



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

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ABSTRACT

The study involves quantitative analysis of eight (8) different brands (samples) of Paracetamol 500mg tablets used in Maiduguri, 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 the HPLC method. The results obtained were compared with that of the standard. Percentage content and content in mg for each sample was calculated using the absorbances and peak areas of the samples and that of the standard, to see if it is within the specified limit by official books (90%-110% according to USP). The percentage content of the analyzed samples using HPLC method ranges from 51.04-103.84%, while using UV method it ranges from 50.19-109.1%, indicating none of the samples contains less than 50% of the active principle. It was observed that five (5) samples Neimeth, Unclu P, Palmol, Emzol, Fidson, out of the eight (8) Neimeth, Unclu P, Palmol, Emzol, Shekdol, Fidson, Nemel, Arenol, analysed meet up the USP specified limit. After the calculation of the standard deviation and coefficient of variation of the two methods used, which are 123.5 and 27.7% respectively for UV method and 82.67 and 20.4% respectively for HPLC method, it was also observed that the HPLC method is more suitable for such kind of studies than the UV method.

Keywords: Paracetamol, HPLC, Ultra Violet Spectrophotometry

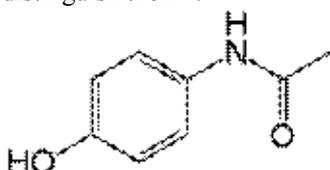
INTRODUCTION

Analysis means the examination of something in details in order to understand it better or draw conclusions from it¹

Chemical analysis involves a body of procedures and techniques used to identify and quantify the chemical composition of a sample of a substance,¹

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 preparations,²

Paracetamol is part of the drugs known as “aniline analgesics”. It is the only such drug still in use today³. It is classified as non-steroidal anti-inflammatory drug (NSAID) by some sources, and not as NSAID by others, while most sources clearly distinguish them⁴.



(<http://en.wikipedia.org/wiki/File:Paracetamol-skeletal.svg>)⁵

Paracetamol (C₈H₉NO₂) also called acetaminophen is a 4'-hydroxyacetanilide and a derivative of aniline, it is the most widely used analgesic and antipyretic drug,⁶. It is available in different formulations that are used worldwide due to the higher efficiency and tolerance, lower adverse effects and toxicity than other substances⁷

EVALUATION OF PARACETAMOL TABLETS

Like for any other tablet, evaluation of paracetamol tablet involves quantitative evaluation and assessment of tablet's chemical, physical and bioavailability properties. These are important in the design of drug and to monitor its quality⁸

There are various standards that have been set in the various pharmacopoeias regarding the quality of paracetamol tablets. These include diameter, size, shape, weight, thickness,

hardness, disintegration and dissolution characters. The following standards or quality control tests should be carried out on paracetamol tablets

- General appearance
- Content uniformity
- Mechanical strength of tablet
- Disintegration test
- Dissolution test

METHODOLOGY

Many methods are available in literature for the assay of Paracetamol tablets, many of them now only of historical interest. For accurate research purposes high performance liquid chromatography is favored for its sensitivity, precision and simplicity⁹

However, for rapid assay of Paracetamol in hospital patient, simple calorimetric enzyme based methods are commonly used.

Paracetamol can be assayed by quantitative estimation using UV Spectrophotometry or by back titration using 0.1M ammonium ferric sulphate as titrant and ferrous sulphate solution as indicator¹⁰

SAMPLE COLLECTION

Eight (8) samples of Paracetamol 500mg tablets were obtained from various pharmacy shops within Maiduguri, 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

The tablets were assayed spectrophotometrically using the following procedures

1. The average weight of tablet from each sample was determined by weighing ten (10) tablets and dividing the result by ten.

- Two (2) tablets were then crushed using a clean pestle and mortar (i.e for each sample).
- For each sample, powder containing 0.15g (150mg) of Paracetamol was accurately weighed and transferred into different 200ml volumetric flasks. All the 8 samples were labeled using a pen and a masking tape.
- 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 200ml with distilled water.
- The mixture in each flask was then mixed well and filtered through a filter paper into clean beakers.
- 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.
- 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.
- 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.
- The same procedure was repeated for the standard using 150mg of the powdered standard, and the absorbance determined, which was used to calculate the percentage content and content (in mg) of Paracetamol from each brand.
- The concentration of each sample was also determined using Beer Lambert's law according to BP¹¹.

The tablets were assayed by High Performance Liquid Chromatography, using the following procedure

- The mobile phase containing methanol and water in the ratio of 20:80 was prepared. This was done by measuring 300ml of methanol and 1200ml of distilled water into a 2000ml measuring cylinder, and put onto a sonicator for ten (10) minutes. This was then removed and filtered using a membrane filter and a vacuum pump.

- From the powdered drug samples, powder containing 20mg of Paracetamol was weighed from each sample, and then transferred into a 50ml volumetric flask each, and was labeled.
- 50ml of the mobile phase was measured and added to each of the volumetric flask, and was put onto a sonicator for five (5) minutes, for the drug molecules to dissolve.
- After sonicating for five minutes, the solutions were then filtered through a filter paper into clean beakers.
- 5ml of each filtrate was taken and put into different 50ml volumetric flask, and the mobile phase was added to make up the volume.
- 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.
- 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.
- The same procedure was carried out using 20mg of the standard Paracetamol powder, and the result was used to calculate the percentage content and content (in mg) of each sample

RESULTS AND DISCUSSION

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

SAMPLE A	WEIGHT (mg)
SAMPLE A	603.57mg
SAMPLE B	547.95mg
SAMPLE C	576.76mg
SAMPLE D	548.29mg
SAMPLE E	596.41mg
SAMPLE F	562.92mg
SAMPLE G	600.65mg
SAMPLE H	546.01mg

TABLE 2 SHOWING THE RESULTS OBTAINED USING UV METHOD.

SAMPLE SOLUTION	CONCENTRATION (mg/ml)	ABSORBANCE	%CONTENT (%)	CONTENT(mg)
A	0.000787	0.563	109.1	545.5
B	0.000669	0.479	92.8	464
C	0.000648	0.464	89.92	449.6
D	0.000718	0.514	99.6	498
E	0.000612	0.438	84.88	424.4
F	0.000913	0.653	126.55	632.75
G	0.000362	0.259	50.19	250.95
H	0.000437	0.313	60.65	303.25
STANDARD	0.000723	0.516		

TABLE 3 SHOWING THE RESULT OBTAINED USING HPLC METHOD

SAMPLE SOLUTION	CONCENTRATION(mg/ml)	PEAK AREA	% CONTENT (%)	CONTENT (mg)
A	0.048	3114454	91.30	456.5
B	0.043	2747979	80.56	402.8
C	0.046	2894978	87.50	437.5
D	0.043	2883187	84.52	422.6
E	0.047	2903289	85.11	425.6
F	0.045	3542274	103.84	519.2
G	0.048	1740913	57.04	255.3
H	0.043	2156272	63.2	316.0
STANDARD	0.040	3411157		

Table 4 showing calculation of standard deviation and coefficient of variation of UV method

SAMPLES	Mg CONTENT (X)	X-X	(X-X) ²
A	545.9	99.8	9960.04
B	464	17.9	320.41
C	449.6	3.5	12.25
D	498	51.9	2093.61
E	424.4	-21.7	470.89
F	632.8	186.7	34856.89
G	250.95	-195.15	38083.52
H	303.3	-142.8	20391.84

Table 5 showing calculation of standard deviation and coefficient of variation of HPLC method.

SAMPLES	Mg CONTENT (X)	X-X	(X-X) ²
A	456.5	52.1	2714.41
B	402.8	-1.6	2.56
C	437.5	33.1	1095.61
D	422.5	18.1	327.61
E	425.6	21.2	449.44
F	519.2	114.8	13179.04
G	225.2	-179.2	22260.64
H	316	-88.4	7814.56

Table 6 showing the mean, variance, standard deviation (SD) and coefficient of variation (CV) of the two methods

METHOD	MEAN (X)	VARIANCE (S ²) = $[\sum(x-x)^2/n-1]$	SD = $\sqrt{S^2}$	CV = $SD/X \times 100\%$
UV	446.1	15255.63	123.5	27.7
HPLC	404.4	6834.83	88.67	20.4

DISCUSSION

According to the United State Pharmacopoeia (U.S.P) ¹², a paracetamol tablet should contain not less than 90% (450mg) and not more than 110% (550mg) of paracetamol.

The percentage content of the analyzed samples using HPLC ranges from 51.04-103.84%, while using UV it ranges from 50.19-109.1%, indicating none of the samples contains less than 50% of the active principle.

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

The result obtained using the High Performance Liquid Chromatography (HPLC) shows that only samples A and F passed as compared to the specified limit in the U.S.P, because they all fall within the limit. While B, C, D, E, G and H all failed because they contain less than the limit specified.

CONCLUSION

Paracetamol is the most widely used agents to relieve mild to moderate pain, including instances of tension headache, migraine headache, muscular aches, neuralgia, backache, joint pain, rheumatic pain, general pain, toothache, teething pain, and period pain. It is suitable for most people, including the elderly and young children because of its fewer side effects.

Paracetamol is also used as anti pyretic which can reduces fever by affecting the part of the brain known as the hypothalamus that regulates the temperature of the body. Specifically, paracetamol has been given to children after they have been giving vaccinations in order to prevent them developing post-immunization pyrexia or fever.

It can thus be concluded that samples A, B, C, D and F are the only brands that are within the specified limit as laid down by the U.S.P, as A passes in both the two methods, B, C, D in UV method and F in HPLC method.

The HPLC method is more suitable for the assay of paracetamol tablets than the UV method because it procedures require less dilution of the sample before analysis, which may reduce the possibility of errors associated with measurement. Also, the standard deviation (SD) and coefficient of variation (CV), which are 123.5 and 27.7% respectively for UV method and 82.67 and 20.4% respectively for HPLC method serve as evidence for difference between the two methods, indicating that the HPLC method is more accurate and sensitive than the UV method.

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