DR. B.C.ROY COLLEGE OF PHARMACY & AHS

REPORT ON PRACTICE SCHOOL ON THE TOPIC

"*PREFORMULATION & MANUFACTURING OF SOLID DOSAGE FORM*"

Practice school Attended by :	Supervised by :
18901920048 - SAYAN KAR 18901920060 - SHOAIB AKHTAR 18901920064 - SUMANA DAS 18901920065 - SAYAN HATI 18901920067 - ROHAN MONDAL 18901920071 - ARIJIT SIL 18901920072 - SUJATA BURNWAL 18901920077 - BAPI KONAI 18901920078 - SHRABANI DAS 18901920091 - BIBEKANANDA BHUIN 18901920094 - APARESH BERA 18901920098 - NABANITA SEN 18901920100 - PRITAM DE 18901920101 - SINCHAN KUMAR ROY 18901920104 - PRIYANKA JANA 18901921106 - POULAMI BISUYI 18901921107 - SURANJANA BASAK 18901921110 - SAMPRITI PRAMANICK 18901921111 - DEBJYOTI DEY 18901921112 - SAYAK MONDAL 18901921113 - RIYA KUNDU 18901921114 - BUBAI MOHISH	Dr. Falguni Patra Associate Professor of Division of Pharmaceutics, BCRCP. Mr. Waizul Haque Associate Professor of Division of Pharmaceutics, BCRCP.

This report is submitted as per requirement of paper Practice School (PT-781) of B.Pharm , 7th Semester
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MAULANA ABUL KALAM AZAD UNIVERSITY OF TECHNOLOGY, WEST BENGAL
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Univ. Roll No	NAME OF THE STUDENT	SIGNATURE
18901920048	SAYAN KAR	
18901920060	SHOAIB AKHTAR	
18901920064	SUMANA DAS	
18901920065	SAYAN HATI	
18901920067	ROHAN MONDAL	
18901920071	ARIJIT SIL	
18901920072	SUJATA BURNWAL	
18901920077	BAPI KONAI	
18901920078	SHRABANI DAS	
18901920091	BIBEKANANDA BHUIN	
18901920094	APARESH BERA	
18901920098	NABANITA SEN	
18901920100	PRITAM DE	
18901920101	SINCHAN KUMAR ROY	
18901920104	PRIYANKA JANA	
18901921106	POULAMI BISUYI	
18901921107	SURANJANA BASAK	
18901921110	SAMPRITI PRAMANICK	
18901921111	DEBJYOTI DEY	
18901921112	SAYAK MONDAL	
18901921113	RIYA KUNDU	
18901921114	BUBAI MOHISH	

Dr. B.C.Roy College of Pharmacy & AHS

Dr.Megnad Saha Sarani,Bidhannagar,Durgapur,713206

Practice School

Supervisor

Dr. Falguni Patra

Associate Professor

Division of Pharmaceutics, BCRCP

Mr. Waizul Haque

Associate Professor

Division of Pharmaceutics, BCRCP

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ABSTRACT:

Drug development is a complicated and lengthy procedure including discovery of drug, studies testing in laboratory, clinical trials and regulatory registration to increase the safety and efficacy of drug product after approval. Regulatory agencies like FDA [food and drug administration] required to testing of drug product for strength, identity, purity, quality, stability before using and releasing in market. This was the reason pharmaceutical validation and process control are required for problems to be controls. In process quality control is one of the most important terms used in pharma industry to control the quality of the pharmaceutical product under quality control system IPQC tests are important to remove problems from production lines. Those standards are provided in pharmacopoeias.

Preformulation & manufacturing of solid dosage form is a long procedure by which a proper solid dosage form of a particular API is going to be developed. Here all the Physicochemical & biopharmaceutical properties of APIs including all the excipients going to be used in that dosage form is evaluated to obtain a proper safe, efficacious& stable dosage form.

INTRODUCTION

Solid medicaments may be administered orally as powder, pills, cachets, capsules or tablets. These dosage forms contain a quantity of drug which is given as a single unit and they are known collectively as solid unit dosage forms, even in the case of sustained action preparations which, technically, contain the equivalent of several normal doses of drug The stringent formulation requirements of modern medicaments, the many advantages of tablet and capsule medication, coupled with expanding health services and the commitment need for large-scale economic manufacture, have led to a steady decline in the prescribing of powders and pills Tablets and capsules, on the other hand, currently account for well over two third of the total number and cost of medicines produced all over the world.

WHAT IS TABLET?

Tablet is defined as a solid unit dosage form containing medicaments with or without excipients and prepared by compression techniques.

According to the Indian Pharmacopoeia Pharmaceutical tablets are solid, flat or biconcave dishes, unit dosage fam, prepared by compressing a drug or a mixture of drugs with or without diluents. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of Tablet All medicaments are available in the Tablet form except where it is difficult to formulate or administer.

ADVANTAGES OF TABLET DOSAGE FORMS

1. They are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
2. Cost is lowest of all oral dosage form.
3. Lighter and compact.

4. Easiest and cheapest to package and strip.
5. Easy to swallowing with least tendency for hang up
6. Sustained release product is possible by enteric coating.
7. Objectionable odour and bitter taste can be masked by coating technique.
8. Suitable for large scale production.
9. Greatest chemical and microbial stability over all oral dosage form.
10. Product identification is easy and rapid requiring no additional steps when employing an embossed and/or monogrammed punch face.

DISADVANTAGES OF TABLET DOSAGE FORMS

1. Difficult to swallow in case of children and unconscious patients.
2. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
3. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.
4. Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.

PROPERTIES OF TABLET DOSAGE FORMS

- A tablet should have elegant product identity while free of defects like chips, cracks, discoloration, and contamination.
- Should have sufficient strength to withstand mechanical shock during its production packaging, shipping and dispensing.
- Should have the chemical and physical stability to maintain its physical attributes over time.
- The tablet must be able to release the medicinal agents in a predictable and reproducible manner.
- Must have a chemical stability over time so as not to follow alteration of the medicinal agents.

DIFFERRENT TYPES OF TABLETS

(A) Tablets ingested orally

1. Compressed tablet, eg. Paracetamol tablet.
2. Multiple compressed tablets.
3. Repeat action tablet.
4. Delayed release tablet, et Enteric coated Bisacodyl tablet.
5. Sugar coated tablet, eg. Multivitamin tablet.
6. Film coated tablet, eg. Metronidazole tablet.
7. Chewable tablet, eg Antacid tablet.

(B) Tablets used in oral cavity:

1. Buccal tablet, eg. Vitamin c tablet.
2. Sublingual tablet, eg Vicks Menthol tablet.

3. Troches or lozenges.
4. Dental cone.

(C) Tablets administered by other route:

1. Implantation tablet.
2. Vaginal tablet, eg. Clotrimazole tablet.

(D) Tablets used to prepare solution:

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

DIFFERENT INGREDIENTS OF TABLETS

In addition to active ingredients, tablet contains a number of inert materials known as additives or excipients. Different excipients are:

1. Diluent :- Diluents are fillers used to make required bulk of the tablet when the drug dosage itself is inadequate to produce the bulk.

Ex.-Calcium sulphate dihydrate, Mannitol, Sorbitol, Sucrose, Dextrose etc.

2. Binder and adhesive:- These materials are added either dry or in wet- form to form granules or to form cohesive compacts for directly compressed tablet.

Ex:- Acacia, tragacanth, Methyl cellulose, Hydroxypropyl methyl cellulose, Hydroxypropyl cellulose ,Gelatin etc.

3. Disintegrants :- Added to a tablet formulation to facilitate its breaking or disintegration when it contact in water in the GIT.

Example: Starch, bentonite, sodium carboxymethyl cellulose, PVP (Polyvinylpyrrolidone) etc.

4.Superdisintegrants: Swells up to ten fold within 30 seconds when contact water.

Example: Cross carmellose sodium, cross-linked cellulose, Cross povidone cross-linked povidone (polymer), Sodium starch glycolate cross-linked starch.

5. Lubricants and glidants:- Lubricants are intended to prevent adhesion of the tablet materials to the surface of dies and punches, reduce inter particle friction and may improve the rate of flow of the tablet granulation .

Glidants are intended to promote flow of granules or powder material by reducing the friction between the particles.

Example: Lubricants - Magnesium stearate, Talc, PEG Surfactants etc.
Glidants- Corn Starch, Talc, Cab-O-Sil, Syloid, etc.

6. Colouring agents:- The use of colors and dyes in a tablet has three purposes:

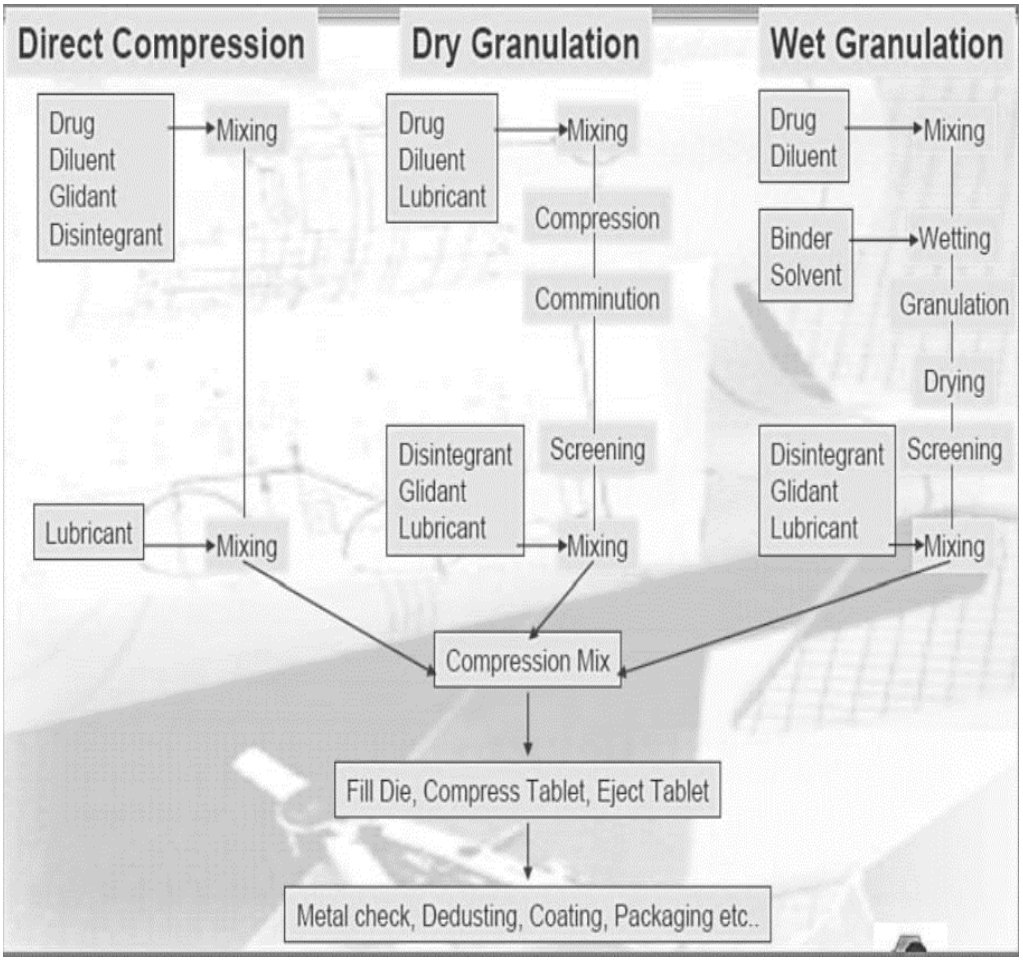
(1) Masking of off color drugs
(2) Product Identification
(3) Production of more elegant product.

Example: FD & C yellow 6 sunset yellow, FD & C yellow 5 Tartrazine,
FD & C green3- Fast Green, D&C red 3-Erythrosine, etc.

7. Flavoring agents:- For chewable tablet-flavor oil are used.

8. Sweetening agents:- For chewable tablets: Sugar, mannitol. Saccharine (artificial): 500 time's sweeter than sucrose, etc.

TABLET GRANULATION PROCEDURES:



TABLET COMPRESSION MACHINE

Tablets are made by compressing a formulation containing a drug or drugs with excipients on stamping machine called presses. Tablet presses are designed with following basic components.

1) Hopper for holding and feeding granulation.

2) Dies that define the size and shape of the tablet.

3) Punches for compressing the granulation within the dies.

4) Cam tracks for guiding the movement of the punches.

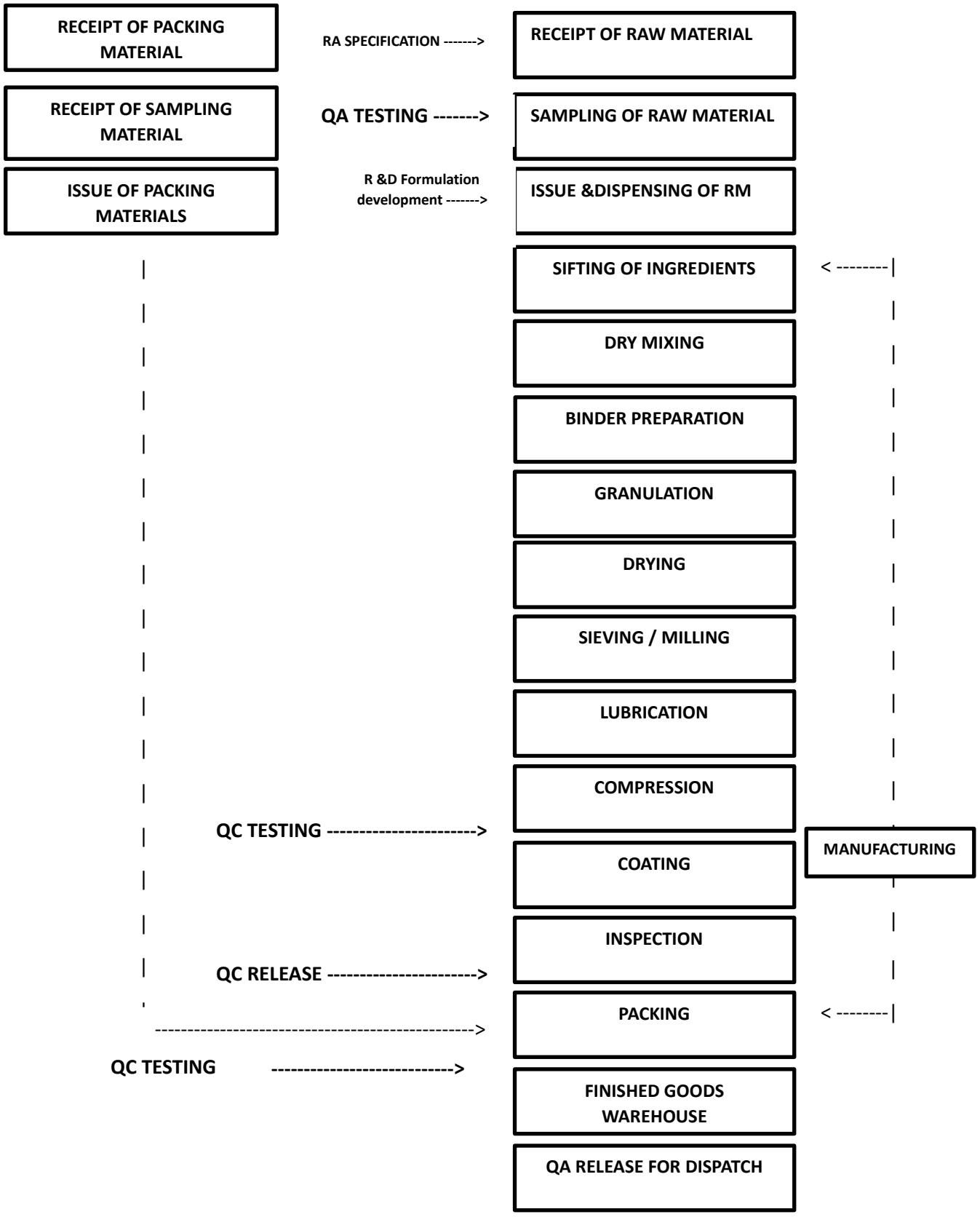
5) A feeding mechanism for moving granulation from hopper into the dies.

Fig -1: Tablet Punching Machine

RATIONALE FOR THE STUDY

To develop and manufacture robust Paracetamol tablets 500 mg in Dr. B. C Roy College of Pharmacy & AHS we have to be shown similar critical quality attribute of marketed PCM as a part of pharmacy practice school.

GENERAL PLAN OF WORK



Team Division

Sl. no	Team	Team Leader	Members
1	PRODUCTION	SAYAN HATI	SAYAN KAR
2			SHOAIB AKHTAR
3			SUMANA DAS
4			SAYAN HATI
5			ROHAN MONDAL
6	RESEARCH AND DEVELOPMENT	BIBEKANANDA BHUIN	ARIJIT SIL
7			SUJATA BURNWAL
8			BAPI KONAI
9			SHRABANI DAS
10			BIBEKANANDA BHUIN
11	QUALITY ASSURANCE	SINCHAN KUMAR ROY	APARESH BERA
12			NABANITA SEN
13			PRITAM DE
14			SINCHAN KUMAR ROY
15	QUALITY CONTROL	SAMPRITI PRAMANICK	PRIYANKA JANA
16			POULAMI BISUYI
17			SURANJANA BASAK
18			SAMPRITI PRAMANICK
19	REGULATORY AFFAIRS	DEBJYOTI DEY	DEBJYOTI DEY
20			SAYAK MONDAL
21			RIYA KUNDU
22			BUBAI MOHISH

Regulatory Affair Department

MATERIAL

Date:- 07.11.2023

Detail of marketed tablets

We have selected Calpol-500 as standard marketed product for development of solid dosage form of Paracetamol 500.

The reasons behind choosing Calpol-500 as a Standard product:

Calpol 500 is marketed by Glaxo Smith Kline in India. It is one of highest selling Paracetamol -500 mg Tablet in all over India till today.

From Market research we came to know that Calpol-500 has better bioavailability than other marketed products & it has long shelf life (About 2 years)

Manufacturing company: Glaxo Smith Kline
Brand name: Calpol-500
Quantity: 45
Mfg. Date: 25/07/2023
Exp. Date:24/07/2025

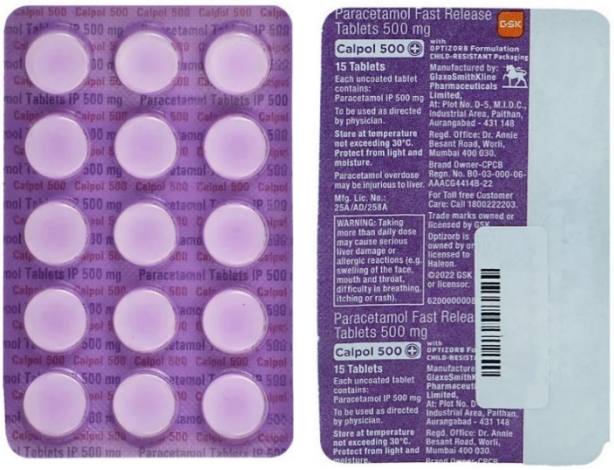


Fig -2: Marketed Tablets

API and Excipients name and manufacturer

BILL OF MATERIAL(BOM)								
S.No	**Material name**	**Batch no/ Lot no**	**Mfg date**	**Exp.date**	**Quantity required (gm)**	**Quantity dispensed (gm)**	**Done by RA**	**Checked by(QA)**
1	Paracetamol (API)				25			
2	Lactose monohydrate				25			
3	Microcrystalline cellulose				20			
4	Starch				20			
5	Talc				5			
6	Mg. Stearate				5			

	Prepared By	Reviewed By				Approved By
Department	**RA**	**R & D**	**QC**	**RA**	**PR**	**RA**
Signature						

R & D and Technology Transfer

MANUFACTURING OF PARACETAMOL TABLETS

Aim: To formulate 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.

Procedure: -

Paracetamol tablets are mainly prepared by 3 basic methods

• Wet granulation • Dry granulation • Direct compression

Why we selected wet granulation for paracetamol preparation?

Wet granulation is commonly used in pharmaceutical and related industries for several reasons. It helps improve the flow properties of powders, enhances the uniformity of the mix, reduces dust generation, and aids in the formation of granules with better compressibility. Additionally, wet granulation can be advantageous for the incorporation of moisture-sensitive or hydrophobic ingredients.

Steps involved in wet granulation method are:

1. Accurately weigh the 20g of paracetamol ,5g of starch paste, 6g of lactose,2g of starch, 1g of magnesium stearate,1g of talc for 40 tablets by using calibrated digital balancing machine
2. The active ingredient, diluent and disintegrants are mixed or blended well until uniform powder is formed by geometric mixing

3. A damp mass of the mixture is prepared by adding appropriate amount of the 5% starch mucilage and kneading by hand.
4. Wet mass is subsequently passes through a 12-mesh sieve/screen to form wet granules.
5. Resulted granules are spread evenly on a large piece of paper in a tray and dried at 40ºC to 60ºC for 30min in an oven.
6. Dried granules are passed through a sieve 12 # and mixed with magnesium stearate and talc.
7. Resulting granules mixture is compressed in a tablet compression machine to obtain tablets.
8. Prepared tablets are handed over to qc for further evaluation.

Fig -3: Prepared Tablets

Ingredients table (Formula) for 500 mg of Paracetamol Tablet I.P :-

S. NO	INGREDIENTS	1 TABLET (mg)	40 TABLETS (g)	PURPOSE
1	PARACETAMOL(API)	500	20	Analgesic & Antipyretic
2	5% STARCH PASTE	125	**5**	Binding agent
3	LACTOSE MONOHYDRATE	150	6	Diluent
4	STARCH MONOHYDRATE	50	2	Disintegrant
5	TALC	25	1	Glidant
6	MG. STEARATE	25	1	Lubricant

.

	Prepared By	Reviewed By				Approved By
Department	**R & D**	**R & D**	**QC**	**RA**	**PR**	**R & D**
Signature						

TESTS FOR RAW MATERIALS AND INTERMEDIATE SAMPLES

SOP OF BULK DENSITY OF THE RAW MATERIALS AND INTERMIDIATE SAMPLE

PURPOSE: -To describe procedure for operation of property in sample like **Bulk Density.**

SCOPE: - The sop is applicable for operation of flow property in sample.

SOP: - A Standard Operating Procedure is a document, which describes the step-by-step methodology to be followed for performing a job or task.

SOP should be an operating guideline, a training aid for personnel, precise, informative and written in simple and directive language.

PROCEDURE: -

DETERMINATION OF BULK DENSITY: -

1. Take clean and dry measuring cylinder.
2. Weigh accurately adequate amount of powder (w1).
3. Place it in dried graduated measuring cylinder and note volume as V1 mL
4. Place the cylinder containing sample in bulk density apparatus. Adjust apparatus and operate it for 100 tapping. Record the volume occupied by the powder as V2 ml.

Bulk density = mass(W1)/volume(V2)

SOP OF TAPPED DENSITY OF THE RAW MATERIALS AND INTERMIDIATE SAMPLE

PURPOSE: -To describe procedure for operation of property in sample like **Tapped Density.**

SCOPE: - The sop is applicable for operation of flow property in sample.

PROCEDURE: -

DETERMINATION OF TAPPED DENSITY: -

1. Carry out 500 tapping previous sample placed in measuring cylinder.
2. Measure the tapped volume (v1).

Tapped density = Bulk weight / tapped volume.

SOP OF FLOW PROPERTY OF THE RAW MATERIALS AND INTERMIDIATE SAMPLE

PURPOSE: -To describe procedure for operation of property in sample like **Flow Property.**

SCOPE: - The sop is applicable for operation of flow property in sample.

PROCEDURE: -

DETERMINATION OF ANGLE OF REPOSE: -

1.Take a clean and dry funnel with a round stem of 20 to 30 mm diameter with flat tip and attach it to the burette stand.

2. Place a graph paper sheet below the funnel, on clean and dry platform.

3. Adjust the distance between lower tip of the funnel and sheet to some specified height (say 1 cm or 2 cm).

4. Gently pour sample in funnel from top till a heap of powder forms and touches the lower tip of the funnel.

5. Using a pencil draw a circle around the heap covering approximately 90 percent of total powder.

6. Repeat the procedure four times to obtain average reading.

7. Find out average diameter and radius of each drawn circle as shown in Fig.

Angle Of Repose $=\tan^{-1}(h/r)$

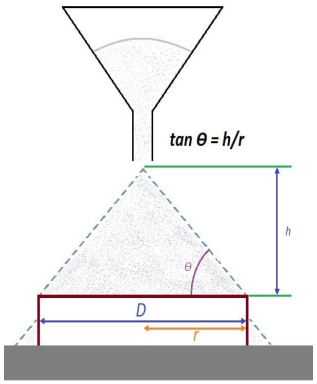


Fig -4: Angle of Repose

SOP OF MOISTURE CONTENT AND LOSS ON DRYING TEST OF RAW MATERIALS AND INTERMEDIATE SAMPLE

PURPOSE: - The standard Operating procedure is standard test method for measuring moisture content and loss on drying of samples. This sop covers the determination of the moisture content and loss on drying in sample.

SCOPE: - This sop is applicable for operation of moisture content and loss on drying in sample.

PROCEDURE: -

1. Take clean dry Petri dish and weight it (x)
2. Weigh 1g of Sample and transfer to Petri dish and weight it.
3. Place the Petri dish in tray dryer and weigh it at every 15 min for moisture content and 1hr for loss on drying.
4. Allow it to dry until it's constant weight the down the constant dry weight in case of moisture content.
5. Calculate the percentage loss on drying and percentage moisture content for the given sample.

SOP OF PARTICLE SIZE OF THE RAW MATERIALS AND INTERMIDIATE SAMPLE

PURPOSE: -The standard Operating procedure is standard test method for particle size analysis of samples. This sop covers the quantitative determination of the distribution of the particle sizes in sample. The distribution of particle sizes is determined by sieving method. It provides technical guidance and procedures to be employed for particle size analysis including the required equipment, procedure and personnel responsibilities.

SCOPE: -This sop is applicable for operation of particle size analysis

SOP: - A standard operating procedure is a document, which describe the step-by-step methodology to be followed for performing a job or task.

PROCEDURE: -. Arrange the set of sieves (IP or USP standard) in descending order. (Place sieve

number 10 at top, below which place sieve numbers 20, 40, 60, 80, 100, respectively and 120 at the bottom).

2. Weigh, accurately, the given sample and place in the top sieve. Cover with lid to avoid loss during shaking.

3. Operate the sieve-shaking machine for 5 min.

4. Collect fractions of samples retained on each sieve and on receiver at the bottom of set.

5. Weigh samples using weighing balance.

6. Calculate per cent frequency of each size of particles.

Fig -5: Sieve Shaker

CALCULATIONS: -

1.Calculation of cumulative % weight retained:

%Weight retained on sieve=weight retained on sieve/ Total weight of powder*100

2. Calculation of % cumulative frequency:

% Cumulative frequency=% weight retained on previous sieve+ % weight retained on sieve under consideration.

QUALITY ASSURANCE

CERTIFICATE OF ANALYSIS

Date:- 9.10.2023

Material: - Paracetamol
API Specification No: - RAW PCM-001
Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Acceptance Criteria	Amount Of Drug Allotted
01	Bulk Density	As Applicable	5gm
02	Tapped Density	As Applicable	5gm
03	Angle of Repose	As Applicable	10gm
04	Particle Size	As Applicable	10gm
05	Moisture Content	2.5% to 3.5%	1gm
06	Loss on Drying	0.1% to 0.5%	1gm

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

Material: - Magnesium Stearate

Specification No: - RAW-MS-001

Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Acceptance Criteria	Amount Of Drug Allotted
01	Bulk Density	As Applicable	5gm
02	Tapped Density	As Applicable	5gm
03	Angle of Repose	As Applicable	10gm
04	Particle Size	As Applicable	10gm
05	Moisture Content	2.5% to 3.5%	1gm
06	Loss on Drying	0.1% to 0.5%	1gm

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

Material: - Microcrystalline Cellulose

Specification No: - RAW-MCC-001

Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Acceptance Criteria	Amount Of Drug Allotted
01	Bulk Density	As Applicable	5gm
02	Tapped Density	As Applicable	5gm
03	Angle of Repose	As Applicable	10gm
04	Particle Size	As Applicable	10gm
05	Moisture Content	Not more than 5%	1gm
06	Loss on Drying	Not more than 5%	1gm

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

Material: -Talc
Specification No: -RAW-TALC-001
Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Acceptance Criteria	Amount Of Drug Allotted
01	Bulk Density	As Applicable	5gm
02	Tapped Density	As Applicable	5gm
03	Angle of Repose	As Applicable	10gm
04	Particle Size	As Applicable	10gm
05	Moisture Content	2.5% to 3.5%	1gm
06	Loss on Drying	0.1% to 0.5%	1gm

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

Material: -Lactose
Specification No: -RAW-LAC-001
Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Acceptance Criteria	Amount Of Drug Allotted
01	Bulk Density	As Applicable	5gm
02	Tapped Density	As Applicable	5gm
03	Angle of Repose	As Applicable	10gm
04	Particle Size	As Applicable	10gm
05	Moisture Content	Not more than 5%	1gm
06	Loss on Drying	Not more than 5%	1gm

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

QUALITY ASSURANCE

Material: -Starch
Specification No: -RAW-STR-001
Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Acceptance Criteria	Amount Of Drug Allotted
01	Bulk Density	As Applicable	5gm
02	Tapped Density	As Applicable	5gm
03	Angle of Repose	As Applicable	10gm
04	Particle Size	As Applicable	10gm
05	Moisture Content	11% to 14%	1gm
06	Loss on Drying	11% to 14%	1gm

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

QUALITY ASSURANCE

Date: - 06.11.2023

Material: - Intermediate Samples
Specification No: - INT-PCM-001
Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

Sr. no	Experiment	Amount Of Intermediate Sample Used
01	Flow Property	30 gm
02	Bulk Density	30 gm
03	Tapped Density	30 gm
04	Particle Size	30 gm
05	Moisture Content	1 gm
06	Loss on Drying	1 gm
07		
08		
09		
10		

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

QUALITY CONTROL

Date: -11.10.2023

TEST RESULTS OF RAW MATERIALS

Sr. no	Material	Bulk Density (in gm/ml)
1	Paracetamol API	0.264
2	Magnesium Stearate	0.234
3	Micro-crystalline Cellulose	0.229
4	Talc	0.215
5	Lactose	0.583
6	Starch	0.625

Sr. no	Material	Bulk Density (in gm/ml)
1	Paracetamol API	0.264
2	Magnesium Stearate	0.234
3	Micro-crystalline Cellulose	0.229
4	Talc	0.215
5	Lactose	0.583
6	Starch	0.625

Sr. no	Material	Tapped Density (in gm/ml)
1	Paracetamol API	0.625
2	Magnesium Stearate	0.474
3	Micro-crystalline Cellulose	0.392
4	Talc	0.377
5	Lactose	0.674
6	Starch	0.909

Sr. no	Material	Moisture Content
1	Paracetamol API	3%
2	Magnesium Stearate	5%
3	Micro-crystalline Cellulose	4%
4	Talc	6%
5	Lactose	3%
6	Starch	11%

Sr. no	Material	Loss on Drying
1	Paracetamol API	3%
2	Magnesium Stearate	5%
3	Micro-crystalline Cellulose	3%
4	Talc	6%
5	Lactose	4%
6	Starch	17%

	Prepared By	Reviewed By				Approved By
Department	**QA**	**R & D**	**QC**	**RA**	**PR**	**QA**
Signature						

QUALITY CONTROL

Date: -11.10.2023

PARTICLE SIZE DISTRIBUTION RESULTS OF RAW MATERIALS

PARACETAMOL API (WEIGHT 25gm)

Sr. No	Sieve No.	Particle Retained (in gm)	% Weight Retained on Sieve	% Cumulative frequency
1	22	0.4	1.6	1.6
2	85	1.23	4.92	6.52
3	72	12.47	49.88	56.4
4	Last	10.75	43	99.4

STARCH (WEIGHT 20gm)

Sr. No	Sieve No.	Particle Retained (in gm)	% Weight Retained on Sieve	% Cumulative frequency
1	22	-	-	-
2	85	0.25	1.25	1.25
3	72	1.25	6.25	7.5
4	Last	18.25	91.25	98.75

MICRO-CRYSTALLINE CELLULOSE (WEIGHT 20gm)

Sr. No	Sieve No.	Particle Retained (in gm)	% Weight Retained on Sieve	% Cumulative frequency
1	22	-	-	-
2	85	0.47	2.35	2.35
3	72	1.03	5.15	7.5
4	Last	18.48	92.4	99.9

LACTOSE (WEIGHT 25gm)

Sr. No	Sieve No.	Particle Retained (in gm)	% Weight Retained on Sieve	% Cumulative frequency
1	22	0.80	3.2	3.2
2	85	2.25	9	12.2
3	72	12.25	49	61.2
4	Last	9	36	97.2

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QUALITY CONTROL

Date: - 06.11.2023

Material: - Intermediate Samples

Specification No: - INT-PCM-001

Manufacturing Site: - Dr. B. C. Roy College of Pharmacy and Allied Health Sciences.

TEST RESULTS OF INTERMEDIATE SAMPLES

Sr. no	Experiment	Results
01	Flow Property	28.7867°
02	Bulk Density	0.46413 gm/ml
03	Tapped Density	0.08 gm/ml
04	Particle Size	
05	Moisture Content	9%
06	Loss on Drying	10%

PARTICLE SIZE RESULT: -

Sr. No	Sieve No.	Particle Retained (in gm)	% Weight Retained on Sieve	% Cumulative frequency
1	**12**	**4.7**	**15.67%**	**15.67%**
2	**22**	**21.9**	**73%**	**88.67%**
3	**Last**	**3.4**	**11.33%**	**100%**

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Finished & Marketed product Testing

Regulatory Affair Department

THICKNESS AND DIAMETER MEASUREMENT

Theory:

- Thickness and diameters are unofficial tests.
- Thickness and diameter should be controlled within ±5% variation of a standard value.
- Thickness and diameters of tablet can be measured by two equipments,

1.Micrometer: Here, put the tablet between two anvils and read it's thickness by scale. It is measured in micrometre (mm).

2.Vernier calipers: Here, tablet is put between two jaws of vernier caliper and measure thickness of tablet by reading scale. It is measured in centimetre(cm).

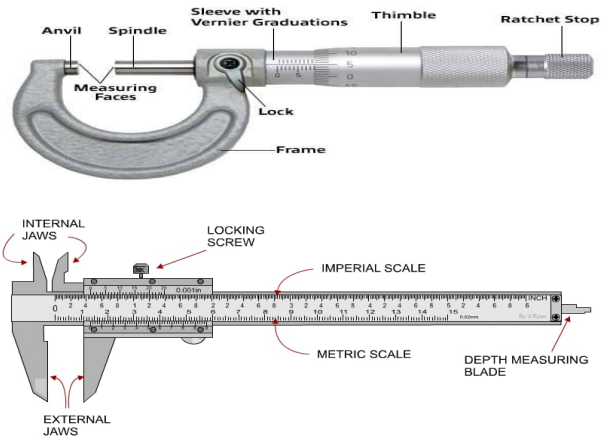

Fig -6: Micrometer & Vernier calipers

Procedure:

Here, we have used vernier calliper for thickness and diameter measurement.

We have taken 10 tablet sample (PARACETAMOL) from the market and we have measured the thickness and diameter and then we have taken 10 prepared tablet (PARACETAMOL) and we have measured there thickness and diameter as well. Now, we will compare them and conclude whether it is qualified or not.

FOR MARKETED TABLETS :-

TABLET NO.	THICKNESS (CM)	DIAMETER (CM)
TAB-1	0.28	0.67
TAB-2	0.26	0.65
TAB-3	0.29	0.68
TAB-4	0.30	0.68
TAB-5	0.28	0.66
TAB-6	0.25	0.69
TAB-7	0.29	0.70
TAB-8	0.26	0.66
TAB-9	0.30	0.65
TAB-10	0.28	0.68
AVERAGE	0.28	0.67

FOR PREPARED TABLET :-

TABLET NO.	THICKNESS (CM)	DIAMETER (CM)
TAB-1	0.31	0.69
TAB-2	0.27	0.67
TAB-3	0.28	0.69
TAB-4	0.28	0.69
TAB-5	0.29	0.68
TAB-6	0.29	0.70
TAB-7	0.30	0.72
TAB-8	0.30	0.68
TAB-9	0.30	0.68
TAB-10	0.28	0.71
AVERAGE	0.29	0.69

THE AVERAGE OF THICKNESS OF,

Marketed tablet= 0.28cm
Prepared tablet= 0.30cm
So, the percentage average of deviation of thickness is,

$$\frac{(0.29-0.28)}{0.28} \times 100\%$$

$$= 3.57\%$$

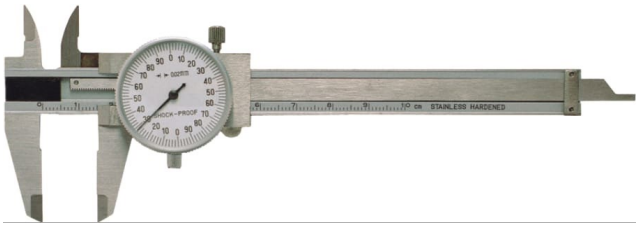

Fig -7: Vernier Calipers

Here deviation of thickness is under ±5%. So, our expected quality matched.

THE AVERAGE OF DIAMETER OF,

Marketed tablet= 0.67cm
Prepared tablet= 0.69cm
So, the percentage average of deviation of diameter is,

$$\frac{(0.69-0.67)}{0.67} \times 100\%$$

$$= 2.98\%$$

Here deviation of diameter is under ±5%. So, our expected quality matched.

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FRIABILITY TESTING

Theory- Friability is defined as the percentage of weight loss by tablets due to mechanical action during the test. The tablets are weighed before and after testing. The friability is expressed as percentage loss on pre test weight. Friability refers to the ability of the compressed tablet to avoid fracture and breaking during the transport.

Fig -8: Friability Test Apparatus

Procedure –

- 10 tablets were selected and weighed.

- The tablets were put into the drum of the tablet abrasion and friability tester. The rate of rotation was set to 25 rpm, time to 10 minutes and the operation was started.
- At the end of the operation, all the tablets were removed and free from dust or powder was ensured(brush was used).The tablets were reweighed. The percentage loss of weight was determined.
- Compressed tablet should not loss more than 1% of its weight.

Result-

Product	Initial Weight	After test Weight
Marketed Product	6.68 gm	6.64 gm
Prepared Product	7.87 gm	7.81 gm

Calculation-

Marketed Product	Prepared Product
Initial weight = 6.68 gm After weight = 6.64 gm Weight difference = (6.68 - 6.64) gm = 0.04 gm Percentage loss of weight = (0.04 / 6.68)*100% = 0.598 %	Initial weight = 7.87 gm After weight = 7.81 gm Weight difference = (7.87 - 7.81) gm = 0.06 gm Percentage loss of weight = (0.06 / 7.87)*100% = 0.762 %
Deviation: [(0.762 -0 .598)/0.598]*100 =27.42 %	

Conclusion-

The test is considered as a success when the percentage of weight loss of tablets does not exceed 1%. If not , the tablets are considered as poor quality and fail to comply with the assessment standard. Thus ,base on our result ,it shows that experiment was successfully conducted to comply with standard.

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WEIGHT VARIATION TEST

THEORY:-

Tablet weight is mainly affected by factors such as tooling of the compression machine, head pressure, machine speed and flow properties of the powder. Inconsistent powder or granulate density and particle size distribution are common sources of weight variation during compression.

Variation between tablet with respect to dose and weight must be reduced to a minimum. Uniformity of weight is an in process test parameter which ensures consistency of dosage units during compression.

Fig -9: Digital Weighing Balance

PROCEDURE:-

1. Weigh individually 20 units selected at random and calculate the average weight.
2. Not more than two of the individual weights deviates from the average weight by more than the percentage given in the pharmacopeia and none deviates by more than twice that percentage. IP/BP & USP limits for tablet weight variation is given below.

IP/BP	LIMIT	USP
80mg/less	±10%	130mg/less
More than 80 mg or less than 250mg	±7.5%	130mg to 324 mg
250mg or more	±5%	More than 324 mg

OBSERVATION & CALCULATION:-

WEIGHT VARIATION OF MARKETED PARACETAMOL TABLET

SL NO	WEIGHT VARIATION (mg)
1	0.633
2	0.653
3	0.637
4	0.658
5	0.653
6	0.634
7	0.674
8	0.653
9	0.637
10	0.638
11	0.639
12	0.648
13	0.644
14	0.652
15	0.629
16	0.652
17	0.643
18	0.637
19	0.619
20	0.671
MIN	0.619
MAXIMUM	0.674
AVERAGE	0.6452

WEIGHT VARIATION OF PREPARED PARACETAMOL TABLET

SL NO	WEIGHT VARIATION (mg)
1	0.729
2	0.718
3	0.737
4	0.724
5	0.740
6	0.735
7	0.739
8	0.740
9	0.728
10	0.732
11	0.722
12	0.738
13	0.742
14	0.729
15	0.736
16	0.729
17	0.723
18	0.742
19	0.737
20	0.742
MIN	0.718
MAXIMUM	0.742
AVERAGE	0.733

RESULT:-

As per the test the average weight of marketed product and prepared product are 0.645mg and 0.733mg.

Deviation: [(0.733-0.6452)/0.733]*100

=13.6%

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HARDNESS TEST

- **Theory :-**

Hardness of Tablets Hardness may be defined as the resistance of tablets to capping, abrasion or breakage under conditions of storage, transportation and handling. Tablet hardness has been associated with other tablet properties such as density and porosity. Hardness generally increases with normal storage of tablets and depends on the shape, chemical properties, binding agent and pressure applied during compression. It is non-official quality control method. It is not prescribed by I.P. Hardness test: The small and portable hardness tester was manufactured and introduced by Monsanto in the Mid1930s. It is now designated as either the Monsanto or Stokes hardness tester. The instrument measures the force required to break the tablet when the force generated by a coil spring is applied diametrically to the tablet. Hardness generally measures the tablet crushing strength. Various devices used to test hardness are: Monsanto tester, Pfizer tester, Strong-cobb tester and schleuniger tester, erweka tester.

Fig -10: Pfizer Hardness Tester

- **Unit Of Hardness Of Tablet** - As we know, all measurements have some specific units and the same is the case for tablet hardness. The tablet hardness is a force, so tablet hardness is measured in the following units
  - Kilograms (kg)
  - Newton (N)
  - Pound (lb)

- Kilo pound (kp)
- Strong Cobb (SC)

We have used **Pfizer hardness tester** which gives tablet hardness in **Kgs**

- **PROCEDURE: -**
  - Take 5 Tablets
  - Take a Pfizer Apparatus .
  - Put the Tablet on the neck of the Apparatus & set the point to 0 reading .
  - Applied pressure until The Tablet totally broken .
  - Take The reading of all 5 tablets .

- **OBSERVATION TABLE :-**

Marketed Tablet	Hardness (Kg)
1	11.2
2	12.8
3	12.1
4	12..8
5	12.9
Average	12.36

Prepared Tablet	Hardness (Kg)
1	9.8
2	9.7
3	10.1
4	9.8
5	10.2
Average	9.92

Result:

The average hardness of marketed tablet = 12.35 kg
& the average hardness of prepared tablet = 9.92 kg

Deviation: [(12.35-9.92)/ 12.35]*100
=19.676%

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Quality Control Department

PREPARATION OF STANDARD CURVE OF PARACETAMOL

THEORY:-

In analytical chemistry ,a calibration curve or standard curve is a general method for determining the concentration of a substance in an unknown sample by comparing the unknown to a set of standard samples of known concentration. In spectrophotometric analysis a series of standard solutions of known concentrations are prepared and absorbance is measured using spectrophotometer instrument to determine the unknown concentration of sample by Beer's Law.

Fig -11: UV Spectrophotometer

A calibration is a graph where concentration is plotted against absorbance then a straight line (Beer's Law) is fit to the data that we obtained and the resulting equation is used to convert absorbance of the unknown sample into concentration.

PROCEDURE :-

Preparation of standard solution :-

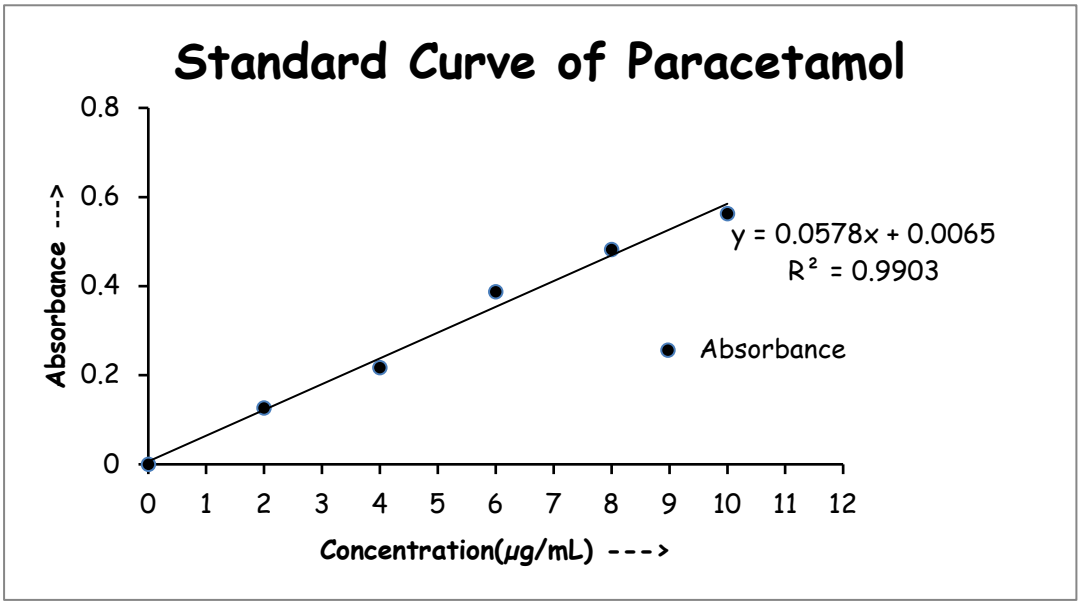
1. Weigh 0.15 gm powdered drug of paracetamol and add 50 ml of 0.1 N Sodium Hydroxide solutions.
2. Dissolve the powdered contain of paracetamol using sufficient quantity of water for homogenize the content shaking vigorously for It an about 15 min and add water to produce a volume up to 200 mL.
3. The above solution filtered using Whatman No. 41 Filter paper.
4. Prepare stock solution from the filtrate pipette out the 10 ml filtrate in a 100 mL previously cleaned volumetric flask then volume make up to the mark with the help of water and add 10 mL water.
6. Resulting solution to 10 mL of 0.1 N Sodium hydroxide solution scan in ultraviolet range UV Spectrophotometer in the 200 to 400 nm.

Preparation Standard Calibration Curve:-

1. From prepared stock make working solution in a series of 2 to 10 µg/mL using prefiltered solution of 0.1 N Sodium hydroxide.
2. Take an absorbance of different working solution at 257 nm.
3. Plot the graph between for obtained absorbance (nm) and concentration of different working solution.

OBSERVATION:-

Concentration (µg/ml)	Absorbance
0	0
2	0.126
4	0.217
6	0.387
8	0482
10	0.562



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QUALITY CONTROL DEPARTMENT

DISINTEGRATION TEST

THEORY: The test is performed to determine that whether the tablets disintegrate within the prescribed time period when placed in liquid medium under the specified experimental condition or not.

The test is used to show how quickly the tablets breakdown into smaller particles allow in a greater surface area for dissolution.

Fig -12: Disintegration Apparatus

PROCEDURE:

- The disintegration test apparatus consists of a basket rack assembly. The basket rack assembly holds 6 plastic tubes that are 3" long; open at top and the bottom of the tubes is covered with 10 mess wireless stainless-steel wire screen.
- To test for disintegration time, one tablet is placed in each tube and the basket risk is positioned in a 1-L beaker of water, simulated gastric fluid or simulated intestinal fluid at 37±2°C
- In that case, the tablet remains 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement.
- Move the basket containing the tablets up and down through a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. Floating of the tablets can be prevented by placing perforated plastic discs on each tablet.
- According to the test the tablet must disintegrate and all particles must pass through the 10-mesh screen in the time specified. If any residue remains, it must have a soft mass. Time was recorded and average time was calculated.
- The preparation compiles with the test if the time to reach the end point (completely disintegration) is below a given limit.
- Disintegration time: Uncoated tablet should be within 5 -30 min.
  Enteric Coated tablet: > 1 hour in simulated gastric fluid
  2 hours in simulated intestinal fluid

DISINTEGRATION TEST OF MARKETED PRODUCT:-

Sl No.	D_t (min)	$\overline{D_t}$ (min)	$(D_t - \overline{D_t})$	$(D_t - \overline{D_t})^2$	Standard Deviation
1	1.20	1.213	-0.013	0.000169	S.D = $\sqrt{\frac{\Sigma(D_t-\overline{D_t})^2}{n-1}}$
2	1.23		0.017	0.000289	
3	1.21		-0.003	0.000009	

Here D_t (min) =Disintegration time of individual tablets (min)

$\overline{D}_t$=Average disintegration time of tablet

n = Total number of tablets

Calculation,

Root mean square deviation in disintegration time of individual tablets

Avg. disintegration time of tablets = 1.213 min

So, percentage deviation = $\frac{0.0152}{1.213} \times 100\%$ = 1.253%

DISINTEGRATION TEST OF FINISHED PRODUCT :-

Sl No.	D_t (min)	$\overline{D}_t$ (min)	$(D_t - \overline{D_t})$	$(D_t - \overline{D}_t)^2$	Standard Deviation
1	4.15	4.186	-0.036	0.001296	S.D = $\sqrt{\frac{\Sigma(D_t-\overline{D}_t)^2}{n-1}}$
2	4.20		0.014	0.000196	$= \sqrt{\frac{0.002068}{3-1}}$
3	4.21		0.024	0.000576	$= \sqrt{0.001034}$ = 0.0321

Calculation,

Root mean square deviation in disintegration time of individual tablets

Avg. disintegration time of tablets = 4.186 min

So, percentage deviation = $\frac{0.0321}{4.186} \times 100\%$ = 0.766%

RESULT:

- For marketed product, We found the average disintegration time of a tablet is 1.213 min. and the percentage deviation was 1.253 %
- For finished product,We found the average disintegration time of a tablet is 4.186 min. and the percentage deviation was 0.766 %.

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DISSOLUTION TEST

Theory:

Dissolution is pharmaceutically defined as the rate of mass transfer from a solid surface into the dissolution medium or solvent under standardized conditions of liquid/solid interface, temperature and solvent composition. It is a dynamic property that changes with time and explains the
process by which a homogenous mixture of a solid or a liquid can be obtained in a solvent.
In the pharmaceutical industry, drug dissolution testing is routinely used to provide critical in vitro drug release information for both quality control purposes, to assess batch-to batch consistency of solid oral dosage forms such as tablets, and drug development to predict in vivo drug release profiles.
In vitro drug dissolution data generated from dissolution testing experiments can be related to in vivo pharmacokinetic data by means of in vitro-in vivo correlations (IVIVC). A well-established predictive IVIVC model can be very helpful for drug formulation design and post-approval manufacturing
changes.

PROCEDURE:

Preparation of solutions for Calibration curve:
Stock solution 1: Stock solution of drug (1mg/ml) is prepared by dissolving 100 mg of drug in 100 ml solution of methanol and phosphate buffer pH 6.8 (in 1:3 ratio) in 100 ml volumetric flask (to get 1000 µg/ml drug solutions) with vigorous shaking and further sonicated for about 10 minutes.

Stock solution 2: 10 ml of this (stock solution 1) is diluted to 100ml with phosphate buffer pH 6.8 to get a stock solution containing 100 µg/ml of drug. The stock solution was filtered through Whatman filter paper No.41.

Dilutions: Take the respective samples (0.2ml, 0.4ml, 0.6ml, 0.8ml, 1ml, 1.2ml, 1.4ml, 1.6ml, 1.8ml, 2ml, 2.2ml, 2.4ml) in each test tube, add phosphate buffer pH 6.8 to make total volume of 10 ml to produce (2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24µg/ml) respectively.

Determination of absorption maxima:

A UV absorption maximum was determined by scanning 10µg/ml solution of paracetamol in phosphate buffer 6.8, in between 200-400 nm by using UV visible spectrophotometer. Further a representative spectrum was drawn of paracetamol in phosphate buffer pH 6.8.

Preparation of Calibration curve:
The standard solutions for the drug having concentration 2, 4, 6, 8, 10 µg/ml was prepared with phosphate buffer pH 6.8 from the stock solution. The absorbance of solutions of absorbance v/s concentration to get the linearity and regression equation.

Phosphate buffer preparation:

Phosphate buffer: Place 50ml of 0.2 M Potassium di-hydrogen phosphate in a 200ml volumetric flask, add the specified volume of 0.2 M sodium hydroxide and then add distilled water to make up the volume 200ml.

Preparation of 0.2 M Potassium di-hydrogen phosphate solution:
Dissolve 27.218g of potassium di-hydrogen phosphate in sufficient distilled water containing in the 1000ml volumetric flask and to make up to the volume 1000ml.

dissolving 40 gm of sodium hydroxide in sufficient distilled water containing in the 1000ml volumetric flask and make up to the volume 1000ml.

Fig -13: Dissolution Apparatus

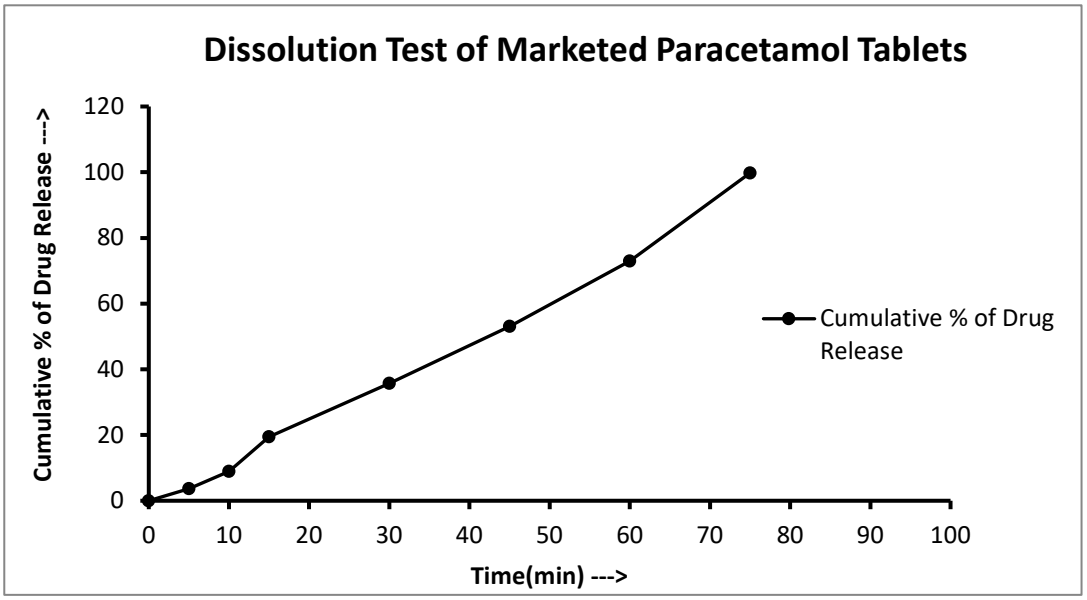
Dissolution study procedure:

1. Switch the heater of the dissolution device on and manage the temperature to reach 37°C.
2. Wash the vessel (of dissolution apparatus) using water and soap then put 900 ml of medium (phosphate buffer pH 6.8) in each.
3. Elevate the paddle 25±2 mm from the bottom of the vessel.
4. Operate the paddle on a rotation speed equals to 50 rpm.
5. Add one 500 mg tablet in one vessel which you previously cleaned and at once start timing.
6. At specified time intervals (5, 10, 15, 30, 45, 60 & 75 min) Withdraw 5 ml using the volumetric pipette from each filtrated sample (filtrate) and put it in 10 ml volumetric flask. (clean and neat).
7. Check the absorbance, if it goes above 1.000 then 1 ml sample taken in a 10 ml volumetric flask & complete the volume up to 10 ml by the medium (phosphate buffer at pH=6.8).
8. Replace the same volume into dissolution vessel by another volumetric pipette.
9. Read the absorbance of the diluted sample solutions at λ=257 nm using the buffer as a blank.
10. Plot a graph between Time intervals on x-axis vs % of drug release on y-axis.
11. Find out the slope, concentration, amount of drug release, percentage of drug release and report it.

OBSERVATION TABLE & CALCULATION:

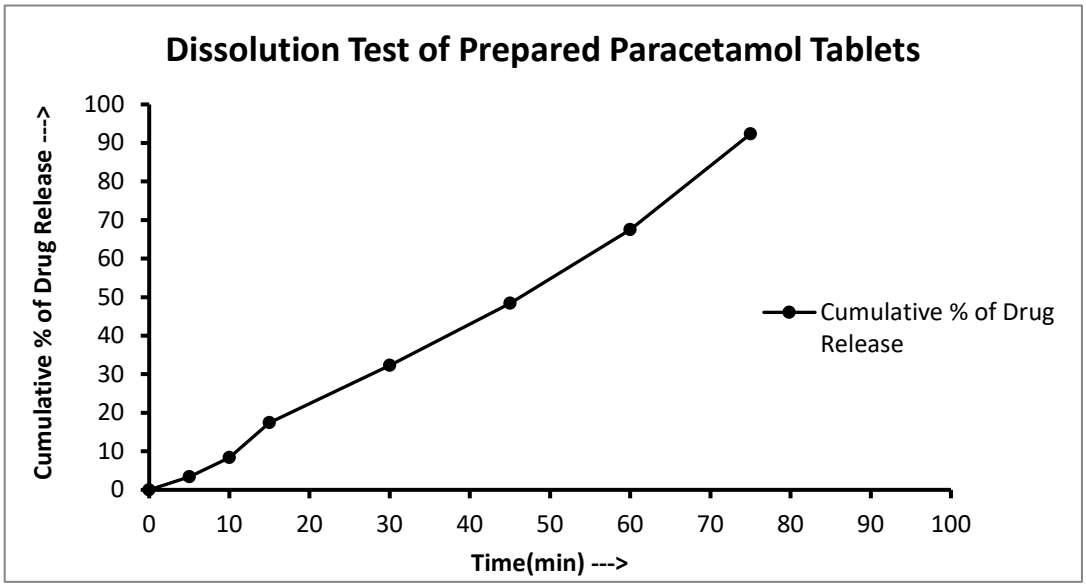
DISSOLUTION TEST OF MARKETED PARACETAMOL TABLET:

		Slope=0.0578	Dilution Factor =10	Drug =500mg			
		A	B	C	D	E	F
Time	**Absorbance**	**Concentration (µg/ml)**	**Concentration (mg/ml) B= A× 10^{-3}**	**Concentration (DF × B) C= B× 10**	**Amount in 5 ml D=5×C**	**Amount in 900 ml E=900×C**	**Cumulative % Release F= (E× 100) ÷ 500**
0	0	0	0	0	0	0	0
5	0.598	10.233	0.0102	0.0102	0.051	9.18	3.672
10	0.849	14.576	0.0145	0.0145	0.0725	13.12	8.92
15	0.178	2.967	0.0029	0.029	0.145	26.24	19.416
30	0.269	4.541	0.0045	0.045	0.225	40.72	35.704
45	0.285	4.818	0.0048	0.048	0.24	43.44	53.08
60	0.329	5.579	0.0055	0.055	0.275	49.77	72.988
75	0.438	7.465	0.0074	0.074	0.37	66.97	99.776



DISSOLUTION TEST OF PREPARED PARACETAMOL TABLET:

		Slope=0.0578	Dilution Factor =10	Drug =500mg		
Sl. No	**Time (min)**	**Absorbance (ƛ: 257nm)**	**Concentration (µg/ml.)**	**Amount present in 5ml (mg)**	**Amount present in 900mL (mg.)**	**CPR (Cumulative % release)**
1	0	0	0	0	0	0
2	5	0.548	9.368	0.046	8.33	3.332
3	10	0.827	14.195	0.070	12.58	8.36
4	15	0.151	2.5	0.125	22.68	17.43
5	30	0.245	4.126	0.206	37.062	32.26
6	45	0.267	4.50	0.225	40.41	48.42
7	60	0.314	5.320	0.264	47.59	67.46
8	75	0.410	6.980	0.349	62.82	92.35



Result:

The Cumulative % of Drug Release of Prepared Paracetamol Tablets in 75 mins is 92.35%

The Cumulative % of Drug Release of Marketed Paracetamol Tablets in 75 mins is 99.776%

Deviation: [(99.776-92.35)/ 99.776]*100

=7.442%

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Department	QC	R&D	QA	RA	PR	QC
Signature						

DISCUSSION

- The percentage deviation of thickness between marketed & prepared tablets was found to be 3.57%
- The percentage deviation of diameter between marketed & prepared tablets was found to be 2.98%
- The percentage deviation of friability test between marketed & prepared tablets was found to be 27.42 %
- The percentage deviation of weight variation test between marketed & prepared tablets was found to be 13.6%
- The percentage deviation of hardness test between marketed & prepared tablets was found to be 19.676%
- The percentage deviation of dissolution test (Cumulative % of Drug Release) between marketed & prepared tablets was found to be 7.442%
- The percentage deviation of disintegration test between marketed & prepared tablets was found to be
- For marketed product, we found the average disintegration time of a tablet is 1.213 min. and the percentage deviation was 1.253 %
- For finished product, we found the average disintegration time of a tablet is 4.186 min. and the percentage deviation was 0.766 %.

CONCLUSION

Following the General plan of work all works have been done by respective teams. Production team prepared the tablets as per the formula given by R & D. RA prepared the specifications for raw materials as the quality needed. All the raw material & intermediate product tests have been done by QA. We got the fruitful result as per our need. QC & RA have been completed all finished product & marketed product testing, based on the above trial it can be conclude that our formulation is similar with respect to quality and efficacy of marketed PCM tablets.

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