



Characterisation Study on Different Brands of Paracetamol Tablet Available in Market

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ABSTRACT –

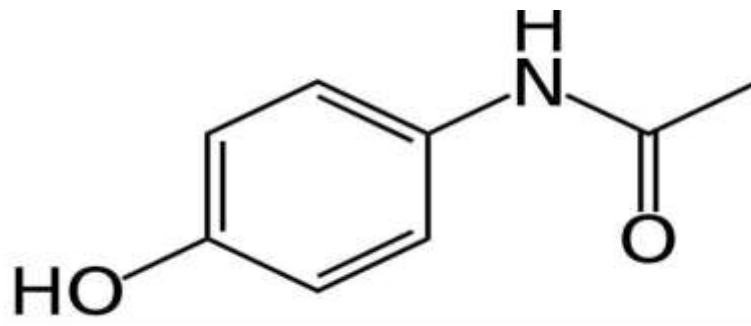
To study the characterisation of Quality control and quality assurance of solid dosage form we use the Paracetamol Tablet as a main API with different Brands. For characterisation we use Paracetamol because recently paracetamol tablet is widely used to treat fever and moderate Pain and it is a analgesic& antipyretic drug.

Characterisation study of QC & QA of paracetamol Tablet based on

physical evaluation Weight variation, Hardness, Friability, disintegration test and also assay performance carried to determine ingredient and Quality of Content evaluation parameter study on five brands of paracetamol tablet shows the difference on their characteristics.

Introduction –

- Paracetamol is a active pharmaceutical ingredient available in pure as well as combination form to treat moderate pain and fever.
- Paracetamol drug have analgesic and antipyretic properties with 70 to 90 % Bioavailability.



General structure of Paracetamol

Formula and molar mass of Paracetamol is C₈H₉NO₂ and 151.163 g/mol respectively.

- It is also known as Acetaminophen. They penetrate BBB and blocks cyclooxygenase in brain due to decrease the formation and release of PGE in the CNS then inhibit action of endogenous pyrogen in the brain and produce antipyretic effect.
- Paracetamol is a 4-hydroxy acetanilide.
- Solubility:-Soluble in solution of alkali hydroxides and insoluble in ether and benzene.
- Physical properties are white colour, odourless crystalline powder with a bitter taste.
- Paracetamol is a drug which is consumed without prescription in city. As well as rural areas.

MATERIALS AND METHODS-

- **Study area- and period –**

The study was conducted from september to December 2023 at the Sanjay Ghodawat University, Kolhapur.

- **Study Design –**

Tablet tests are performed to determine the difference between the characteristic of five different paracetamol brands.

- **Sample collection –**

For characterisation study of five different brand of paracetamol was online purchased. The tablets are Febrex tablet mfg by Indoco Remedies ltd, paracip tablet Mfg by cipla Ltd. Calpol 500 mg tablet mfg. by Glaxo SmithKline Pharmaceuticals. Ltd. Fepanil tablet mfg by veritaz Healthcare Ltd and K-mol 500 mg tablet mfg by Kentreck Laboratories Pvt Ltd. All the brand labeled to contain 500 mg of paracetamol per tablet.

- **Instruments –**

Tests	Instruments & equipment's
Weight variation	Digital balance
Friability	- Friability test apparatus - Digital balance
Hardness	Hardness tester
Disintegration	- Disintegration test apparatus - stop watch
Assay	- Digital balance - Volumetric Flask - mortar pestle. - Volumetric pipette - Funnel, Beaker

Test –

All tests are same for five different brands of paracetamol tablet.

1.Physical evaluation –

Physical evaluation detect the colour, shape, odor and solubility Of paracetamol tablet

2.Weight variation –

- 10 tablet select Randomly.
- Then weighed each tablet using an weighing machine
- Then determine mean
- Finally determine % of weight variation by using following formula

Weight Variation = $(Iw - Aw)/Iw \times 100\%$

3.Friability –

- 10 tablet select Randomly.
- Each tablet Weighed and note down intial weight.
- Tablet placed in friability tester and Rotated at speed 25 rpm.

For 4 min.

- Finally % friability calculated by the following formula :-

% Friability = $(Iw - Fw) / Iw \times 100\%$

4.Hardness –

- 1 tablet select and placed in a Pfizer Tablet Hardness Tester.

- Then press the both handle until the breaking of tablet occurs.

Average Hardness = Total hardness / No. of tablets

5. Disintegration –

- 6 tablet select Randomly.
- Placed in the disintegration apparatus.
- Which is filled by 900 ml of distilled Water maintained at 37°C
- Tablet time taken to disintegrate and pass through mesh.
- Finally mean of time was calculated.

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6.Assay –

1. Preparation of 0.1 N NaOH solution.

- Dissolve 0.4gm of NaOH in 100 ml distilled water

2. Preparation of standard solution of paracetamol.

- Weigh accurately 10mg paracetamol pure powdered drug and dissolve in 100ml of 0.1N NaOH.
- Prepare 5 standard solution from stock solution by diluting 1ml, 2ml, 3ml,4ml,5ml to 10 ml with 0.1N NaOH.
- Measure absorbance of 5 standard dilutions of 10µg/ml, 20µg/ml, 30µg/ml, 40µg/ml and 50µg/ml concentration against blank.
- Plot calibration curve between absorbance vs concentration at 257nm. Find out the equation of line.

3. Preparation of sample solution

- Weigh 10 tablets and powder them.
- Take the weight of tablet powder equivalent 10mg of paracetamol and dissolve in 100ml 0.1N NaOH.
- Take 2ml of the above solution and dilute up to 10 ml with 0.1N NaOH.
- Calculate the concentration of unknown sample by calibration curve or by using regression equation $Y=mx+c$.

Result –

Table No 1 Name, Dosage, mfg, Mfg Date and expire Date of Different paracetamol Brand.

Table	Code	Name	Dosage	Manufacturer	Mfg	Expiry	No.2
	1	K-mol	500 mg	Kentreck Laboratories P.Ltd	Oct 2021	Sep 2024	
	2	Paracip	500 mg	Cipla LTD	Jul 2023	Jun 2025	
	3	Febrex	500 mg	Indoco. Remedies. LTD.	Oct 2023	Sep 2025	
	4	Fepanil	500 mg	Veritaz Healthcare Ltd	Feb 2023	Jan 2026	
	5	Calpol	500 mg	Glaxosmithkline P.LTD	Jul 2023	Jun 2025	

Friability, Hardness ,Weight variation, Disintegration and Assay of Different Paracetamol Brand.

Code	Friability	Hardness	Weight Variation	Disintegration	Assay (% Purity)
1	0.34 %	16.12 kg	1.52 %	0.27 min	95.55 %
2	0.94 %	11.28 kg	1.66 %	3.20 min	96.84 %
3	0.52 %	13.72 kg	0.68 %	4.00 min	97.63 %
4	0.68 %	11.44 kg	0.67 %	4.27 min	98.45 %
5	0.74 %	13.88 kg	0.29 %	5.20 min	99.07 %

Conclusion –

The project study showed that all brands of paracetamol tablet have different quality control test result shows variation in their specification.

Reference –

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