

Chemical and microbial analysis of different brands of Ibuprofen solid dosage formulations sold in Ilorin, Kwara State

Kamaldeen Abu-Saeed¹ and Jamiu O. Muslim²

¹Research Unit, Peace Standard Pharmaceutical Industries Limited, Ilorin. Nigeria

²Department of Clinical Pharmacy, Faculty of Pharmaceutical Sciences, University of Ilorin. Nigeria.

Corresponding author: Kamaldeen Abu-Saeed

Email kamal.abusaeed@yahoo.com Phone +2348033898351

ABSTRACT

Background: Fake and substandard drugs have embarrassed healthcare providers and eroded the confidence of the public on healthcare delivery system. They have led to therapeutic failure, adverse effects and microbial resistance to drugs. Therefore, there is the need to routinely determine the quality of drugs in the market to ascertain that they are stable, efficacious and safe for consumption.

Objective: This work was aimed at carrying out chemical and microbiological analysis on thirteen brands of Ibuprofen solid dosage formulations sold across licensed Pharmacies in Ilorin, Kwara state and comparing results with brand used as standard using t-test analysis.

Methods: Chemical analysis was done using titrimetric method as described by International Pharmacopeia to determine the percentage contents of the active components of the various samples of Ibuprofen solid formulations. Microbiological analysis was done using pour plate method to determine bacteria and fungi counts of samples. Analysis was done using Statistical Package for Social Science (SPSS) computer software and p values less or equal 0.05 were considered statistically significant.

Results: The percentage content of Ibuprofen in two of the brands were below specification as stated in British Pharmacopeia and United States Pharmacopeia. These two brands were foreign brands. One of these two brands failed the microbiological analysis in addition. Sample t-test analysis showed that all but one of the test samples varied significantly ($p \leq 0.05$) in terms of percentage content of Ibuprofen from sample used as standard.

Conclusion: Generally, majority of the various brands of Ibuprofen samples examined complied with official standards.

Keywords: Ibuprofen, Chemical analysis, Microbiological analysis, Ilorin, Fake/Substandard drugs.

Analyse chimique et microbienne des différentes marques des formulations de doses solides d'Ibuprofen vendu à Ilorin, Kwara State

Auteur correspondant : Kamaldeen Abu-Saeed
E-mail kamal.abusaeed@yahoo.com Téléphone : +2348033898351

RESUME

Contexte: Les médicaments contrefaits et de qualité inférieure ont mis les fournisseurs de soins de santé dans l'embarras et ont miné la confiance du public sur le système de prestation des soins de santé. Ils ont conduit à l'échec thérapeutique, aux effets indésirables et à la résistance microbienne aux médicaments. Par conséquent, il est nécessaire de déterminer systématiquement la qualité des médicaments sur le marché pour vérifier s'ils sont stables, efficaces et sans danger pour la consommation.

Objectif: Ce travail avait pour but de procéder à une analyse chimique et microbiologique sur treize marques de formulations de dose solide d'Ibuprofen vendu dans toutes les pharmacies d'Ilorin, Kwara state et de comparer les résultats de la marque utilisée comme standard à l'aide de l'analyse t-test.

Méthodes: L'analyse chimique a été faite à l'aide de la méthode de titrimétrie comme décrit par International Pharmacopeia pour déterminer le pourcentage des contenus des composants actifs des différents échantillons de formulations solides d'Ibuprofen. L'analyse microbiologique était effectuée à l'aide de la méthode de la plaque pour déterminer le taux d'échantillons de bactéries et de champignons. L'analyse a été effectuée à l'aide du logiciel informatique de statistique pour les sciences sociales (SPSS) et des valeurs p inférieures ou égales à 0,05 étaient considérées comme statistiquement significatives.

Résultats: Le pourcentage de la teneur en Ibuprofen dans deux des marques était inférieur aux normes établies dans la British Pharmacopeia et United States Pharmacopeia. Ces deux marques étaient des marques étrangères. L'une de ces deux marques a échoué à l'analyse microbiologique en plus. L'analyse t-test de l'échantillon a indiqué que tous sauf un des échantillons d'essai variaient de manière significative ($p \leq 0,05$) en termes de pourcentage de la teneur en Ibuprofen à partir de l'échantillon utilisé comme type.

Conclusion: En général, la majorité des différentes marques d'échantillon d'Ibuprofen examinées étaient conformes aux normes officielles.

Mots clés: Ibuprofen, analyse chimique, analyse microbiologique, Ilorin, médicaments contrefaits/de qualité inférieure.

INTRODUCTION

Production and sales of quality drugs is important in promoting good health in any population. A large number of ailments require the use of drug for treatment and as such, high quality drugs are necessary to prevent treatment failure and relapse. Proliferation of poor quality drugs globally and in Nigeria specifically is becoming more evident based on previous researches that have been conducted.¹⁻³ Poor quality of drugs could be as a result of certain key factors. Commonest among them include counterfeiting which brings about the production and sales of fake and adulterated drugs; use of formulations or methods of production by manufacturers that promote instability of products within their shelf lives which in turn may lead to proliferation of substandard drugs and also poor storage of drugs by wholesaler, retailers and end users which may lead to deterioration of the active ingredients of the drug and may also promote microbial contamination of such products.

International health care organizations have estimated that in Africa as a whole, 25 to 50 percent of the pharmaceutical market is counterfeit, with Nigeria being the most affected, accounting for 50 percent of the total sales of fake drugs.⁴ In Nigeria, the Ebonyi State Task force on Counterfeit and fake drugs reported that approximately 48% of goods and drugs imported into the country were substandard or counterfeit.⁵ Medicines counterfeiting undermines the ability of Research and Development (R&D) based companies to invest in future innovation.⁶ It also negatively affects the R&D companies by reducing their sales. Counterfeiting also causes serious harm to the reputation of the genuine pharmaceutical manufacturers and makes them liable to any harm that may result from consumers ingesting counterfeit medicines. In addition, counterfeiting increases the expenditure of the legitimate manufacturers as they have to constantly develop new strategies to thwart counterfeiting. In addition to these, medicines counterfeiting reduces public trust in healthcare providers, undermines the credibility of health systems, dispensing processes and the government. This may lead to non-adherence of patients to their medicines or importation of costlier branded medicines which the patients consider to be more potent.⁷ Furthermore, counterfeiting can be detrimental to national economies. This is because genuine manufacturers compete with illegal manufacturers who do not pay any import duties and sales tax of the medicines they sell.⁸ Although it is a difficult task to trace illness and death to counterfeit or substandard medicines, evidence shows that poor

quality medicines pose significant threats to consumers as they cause adverse reactions, lack of successful treatment and possibly death.⁹

Studies carried out in Nigeria have shown that analgesics and antibiotics are among the most prescribed drugs.¹⁰⁻¹² In addition Ibuprofen has been found to be among the most prescribed analgesics and antibiotics.¹³⁻¹⁷

Ibuprofen is a Non Steroidal Anti inflammatory drug (NSAID). It is a colorless crystals or white, crystalline powder with a characteristic odor. It has a relative molecular mass of 206.3. It is practically insoluble in water, soluble in 1.5 parts of ethanol (750g/L), in two parts of ether R, and in 1.5 parts of acetone. It has a melting point range of between 75 to 78°C. It has analgesic, anti inflammatory and antipyretic properties. Its anti-inflammatory properties may be weaker than those of some other NSAIDs. It is indicated in pain and inflammation in rheumatic disease and other musculoskeletal disorders including juvenile arthritis; mild to moderate pain including dysmenorrhea, headache, pain in children and acute migraine attack. It may also be of value in the less well defined conditions of back pain and soft tissue disorders. Like with other NSAIDs, caution should be exercised in the treatment of the elderly, in allergic disorders, during pregnancy and breastfeeding. In patients with renal, cardiac or hepatic disorders, the dose should be kept as low as possible and renal function should be monitored.¹⁸

Stabilities of drug are very important in ensuring that it remain intact throughout its shelf life. Different types of drug stability have been identified including physical, chemical, microbiological, therapeutic and toxicological stabilities.¹⁸ These stabilities serve as the control parameters that can be tested regarding Quality control of tablets. Physical stabilities include appearance, palatability, uniformity, disintegration, dissolution, weight uniformity, hardness, friability and suspendability of the product; Chemical stability include the active components of the product; Microbiological stability tests for microbial growth or quality of the product; Therapeutic stability test for therapeutic efficacy of the product while Toxicological stability ensures that toxic effect of the drug is within safe limits and not increased throughout the shelf life of the drug.¹⁹

Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients with insufficient active ingredients or with fake packaging.²⁰ Substandard

medicines on the other hand are products whose composition and ingredients do not meet the correct scientific specifications and which are consequently ineffective and often dangerous to the patient.²¹ The emphasis on these definitions is on the active ingredients of the drugs which correspond to the chemical stability of a drug.

This work therefore focuses on two quality control parameters: chemical and microbiological analysis of a common solid dosage form of Ibuprofen. This in turn provides information on these drugs to the regulatory agencies and also ensures that these drugs being consumed by a large number of people in Nigeria are of standard and good quality. This work was also carried out in an area where studies specifically on Ibuprofen in relation to the scope of this study have not been done. This study also adds to knowledge based on frequently prescribed drug like Ibuprofen to collaborate earlier works done in this regards.

METHODS

Collection of samples

Thirteen samples of Ibuprofen solid dosage forms including tablets, caplets and capsules available and obtainable in Ilorin metropolis, Kwara State as at the time this study was conducted were used. Samples were drawn from a total of fifteen (15) registered Pharmacy outlets. Seven different brands of Ibuprofen tablets, two brands of Ibuprofen caplets and four different brands of Ibuprofen capsules were obtained making it a total of thirteen (13) brands of Ibuprofen. Standard samples of Tabalon[®] tablets for Ibuprofen used for this study were obtained directly from company manufacturing it using the Company's sales representatives in Kwara State.

Chemical analysis

a) Determination of percentage content of ibuprofen in ibuprofen tablets and capsules

A total of thirteen samples were analyzed. The procedure as specified in the International Pharmacopeia, 2006 was adopted. For each sample of Ibuprofen, 20 tablets were weighed on a Metler balance (Gallenkamp, England) and powdered for tablets and caplets while the content of 20 capsules was emptied for capsules. Then, 60 mL of Chloroform was added to a quantity of the powder equivalent to 0.5 g of Ibuprofen (The quantity of powder equivalent to 0.5 g of Ibuprofen varied from sample to sample and dependent on the label claim and weight of individual tablet, caplet or capsule) and this was shaken for 15 minutes. This was then filtered through a filter paper (Whatman[®] Cat No

1001 125) under reduced pressure. The residue was washed with two quantities each of 20 mL of Chloroform and the combined filtrate was evaporated in a current of air until just dry.

The residue was then dissolved in 100 mL of neutralized ethanol and titrated with Sodium hydroxide (0.1 mol/L), determining the end point when the indicator (phenolphthalein) changed color from colorless to red. Each mL of Sodium hydroxide (0.1 mol/L) is equivalent to 20.63 mg of Ibuprofen.²²

This test was done in triplicate and the average value and standard deviation calculated and recorded for every sample.

Microbiological analysis

a) Preparation of media

All the dehydrated media were reconstituted with freshly distilled water according to the Manufacturer's instructions. They were distributed into test tubes and bottles and sterilized at a pressure of 15 psi and temperature of 121 °C for 15 minutes in a portable autoclave (Lab-tech, India). The sterilized media were kept until ready for use.

b) Sterilization of glass wares

Sterilized glass wares included bottles, pipettes and beakers. All glass wares were washed using soap solution and properly rinsed with distilled water. They were allowed to dry, packed in appropriate containers or wrappers and then subjected to dry heat sterilization at 60 °C for one hour in a Laboratory oven.

c) Screening for bacterial contamination of the products

The procedure for bacteria count involved the following:

10 g of tablets, caplets or capsule content was mixed with 90 mL of sterilized deionized water. Then 10 mL of the resulting mixture was pipetted into 90 mL of Nutrient broth and mixed properly.

Then 1 mL of the resulting mixture (as described above) was pipetted into sterile petri dishes in triplicates and 20 mL of prepared sterile Nutrient Agar (NA) was also poured into each petri dish and cooled to 45 °C. The petri dishes were swirled for even distribution and allowed to solidify. The dishes were incubated at 37 °C for 48 hours. Bacteria count was estimated using a colony counter and then multiplied by the dilution factor to obtain the total count.²³

The procedure above was repeated in triplicate for every sample of Ibuprofen tablet, caplet and capsule.

Analysis of brands of Ibuprofen in Ilorin

The average value and standard deviation for every sample was obtained and recorded.

d) Screening for fungal contamination of the products

The procedure for fungi count included:

For tablets and capsules, 10 g of tablets or capsule content was mixed with 90 mL of sterilized deionized water. Then 10 mL of the resulting mixture was pipetted into 90 mL of Nutrient broth and mixed properly.

Then, 1 mL of the resulting mixture was pipetted into two sterile petri dishes and then 20 mL of sterile Sabourand Dextrose Agar (SDA) was poured into each dish and swirled to allow for even distribution. The plates were incubated at 25°C for five days. The fungal count was estimated using a colony counter and then multiplied by the dilution factor to obtain the total count. This procedure was repeated in triplicate for every sample used for this study.²³

The average value and standard deviation for every sample was obtained and recorded.

Statistical analysis

Average percentage content of active components in the samples was determined using arithmetic mean of the values obtained from performing the tests in

triplicate.

Sample t- test analysis was used to determine statistical significance of average percentage content of the test samples with the standard samples. Statistical Package for Social Sciences (SPSS) version 15 computer software was used for analysis and p values less than 0.05 were considered statistically significant.

RESULTS

A total of thirteen different samples of Ibuprofen solid oral dosage forms found in Ilorin metropolis, Nigeria were used for this study.

Table 1 shows the general characteristics of the Ibuprofen samples used for this study. About 31% of the samples were capsules, 15% were caplets and 54% were tablets. Six (46%) of the brands used had a claimed strength of 200 mg per dosage form (capsule, caplet or tablet) while the remaining seven (54%) claimed to have a strength of 400 mg per dosage form.

Five of the brands (three tablets, one caplet and one capsule) amounting to about 38% of the samples used was imported from other countries: India and USA while the rest were locally produced in Nigeria. None of the samples had expired as the time analysis was carried out on them. All brands except brand IB12 had NAFDAC registration numbers on the packs.

Table 1: Characteristics of Ibuprofen samples

Code	Batch number	Dosage form	Claimed strength per unit (mg)	Date of Manufacture	Expiry date	Place of manufacture
IB01	G130295	Capsules	400	May, 2013	April, 2015	Gujarat, India
IB02	V59	Capsules	200	February, 2013	January, 2016	Lagos, Nigeria
IB03	MP096	Capsules	400	August, 2013	July, 2016	Ilorin, Nigeria
IB04	M10D01	Capsules	400	August, 2013	August, 2016	Lagos, Nigeria
IB05	KP1403	Caplets	400	January, 2014	January, 2016	Ibadan, Nigeria
IB06	12ID45	Caplets	400	February, 2012	January, 2015	Panipat, India
IB07	883	Tablets	200	November, 2013	October, 2016	Asaba, Nigeria
IB08	T3032	Tablets	400	May, 2012	April, 2015	Mumbai, India
IB09	2512676	Tablets	400	May, 2013	April, 2016	Mumbai, India
IB10	RG1203	Tablets	200	July, 2012	June, 2015	Lagos, Nigeria
IB11	BNO/05	Tablets	200	January, 2014	December, 2017	Akwa, Nigeria
IB12	P73348	Tablets	200	Not mentioned	September, 2014	Connecticut, USA
IB13	007	Tablets	200	May, 2013	May, 2016	Onitsha, Nigeria
Tabalon [®]	D1001	Capsules	400	April, 2013	April, 2016	Lagos, Nigeria

Table 2: Chemical analysis of active component of Ibuprofen samples

Code	Average percentage content of Ibuprofen
IB01	52.53 ± 0.29
IB02	97.59 ± 0.59
IB03	98.67 ± 0.29
IB04	96.11 ± 0.29
IB05	100.87 ± 0
IB06	86.64 ± 0.30
IB07	104.15 ± 0.59
IB08	97.13 ± 0.30
IB09	103.94 ± 0
IB10	102.71 ± 0.59
IB11	104.15 ± 0.59
IB12	99.74 ± 0.59
IB13	104.76 ± 0.59
Tabalon®	100.36 ± 0

Table 3 used paired sample t-test statistical method to compare all brands of Ibuprofen used for this study with Tabalon® tablet used as standard. The table shows that only sample IB12 had p values greater than 0.05. Others had values less than 0.05

Table 3: Paired sample T-test for percentage content of Ibuprofen using Tabalon® tablet as standard sample

Code	T value	p value
IB01	280	0.000
IB02	8	0.015
IB03	10	0.001
IB04	25	0.002
IB05	-2	0.000
IB06	80	0.000
IB07	11	0.008
IB08	19	0.003
IB09	-20	0.000
IB10	7	0.020
IB11	11	0.008
IB12	2	0.184
IB13	13	0.006

Table 4 showed the result obtained from the microbiological analysis of Ibuprofen samples. Sample IB06 had the highest mean bacteria count of 1020 cfu/g while samples IB01, IB02 and IB12 had no bacteria count. All samples except IB03 had no fungi count.

Table 4: Microbiological analysis of Ibuprofen samples

Code	Mean bacteria count (cfu/g)	Mean fungal count (cfu/g)	Pathogens (cfu/g)
IB01	0 ± 0	0 ± 0	0 ± 0
IB02	0 ± 0	0 ± 0	0 ± 0
IB03	160 ± 14.14	10 ± 8.16	0 ± 0
IB04	50 ± 0	0 ± 0	0 ± 0
IB05	10 ± 8.16	0 ± 0	0 ± 0
IB06	1020 ± 45.46	0 ± 0	0 ± 0
IB07	20 ± 0	0 ± 0	0 ± 0
IB08	70 ± 8.16	0 ± 0	0 ± 0
IB09	70 ± 14.14	0 ± 0	0 ± 0
IB10	40 ± 0	0 ± 0	0 ± 0
IB11	50 ± 8.16	0 ± 0	0 ± 0
IB12	0 ± 0	0 ± 0	0 ± 0
IB13	20 ± 14.14	0 ± 0	0 ± 0
Tabalon®	10 ± 0	0 ± 0	0 ± 0

DISCUSSION

This work focuses on Ibuprofen solid dosage forms usually purchased and consumed by people. The drug selected for this study was chosen because they are frequently consumed by people and similar work has not been carried out on them in Ilorin metropolis specifically and north central parts of Nigeria generally. Solid dosage forms of Ibuprofen are affordable over-the-counter drug that a lot of people use in the treatment of all sorts of pains.

The focus of this work is on chemical analysis and microbiological analysis of Ibuprofen. Chemical analysis was chosen because definition of counterfeit and substandard drugs emphasized majorly on the active ingredient of a drug.^{19, 20} Microbiological analysis was also chosen to ensure that the drugs have the minimal organisms acceptable for consumption according to standards specified in the official books.

It was ensured that all samples purchased for this study were not expired. Drugs are expected to remain stable and intact throughout their shelf lives. During this period, the active components are supposed to remain within acceptable limit according to specified standards and the preservatives within the drugs are expected to keep the drugs safe from harmful microorganisms. Use of unexpired drugs therefore gives us a true picture of the chemical components of drug and its microbiological status.

Although Ibuprofen tablets, caplets and capsules can be manufactured by many indigenous pharmaceutical companies, results show that some of the brands present in the market are foreign brands which indicate that some brands are being imported into the country (Table 1). This observation also presents the

opportunity of comparing local and foreign brands where necessary within the scope of this study.

Ibuprofen solid dosage form comes in different forms: tablets, caplets and capsules. The samples used for this study are composed of these three different solid dosage forms. Similarly, Ibuprofen solid dosage forms in the market come in two major strengths: 200 mg and 400 mg. These strengths were also represented in the samples obtained. The varied dosage forms and strength gives opportunity to compare them without limiting or being restricted to only one type.

Results revealed that eleven out of the thirteen brands of the Ibuprofen tablets passed the titrimetric method of chemical analysis performed on them based on official standards which state that percentage composition of Ibuprofen in the tablets should be within 95% and 105% or within 90% and 110% according to British Pharmacopeia (BP) and United States Pharmacopeia (USP) respectively.²⁴⁻²⁵ Samples IB01 and IB06 failed the titrimetric test. Sample IB01 contained only about half of the expected quantity of Ibuprofen in the formulation. This gives an impression that manufacturer of IB01 should have labeled this drug as containing 200 mg of Ibuprofen per capsule instead of the label claim of 400 mg of Ibuprofen per capsule. The 52.53% result obtained is far below the specified limit. IB06 on the other hand, gave an average value close to 90% which is the specified lower limit according to USP standards but since this value is not up to the lower limit, it can be concluded that the drug content is below the required quantity of Ibuprofen expected to be found in the drug and has failed the test.

Previous studies has shown that one of the implication of substandard drugs is increased morbidity and

mortality as the drug does not contain the required quantity of active component for therapeutic use and may thus, have reduced therapeutic effect or total therapeutic failure.²⁶⁻²⁷

Some of the Ibuprofen samples: IB07, IB09, IB11 and IB13 had average percentage content of active ingredients well above 100% but below the upper limits of BP and USP standards. This may be as a result of the provision for overage of Ibuprofen during the course of production to forestall any possibility of its shortage in the product which may result from accidental addition of excess excipients or accidental spillage of the raw material. This in turn prevents the production of substandard products. However, manufacturers must be careful not to put excess overage that will eventually make the content of the drug rise above acceptable upper limit and may probably lead to toxic or adverse reaction among other negative consequences.²⁸

Tabalon[®] is brand of Ibuprofen manufactured by a Pharmaceutical company of International repute and which has been a well-known brand in the market. This is the reason why it was used as a standard.

Although official standards proved that eleven out of the thirteen samples of Ibuprofen passed, comparisons using paired sample t-test with a standard product of Tabalon[®] tablets showed that only one out of thirteen brands is not statistically different from the product used as standard in terms of average percentage and relating them to the p values obtained (Table 3). This sample is IB12 ($p > 0.05$). Others samples showed statistical difference from the standard ($p < 0.05$). The difference may be as a result of the varying standard deviation along with percentage obtained for individual sample. Sample IB1 and IB6 showed the highest statistical difference from the standard sample ($t = 280$; $p = 0.000$ and $t = 80$; $p = 0.000$ respectively). This is not surprising because these two samples failed the chemical analysis carried out on them.

The microbiological analysis of the Ibuprofen samples revealed that only sample IB06 failed in addition to failing the chemical analysis (Table 4). The average bacteria count of 1020 cfu/g obtained exceeds the specified standards which allow bacteria count of not more than 10^3 cfu/g or mL, fungal load of not more than 10^2 cfu/g or mL and the absence of pathogens in all oral pharmaceutical preparations.^{23,24,29} IB02 and IB12 had no bacteria growth. In addition, it is worthy to mention that all thirteen samples except IB03 had no fungal growth. The mean fungal count of 10 for IB03 is also well within acceptable limits. The mean bacterial and fungal counts of the standard, Tabalon[®] were also very low and

well within acceptable limits. The presence or absence of microbes in a manufactured drug depends largely on the adherence to current Good Manufacturing Practice (cGMP) within the production environment. Cleanliness of equipment and personnel goes a long way in eliminating or reducing the microbial load in the drug. Also, adequate microbiological analysis of purchased raw materials and excipients is also important to eliminate or reduce inclusion of microbes from raw materials and excipients into the products. In addition, contamination of pharmaceutical may also result from mishandling of drugs by untrained personnel which could lead to serious health hazards.³⁰

Although sterility is not a requirement of non-sterile pharmaceuticals in official compendia for non-sterile pharmaceuticals, bio-burdens need to be within acceptable limits. Contamination of pharmaceuticals with microorganisms irrespective whether they are harmful or non-pathogenic can bring about changes in physicochemical characteristics of the medicines.³¹ They can cause spoilage of the product with loss of its therapeutic properties and if they are pathogenic, serious infections can arise.³²

In general, two brands of Ibuprofen samples (IB01 and IB06) failed the quality control carried out on them and interestingly these two brands are foreign brands produced in India. Regulatory activities by regulatory bodies like NAFDAC should be intensified on foreign products to ensure that what is being supplied into the country are of standard and good quality. This could be achieved through routine inspection of foreign manufacturing outfits that import drugs into Nigeria, routine quality control of foreign drugs in the Nigerian drug markets etc.

The result obtained from this study differs from a similar one done in Mumbai, India where all four brands of Ibuprofen used for the study passed all the in-vitro analyses carried out on them with respect to percent content of Ibuprofen within them.³³ It also differs from another work carried out in Bhilai, India where all three brands sampled were within standard specifications.³⁴ Similarly, a work done in Bangladesh showed that all six samples of Ibuprofen used for the work satisfied the required standards.³⁵ This present study however revealed that only two out of the four Indian brands of Ibuprofen passed the analyses.

An indigenous study carried out in Niger Delta area of Nigeria showed similarities and differences when compared with the present study. Their result showed that three out of the six brands of Ibuprofen assessed failed the standard specification using the titrimetric

method. The study further showed that out of three brands of Ibuprofen manufactured in India that were assessed, one of the brands failed the analysis.³⁶ In addition, another study carried out in three states of Nigeria shows that only 12 out of 19 brands of Ibuprofen analyzed passed the uniformity of content test.³⁷

CONCLUSION

This work focused on chemical analysis using the titrimetric method and microbiological analysis using the pour plate method on thirteen brands of Ibuprofen solid dosage forms. Two out of thirteen brands of Ibuprofen failed: IB01 failed only the chemical analysis while IB06 failed both chemical and microbiological analysis. Generally, majority of the various brands of the drug under examination in Ilorin metropolis complied with official standards. However, when compared with standard samples of Ibuprofen tablet using t-test analysis, twelve samples of Ibuprofen differed significantly (p-value less than 0.05) from the standard sample when the average content of ibuprofen was compared. This research work has added more data to the existing scanty information about the kinds of Ibuprofen solid dosage forms we have in the country with emphasis on Ilorin metropolis. This information is useful to regulatory bodies as it will help in intensifying their efforts in routine quality control checks on Ibuprofen brands in the Nigerian markets. However, other quality control parameters not within the scope of this study can be carried out in future to make findings more elaborate.

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