

A Comparative Evaluation of Percentage Label Claim of Different Brands of Marketed Paracetamol Tablets

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ABSTRACT: Paracetamol is a widely used non-opioid analgesic and antipyretic available in various commercial forms. To ensure safety and effectiveness, evaluating the pharmaceutical equivalency of different brands is vital. This study compared ten brands of paracetamol tablets using a UV-visible spectrophotometric assay, measuring absorbance at 259.6 nm with 0.1M NaOH as the solvent.

Based on absorbance values, the percentage drug content of various paracetamol brands was evaluated, with most meeting the USP limit of 95-105%, showing values from 86.23% to 108.08%. Variations can be attributed to manufacturing quality and formulation. The findings indicate that the brands are pharmaceutically equivalent and suitable for clinical use, with UV spectrophotometry proving to be an efficient and cost-effective method for quality evaluation

KEYWORDS: Paracetamol tablet, UV- Visible spectrophotometry, Standard absorptivity method, calibration curve method.

Acetaminophen, also known as paracetamol, is an OTC medication with analgesic and antipyretic properties, classified as a non-opioid analgesic within the NSAID subclass.[1]

Paracetamol has been a common home remedy in India for over 30 years, widely recognized for its effectiveness in treating fever and pain in both adults and children. Its safety at recommended dosages has led to its widespread use as an analgesic and antipyretic globally. However, prolonged use and overdoses can cause severe liver damage and renal toxicity, making paracetamol overdose a significant cause of poisoning. Additionally, it inhibits DNA synthesis, raising concerns about genotoxicity and carcinogenicity.[2]

Paracetamol has limited anti-inflammatory effects due to its inefficacy at inhibiting CycloOxygenase (COX) at high peroxide concentrations. Recommended dosages are 0.5–1 g daily for adults (maximum 4 g) and 10–15 mg/kg every 4–6 hours for children. Various dosage forms available include tablets, capsules, liquid suspensions, extended-release tablets, oral disintegrating tablets, suppositories, and injectable forms.[3]

I. INTRODUCTION

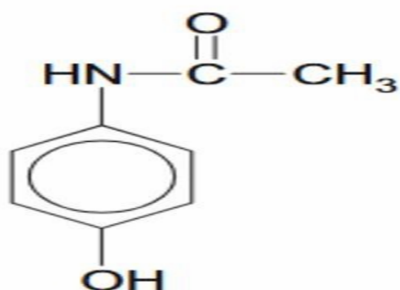


Figure no :1 Chemical Structure of Paracetamol

Sl.NO	PHYSICAL AND CHEMICAL PROPERTIES	
1	MOLECULAR WEIGHT	151.165 g mol ⁻¹
2	ODOUR	ODOURLESS
3	COLOUR	WHITE POWDER
4	TASTE	SLIGHTLY BITTER
5	MELTING POINT	168°C
6	SOLUBILITY	>22.7 µg ML ⁻¹

Table no :1 Physical and chemical properties of Paracetamol[4,5]

BEERS LAMBERTS LAW

The Beer-Lamberts Law relates the attenuation of light to the properties of the material through which the light is travelling.

If the intensity of the light passing through the sample, I is less than I₀ then the sample has absorbed some of the light.

Beers law states that the absorbance is directly proportional to the concentration (c) of the solution of the sample used in the experiment.

$$\text{i.e.; } A \propto C$$

The absorbance (A) is defined via the incident intensity I₀ and transmitted intensity I by

$$A = \log_{10}(I_0/I)$$

Lamberts law states that the absorbance is directly proportional to the length of the light path (l), which is equal to the width of the cuvette.

$$\text{i.e.; } A \propto l$$

therefore $A \propto cl$

$$A = \epsilon cl$$

The constant ϵ is called Molar Extinction Coefficient and is a measure of the probability of the electronic transition.

II. MATERIALS AND METHODS

Reagents:

Pure sample of Paracetamol (gifted by Sahana Pharmaceuticals(p)ltd), Different brands of Paracetamol tablets, Distilled water, NaOH.

Apparatus:

Standard volumetric flask (100 ml), Standard volumetric flask (50 ml), Standard volumetric flask (10 ml), Measuring cylinder, Beaker, Funnel, Pipette (10 ml), Pipette (1 ml), UV Spectrophotometer

III. METHODOLOGY

Selection of Methods: The methods employed for this study are the UV-Visible Spectrophotometric methods.

- 1) Using standard absorptivity value (IP method)
- 2) Calibration curve method

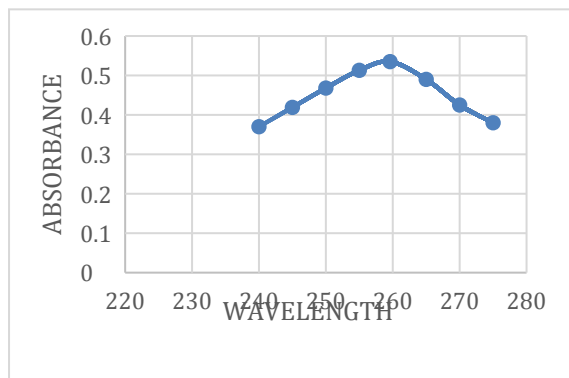
Absorption spectral data for paracetamol

Drug concentration - 10 µg/ml

Sl.no	Wavelength in nm	Absorbance
1	275	0.380
2	270	0.425
3	265.0	0.490
4	259.6	0.535
5	255	0.513
6	250	0.468
7	245	0.419
8	240	0.370

Maximum absorbance:

The maximum absorbance was measured at 259.6nm



Preparation of 0.1M NaOH:

4g of Sodium Hydroxide was taken into a 1000ml volumetric flask and dissolved in a sufficient amount of distilled water to produce 1000ml. The followed concentration was 0.1M NaOH.[6]

Assay procedure:

All brands of paracetamol tablets were assayed spectrophotometrically by using the following methods

1. Using standard absorptivity value (IP Method): 20 Tablets of Paracetamol from each brand were weighed and finely powdered by using a mortar and pestle. An accurately weighed quantity of powder equivalent to 75mg of Paracetamol was transferred to a 100ml volumetric flask, 25ml of 0.1M NaOH and 50ml of distilled water were added and mechanically shaken for 15 minutes, then diluted with a sufficient amount of distilled water to produce 100ml. The resulting solution was then filtered by passing through Whatman filter paper No. 41. 10ml of the filtrate was transferred to a 100ml volumetric flask and further diluted to 100ml with distilled water. Again to 10ml of the resulting solution, 10ml of 0.1M NaOH was added and diluted to 100ml with distilled water and mixed thoroughly. The UV Spectrophotometer was put at zero by running a baseline (between 400-200nm) using 0.1M NaOH solution as blank. The absorbance of each sample was determined at 259.6nm. The content of Paracetamol was calculated taking 715 as the specific absorbance at 259.6nm λ_{max} of Paracetamol.[7,8]

2. Calibration Curve Method:

Preparation of standard stock solution:

Standard stock solution of Paracetamol (100 μ g/ml) was prepared by dissolving 100mg of paracetamol pure powdered drug in 25ml of 0.1M NaOH solution and diluted to 100ml with distilled water. 10ml of the above solution was transferred to a 100ml volumetric flask and further diluted to 100ml with distilled water.[9]

Preparation of standard dilutions:

6 standard dilutions were prepared from the above stock solution of 100 μ g/ml by diluting 0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml, 1.0 ml, and 1.2 ml to 10 ml with 0.1M NaOH. The absorbance of 6 standard dilutions of concentrations 2 μ g/ml, 4 μ g/ml, 6 μ g/ml, 8 μ g/ml, 10 μ g/ml, and 12 μ g/ml were determined against 0.1M NaOH solution as a blank. The calibration curve was plotted between absorbance vs concentration at 259.6nm.[10]

Preparation of Sample solution:

20 tablets were weighed and finely powdered by using a mortar and pestle. An accurately weighed quantity of powder equivalent to 75mg of Paracetamol was placed in a 100ml volumetric flask, to which 25ml of 0.1M NaOH and 50ml of distilled water were added and shaken by mechanical means for 15 minutes, then diluted with sufficient amount of distilled water to produce 100 ml. The resulting solution was then filtered by passing it through Whatman filter paper No. 41. 10 ml of the filtrate was transferred to a 100ml volumetric flask and further diluted to 100ml with distilled water. Again to 10ml of the resulting solution, 10ml of 0.1M NaOH was added and diluted to 100ml with distilled water and mixed thoroughly. The UV Spectrophotometer was put at zero by running a baseline (between 400-200nm) using 0.1M NaOH solution as blank. The absorbance of each sample was determined at 259.6nm.[11,12].The percentage content of paracetamol was calculated using a linear regression equation obtained from the standard calibration plot (as shown in figure 3).

IV. RESULTS AND DISCUSSION

PURE SAMPLE

Values of Pure Sample at 259.6 nm

Table no: 2 Values of pure sample at 259.6 nm

CONCENTRATION	ABSORBANCE
2	0.107
4	0.216
6	0.323
8	0.428
10	0.535
12	0.646

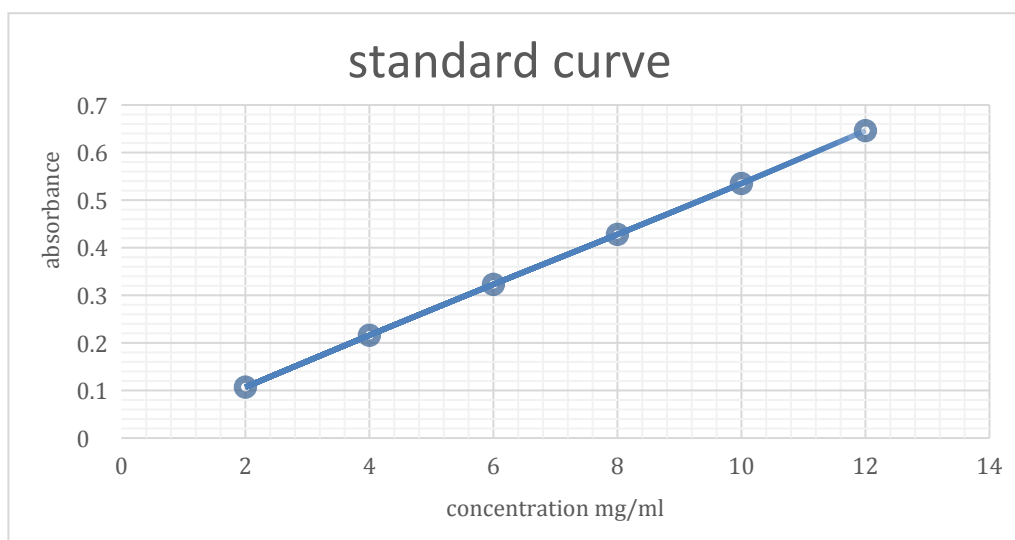


Figure no: 3 Standard Calibration Curve of Paracetamol

I.

The assay of ten brands of paracetamol tablets manufactured by different manufacturers was performed in this study. The average weight and percentage content of paracetamol in different brands of paracetamol tablets were calculated and evaluated by using UV- Visible Spectroscopic methods.

The results obtained by the IP method are tabulated below in Table 3

Sl.No.	Brand Name	Label Claim (in g)	Average Weight (in g)	Percentage content (in %)	IP Specification (in %)	Inference
1	B 1	0.65	0.84515	86.23	95.0-105.0	Fail
2	B 2	0.5	0.58345	101.86		Pass
3	B 3	0.65	0.829	95.57		Pass
4	B 4	0.5	0.597	96.6		Pass
5	B 5	0.5	0.6667	101.82		Pass
6	B 6	0.65	0.8676	108.08		Fail
7	B 7	0.65	0.7495	98.26		Pass
8	B 8	0.65	0.80415	100.99		Pass
9	B 9	0.5	0.58685	87.06		Fail
10	B 10	1	1.1332	98.46		Pass

Table no: 3 Comparison of different brands of Paracetamol Tablets 500mg, 650mg and 1000mg by IP method

The percentage content of Paracetamol in various brands of Paracetamol Tablets is compared by using Standard Absorptivity Value (IP Method).

From the results obtained using the IP method, it was observed that Seven out of ten brands of paracetamol tablets passed the assay since the percentage content of all of them are within the limit specified by the Indian Pharmacopoeia, while three brands failed where two of them contain below and one contains above the specified limit.

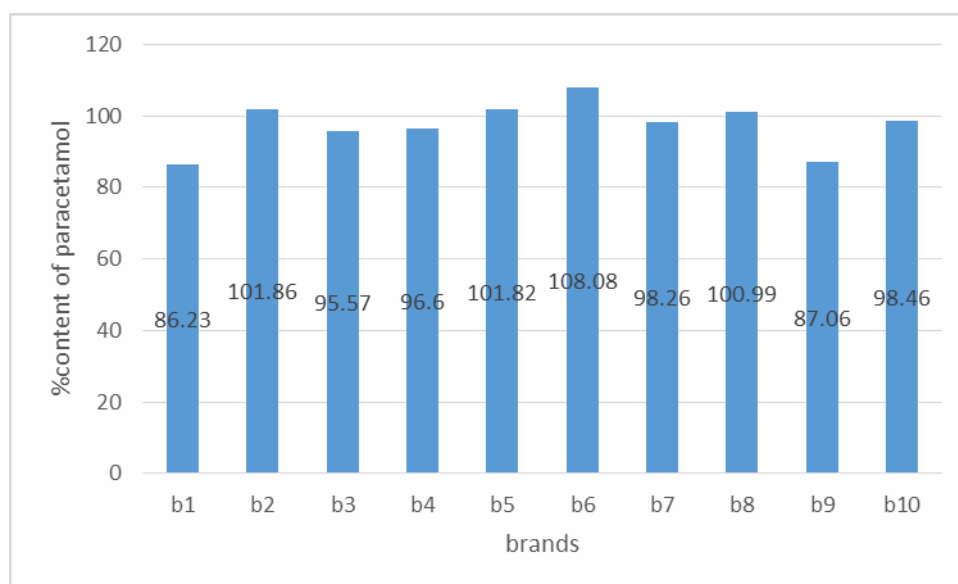


Figure no: 4 Comparison of various brands of Paracetamol tablets by IP method

Figure 4 shows the graphical representation of the comparison of the percentage content of paracetamol in various brands of paracetamol tablets by IP Method.

V. CONCLUSION

The study utilized UV-visible spectrophotometry to assess the percentage label claims of ten paracetamol tablet brands, verifying the pharmaceutical quality and reliability of most brands according to Indian Pharmacopoeia standards (95.0–105% of labelled content). However, some brands fell outside acceptable limits, indicating variations in manufacturing quality and the need for rigorous quality control. It emphasizes the importance of continual monitoring of commercial formulations for safety and efficacy and affirms UV spectrophotometry as a suitable method for routine quality assessment of paracetamol tablets.

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