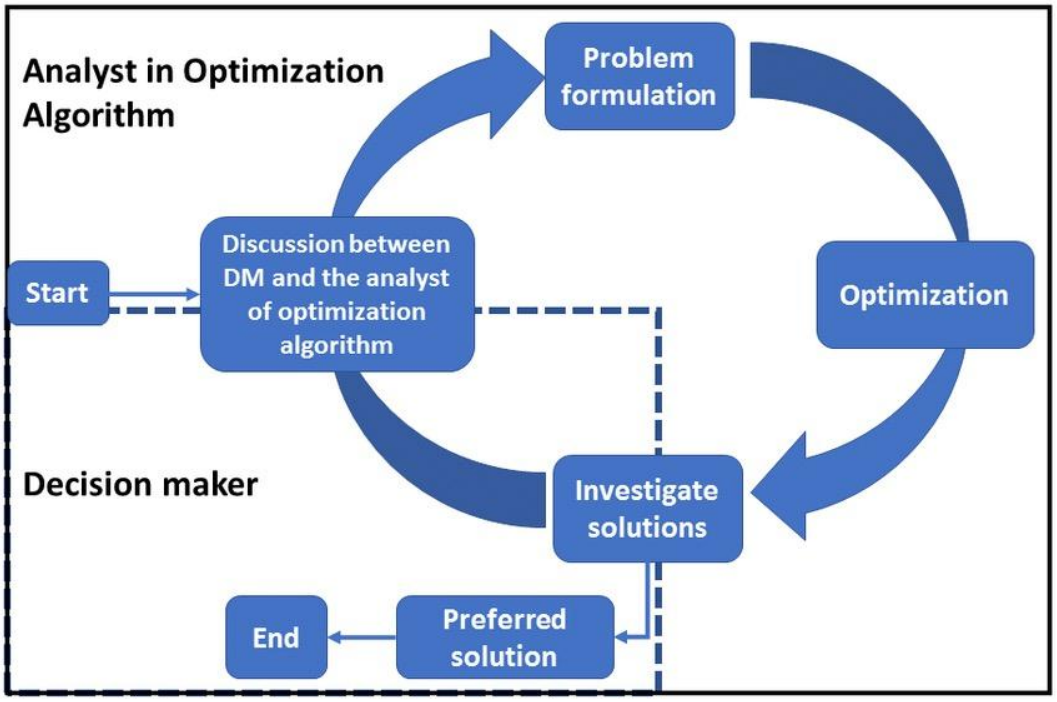

Fig.1

• Evaluation of Formulation:

1) Solid dosage forms:

Tablet: weight variation, disintegration & dissolution time, content uniformity, mechanical strength.

Granules: Flow property.

Particle & powder: - of Angle of repose, density.

2) Semi-solid dosage forms: -Penetration, Rate of release Irritant effect of medicaments,

Absorption of medicaments into blood stream.

3) Liquid dosage form: uniformity of weight/ volume, Viscosity, Stability testing. Leakage test, Clarity test.

2) Stability study: According to USP Stability of pharmaceutical product is the extent to which a product remains within its specific limit of physical, chemical, microbiological, therapeutic and toxicological specifications throughout the period of storage i.e., its shelf Life.

Shelf life-A length of time you can expect a product to look & act as expected; to stay safe for use.

Type of Stability that must be considered for any drugs:

1) Chemical stability
2) Physical stability
3) Microbiological stability.
4) Therapeutics stability
5) Toxicological stability.

Requirement listing and procurements:

Procurement is defined as a process of acquiring. Supplies through purchases from the agent supplies manufactures like distributor or from private or public supplier.

Purchasing of medicine starts with the framing of buying policies and ends with receiving. stocking & Payment.

Methods of Procurements:

1. Direct purchase from the manufacturer or the regional Centers
2. Direct purchase from wholesaler of stockiest.
3. Purchase from rack jobbers.
4. In purchase through beads

Open tenders
Restricted tenders
Quotation invitation
Purchase through a contract.

1) Right source
2) Right quality
3) Right quantity
4) Right price
5) Right time
6) Right mode of transportation.

The equipment and instrument procurement should be Follows the-WHO guideline, USFDA guidelines, MHRAT TGA guideline.

SOP Handling:

A standard operating procedure (SOP) is a set of step-by-step instructions compiled by an organization to help worker carry out routine operation. A SOP aim to achieve efficiency, quality

output, uniformity of performance, while the reducing miscommunication & failure to comply with industry regulations.

Preparations of SOP For Different Instraments & Eanipment'si

Oven/ Hot air oven:

Fig.2

Inspection the Oven-

Make sure electric power of connection are made correctly of the power cable is not damaged. Area around the oven should be the oven should have 6 inches clearance around it.

Start heating:

Turn the oven by pressing the main power switch in the lower right.

Temp should set to appropriate point.

Load the Specimen:

Before putting anything in the oven make sure it is safe to heat this part of desired temperature make sure you have everything you are going to need.

Make sure about clear & safety place

• Open the oven store.
• Load your specimen.
• Close the door.
• Clean up area around the oven and store the protective equipment.
• Removing the specimen, turn off oven and clean up area inside the oven.

Weighing balance:

Fig.3

• Clean the container & wipe.
• Basic weighing functions: Turn on the balance scale
• Place the container on balance.
• Tare the balance and place the sample in container & note down the weight.

Magnetic stirrer:

• Place the vessel on the stirrer so i.e., centered.
• Turn the instrument on.
• Set the stirring speed.

When stirring is completed turn off magnetic stirrerd remove sample Stirrer

Fig.4

Various eguipment and instruments handling:

Tablet compression machine:

Objectives: To the describe the procedure for the a operation maintenance of the tablet compression machine.

Fig.5

Procedure:

-lubricate the machine & clean it.
-Adjust the lower fupper punch & die cavin
-Cheat the movement of hopper shoe for proper
-filing the die cavity

-place the granules mixture in hopper as per cavity
- Ensure the die cavity is filled
-Rotate the wheel by hand in clock wise and for single rotation
-Collect the ejected tablet
-Repeat the cycle
-property clean the machinery.
-Lubricates the part of machine.

Capsule filling machine:
Objective: To describe the procedure for the operational and maintenance of capsule filling machine.

Fig.6

Procedure:
This can be done manually or with the help of an orientation machine
The loading tray is placed on the bed of the filling machine and attached properly to
Cam handle is pushed to lock the capsule bodies in the filling with a help of sliding sheets.
-The lever is pushed to separate the caps and the bodies in of the capsule The loading tray with the caps is pulled up & kept aside.
-The cam handle is pushed away to drop the capsule bodies in such away So that they are aligned with Machine bed.
-The power frame / tray is placed on the filling machine.

Others:
Disintegration test apparatus:

Fig.7

Procedure:
-Take the specified liquid in the beaker & maintained the temperature at 37°C. by temperature controller.
-placed the tablet into each plastic tubes.
-The dise to each tube
-Suspend the assembly.
-Switch on the main plug on motor plug-
-Tablets allows passing the test

2) Friability test apparatus:
Objectives: To describe the procedure for operation & maintenance of friability test apparatus.

Fig. 8

Procedure:
-Clean the apparatus and switch the mains on.
-Open the plastic chamber & placed go tablets which are previously weighed of taken for testing purpose.
-Close t'plastic chamber lid and switch the main knob OD.
-Adjust the timer for four minutes to resolution.
-Tablets are removed by from the chamber after 100 revaluations & weighed.
-Switch the instrument off.

Formulation of Conventional Dosage Form:
1. Tablets:
Aim: To prepare Aspirin tablet by Dry granulation method (20 tablets).

Requirements:
Chemicals: -Aspirin, starch powder, tale.
Glass ware: -Granulating sieve, standard sieve, ete
Equipment's: -Tablet compressing machine
Formulation table:

Incredients	Official formula	Working formula	Role of ingradient
Aspirin powder	0.300gm	6.0gm	Anticoagulant
Tale powder	0.60gm	1.2gm	Glidant
Starch powder	0.015gm	0.30gm	Disintegrating agent

Table No: 1

Procedure:
-Weigh & pass aspirin powder through #60 sieves.
-Compress into slug using 18mm flat face punishes.
-mix all the above ingredients (except) 50% of starch tale & magnesium separate; Grind the slugs using 20 mesh screens
-Transfer into polythene bag and add the reminder disintegrate and lubricant, mix for 10 Minutes.
-Prepare granules and subjected for the preparation of tablets by using tablet
Punching machine

Result: **The aspirin tablet by dry granulation method was prepared and stored in suitable container.**

Aim: To prepare Paracetamol tablet by wet granulation method. (30 tablets)
Requirements:
Chemicals: Paracetamol, starch powder, tale.
Glassware: -measuring cylinder, beaker, mortar and pestle, granulating sieve
Equipment's: -Tablet punching machine.
Formulation table:

Ingredients	Official formula	Official formula	Role of ingredients
Paracetamol	0.500gm	15gm	Antipyretic
Starch powder	0.025gm	0.75gm	Binder
Starch paste	QS	QS	Binder
Tale	QS	QS	Glident

Table No.2
Procedure:
-Weigh and pass Paracetamol powder through # 100 sieves.
-Mix Paracetamol & starch powder uniformly in mortar and pestle.
-Prepare 10% Starch paste in boiling water till it becomes translucent.
-Add starch paste drop wise in mortar to get cohesive mass Record quantity of Starch paste used for granulation.
-Screen prepared cohesive mass of through 12 granulating sieve and collect it on Granulatingtray
-Dry granules in tray at 50°C for 30min.Pass 50% Dried granules through #16 sieve to get uniform particle. Size and continue drying for 50 min.
Result: The Paracetamol tablet by wet granulation method was prepared and a stored in well closed containers.

Capsule:
Aim: To prepare and submit the Tetracycline hydrochloride Capsules(10capsules)
Requirements:
Chemicals: Tetracycline HCI, Starch, Magnesium Stearate.
Glassware: Beaker, #100mesh.
Equipment: Capsule filling machine.
Formulation table:

Ingredients	Official formula	Working formula	Role of Ingredients
Tetracycline HCl	250mg	2.75 gm	Antibiotics
Starch	5mg	0.055gm	Disintegratint agent
Magnesium Stearate	2.5 mg	0.25mg	Lubricent
Tale	2.5mg	0.25mg	Lubricent
Lactose	40mg	0.44mg	Diluents

Table No: 3
Procedure:
-Calculate the quantity of all ingredients.
-Calculate the quantity for one extra capsule Select the capsule size per required Filling weight.
-Accurately weigh & pass all ingredients through 100sieve fill the capsule by using hand -operated capsule filling machine.
-Evaluate the filled capsule for various quality control parameters.
Result: 10 capsules of tetracycline HCI was prepared and stored in well close Container.
Parenteral:
Aim: to prepare and submit 2 ampoules of calcium Gluconate injection by tip sealing method.
Requirements:
Chemicals: Caleium Gluconate, Calcium D-Saccharate
Glassware: Measuring cylinder, beaker, syringe, and pipette.

Formulation table:

Sr. No.	Ingredient	Official formula	Working and formula	Role of the formula
1.	Calcium Gluconates.	9.65gm	0.38gm	Calcium suppliments.
2.	Calcium	D- 0.35g	0.014gm	Stabilizing

	saccharate	m		agent
3.	Water injection	for Os to 100ml	Qs to 4 ml	vehicle

Table No.4

Procedure:
-Accurately weigh all the ingredients de triturate it for reducing particle size
-Dissolve Calcium Gluconate in portion of water for injection slowly under constant Stirring & remote
-The Dissolved oxygen by nitrogen bubbling.
-Add and dissolved calcium D-Saccharate in solution. PH is adjusted to 5-8 Using 10% mNaOH solution. Make the volume of mix with water for injection.
-Sterilize the solution by passing through sterilize 0.45 membrane filler into Sterilized vessel. Aseptically fill in sterilize two ampoules of seal them.
Result:Two Ampoules of calcium Gluconate injection by pull method was prepared &submitted.

Ascorbic acid injection:
Aim: To prepare and submit two Ampoules of ascorbic acid injection by tip Sealing.
Requirements:
Chemicals: Ascorbic acid, Sodium Bicarbonate, p-Choro m-Cresol, water for Injection.
Glassware: measuring cylinder, beaker, pipette, two, Ampoules.

Formulation table:

Sr. No.	Ingredients.	Official and formula	Working of formula	Role of formula
1.	Ascorbic acid	25gm	0.5gm	Antiscorbutic
2.	Sodium bicarbonate	14.58gm	0.2gm	Stabilizing agent
3.	P-Choro m-Cresol	0.1 gm	0.02gm	Preservation
4.	Water for injection	QS to 100ml	Q5 to 2 ml	Vehicle

Table No: 5
Procedure:
Accurately weigh all ingredients & triturate Remove the dissolved oxygen by
Nitrogen bubbling. Add NaHCO3 stir slowly.
Add p-Chloro-m-cresol vigorously is adjusted 5.5 to 6.5 using NaOH or Ascorbic acid self.
- The solution by passing through sterilized. 0.22 u membrane filters into sterilized Vessel.
-Aseptically fill in sterilized 5ml amber colored ampoule.

Result:
Two Ampoules of ascorbie acid injection was prepared by tip sealing method &submitted.
Evaluation:
For solid dosage form:
1. Disintegration test:
Aim: To perform disintegration test for Aspirin and Paracetamol Tablet and tetracycline HCl capsule
Requirements:
Chemicals: Paracetamol and aspirin tablet and capsule.
Glassware: disintegration test apparatus.
Procedure:
-Place on table in each of six tubes of basket & operate the apparatus Using water maintained at 37degree C as the immersion fluid.
-At the end of the time limit specified, lift the basket from the fluid observe the tablets.
If or 2 tablets fails to disintegrate completely repeat the test on 12 additional tablets
-Not less than 16 of the totals of the 18 tablets tested a disintegrate completely.
Observation table:

Tablet name	Hardness in kg/cm2	
	Pfizer harness tester	Monsanto hardness tester
Aspirin tablet	8kg	7.8kg
Paracetamol tablet	4.51g	4.2 kg

Table No: 6

Result: the hardness of Paracetamol and Aspirin tablet is 8kg and 4.5kg Respectively.
Friability test:
Aim: To perform Friability test for Paracetamol and Aspirin tablet.
Requirements:
Chemicals: Paracetamol and Aspirin tablet.
Equipment: Friability test apparatus
Procedure:
-Select to a 20 tablets randomly and weigh the tables in friability drum switch on.
-placed apparatus adjusting the timer at 4 min. (25 rpm).
-At the end of this operation remove the tablets from the friability test apparatus. Reweigh.
-calculate the % friability. %
Friability: 100X (IW-EW)IW

Calculation:
For Paracetamol tablet;
Weight of tablet before Friability -2.47gm
Weight of tablet after Friability -2.35 gm
% Friability=100× (2.47-2.35)/2.47 -4.8%

For aspirin tablet;
Weight of tablet before Friability - 1.97gm
Weight of tablet after Friability -1.95
%Friability=100× (1.97-1.95)/1.97=1.01%

Result: %friability of Paracetamol and Aspirin is 4.8%and 1.01% respectively

Weight variation test:
Aim: To perform weight variation test for capsule.
Requirements:
Chemicals: tetracycline HCl capsule.
Equipment: weighing balance.
Procedure:.
-The individual weight should be within limit of 90-110% of average weight.
-If not all capsule fall within the limits weigh 20 capsules. Individually remove the net content of each capsule with the help of small brush.
-Weigh the empty shell individually.
-Net Weight of content individually = weight of shell-gross weight.
-Average weight (Aw) =0.404

Observation table:

Sr No.	Weight of empty capsule (gm)	Weight of capsule (Wi) gm	% Difference
1.	0.09	0.400	-1%
2.	0.10	0.420	3.9%
3.	0.09	0.390	3.4%
4.	0.10	0.400	-1%
5.	0.09	0.400	-1%
6.	0.09	0.390	3.4%
7.	0.09	0.410	1.4%
8.	0.10	0.410	1.4%
9.	0.09	0.400	-1%
10.	0.10	0.420	3.9%
11.	0.09	0.400	3.9%
12.	0.10	0.420	3.9%
13.	0.09	0.420	-1%
14.	0.09	0.420	3.4%
15.	0.10	0.400	-1%
16.	0.09	0.390	3.4%
17.	0.10	0.390	3.4%
18.	0.09	0.400	-1%
19.	0.10	0.400	-1%
20	0.10	0.410	1.4%

Result: The weight variation of tetracycline HCI capsule (0.404 gm) in between
-1% to and3.9%. The test is passed

For liquid dosage form:
Aim: To perform leakage test and clarity test.
Requirements: Two Ampoules.
Procedure for leakage test:
-The ampoules are immersed in vacuum chamber.
-Consisting of 1% methylene blue solution.
-This causes the sol is to enter the ampoules with Defective sealing.
-The vacuum is released and ampoules are observed.
-leakage is present the sol in the ampoules appears Blue Color.
Procedure for clarity test:
-Manual inspection by the naked eye by using fluorescent lamp, Incandescent lamp and polarizing light as lightening.
-Uses background to see particle (black background-to see white particle, and white background to see black or colored particle).

Observation table:

Test	Result
Clearity test	No any particular matter is present, test is passed
Leackage test	No blue color appears, test is passed

Result: The leakage test and clarity test were performed.

Packaging and labeling:
Type of packaging:
I. Primary packaging: These are the material that first envelope the product and hold it.
For example: ampoules, vials, closure, syringe, strips, etc.
II. Secondary packaging: It is the outside the packaging perhaps used to groups' primar
package to a together. For example: paper and board, cartons, ete.
Packaging materials:
• **Rubber**: Excellent material for scaling, used to closure such as bungs for vials of gasket in aerosols in similar applications such as cans.
Categories of rubbers-
1) Natural rubber
2) Synthetic rubber.
• **Metals:**
For non-parenteral products the metal are used for packaging. Metal is strong.
opaque, impermeable to moisture, gases, odors, and bacteria. It ideal packaging materials for pressurized container. For example, gas cylinder, tubes, and sprays.
• **Plastics:**
There are two classes of plastic, reflecting the behavior with respect to individual or repeated exposure to heating of coaling.
Thermoplastic: polystyrene, polyethylene, polyvinyl chloride

Thermosets: -Phenolic area of melamine is representative for thermoset.

• Glass materials:

U.S.P. Glass Types and Test Limits			
Type	General test	Type of test	General use
I	Highly brosicicate class resistent	Powdered glass	Buffered and unbuffered aqueous solution, all other uses
II	Treated soda Lime glass	Water attack	Buffer aqua solution with PH below 7.0 dry powder, olegeneous solution
III	Soda lime glass	Powder glass	Dry powder olegeneous solution
IV	General purpose, soda, lime glass	Powder glass	Not for paretureals For tablets, oral solution, ointment, and external liquids

• Fibrous material:

These are important part of packaging. They include papers, labels, cartons, bags, outer layer boards.

• Strip packaging:

Commonly used for packaging of tablets and capsules. The material used for strip Package is cellophane, polyesters, polyethylene, polypropylene, polyvinyl Chloride.

To study the disintegration time of different marketed product.

Requirements: disintegration test apparatus, 10 tablets of paracip500

Procedure:

-At the end of the time limit specified, lift the basket from the fluid and observe it.

Result: The disintegration time at 37degree immersion fluid was 3 min 12sec.

To study the flow properties of powder.

Requirements:

Apparatus: Funnel beaker, measuring cylinder, and stand.

Chemicals: starch powder, microcrystalline cellulose, calcium Carbonate.

Flow properties	Angle of repose
Excellent	25-30
Good	31-35
Fair	36-40
Passable	41-45
Poor	46-45
Very poor	56-60
Very, Very Poor	>66

Procedure:

-weigh amount of powder is taken (starch, MCC, calcium carbonate 10gm respectively.)

-powder pass from #10mesh sieve.

-set the assembly of funnel with a clamp or on ring support over a glass Plate

-Adjust the height of funnel.

-Passed the powder into the fennel

-Measure height and radius of pile Calculate the angle of repose and their flow properties

Observation table:

For starch powder:

Height of the pile (h)	Radius of a the pile (r)	Angle of reposes
2.0cm	3.2cm	30degree having a excellent flow property
2.0cm	3.3cm	
2.0cm	3.7cm	

For microcrystalline cellulose:

Height of the pile(h)	Radius of the pile (r)	Angle of repose
2.5cm	3.6cm	34degree having a excellent flow property
2.5cm	3.5cm	
2.5cm	3.7cm	

For calcium carbonate power:

Height of the pile(h)	Radius of the pile (r)	Angle of repose
2.5cm	3.4cm	35degree having a excellent flow property
2.5cm	3.7cm	
2.5cm	3.6cm	

Result:

The flow property of starch, MCC, calcium carbonate was excellent, good, and good respectively.

Determination of different bulk characteristics like bulk density and tapped

Density:

Reguirements

Glassware: beaker, measuring clinder, weighing balance

Equipment: bull density apparatus.

Chemicals: starch, lactose, calamine.

Procedures For bulk density.

-pass a quantity of powder sample through a sieve with aperture greater than or Equal to 1.0mm.

Gently introduce 10gm of sample into a dry graduate measuring eylinder of 25ml. carefully to a level the

powder without and read the unsettled apparent volume.
Bulk density mass/bulk volume.
Calculation for bulk density:
• Lactose: bulk density -10gm/17ml =0.589gm/cm'
• Starch: bulk density=10gm/12.5ml-0.89gm/em'
• Calamine: bulk density=10gm/15ml-0.69gm/cm'
Result: The bulk density of lactose starch and calamine was 0.58, 0.89, 0.69 gm/em' respectively.
Procedure: for tapped density.
Secure the cylinder in the holder of bulk density apparatus.
Carry out 10, 500, 1250 taps on the same powder sample.
Calculate the tapped density by using formula:
Tapped density=Mass/Tapped volume
Calculation for tapped density:
• Lactose: tapped density
= 10/12
= 0,83 em/em
* Starch: tapped Density
÷1077
=1.42 gmiem'
Calamine: tapped density
=10/11.51
=0.86 gm/em'

Result: The tapped density of lactose, starch sod calamine nas calexlated, fuey are 0.83,1.42, 0.86 g/eme as respectively.

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