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Formulation and Evaluation of Paracetamol Ip 75 Mg Immediate Release Tablet

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ABSTRACT
The aim of the present study was to formulate and develop an immediate release (IR) tablet of paracetamol at a low dose of 75 mg, suitable for paediatric or low-dose adult applications. Paracetamol, a widely used analgesic and antipyretic, requires prompt onset of action, making rapid disintegration and dissolution crucial for therapeutic effectiveness. The formulation was designed using direct compression and wet granulation techniques with various combinations of excipients including microcrystalline cellulose, Binders, and super disintegrant such as croscarmellose sodium. Tablets were evaluated for pre-compression and post-compression parameters including hardness, friability, weight variation, disintegration time, and in vitro drug release profile. The optimized formulation exhibited rapid disintegration within 5 min and released more than 85% of the drug, complying with pharmacopeial specifications for immediate release dosage forms. The study successfully demonstrates that a 75 mg paracetamol IR tablet can be effectively formulated using standard excipients and techniques, providing a reliable low-dose option with fast therapeutic action.

Key words: Analgesic,antipyretic, Immediate release, Paediatric dose,Paracetamol

I. INTRODUCTION

Paracetamol also known as acetaminophen. It is a widely used analgesic and Antipyretic agent. It is most commonly used over-the-countered drug used for pain and relief. Paracetamol is the drug's name assigned using the international non-proprietary name (INN) generic name system.

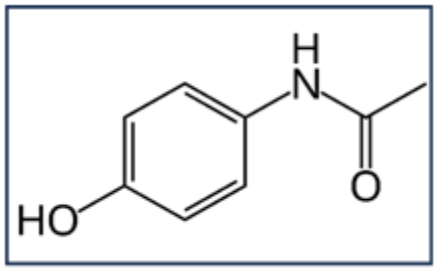
Acetaminophen is the generic name assigned using the United States Adopted Names (USAN) system. Paracetamol was first made in 1878 but only become more widely used in the 1950's. todayparacetamol is one of the most widely used painkillers in the world. Branded and generic version of this drug are available. paracetamol has been in use for more than 70 years.

Main key functions of paracetamol are:

1. Analgesic: Effective for mild to moderate pain such as headaches, menstrual cramps, toothaches, musculoskeletal pain.
2. Antipyretic: Commonly used to reduce fever in both children and adults.

Paracetamol primarily acts within the central nervous system so its effects are focused on neuronal and glial cells in the brain and spinal cord rather than peripheral tissues.

Structure:



Molecular formula: $C_8H_9NO_2$
Molecular Weight: 151.16g/mol

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Mechanism of action:

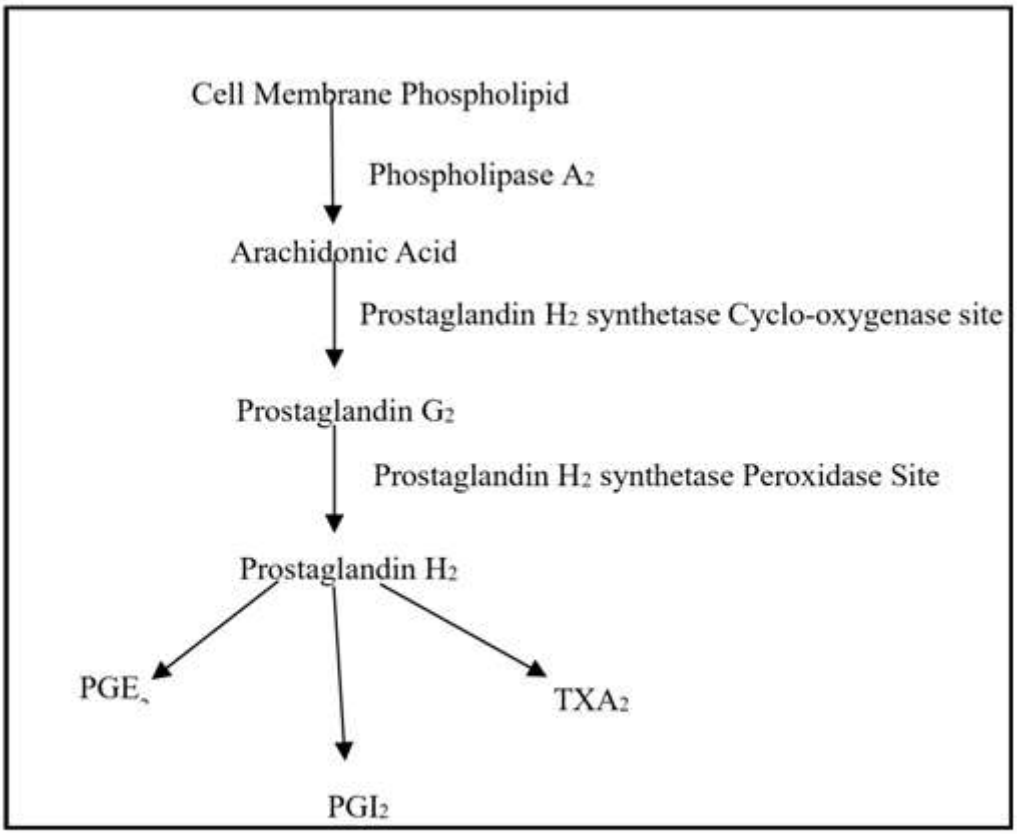

Fig.1: Mechanism of action of paracetamol.

Paracetamol comes in the following forms:

1. Tablets
2. Capsules
3. suppositories
4. soluble powders
5. liquids

Dose and their quantity according to age:

Child dose (2 Month to 6 yrs)		**Child dose (6 yrs plus)**		**Adult dose**
Age	Dose	Age	Dose	500mg to 100mg every 4-6 hours as needed Maximum 4000mg (4g) in 24 hours
2-3 M	60mg (2.5ml) 1 dose then 60mg (2.5ml) after 4-6H	6-8Y	250mg (5ml) up to QDS	
4 M	60mg 1 dose then 60mg after 4-6H Max 4 doses in a day	8-10Y	375mg (7.5ml) up to QDS	
3-6M	60mg (2.5ml) up to QDS	10-12Y	500mg (10ml) up to QDS	

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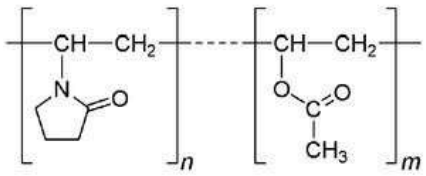
6-24M	120mg (5ml) up to QDS	12-16Y	500-750mg (10-15ml) up to QDS	
2-4Y	180mg (7.5ml) up to QDS	>16 Y	500-1000mg (10-20ml) up to QDS	
4-6Y	240mg (10ml) up to QDS			

Composition of Immediate Release Tablet

In formulation of Paracetamol immediate Release tablet IP 75mg, excipients were added to improve its quality. In formulation paracetamol is used as active pharmaceutical ingredient, Kollidon® VA 64, Klucel® EXF and Peg 4000 were used as binders, polyplasdone® xl-10 were used as super disintegrants, avicel® PH-200 was used as a filler, Mg-stearate and aerosol® 200 were utilized as glidants.

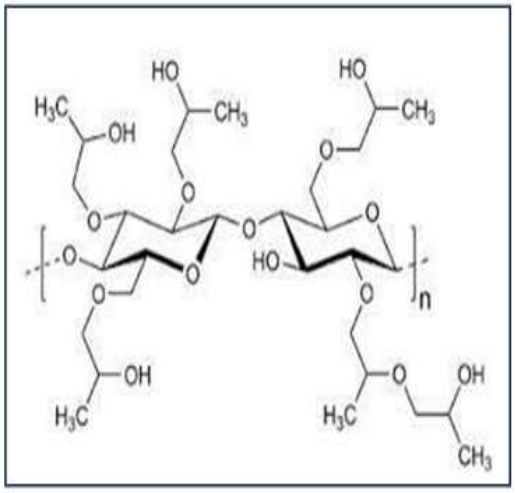
1.KolidonVA 64

It is a Vinylpyrrolidone-Vinyl acetate copolymer used as a binder and granulating agent in pharmaceutical industries. Kollidon VA 64 is a vinylpyrrolidone-vinyl acetate copolymer that is soluble both in water and in alcohols.



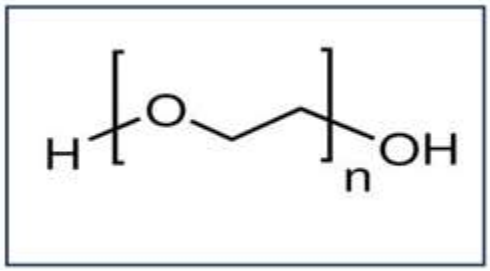
3. **KlucelEXF**

It is an Ultra-fine Hydroxy-Propyl Cellulose (HPC) is used as tablet binder in pharmaceutical industries. It improves tablet strength, low flowability and enhance compaction behaviour. Due to its fine particle size and high plasticity makes binding effective, especially for Active Pharmaceutical Ingredients which are difficult to compress.



3.Peg 4000

Used as binder in tablet formulation. It provides adhesive properties, helps to hold tablet components together during tablet compression. It improves tablet appearance and stability.



4.Polyplasdone® XL-10

It is a super disintegrant. Synthetic but rapidly swellable. It provides rapid disintegration and dissolution to oral solid dosage forms. Its particles are granular and porous as compare to other disintegrants. Due to its high interfacial Activity, it enhances the dissolution of poorly soluble drugs

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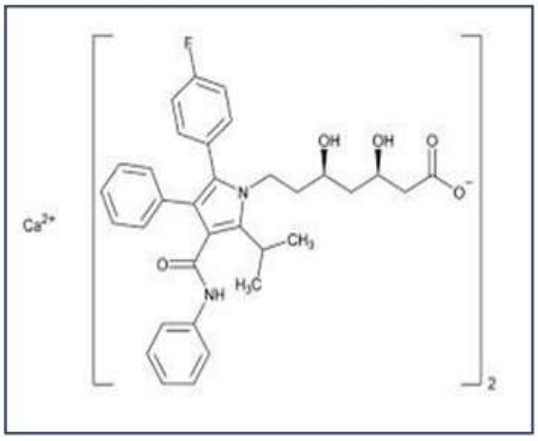
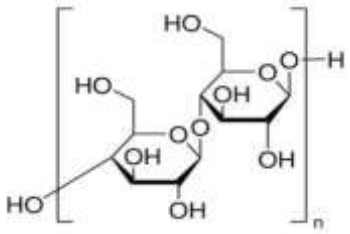
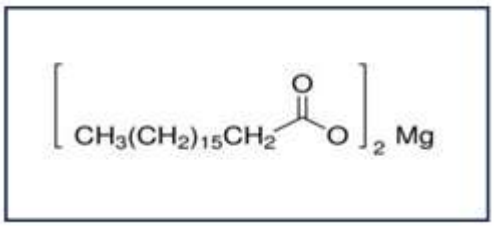


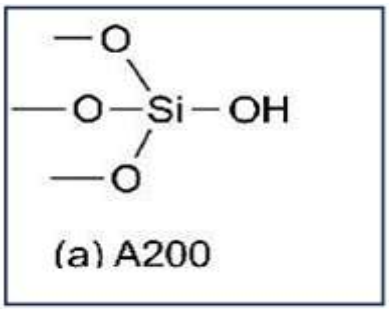
5. **Avicel PH-200** it is a micro-crystalline cellulose (CMC). Suitable for tablet compression and dry granulation process. It offers a good powder flow and compressibility for tablet manufacturing.



6. **Mg-stearate** used as lubricant and anti-adherent in pharmaceutical formulation. It reduces friction between particles and prevent them from sticking to the equipment. By reducing friction and stickiness it enhances the flowability of powder and provide consistent filling of tablet.



7. **Aerosol® 200** aerosol is a brand name of colloidal silicon dioxide. It improves powder flow by reducing tendency of particles to clump. By distributing powder more uniformly within the tablet equipment it helps to achieve more consistent tablet weight. It evenly distributes Active Pharmaceutical Ingredient (APIs) throughout the tablet mass.



II. MATERIALS AND METHODOLOGY

1.Materials:

Ingredient	F1	F2	F3	F4	F5	F6	F7
Paracetamol	75	75	75	75	75	75	75
Kolidon VA 64	4	2	1	3	4	3	1
Klucel EXF	2	4	2	3	1	4	3
Peg 4000	1	1	1	1	1	1	1
Polyplasdone XL10	5	3	2	4	4	3	5
Avicel PH-200	9	11	14.5	10	11.5	9.5	13
Mg-stearate	1	2.5	2	3	1.5	2	1
Aerosol 200	3	1.5	2.5	1	2	2.5	1

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2.Instruments

1. A weighing balance was used to measure the quantity of product.
2. A Tablet granulation machines was used to transform fine powder into larger, uniform granules, which are then used to create tablets.
3. A straining mesh or cloth served as the filtering instrument for the mixture.
4. A double cone blender was used to mix the ingredients thoroughly.
5. A hot air oven was used to sterilize the powdered mixture.
6. A tablet compression machine was used to form or compress granulated powder in consistent shape and size to form tablet.
7. A friability tester was used to evaluate the durability of tablets.
8. A disintegration apparatus was used to evaluate how quickly and completely a tablet dosage form breaks down in a liquid medium.
9. A dissolution tester was used to test immediate-release formulations, where the drug is released quickly.

3.Methodology for Formulation of Paracetamol Immediate Release Tablet

Method

Direct Compression method was used in tablet formulation.

Direct compression method is a popular way to make tablets in today's pharmaceutical Industry. It compresses the mixture of active ingredients and direct compression excipients Directly into tablet form.

Following are the steps involved in tablet formulation:

1. Add kolidonVA64 + polyplasdoneXL-10 + Avicel PH 20 + klucel EXF + PEG 4000 + Aerosil 200 all are mix and pass through 60 no sieve.
2. paracetamol drug pass through 40 number Sieve.
3. Mix drug and excipients in double cone blender at speed of 30-100rpm add mg stearate mix well.
4. Remove mixture from double cone blender Blend powder fill in single punch tablet compression machine. Compress the tablet and lower punch to push the formed tablet out of the die cavity.

III. EVALUATION TEST AND RESULTS

1.Organoleptic Properties

Property	Description
Appearance	Solid, round tablet
Colour	White
Odor	Odourless
Taste	Slightly bitter
Texture	chalky or slightly grainy surface

2.Bulk Density

It is defined as the mass of a material per unit volume, including the space between particles (voids). Formula for Bulk density is:

$$\text{Bulk Density} = \frac{\text{Mass (g)}}{\text{Volume (ml)}}$$

Mass of the powder = 5g
Volume of the powder = 25ml

$$\text{Bulk density} = \frac{5}{25}$$

= 0.2g/ml

3.Tapped Density

It is defined as the mass of a material divided by its volume after it has been mechanically tapped down to minimize the void spaces between particles.

It is a volume after tapping the cylinder until the powder settles fully.

Mass of the powder = 5g
Powder Volume before tapping = 25ml
Powder volume after tapping = 21

$$\text{Tapped Density} = \frac{\text{Mass (g)}}{\text{Final volume of powder after tapping}}$$

= 5

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21
≈ 0.238g/ml

4.Carr's Index

It is also known as the Carr Compressibility Index. It helps assess how easily a powder can flow and compact, which is important in tablet manufacturing.

$$\text{Carr's Index} = \frac{(\text{Tapped Density} - \text{Bulk Density}) \times 100}{\text{Tapped Density}}$$

$$= \frac{0.238 - 0.2 \times 100}{0.238}$$

= 15.97%

5.Hausner's ratio

Hausner's Ratio is the ratio of Tapped Density to Bulk Density of a powder.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

$$= \frac{0.238}{0.2}$$

≈ 1.19

6.Angle of repose

The Angle of Repose is the angle formed between the horizontal surface and the slope of a heap of powder when it is poured freely onto a flat surface.

Angle of repose depends on

1. particle size and shape
2. surface texture
3. moisture content

To calculate the angle of Repose, follow the following steps

1. Pour the powder into a cone shaped pile
2. Measure the height and radius of the pile base
3. Find the angle of repose by using formula

$$\Theta = \text{Tan}^{-1} \frac{h}{r}$$

where, Θ = is the angle of repose
h = is the height in (cm)
r = is the radius in (cm)
according to formula h = 3.5
r = 4.4

Hence,

$$\Theta = \text{Tan}^{-1} \frac{3.5}{4.4}$$

$$= \text{Tan}^{-1} (0.7955)\ \Theta$$

≈ 38.4°

7.Friability Test

Friability test was carried out by using friability test apparatus also called as Rotating drum. The test was carried out to check durability of tablets. Test basically involves placing a sample into rotating drum that rotates at 25 rpm (Revolution per minute).

We have taken 20 tablets and placed them into rotating drum for 4 minutes and calculated the variation.

calculating Friability:

The percentage of weight loss is calculated by given formula.

$$\text{Percentage Weight Loss} = \frac{(\text{Initial Weight} - \text{Final Weight}) \times 100}{\text{Initial Weight}}$$

The value should not more than 1%

As Formulation 1 tablet is of 100mg so According to above formula,

Initial weight of 20 tablets = 2000mg
Final weight of 20 tablets = 1985mg

$$\% \text{ Weight Loss} = \frac{2000 - 1985}{2000} \times 100$$

= 0.75%

Result value isn't more than 1% hence formulated paracetamol immediate release tablet passed the friability test.

8.Dissolution Test

A Dissolution Testis a procedure used to determine the rate and extent to which the active drug ingredient is released from a solid dosage form (like a tablet or capsule) into solution

Purpose:

- To assess drug releasefrom dosage forms.

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- To ensure batch-to-batch consistency**.**
- To predict bioavailability.
- To meet regulatory requirements(e.g., USP, FDA, EMA).

A tablet must release at least 80% of the active ingredient within 30 minutes

Procedure:

- Apparatus setup:

Apparatus: USP Apparatus 2 (paddle) used With 900 mL of phosphate buffer having pH 6.8. MaintainingTemperature 37°C +/- at 50 rpm agitation speed.

- Sample preparation:

Weigh and record the average weight of 10 tablets. Place one tablet into each dissolution vessel.

- Sampling procedure:

Withdrawn 1 mL of sample at specified time intervals: 5, 10, 15, 20, 25, 30, 45, and 60 minutes. Diluted each sample to 10 mL with the dissolution medium.
Replaced the withdrawn volume with an equal volume of fresh dissolution medium.

- Analysis

Measured the absorbance of each sample at λ_max = 243 nm using a UV-Vis spectrophotometer. Calculated the concentration of paracetamol in each sample using a previously constructed calibration curve. Determined the cumulative percentage of drug released (% CR) at each time point.

Result

Time (min)	Absorbance	Concentration (ug/ml)	% drug released
0	0.000	0.00	0.00
5	0.460	5.48	39.48
10	0.510	6.16	44.36
15	0.566	7.06	50.86
20	0.599	7.78	54.70
25	0.612	7.81	56.21
30	0.634	8.16	58.76
45	0.650	8.50	60.61
60	0.670	8.85	62.13

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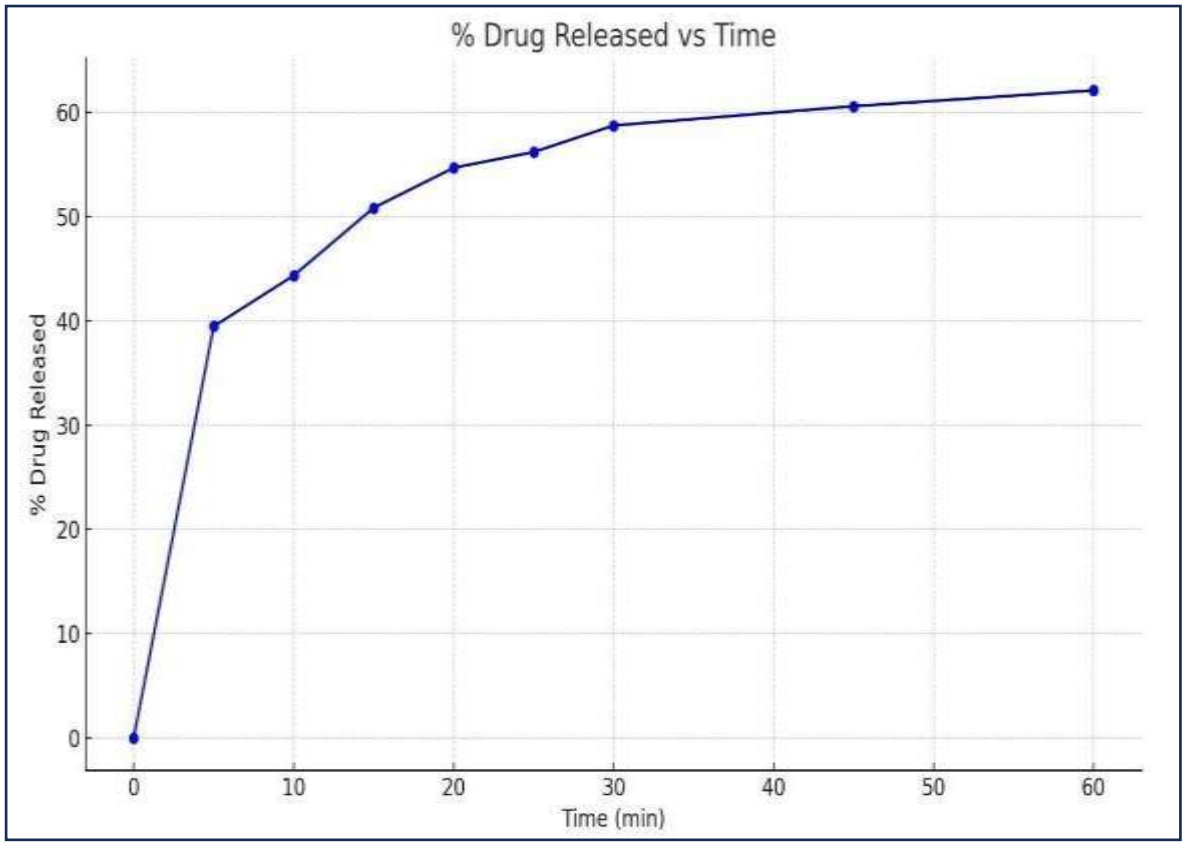

Fig.2: Graphical Representation of Dissolution test result.

9.Disintegration Test

Disintegration is the process by which a solid dosage form (like a tablet or capsule) breaks down into smaller fragments in a specified liquid medium under standardized conditions.

Define as the time it takes for a tablet or capsule to break apart into particles small enough to pass through a predefined mesh under the action of liquid and temperature, simulating the conditions of the gastrointestinal tract.

It is a critical quality control test used to ensure that the drug will be available for absorption in the body within the intended timeframe.

Procedure:

- Disintegration Test Apparatus was used to carry out the process.

The apparatus has one beaker containing basket rack with 6 tubes.

- Apparatus setup:

Fill each tube with distilled water at temperature 37°c.

Place one tablet in each of the 6 tubes of the basket rack.

Use a disc in each tube to ensure even pressure.

Suspend the basket in the beaker containing the medium.

- Method:

Started the apparatus and observed the tablets.

Recorded the time when each tablet has disintegrated completely (no residue, except fragments of insoluble coating).

As per BP/USP, all 6 tablets should disintegrate within 15 minutes (for uncoated tablets).

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- **Result:**

Tablet number	Disintegration time (min)
1	4.5
2	4.7
3	4.6
4	4.8
5	4.4
6	4.5

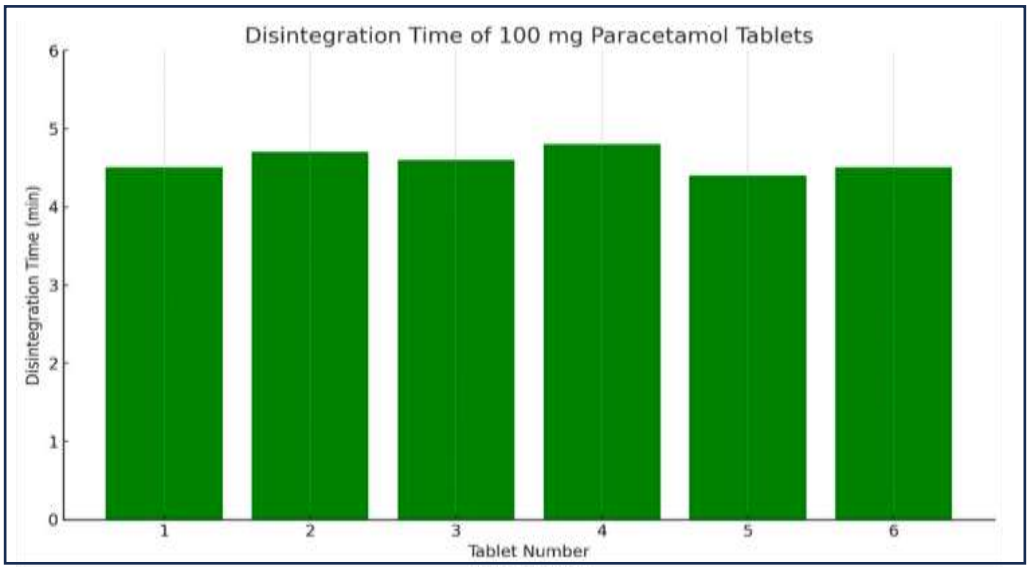

Fig.3: Graphical Representation of Disintegration Test result Average

Disintegration Time: 4.58 minutes**.**
Acceptance Criteria: All tablets passed the test (within 15 minutes)

10.UV Spectroscopy

UV Spectroscopy (Ultraviolet Spectroscopy) is an analytical technique used to measure how much ultraviolet (UV) light a chemical substance absorbs. It is commonly used to determine the concentration of compounds and to study molecular structures.

Principle:

When UV light passes through a substance, molecules absorb specific wavelengths based on their electronic structure, causing electrons to move to higher energy levels (excitation). Absorbance (A): Measured using a UV-Visible spectrophotometer. It follows Beer-Lambart Law.

Beer-Lambert Law: A = εcl

Here,
A = Absorbance
ε = molar absorption coefficient c=molar concentration
l= Optical path length

Procedure:

- **Preparation of Standard Solution:**

Dissolve an accurately weighed quantity of pure paracetamol in a suitable solvent (commonly ethanol or distilled water).
Dilute to obtain a known concentration (e.g., 10 µg/ml).

- **Preparation of Sample Solution**:

Crush a 100 mg paracetamol tablet.
Dissolve in the same solvent and filter.
Dilute to the same concentration as the standard.

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- **Measurement**:

Use a UV-Visible spectrophotometer.

Scan the solution over a wavelength range (typically 200–400 nm).
Record absorbance vs. wavelen

Result:

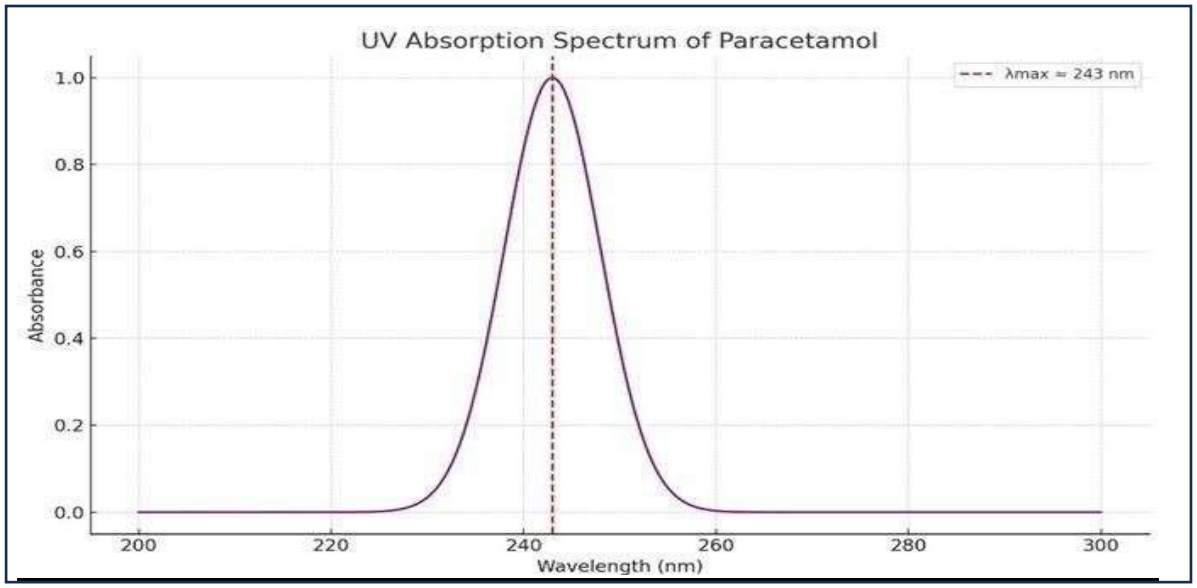

Fig.4: Graphical Representation of UV Spectroscopy result

Paracetamol shows a maximum absorbance (λmax) at ~243 nm.
This is the simulated UV absorption spectrum for a 100 mg paracetamol tablet. As shown, the maximum absorbance (λmax) occurs around 243 nm, which is typical for paracetamol in solution.

IV. CONCLUSION:

- The successful formulation and development of Paracetamol IP 75 mg tablets required a comprehensive understanding of pharmaceutical principles, including drug-excipient compatibility, tablet compression parameters, and quality control measures.
- The formulation process ensured that the final product of batch F7 meets the required standards for identity, strength, quality, and purity as per Indian Pharmacopoeia (IP) specifications.

1. High Polyplasdone XL-10 (5%) is good for rapid disintegration.
2. AvicelPh 200 (13%) promotes breakdown of tablet.
3. Low magnesium stearate has less hydrophobic barrier which is good for dissolution.

- Through careful selection of excipients and optimization of the manufacturing process, a stable and effective dosage form has been achieved. Ultimately, the development of a low-dose paracetamol tablet provides an important therapeutic option, particularly suited for paediatric use or patients requiring mild analgesic and antipyretic action with minimal risk of toxicity.

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