DETERMINATION OF THE LEVEL OF PARACETAMOL IN COMMERCIALLY BRANDED PARACETAMOL /ANALGESIC (TABLET)

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Abstract

The study involves quantitative analysis of ten different brands of paracetamol 500mg tablets, using Ultra violet Spectrophotometry method. The samples were dissolved in 0.1M NaOH and distilled water and their various absorbances were determined at wavelength of 257nm. The results obtained were read off the graph (standard curve) prepared from pure samples of paracetamol. Percentage content for each sample was calculated using absorbance's gotten from spectrophotometry method, to deduce if it is within the specified limit by official books (90%-105% according to British Pharmacopoeia). The percentage content of the analyzed samples using UV Spectrophotometry method ranges from 84.32%-104.93%, indicating that none of the samples contains less than 80% of the active principle. It was observed that seven samples (NGC, Paingo, Fidson, Bonadol, Suremol, Painkill and M&B) out of the Ten Samples met the Standard limit of the British Phamacopoeia, whereas three samples (Easadol, Josedol and Emzor) were below the standard limit.

1.0 Introduction

Paracetamol (acetaminophen) is one of the world's most widely used non-prescription medicines from cradle to grave. It is readily available and inexpensive. As an analgesic, paracetamol is better tolerated than the non-steroidal anti-inflammatory drugs (NSAIDs) although it may be somewhat less efficacious (Belay *et al.,* 2007). During the 1980s a decline in the use of aspirin due to its association with Reye's syndrome allowed paracetamol to become the antipyretic and analgesic of choice in children (Belay *et al.*, 2007) and it is now the standard antipyretic and analgesic in all age groups. Although a useful and important drug, the dose of paracetamol is inconveniently large and a full dose of 4 g daily requires a large number of tablets to be taken. In his Nobel Prize-winning work on the mechanism of action of aspirin and other NSAIDs, Vane (1971) demonstrated that these drugs inhibit the formation of prostaglandins (PGs), local factors that are associated with pain, fever and inflammation. However, paracetamol did not appear to inhibit PG synthesis, despite its actions similar to those of the NSAIDs (Wrigth and Stephen, 2007).

The mechanism of the basic pharmacological effects of paracetamol is only now becoming clearer and it is now recognized to be an in hibitor of PG synthesis in cellular systems under specific conditions and has an apparent selectivity for one of the cyclo oxygenase (COX) enzymes, namely COX-2 (Strange *et al., 2010*).This article is a review of the pharmacology of paracetamol, particularly on its mechanism of action and therapeutic effects, with an emphasis

on discoveries that have been made in the past 10 years. Some aspects of the clinical pharmacology of paracetamol, such as its pharmacokinetics, metabolism and adverse effects are not covered in detail although its metabolism by peroxidases and the claimed hepatotoxicity of therapeutic doses are reviewed. New pharmacological actions of paracetamol have been identified in recent years, particularly its inter-action with haem peroxidases, such as myeloperoxidase,that is discussed in this review. These recently discovered actions have largely been detected in vitro but may lead to new clinical uses of this old drug (Uddin *et al.,* 2011).

World Health Organization (WHO) has estimated that medicinal products on sale in various countries in Africa, part of latin America and Asia for consumption has about 30% of it been substandard and counterfeit (WHO, 2006). Meanwhile genuine drug products that do not meet all the quality specification claimed by their manufacturer upon laboratory testing are referred to as substandard drugs (Taylor *et al.,* 2009).

There is evidence that products with the same amount of active ingredient sometimes show distinct differences in their therapeutic effect (Fujii *et al.,* 2009). This therefore put Health practitioners in a dilemma when they have to do generic substitution. Paracetamol tablets usage as an over the counter drug is on an increasing rate.

2.0 Methodology

Sample Collection

The standard stock solution sample was collected from National Institute for pharmaceutical Research Development Abuja.

Experimental Section

An SP 800 spectrophotometer with 1cm cell was used for the electronic measurement of the drugs.

Preparation of Stock Solution

0.15g powdered drug of paracetamol of stock solution was accurately weighed into 50ml volumetric flask and 50ml of sodium hydroxide was added unto it, which was vigorously shaking for about 15min and 50ml volume of distilled water was added unto it to produce a standard volume of stock solution

Preparation of Paracetamol Tablet and Determination of Paracetamol Tablet in Stock Solution

The label claim on the sample is 500mg of NGC, 500mg of Easadol, 500mg of Paingo, 50mg of Josedol, 500mg of Fidson, 500mg of Bonadol, 500mg of Suremol, 500mg of Paingo, 500mg of Emzor and 500mg of M&B paracetamol tablet were used.

The concentration of each paracetamol tablet were prepared as followed; 10 tablet of each paracetamol tablet were crush to powdered into 10 different beaker with clean mortar and pestle, 0.15g of each powered paracetamol were weighed and 50ml of sodium hydroxide with 50ml of distilled water was added unto each of the sample with vigorous shaking for about 10min. The mixture (each) was filtered and the resulting solution was measure at a minimum absorbance of 257nm.

Percentage Content Determination

Percentage content determination was done by comparing the absorbance of test sample with that of standard preparation:

CT=AT/AS x CS

Where:

CT= Total concentration
AT = absorbance of test sample
AS = absorbance of standard preparation.
CS= 0.0075

3.0 Results and Discussion of Results

3.1 Results

The result of each sample is represented in a Table below:

Table 1.1: Absorbance of different paracetamol tablet

Samples	Wavelength	Absorbance
Pure sample	257	0.1601
NGC	257	0.1440
Easadol	257	0.1350
Paingo	257	0.1460
Josedol	257	0.1425
Fidson	257	0.1640
Bonadol	257	0.1500
Suremol	257	0.1670
Painkill	257	0.1680
Emzor	257	0.1391
M & B	257	0.1550

Table 1.2: Result by standardization method

Sample	Absorbance of test solution (AT)	Absorbance of Standard Aolution (AS)	Total Concentration (CT)	Assay
NGC	0.1440	0.1601	0.0068	90.00%
Easadol	0.1350	0.1601	0.0063	84.32%
Paingo	0.1460	0.1601	0.0068	91.19%
Josedol	0.1425	0.1601	0.0067	89.01%
Fidson	0.1640	0.1601	0.0077	102.43%
Bonadol	0.1500	0.1601	0.0070	93.69%
Suremol	0.1670	0.1601	0.0078	104.31%
Painkill	0.1680	0.1601	0.0079	104.93%
Emzor	0.1391	0.1601	0.0065	86.88%
M & B	0.1550	0.1601	0.0073	96.81%

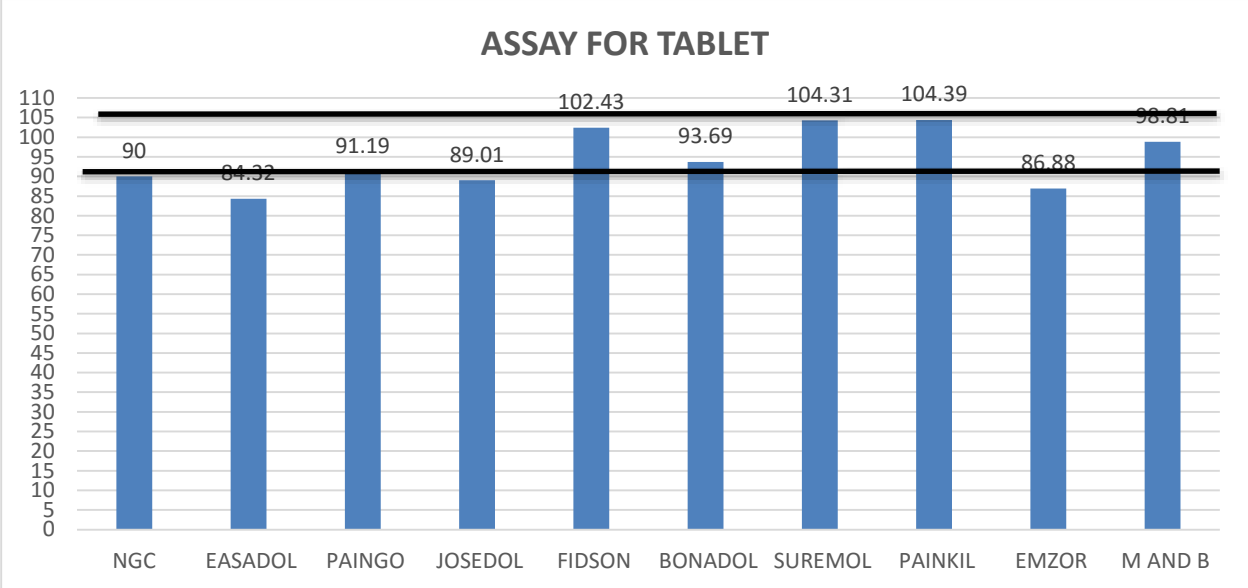

Figure 1: Statistical Analysis of Paracetamol Tablet

3.2 Discussion

Table 1.1 and 1.2 shows the information gathered on the ten (10) selected brands of paracetamol tablets. The shelf life of each of the samples bought had at least 12 month left to expiration to ensure that all analytical procedures will be carried out before product expires. The pure paracetamol (reference standard) was also considered suitable for use as reference standard.

According to the standard of the British pharmacopoeia, (BP 2013), upon assay of a product of paracetamol, between 90% and 105% of the label claim should contain the active ingredient. The result obtained from the UV Spectrophotometer (Table 1.2), showed that seven (7) out of the ten (10) brands had values which fell within the monograph specification, these seven (7) includes; 90% of NGC, 91.19% of Paingo, 102.43% of Fidson, 93.69% of Bonadol, 104.31% of Surmol, 104.93% of Painkill and 96.81 of M&B.

The brands Easadol, Josedol and Emzor had percentage content of active ingredient below the lower limit of 90% (84.32%, 89.01% and 86.88% respectively). These which could be said to be substandard. The deviation from the stated percentage content in drugs Easadol, Josedol and Emzor could be attributed to factors involved in the formulation process. Some of the possible factors include inaccuracy in weighing the active ingredient, lack of effective mixing during the preparation of the samples. The shortage of the active ingredients may also be deliberately done as cost saving measure by the company, thus producing substandard product.

4.0 Conclusion

From the experiment conducted and the deductions made in the discussion, it can thus be concluded that the brands NGC, Paingo, Fidson, Bonadol, Surmol, Painkill and M&B contain paracetamol within limit as laid down by british phamarcopoeia (BP), unlike Easadol, Josedol and Emzor. In the methodology, calibration plot method shows the accurate result compared to single point standardization. By random sampling, 30% of paracetamol Tablets in the market are substandard

5.0 Recommendations

Based on the findings in this study, the following recommendations are made:

1. NAFDAC (National Agency of Food and Drug Administration and Control) should intensify effort at monitoring the production of drug in the co country

2. NAFDAC (National Agency and drug administration and control) should also make name of products and manufacturing substandard pharmaceutical products.

References

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