MAYFEB Journal of Chemistry and Chemical Engineering - ISSN 2560-693X
Vol 2 (2017) - Pages 1-10

Assessment of the Quality of Paracetamol Tablet Brands Sold in Katsina Metropolis Nigeria

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***Abstract*- Paracetamol being the most widely used analgesic and most frequently faked product worldwide. Many studies have been conducted with regards to quality assessment of paracetamol and other drugs within Nigeria and other countries. However, drug counterfeiting suspicion is highest in Border neighboring towns than others and hence the relevance of this study in Katsina. This study was carried out to assess the quality of paracetamol tablet brands sold in the dispensaries/kiosks in metropolitan Katsina. Tablet samples were collected and analyzed quantitatively using Uv-visible spectrophotometry and qualitative analysis techniques. The average active content of the paracetamol tablets samples assayed was found to be 463.108mg. The results obtained from the spectrophotometric analysis were compared with the British Pharmacopeia's permissible range of active content (450-500mg), and world health organization's quality assessment guidelines on qualitative analysis results for paracetamol tablets. Based on the average value of the active content, it could be deduced that all the tablets are within the safety limit**

Key word: **Paracetamol, spectrophotometry, active content, counterfeit drugs**

1. INTRODUCTION

Paracetamol is a pharmaceutical compound widely used as analgesic and antipyretic [1]. It belongs to the class of drugs, known as aniline analgesics, it is commonly used for the relief of headache, other minor aches, pains, inflammations and a major ingredient in numerous cold and flu remedial combination drugs [2]. An estimated 700,000 deaths annually are caused by fake anti-malarial and tuberculous agents, suggesting that the total annual mortality due to the menace will definitely be much higher [16]. About 2500 people died in Niger state of Nigeria following the administration of counterfeits of meningococcal-vaccines (containing no active ingredient) to some 60,000 people during the 1995 meningitis epidemic [14]. Acute renal failure due to poisoning from diethylene glycol packaged as a cough syrup which resulted in hundreds of deaths in Nigeria [10]. There has been an increase in the circulation of counterfeit drugs worldwide in the recent few decades which has been attributed to the lack of effective monitoring of the quality of products being sold in the markets [23].

World health organization and British Pharmacopeia have among others set regulatory guidelines for assessing/confirming the quality/originality of drugs being used for treating different illnesses [10].Despite efforts being made by the relevant authorities in Nigeria such as National agency for food and drug administration (NAFDAC),there has been reports of drug counterfeiting in Nigeria which has been labelled to the lack of resources for controlling and managing the quality of the drugs in our markets/pharmacies. It is well known fact that counterfeit drugs pose a serious threat to the human health due to the inherent mismatch in the active ingredient content [10]. The world health organization has reported in 2003 that 7% of the antimalarial analgesics are fake. Lack of adequate quality assurance measures as well as the decomposition of the active ingredient in drug dosage form due to high temperature and humidity of the storage condition has been identified as the possible cause of the resultant negative effect of the drug on the human health [15] and [17].Drug resistance and treatment failure have been frequently reported due to the inability of government to ensure an effective monitoring of the quality of drugs sold in the market [22]. Many researchers have established the worldwide existence of counterfeit drugs [20]. In Myanmar and Vietnam, about 1.7% of anti-diabetic agents are being faked [24].

The world health organization have in 2007 reported the prevalence of fake medicines in countries with weak regulations, enforcement, and scarcity of supply of basic medicines, unregulated market's and unaffordable prices. Because of these, the quality, safety and efficacy of drug products cannot be guaranteed [4]. Olike Chinwendu in 2008 have reported a dominant market of counterfeit in Nigeria and has attributed it to the weakness in the regulatory agency. Paracetamol samples analyzed in Somalia region of Ethiopia showed that there were unregistered medications in the market and were substandard [8]. Many in vivo and in vitro studies have been conducted with regards to the quality assessment of drugs. An assessment in Addis Ababa and Somali region of Ethiopia on the quality of paracetamol being sold and used in the regions revealed the presence of products which did not fulfill the requirements in the Compendia's [7]. and Pharmacopeia [9]. Ergetie in 2013 have assessed the quality of paracetamol tablets sold in pharmacies and non-pharmacies in Gondar comprising three brands and have showed failure to comply with quality specifications in compendia's for many products indicating the presence of poor quality products in the regions. The British pharmacopeia's guidelines and the physicochemical properties such as content of active ingredient, crushing strength, friability and disintegration time have been widely used worldwide in assessing the quality of different brands of drugs. The quality of seven marketed brands of paracetamol tablets formulation being manufactured by different multinational and national companies in Bangladesh were assessed and the results showed that all the samples complied with the standard specifications for tablet hardness [18].In Nigeria, the quality of ciprofloxacin Hydrochloride tablets has been assayed in different brands being sold in Anambra state and the results showed that all the brands complied with the guidelines except tablet that failed disintegration test [11].

With regards to metformin tablet, Ajala et al.,2014 studied its quality from some samples collected in different pharmacies and dispensaries in Ogun state, Nigeria and has found that all the samples have passed the tests except for two samples that failed the friability test. Paracetamol tablets quality has also been assessed in some paracetamol sample tablets collected from common kiosks in Addis Ababa and has concluded that all the studied samples have parameters within the guidelines [3]. Literature searches have revealed that quality assessment of paracetamol tablets have never been conducted in Katsina metropolis. Hence, the aim of the present study is to evaluate the quality of the paracetamol tablets brands sold in Katsina metropolis.

2. MATERIALS AND METHODS

2.1 Sample Collection and Preparation

Seven brands of paracetamol tablets were obtained from various pharmacies/kiosks within Katsina metropolis, while the sample of the standard paracetamol active ingredient was obtained from Kano state drug and medical consumable supply agency, Kano state Nigeria. Five tablets from each brand were weighed and their average weight were taken, the tablets were then crushed to powder. 500mg from each sample were measured out and were shaken with 20ml of hot ethanol (0.2Molar), filtered and evaporated to dryness. The residue obtained from each sample was used for the qualitative analysis as in [13]. About 0.15g of standard paracetamol active ingredient powder was measured out and transferred into 200ml flat bottom flask, 20ml of 0.1M NaOH was added and made up to 200ml volume with deionized water. The standard paracetamol powder samples were used to prepare standard solutions from which calibration curve was plotted and was utilized in the deduction of the active ingredients of our tablet samples.

2.2 Procedure for Qualitative Test of Tablets

About 0.10g tablet residue was dissolved in 10ml of deionized water and 0.5ml of ferric chloride (25g/l) was then added. For the confirmatory test, 0.10g of the test from each sample was poured in 2ml of HCl (0.2Molar) and boiled for a minute. 10ml of deionized water and a drop of $K_2Cr_2O_7$ (100g/l) were also added and shaken, violet color was slowly developed [13]. For the UV visible Spectrophotometry, each sample containing 0.15g was accurately weighed and transferred into different 200ml volumetric flask. To each volumetric flask, 50ml of 0.1M NaOH and 100ml of deionized water were added and was made up with volume to 200ml with deionized water. From the resulting solution, 10ml was taken and transferred into a 100ml volumetric flask, deionized water was then added to make up the volume.

From the immediate resulting solution, 10ml was taken into 100ml volumetric flask and 10ml of 0.1M of NaOH was added, deionized water was then added and made up the volume. The absorbance of each sample was determined at 257nm, by putting small amount of the sample into a cuvette. 0.1M of NaOH was used as a blank solution [2].

3. RESULT AND DISCUSSION

Table 1 presented some preliminary information on the drug samples used in this study, from the information in the table, it could be observed that majority of the tablet samples have all the required information only for samples A, B that lacks manufacturing number, Samples A. B, C that doesn't have expiry date and sample B that has no batch number. All the samples were assessed using the quality control parameters of weight uniformity, active ingredient and qualitative (identification) test for the tablets. The results of the spectrometric analysis were presented in table 2, table 2 column 5 contains the active ingredient content in milligram. British pharmacopoeia (B.P, 2009) recommends that paracetamol tablets should not contain less than 450mg and not more than 500mg of paracetamol active ingredient The results of the paracetamol active ingredient content in mg obtained from the experimentation were subjected to statistical analysis using Microsoft Excel 2013 and the results were presented in the table 2. From the results it could be observed that the average content in mg for paracetamol active ingredient in the paracetamol tablet samples was 463.108mg with a variation of 27.154 and corresponding coefficient of variance of 5.863 which indicated that the average content in mg is within the limits set by both the pharmacopoeias. Based on these guidelines it could be inferred that the sampled tablets were safe for use as pain reliever in terms of its active ingredient content in mg. The statistical parameters (variance and coefficient of variance) indicated that the sampled paracetamol tablets do not vary significantly from the mean.

TABLE 1. Preliminary Information on the Sampled Drug Samples Used in this Study (*Information not stated on label)

S/N	Average weight of tablet samples (mg)	Sample	Manufacturing date	Expiry date	Batch number	NAFDAC REG NO.
1	604	A.	*	*	16E06	04-4685
2	548	B.	March,2016	*	1268V	*
3	572	C.	*	*	6229M06	04-7111
4	610	D.	14/07/2016	13/06/2019	211M	04-1853
5	556	E.	March,2016	February,2019	T6C68	B4-1593
6	594	F.	March,2016	March,2019	NI6111	04-2019
7	586	G.	July,2016	June,2019	*	A4-1305

TABLE 2. Results of the Spectrophotometric Analysis of the Paracetamol Tablet Samples

Samples	Concentration (mg/ml)	Absorbance	% content	Content (mg)
A	0.0075	0.568	93.729	468.65
B	0.0071	0.564	93.069	465.35
C	0.00693	0.561	92.574	462.87
D	0.00708	0.563	92.904	464.52
E	0.0071	0.564	93.069	465.35
F	0.00693	0.561	92.574	462.87
G	0.00691	0.548	90.429	452.15
Average				463.108

TABLE 3. Results of The Qualitative Analysis of The Sampled Paracetamol Tablets

S/N.	Test	Observation	Inference
1.	sample A+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)}+FeCl_{3(aq)}$ ↓ $CH_3CONHC_6H_5OFeCl_{3(aq)}+Hcl_{(aq)}$	4-hydroxyacetanilide was suspected
	sample A+2ml of HCl+10ml of deionized water+$K_2Cr_2O_7$	A violet colour was observed $CH_3CONHC_6H_5OH_{(aq)}+ K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2+ H_2Cr_2O_{6\,(aq)}$	4-hydroxyacetanilide was confirmed

2.	sample B+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)} + FeCl_{3(aq)}$ ↓ $CH_3CONHC_6H_5OFeCl_{3(aq)} + HCl_{(aq)}$	4-hydroxyacetanilide was suspected
	sample B+2ml of HCl+10ml of deionized water+$K_2Cr_2O_7$	A violet colour was observed $CH_3CONHC_6H_5OH_{(aq)} + K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2 + H_2Cr_2O_{6\,(aq)}$	4-hydroxyacetanilide was confirmed
3.	sample C+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)} + FeCl_{3(aq)}$ ↓ $CH_3CONHC_6H_5OFecl_{3(aq)} + HCl_{(aq)}$	4-hydroxyacetanilide was suspected
	sample C+2ml of HCl+10ml of deionized water+$K_2Cr_2O_7$	A violet colour was observed $CH_3CONHC_6H_5OH_{(aq)} + K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2 + H_2Cr_2O_{6\,(aq)}$	4-hydroxyacetanilide was confirmed

4.	sample D+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)} + FeCl_{3(aq)}$ ↓ $CH_3CONHC_6H_5OFeCl_{3(aq)} + HCl_{(aq)}$	4-hydroxyacetanilide was suspected
	sample D+2ml of HCl+10ml of deionized water+$K_2Cr_2O_7$	A violet colour was observed $CH_3CONHC_6H_5OH_{(aq)} + K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2 + H_2Cr_2O_{6(aq)}$	4-hydroxyacetanilide was confirmed
5.	sample E+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)} + FeCl_{3(aq)}$ ↓ $CH_3CONHC_6H_5OFeCl_{3(aq)} + HCl_{(aq)}$	4-hydroxyacetanilide was suspected
	sample E+2ml of HCl+10ml of deionized water+$K_2Cr_2O_7$	A violet colour was observed $CH_3CONHC_6H_5OH_{(aq)} + K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2 + H_2Cr_2O_{6(aq)}$	4-hydroxyacetanilide was confirmed
5.	sample F+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)} + FeCl_{3(aq)}$ ↓	4-hydroxyacetanilide was suspected

		$CH_3CONHC_6H_5OFecl_{3(aq)}+HCl_{(aq)}$	
	sample F+2ml of Hcl+10ml of deionized water+$K_2Cr_2O_7$	$CH_3CONHC_6H_5OH_{(aq)}+ K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2 + H_2Cr_2O_{6\,(aq)}$	4-hydroxyacetanilide was confirmed
6.	sample G+10ml of deionized water+0.5ml 0f $FeCl_3$	A blue colour was observed $CH_3CONHC_6H_5OH_{(aq)} +FeCl_{3(aq)}$ ↓ $CH_3CONHC_6H_5OFeCl_{3(aq)}+HCl_{(aq)}$	4-hydroxyacetanilide was suspected
	sample G+2ml of HCl+10ml of deionized water+$K_2Cr_2O_7$	A violet colour was observed $CH_3CONHC_6H_5OH_{(aq)}+ K_2Cr_2O_{7(aq)}$ ↓ $CH_3CONC_6H_4O_2K_2 + H_2Cr_2O_{6\,(aq)}$	4-hydroxyacetanilide was confirmed

4. CONCLUSION

Paracetamol is the popular medicines widely used and well established analgesic drug. Paracetamol may be associated with a lot of risks when the active ingredient mismatches the standard recommendations. Hence the need for the assessment of the quality of paracetamol tablets sold and utilized in Katsina metropolis. All the paracetamol tablets tested conformed to British pharmacopeia specifications and the world health organization's guidelines on the quality of paracetamol tablets in terms of the active ingredients. The study therefore shows that all the paracetamol tablets sampled in the metropolitan Katsina are safe and can serve the purpose for which it was intended for. Overall, the quality evaluation

results found in this research corroborate with the results observed from many previous studies of paracetamol tablets obtained from legal drug markets.

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