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ANALYSIS OF DIFFERENT BRANDS OF PARACETAMOL 500mg TABLETS USED IN HYDERABAD, USING ULTRA VIOLET SPECTROPHOTOMETRIC AND HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC (HPLC) METHODS

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ABSTRACT: The study involves quantitative analysis of seven different brands (samples) of Paracetamol 500mg tablets used in Hyderabad (India), using Ultra Violet Spectrophotometric and High Performance Liquid Chromatographic methods, in which the samples were dissolved in 0.1M NaOH and distilled water and their various absorbances determined at wavelength of 257nm and in HPLC by using methanol, water (60:40) samples are prepared. The results obtained were compared with that of the standard. Percentage content and content in mg for each sample was calculated using the absorbances (in spectroscopic method) and peak areas(in chromatographic method) of the samples, to see if it is within the specified limit by official books (99%-110% according to IP). The percentage content of the analyzed samples using HPLC method ranges from 97.96-106.98%, while using UV method it ranges from 79.64-107.52%, indicating none of the samples contains less than 75% of the active principle. It was observed that four samples(B,C,D,G) out of the eight meet up the IP specified limit in spectrophotometric method, whereas six samples(A,C,D,E,F,G)) out of the eight meet up the IP specified limit in chromatographic method. After the calculation of the standard deviation and coefficient of variation of the two methods used, which area108.48 and 22.58%respectively for UV method and108.04 and21.2 % respectively for HPLC method, it was also observed that the HPLC method is slightly more suitable for such kind of studies than the UV method.

INTRODUCTION: The Analysis means the examination of something in details in order to understand it better or draw conclusions from it [1]. Chemical analysis involves a body of procedures and techniques used to identify and quantify the chemical composition of a sample of a substance [1].

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Pharmaceutical analysis refers to the chemical analysis of drug molecules or medicinal agents and their metabolites.

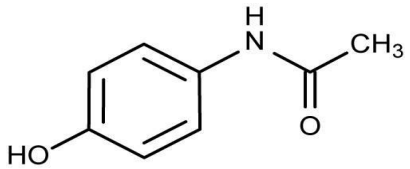
It consists of the estimation of the quality and quantity of drugs and fine chemicals, which are used in pharmaceutical [2].

Pharmaceutical analysis is a branch of practical chemistry that involves a series of process for identification, determination, quantification and purification of a substance, separation of the components of a solution or mixture, or determination of structure of chemical compounds [1, 2].

Paracetamol is classified as a mild analgesic. It is commonly used for the relief of headaches and other minor aches and pains and is a major ingredient in numerous cold and flu remedies. In combination with Opioid analgesics, paracetamol can also be used in the management of more severe pain such as post-surgical pain and providing palliative care in advanced cancer patients [3].

The onset of analgesia is approximately 11–29.5 minutes after oral administration of paracetamol, and its half-life is 1-4 hours [4]. The words *acetaminophen* and *paracetamol* both come from a chemical name for the compound *para*-acetylaminophenol and *para*-acetylaminophenol. In some contexts, it is simply abbreviated as APAP, for acetyl-para-aminophenol [5].

Paracetamol consists of a benzene ring core, substituted by one hydroxyl group and the nitrogen atom of an amide group in the para (1, 4) pattern [6].



METHODOLOGY: For paracetamol numerous methods are present, but very few are of more important. For the accurate research purposes high performance liquid chromatography is preferred because of its sensitivity, precision and simplicity [7]. Generally simple calorimetric enzyme based method used for assay of paracetamol. Paracetamol can be assayed by quantitative estimation using UV Spectrophotometry.

Sample Collection: Seven samples of paracetamol 500mg tablets were obtained from various pharmacy shops within Hyderabad, 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 and high performance liquid chromatographic methods.

Practical Procedure:

A. **By UV Spectrophotometry:** The tablets were assayed spectrophotometrically using the following procedures

Instrument: HI-TECH

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.
9. 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.

10. The concentration of each sample was also determined using Beer Lambert's law according to IP [8].

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

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**.

TABLE 1: SHOWING THE AVERAGE WEIGHT OF TABLETS FROM DIFFERENT BRANDS

Samples	Weight (mg)
SAMPLE A (Fepanil)	568.6
SAMPLE B (Tyfy)	587.78
SAMPLE C (Paracip)	605.59
SAMPLE D (Calpol)	636.19
SAMPLE E (p-500)	579.09
SAMPLE F (Malidens)	621.58
SAMPLE G (Crocin)	672.3

TABLE 2: SHOWING THE RESULTS OBTAINED USING UV METHOD

SAMPLE SOLUTION	CONCENTRATION(mg/ml)	ABSORBANCE	%CONTENT	CONTENT(mg)
A	0.000568	0.393	86.94	568.6
B	0.000587	0.467	103.31	587.78
C	0.000605	0.62	107.52	605.59
D	0.000636	0.45	99.55	636.19
E	0.000579	0.36	79.64	579.09
F	0.000621	0.431	95.35	621.58
G	0.000672	0.452	100	672.3
STANDARD	0.0005	0.452		

Obtained results are subjected to calculation for evaluating standard deviation and coefficient variation of different brands of paracetamol were calculated and tabulated in table 3.

TABLE 3: SHOWING CALCULATION OF STANDARD DEVIATION AND COEFFICIENT VARIATION OF UV METHOD

Samples	Mg content (X)	X-X	$(X-X)^2$
A	535	99.12	9824.77
B	517	96.51	9314.18
C	495	101.74	10351.02
D	471	98.74	9658.95
E	518	100.18	9658.95
F	483	105.39	9658.95
G	446	98.28	9658.95

Standard deviation = 108.48; Coefficient variation = 22.58

B. **By HPLC method:** The tablets were assayed **chromatographic method** using the following procedure

Instrument: Cyber Labs; Software: LC-100

1. The mobile phase containing methanol and water in the ratio of 60:40 was prepared. This was done by measuring 600ml of methanol and 400ml of distilled water into a 1000ml measuring cylinder, and put on to a sonicator for ten (10) minutes. This was then removed and filtered using a membrane filter and a vacuum pump.

2. From the powdered drug samples, powder containing 50mg of paracetamol was weighed from each sample, and then transferred into a 100ml volumetric flask each, and was labeled.

3. 100ml of the mobile phase was measured and added to each of the volumetric flask, and was put on to a sonicator for five (5) minutes, for the drug molecules to dissolve.

4. After sonicating for five minutes, the solutions were then filtered through a filter paper into clean beakers.

5. 10ml of each filtrate was taken and put into different 100ml volumetric flask, and the mobile phase was added to make up the volume.

6. From the above solutions (5), small portion of each was then put into different chromatographic sample vial, and the vials were put into the machine at different locations.

7. Enough of the mobile phase was put into the chromatographic tank, the machine was put on, and settings were made to select the vial to be run. The connected computer displays the result of the analysis on the screen (i.e. the chromatogram), and these were printed with the aid of a connected printer.

8. The same procedure was carried out using 50mg of the standard Paracetamol powder, and the result was used to calculate the percentage content and content (in mg) of each sample.

RESULTS: The Peak area and %content obtained for prepared concentration of different brands of paracetamol tablets were calculated and tabulated in **table 4**.

TABLE 4: SHOWING THE RESULTS OBTAINED USING HPLC METHOD

Sample solution	Concentration (mg/ml)	Peak Area	% Content	Content (mg)
A	0.0535	34785.9	100.61	568.6
B	0.0517	33865.3	97.96	587.78
C	0.0495	35699.3	103.27	605.59
D	0.047	34650.1	100.23	636.19
E	0.0518	35154.0	101.69	579.09
F	0.0483	36982.9	106.98	621.58
G	0.0446	34487.1	99.76	672.3
STANDARD	0.050	34568.2		

The obtained results are subjected to calculation of standard deviation and coefficient variation was calculated by using corresponding formula and results are tabulated in **table 5**.

Comparison of results: The results for standard deviation and coefficient variance obtained by spectroscopic and chromatographic were compared for evaluation of two methods, which are tabulated in **table 6**.

TABLE 5: SHOWING CALCULATION OF STANDARD DEVIATION AND COEFFICIENT VARIATION OF HPLC METHOD

Samples	Mg content (X)	X-X	$(X-X)^2$
A	535	99.12	9824.77
B	517	96.51	9314.18
C	495	101.74	10351.02
D	471	98.74	9658.95
E	518	100.18	9658.95
F	483	105.39	9658.95
G	446	98.28	9658.95

Standard deviation = 108.04; Coefficient variation = 21.2

TABLE 6: SHOWIMG THE MEAN VARIANCE, STANDARD DEVIATION (SD) AND COEFFICIENT OF VARIATION (CV) OF THE TWO METHODS

Method	Mean (X)	Variance $(S)^2=[\Sigma(x-x)^2/N-1]$	SD=√S2	CV= SD/X*100%
UV	480.22	11768.72	108.48	22.58
HPLC	507.5	11673.59	108.04	21.2

DISCUSSION: According to the Indian Pharmacopoeia (I.P), paracetamol tablet should contain not less than 90% (495mg) and not more than 110% (550mg) of paracetamol

From the results obtained using the spectrophotometric method, it can be seen that samples , B, C,D and G passed since all of them are within the limit specified by the I.P, while A,E,F are failed where all of them contain below the specified limit by I.P.

From the results obtained using the Chromatographic (HPLC) method shows that A, C, D, E, F, G passed where only B is failed because it contain less than the specified limit.

CONCLUSION: It can thus concluded that all the brands A, B, C, D, E, F, G are within limit as laid down by I.P. as C, D, G passed in both methods, where B in UV method and A, E, F in HPLC method. That the HPLC method is slightly more suitable for assay of paracetamol tablets than UV method because it procedure required less dilution

of sample for analysis, which may reduce the possibility of errors associated with measurements .Also the standard deviation and coefficient of variation of the two methods used, which area108.48 and 22.58%respectively for UV method and 108.04 and 21.2 % respectively for HPLC method, serve as evidence for difference between the two methods, indicating that HPLC method is slightly more accurate and sensitive than the UV method.

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