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Analysis of different brands of paracetamol tablet used in the market by assay method of UV spectroscopy and its evaluation

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Abstract

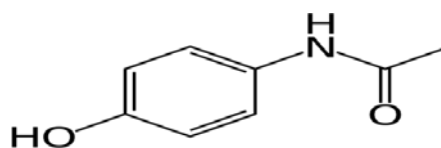
The study included analysis of five different brands of Paracetamol tablets used in market, using the ultra violet spectro-photometric method. The percent purity of the five brands of Paracetamol was determined by assay method on uv spectrophotometer. The result obtained was compared with those of standard. The Percent content of standard Paracetamol in IP contain no less than 95.0 percent and not more than 105.0 percent of the prescribed Paracetamol value.

It was noted that samples A, B, D and E meet the I.P. specified limit in spectrophotometric method where as sample c was out of the specified limit. Also the evaluation test of paracetamol. Were carried out which complies the i.p. limit.

Keywords: Paracetamol, assay, spectrophotometer, IP

Introduction Paracetamol

Acetanilide, phenacetin, and acetaminophen are mild analgesics and antipyretics and are important, along with aspirin, in many non-prescription drugs. Also rose geranium oil used because geranium oil is a natural anti-oxidant and anti-inflammatory oil, it actively boosts skin's health and natural glow^[7]. Ashawagandha is also has anti-inflammatory properties^[8] the discovery that acetanilide was an effective antipyretic came about by accident in 1886 the patient's worms didn't disappear but his fever did - dramatically. In another instance of serendipity, it was soon in production and remained in use for several years because it was so cheap to produce. However, it had a serious side effect involving the deactivation of some of the hemoglobin in red blood cells. However, restrictions have been placed on its use due to kidney damage in long-term users. The publication of Cahn and Hepp describing their experiments with acetanilide caught the attention of Carl Duisberg, director of research at the Bayer Company in Germany. Duisberg was confronted with the problem of profitably getting rid of nearly 50 tons of p-aminophenol; a by-product from the synthesis of one of Bayer's other commercial products. He immediately saw the possibility of converting p-aminophenol to a compound similar in structure to acetanilide, by putting an acyl group on the nitrogen. It was then believed, however, that all compounds having a hydroxyl group on a benzene ring were toxic. Duisberg devised a scheme of structural modification of p-aminophenol to get the compound phenacetin. Phenacetin turned out to be a highly effective analgesic and antipyretic. A common form of combination pain reliever, called an APC tablet, was once available. An APC tablet contained Aspirin, Phenacetin, and Caffeine (hence, APC). Phenacetin is no longer used in commercial pain-relief preparations. It was later found that not all aromatic hydroxyl groups lead to toxic compounds, and today the compound acetaminophen is very widely used as an analgesic in place of phenacetin.



'Acetaminophen' (4-acetamidophenol) is sold as the over-the-counter analgesic "Tylenol". Acetaminophen is a pain-relieving (analgesic) and fever-treating (antipyretic) medication that can be obtained over-the-counter^[1-3].

Formula: C₈H₉NO₂

Molar mass: 151.163 g/mol

Melting point: 169 °C

Metabolism: Predominantly in the liver

Other names: N-acetyl-para-aminophenol (APAP), acetaminophen (USAN US)

Onset of action: Pain relief onset by route: By mouth – 37 minutes; Intravenous – 8 minutes

IUPAC ID: N-(4-hydroxyphenyl) acetamide, N-(4-hydroxyphenyl) ethanamide

MOA: Paracetamol (acetaminophen) is generally considered to be a weak inhibitor of the synthesis of prostaglandins. However, the in vivo effects of paracetamol are similar to those of the selective cyclooxygenase-2 (COX-2) inhibitors. Paracetamol also decreases PG concentrations in vivo but unlike the selective COX-2 inhibitors, paracetamol does not suppress the inflammation of rheumatoid arthritis. It does, however, decrease swelling after oral surgery in humans and suppresses inflammation in rats and mice. Paracetamol is a weak inhibitor of PG synthesis of COX-1 and COX-2 in broken cell systems, but, by contrast, therapeutic concentrations of paracetamol inhibit PG synthesis in intact cells in vitro when the levels of the substrate arachidonic acid are low (less than about 5 μmol/L). When the levels of arachidonic acid are low, PGs are synthesized largely by COX-2 in cells that contain both COX-1 and COX-2. Thus, the apparent selectivity of paracetamol may be due to inhibition of COX-2-dependent pathways that are proceeding at low rates. This hypothesis is consistent with the similar pharmacological effects of paracetamol and the selective COX-2 inhibitors. COX-3, a splice variant of COX-1, has been suggested to be the site of action of paracetamol, but genomic and kinetic analysis indicates that this selective interaction is unlikely to be clinically relevant. There is considerable evidence that the analgesic effect of paracetamol is central and is due to activation of descending serotonergic pathways, but its primary site of action may still be inhibition of PG synthesis. The action of paracetamol at a molecular level is unclear but could be related to the production of reactive metabolites by the peroxidase function of COX-2, which could deplete glutathione, a cofactor of enzymes such as PGE synthase^[4-5].

Methodology

For paracetamol numerous methods are present, but very few are of more important. For the accurate research purposes uv spectro-photometry is preferred because of its sensitivity, precision and simplicity. Generally simple calorimetric enzyme based method used for assay of paracetamol. Paracetamol can be assayed by quantitative estimation using UV Spectro-photometry.

Sample Collection

Five samples of paracetamol 500mg tablets were obtained from various pharmacy shops within sonai, the samples were obtained together with their packs and receipt.

Practical Method: The methods employed for the purpose of this study are the UV Visible spectrophotometric

Practical Procedure

A. By UV Spectrophotometry

The tablets were assayed spectrophotometrically using the following procedures Instrument: JASCO 630, Software: UV-Win

1. The average weight of tablet from each sample was determined by weighing ten tablets and dividing the result by ten.
2. Two tablets were then crushed using a clean pestle and mortar (i.e. from each sample).
3. For each sample, powder containing 0.05g (50mg) of paracetamol was accurately weighed and transferred into different 100ml volumetric flasks. All the 7 samples were labelled using a pen and a masking tape.
4. To Each volumetric flask, 50ml of 0.1 M NaOH and 100ml of distilled water were added, and sonicated for few minutes to dissolve the drug molecule. After sonicating, the volume was made to 100ml with distilled water.
5. The mixture in each flask was then mixed well and filtered through a filter paper into clean beakers.
6. From the filtrate, 10ml was taken using a pipette and transferred into a 100ml volumetric flask; distilled water was then added to make up the volume.
7. From the resultant solution above (6), 10ml was taken with a pipette into a 100ml volumetric flask and 10ml of 0.1M NaOH was added, distilled water was then added and make up the volume (5μg/ml).
8. The UV Spectrophotometer was put at zero by running a baseline (between 200-400nm) using 0.1 M NaOH solution as blank. The absorbance of each sample was determined at 257nm, by putting small amount of the sample into a cuvette, and the cuvette was put into the machine.
8. The same procedure was repeated for the standard using 100mg of the powdered standard, and absorbance determined, which was used to calculate the percentage content (in mg) of paracetamol from each brand.
9. The concentration of each sample was also determined using Beer Lambert's law according to IP 8^[5]

Discussion

According to the Indian Pharmacopoeia (I.P), Paracetamol tablet should contain not less than 95% (495mg) and not more than 105% (502.5mg) of Paracetamol. From the results obtained using the spectro-photometric method, it can be seen that samples, A, B, D, E passed since all of them are within the limit specified by the I.P, where as sample C was out of the specified limit also the evaluation test of Paracetamol were carried out which complies the I.P limit.

Results: Calculation for percent purity of Paracetamol. Average wt of tablet = 567.6 mg

Calculate dilution factor

0.5676 gm powder = 500 mg

$$X \text{ mg} = 150 \text{ mg}$$

$$X = 0.567 \times 150 / 500 \quad X = 0.170 \text{ gm.}$$

$$\% \text{ dilution factor} = 0.170/200 \times 10/100 \times 10/100 \times 100 \\ = 0.00085$$

% purity ^[16]

$$\text{Formula for Paracetamol \% purity} = A / A_{1\%}^{1\text{cm}} \times \\ \text{Avg.wt./l.c} \times 100 / \text{Dilution factor} \\ = 0.51/715 \times 0.5676 / 0.500 \times 100 / 0.00085 \\ = 0.0007132 \times 1.135 \times 117647.05 \\ = 95.6 \%$$

% Purity of Paracetamol is 95.6 %

The average weight of different brands of Paracetamol tablets were calculated and tabulated in table 1 (Used for UV).

The absorbance and % content of different brands of Paracetamol tablets brands are evaluated by using the UV spectroscopy and results obtained are tabulated in table 2. Determination of hardness of the tablets is result given in table 3.

Friability testing of tablet result given in table 4. Disintegration studies on the tablet is given in table 5.

Table 1: Showing the Average Weight of Tablets from Different Brands

Sample	Weight(Mg)
A(Dolo)	567.6
B(Paracip)	587.61
C(Pacimol)	604.50
D(Calpol)	636.20
E(Xykaa)	579.5

Table 2: Showing the Results Obtained Using Uv Method

Sample Solution	Concentration (Mg/MI)	Absorbance	% Content	Content (Mg)
A(Dolo)	0.000567	0.5112	95.6	567.6
B(Paracip)	0.000587	0.5511	103.32	587.61
C(Pacimol)	0.000604	0.5707	107.22	604.50
D(Calpol)	0.000636	0.5292	99.56	636.20
E(Xykaa)	0.000579	0.5204	99.64	579.5
Standard	0.000500	0.5522		

Table 3: Determination of Hardness of the Tablets

Sample	Hardness of sample	Complies with IP
A(Dolo)	4.5 kg/cm ²	Complies with IP
B(Paracip)	5.8 kg/cm ²	Complies with IP
C(Pacimol)	4.0 kg/cm ²	Complies with IP
D(Calpol)	4.8 kg/cm ²	Complies with IP
E(Xykaa)	5.5 kg/cm ²	Complies with IP

Table 4: Friability testing of tablets

Sample	Initial weight	Final weight	%friability	Complies with IP
A(Dolo)	13.00 gm	12.94 gm	0.4 %	Complies with IP
B(Paracip)	13.56 gm	13.51 gm	0.36 %	Complies with IP
C(Pacimol)	13.12 gm	13.06 gm	0.45 %	Complies with IP
D(Calpol)	12.98 gm	12.88 gm	0.77 %	Complies with IP
E(Xykaa)	13.44 gm	13.34 gm	0.74 %	Complies with IP

Table 5: Disintegration studies on the tablets

Sample	Disintegration Time	Complies with IP
A(Dolo)	3.0 min	Complies with IP
B(Paracip)	3.4 min	Complies with IP
C(Pacimol)	3.8 min	Complies with IP
D(Calpol)	3.5 min	Complies with IP
E(Xykaa)	4.2 min	Complies with IP

Conclusion

The quantitative estimation of five brands of Paracetamol was performed. It can be concluded that. It was Observed that sample A,B,,D and E meet the I.P specified limit in spectrophotometric method where as sample C was out of the specified limit also the evaluation test of Paracetamol were carried out which complies the I.P limit. Maximum wavelength of Paracetamol was found to be 257 nm.

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