ANALYSIS OF FIFTEEN BRANDS OF CIPROFLOXACIN HYDROCHLORIDE TABLETS OBTAINED FROM LAGOS METROPOLIS, NIGERIA

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ABSTRACT
The importance of ciprofloxacin especially in the third world countries can be estimated by the high success rate recorded in some high morbidity and mortality ailments. It is then necessary that the various brands of ciprofloxacin in the market must contain the adequate amount of active ingredient as specified in the official pharmacopoeias. A well formulated dosage form of ciprofloxacin ensures that adequate amount of the active constituent of the drug is delivered to the recipient to produce the desired pharmacological response. A substandard formulated dosage form of ciprofloxacin will not produce the desired pharmacological response. This research was carried out to evaluate the physical qualities and percentage purities of some brands of ciprofloxacin hydrochloride in the Nigerian market. The British Pharmacopoeia (B.P) and United States Pharmacopoeia (U.S.P) methods were adopted for the physicochemical tests - weight uniformity, disintegration, friability and dissolution tests. Ultraviolet/visible spectrophotometric calibration plot method was developed for the quantitative assay. The concentration of each brand was derived from the regression equation obtained from the calibration plot. The results obtained showed that 100% of the brands conformed to the physicochemical compendia standards. According to the U.S.P. specification (90-110%), 73.33% of the brands analysed passed the quantitative assay, 26.67% failed (6.67% were below the U.S.P. range and 20.00% were above the range). Conformity of drugs to compendia requirements is very crucial to ensure that the adequate amount of drug required to elicit their pharmacological effect gets to its site of action. Lack of regular electricity supply is affecting the proper storage of drugs resulting in fast decomposition of drugs before the expiry date. Therefore, a regular analysis of drugs is necessary to ensure the administration of quality drugs for effective treatment with the desired result. All the brands analysed passed the physicochemical assay according to the compendia requirement but only 73.33% of the brands passed the quantitative assay, 26.67% failed (6.67% were below the U.S.P. range and 20.00% were above the range). Researchers should continue to carry out physicochemical tests and quantitative assay regularly on drugs manufactured within the country and those imported into the country to ensure that all drugs circulating in the country at any point in time conform to the compendia requirements.

Key Words: Analysis, ciprofloxacin, physicochemical tests, ultraviolet/visible (UV/VIS) spectrophotometry.

Introduction

Ciprofloxacin is a member of the synthetic antibiotic class known as quinolones[1,2]. This class of antibiotics was founded unintentionally by George Lesher and his coworkers in 1962. Nalidixic acid, the first "quinolone" agent, was actually a by-product found in the distillate during the synthesis of chloroquine, an antimalarial agent. Nalidixic acid, however, displayed only moderate serum and tissue kinetics due to high protein binding, and its antibacterial therapy was therefore limited to certain Gram-negative urinary tract infections in humans. Throughout the 1970s and 1980s, alterations were made to its chemical structure to yield more useful, broader spectrum agents which remain in use today[3,4,5,6,7].

Fluoroquinolones, or Quinolones with a fluorine atom at the C6 position (as well as a piperazine ring at C7), were introduced in the 1980s. These agents are equally well absorbed and have an immense tissue distribution, as well as broader spectrum. Since then, approximately 10,000 fluoroquinolone analogues have been synthesized[3,4,5,6,7].

Ciprofloxacin is a bactericidal agents that act by inhibiting DNA Gyrase, a DNA Topoisomerase II enzyme unique to prokaryotes. DNA Gyrase catalyzes the negative supercoiling of DNA, which is necessary for packing, as well as DNA replication and transcription. The overall result of DNA Gyrase inhibition is DNA strand breakage. A second mechanism of these agents also exists, which involves the inhibition of Topoisomerase IV. This enzyme is necessary for the separation of DNA strands after replication as well as during cell division [1,7,8,9,10,11].

Ciprofloxacin does not bind to human Topoisomerases—only those specific to bacteria. They therefore take advantage of the differences between bacterial and human Topoisomerase enzymes[2,4,7]. ▶

Ciprofloxacin shows tremendous clinical efficacy. It has excellent absorption and availability, tissue distribution, overall activity, and an extended spectrum. Ciprofloxacin has been shown to be extremely useful in treating a wide range of infections[1,2,3,4].

Ciprofloxacin is indicated for bacterial infections like Urinary Tract Infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens, Proteus mirabilis, Providencia rettgeri, Morganella morganii, Citrobacter diversus, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus epidermidis, Staphylococcus saprophyticus, or Enterococcus faecali[4]. It is also indicated for acute uncomplicated cystitis in females caused by Escherichia coli or Staphylococcus saprophyticus[4]. Ciprofloxacin is used for the treatment of chronic bacterial Prostatitis caused by Escherichia coli or Proteus mirabilis[3]. It is used in cases of lower respiratory tract infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, or Streptococcus pneumoniae (though ciprofloxacin is not considered drug of choice). In addition, ciprofloxacin is used for the treatment of acute exacerbations of chronic bronchitis, acute sinusitis, skin and skin structure infections, bone and joint infections,[4]. Ciprofloxacin is indicated for the treatment of complicated intra-abdominal infections (used in combination with metronidazole), infectious diarrhea when antibacterial therapy is necessary and typhoid fever (Enteric Fever).

It is not a drug of choice in paediatric patients due to higher incidence of adverse effects found in clinical trials. Additionally, the safety and efficacy of ciprofloxacin in pregnant and lactating women has not been established[1,2,3,4,7,9,10,11].

After administration, ciprofloxacin is widely distributed to all tissues and body fluids (including cerebrospinal). Absolute bioavailability (following oral administration) is 70%, with minimal loss to first pass metabolism. Ciprofloxacin is able to reach concentrations adequate for treatment of systemic infection [1,2,3,4,9,10].

The side effects are generally mild to moderate, and serious side effects are very rare. The most common side effects of ciprofloxacin for all formulations, therapy durations, and indications are nausea, stomach upset, diarrhea, stomach pain, headache, nervousness, agitation, anxiety, abnormal liver function and photosensitivity [1,2,9]. While these are the most common adverse effects, they have all been reported to occur in less than 2.5% of patients[9].

Serious adverse effects of Ciprofloxacin are rare, but include seizures, confusion, shaking tremor that is uncontrollable, hallucination, depression, paranoia, atrial flutter and myocardial infarction [1,3,4].

Formation of complexes between fluoroquinolones and divalent and trivalent metal ions has been reported. The fluoroquinolone– metal complex was not as active as the free drug. Co-administration of fluoroquinolones antibiotics with antacids, haematinics and any formulation including soft drinks and beverages containing these metal ions will reduce their activity[1,12]. The metal ion containing preparation may be administered 2 hours before or after the fluoroquinolone[1].

Concurrent administration of ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related adverse reactions. If concomitant use cannot be avoided, serum levels of theophylline should be monitored and dosage should be adjusted appropriately [1,9].

Some quinolones, including ciprofloxacin, have also been shown to interfere with the metabolism of caffeine. This may result in reduced clearance of caffeine and a prolongation of its serum half-life[1].

There are reports of clinical interactions between ciprofloxacin and phenytoin in the literature [13,14,15,16].

In African countries, the incidence of fake and counterfeit drugs is difficult to estimate because of poor communication, poor drug procurement practice, low literacy levels, low awareness of the existence of fake and counterfeit drugs, political instability, and high level of smuggling of pharmaceutical products in the region[17].

Within the West African sub-region, there are very high activities in inter-boundary trade on pharmaceuticals. Many West African countries, such as Togo, Benin, Ghana and other countries such as Chad and Cameroon buy their drugs from Nigeria because Nigeria has the biggest drug market in the sub-region[17].

Fake and counterfeit drugs were first noticed in Nigeria in 1968, when the Crown Agents divested as the sole distributors of pharmaceuticals in Nigeria. The problem assumed a greater proportion in the early 1980's when the import licence was introduced into the Nigerian economy. Drug importation and distribution became very chaotic; hence, the market was flooded with a lot of counterfeit and substandard pharmaceutical products. The situation worsened with the adverse economic effects of the Structural Adjustment Programme (SAP) introduced in mid 1980s. The situation got progressively worse with time until 2001 when NAFDAC (National Agency for Food and Drug Administration and Control) started an aggressive war against fake drugs[17].

A 1989 study conducted in Nigeria indicated that 25% of samples studied were fake, 25% genuine and 50% inconclusive. Another study conducted in Nigeria in 1990 showed that 54% of drugs in every major pharmacy shop were counterfeit, a figure that had risen to about 80% in the subsequent years. In another study of 581 samples of 27 different drugs from 35 pharmacies in Lagos and Abuja, 279 (48%) of the samples did not comply with set pharmacopoeia

limits and the proportion was uniform for the various types of drugs tested[17].

The pharmaceutical industry and the personal care products industry are riddled with counterfeits. Millions of dollars of counterfeit pharmaceuticals and personal care products are reported to move through various authorized and unauthorized channels. These channels made it possible for counterfeits, expired, repackaged and relabeled products to be shipped internationally[5]. Several criminal networks involved in drug faking and counterfeiting have evolved over the years. They include manufacturers, importers, distributors and retailers. Other collaborators are inspection agents, shipping and clearing agents and corrupt government officials of drug regulatory agencies, customs and police.

Drug counterfeiting was highlighted at the World Health Organization's Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985. At the World Health Assembly (WHA) in May 1988, a number of countries expressed concern over counterfeit drugs that were circulating in their markets. The assembly adopted resolution WHA 41.[16,12] which requested governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labeled, spurious, counterfeited or substandard pharmaceutical preparation[17].

The World Health Organization (WHO), since 1984, has been collaborating and collating data related to counterfeit drugs. This has enabled the organization to develop a database on counterfeit drugs. The World Health Organization received 771 reports of counterfeit drugs from different countries between 1984 and 1999.
32% of these reports came from industrialized countries, while the rest came from developing countries. 46 confidential reports of counterfeit drugs were received by WHO from 20 countries from January 1999 to October 2000. About 60% of these reports came from developing countries while the remaining 40% were reported by developed countries. However, most of these reports, according to WHO, were not independently verified and might not be useful for quantitative purposes. The data also shows that only few countries were willing to provide information about cases detected. This silence is one of the major driving forces for counterfeiting[17].

Due to high incidences of counterfeiting in the African pharmaceutical market, especially Nigeria being one of the biggest markets in the continent, the need to keep an eye on the quality of pharmaceuticals arises.

Fake drugs

A fake drug is defined as:

(a) Any drug or drug product which is not what it purports to be.
(b) Any drug or drug product, which is so coloured, coated, powdered or polished that the damage is concealed, or which is made to appear to be better or of greater therapeutic value than it really is, or which is not labeled in the prescribed manner, or which label or container or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading.
(c) Any drug or drug product whose container is so made formed or filled as to be misleading.
(d) Any drug or drug product whose label does not bear adequate directions for use and such adequate warning for use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of use; any drug or drug product, which is not registered by NAFDAC in accordance with the provisions of the Food, Drugs and Related Products (Registration) Decree[17].

Adulterated drugs

A drug or drug product is regarded as adulterated if:

(a) The methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current Good Manufacturing Practice (GMP) to assure that such drugs meet the requirements of the Food and Drugs Act as to the safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess.
(b) It purports to be or is represented as a drug, the name of which is recognized in an official compendium, has its strength differing from, or its quality or purity falling below the standard set forth in such compendium.
(c) Consists in whole or in part any filthy, putrid or decomposed substance, or has been prepared, packaged or stored under unsanitary conditions where it may have been contaminated with filth or whereby it may have been rendered injurious to health, or is packed in a container which is composed in whole or in part of any injurious or deleterious substance which may render the content injurious to health, or bears or contains for the purposes of colouring any colour other than one which is prescribed, or contains any harmful or toxic substance which may render it injurious to health, or has been mixed with some other substance so as to reduce its quality or strength[17].

Substandard drugs

Substandard drugs are genuine drug products which do not meet quality specifications set for them. The term substandard is used to describe the quality status of genuine drugs produced by legitimate manufacturers. Normally, manufacturers use specifications laid down by official Pharmacopoeias, such as British Pharmacopoeia (BP), United States Pharmacopoeia (USP), and European Pharmacopoeia (EP) for each drug that they produce. If a drug fails to meet the Pharmacopoeia specifications used for its formulation, it is classified as substandard[17]. ▶

Nigeria Definition of Substandard drugs

Individual countries are left to further specify what will constitute mislabeling, misbranding, faking, adulteration or substandard, within the context of the interpretations of fake and counterfeit products in their laws and regulations.

The Nigeria definition combines the provisions of two decrees: The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Decree No. 25 of 1999 and drugs and Related Products (Registration, etc) Decree No. 19 of 199317.

Counterfeit drugs

Various organizations and compendia have given different definitions for counterfeit drugs but all definitions circle around fraudulent labeling with respect to identity and/or source. The World Health Organization (WHO) defined counterfeit drugs as "medicine which is deliberately and fraudulently mislabeled with respect to identity and/or source." According to WHO, 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." According to this definition, what makes a drug or medicine counterfeit is the deliberate or intentional mislabeling of the product[17].

In 1992, the International Pharmaceutical Federation (FIP) defined counterfeit medicines as medicinal products which have been deliberately or fraudulently mislabeled with respect to identity and/or source. These included those products with the correct ingredients, wrong ingredients, no active ingredients, or fake packaging. They excluded substandard products, which were correctly labeled. The U.S. Federal Food, Drug and Cosmetic Act defines a counterfeit drug as "a drug which, or the containers or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer processor, packer or distributor17. According to Pakistan's Manual of Drug Laws, a counterfeit drug is "a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive, the label or outer packing of a drug manufacturer[17].

According to literature, the widely used method for the determination of ciprofloxacin is high performance liquid chromatography (HPLC)[18,19,20] since it possesses high sensitivity and excellent selectivity. This is also the method stated in the International Pharmacopoeia and European Pharmacopoeia.

Additionally, many other methods such as spectrophotometry, capillary zone electrophoresis, micellar liquid chromatography, chemiluminescence, and biosensor were also reported for the analysis of ciprofloxacin. However, electrochemical method for the determination of ciprofloxacin is rarely reported although electrochemical method has many advantages: high sensitivity, rapid response, low cost and simplicity[19,20].
Current methods of the analysis of quinolones are based on liquid chromatography (mainly with fluorimetric detection) with pre- or post- column reaction and/or using liquid chromatography/mass spectrometry, solid phase separation/spectrometric determination, capillary electrophoresis, indirect atomic absorption spectrometry, nuclear magnetic resonance and spectrophotometric detections[21,22].

All tablets must meet physicochemical specifications and quality standards. These include criteria for uniformity of weight, tablet friability, tablet disintegration, drug dissolution and percentage purity[23].

Small variations in the weight of individual tablets are inevitable and admissible, and accordingly, accepted limits are officially specified for uncoated tablets[24]. This is based on a sample 20 or 10 tablets as specified in the Pharmacopoeia. They are weighed individually at random and the average weight determined. Not more than 2 of the individual masses should deviate from the average mass by more than the percentage deviation stated in the Pharmacopoeia[25].

Tablets are constantly subjected to mechanical shocks and abrasion during the manufacturing, packing and transportation processes. Such stresses can lead to capping, chipping, abrasion or even breakage of the tablets. It is therefore important that the tablet is formulated to withstand such stress without damage[26]. In order to monitor the resistance of tablets to such stresses and to decide their suitability for further processing such as coating, tablets are routinely subjected to a friability test which is described in United States Pharmacopoeia (USP). Friability testing involves subjecting tablets to repeated revolutions in a Roche Friability Drum. USP guidelines specify the number of samples, the total number of drum revolutions and the drum revolution per minute to be used[26].

Friability is defined as the % weight lost by the tablets due to mechanical action during the test. Tablets are weighed before and after testing. Friability is expressed as a percentage loss on pre-test tablet weight[24,25,27].

Tablets containing an insoluble or slightly insoluble ingredient when swallowed require an inclusion of disintegrants such as starch to hasten the process of disintegration. It is possible for a badly formulated tablet to pass through the alimentary tract completely whole and thus be useless therapeutically. To guard against this possibility the Pharmacopoeia requirements include a test for the rate of disintegration though it is not a true predictor of how well the dosage form will release its active ingredient in vivo[24].
For the purpose of this test, disintegration does not imply complete solution of the tablet or even of its ▶

active constituent. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus is a soft mass having no palpably film core[25,26].

The United States Pharmacopoeia (USP) sets standards for tablet disintegration testing. This test is standardised in the following ways:

- Water is used at around body temperature.
- A regular degree of movement is involved.
- If necessary, a slight pressure is applied to the tablets.
- Disintegration is judged on final particle size.
- A time limit is involved.

The apparatus is relatively simple. It consists of a basket rack holding six plastic tubes open at the top and bottom. The bottom is covered with a 10 mesh screen. The rack is immersed in a suitable liquid at 37±2. It moves up and down at a specified rate. One tablet is placed into each tube and the time to disintegrate and fall through the screen is noted [24,26].

Since a drug must pass into solution before it can be absorbed, the rate of dissolution is therapeutically more important than its rate of disintegration[24].

Tablet dissolution is a standardised method for measuring the rate of drug release from a dosage form.
This test is most often performed on products that have known absorption problems or known poor solubility. It is also performed on sustained or delayed release products such as enteric coated products, capsules and tablets. This test requires the solution to be tested for concentration of active ingredient over time using a suitable analytical method. A dissolution profile is then constructed (Time versus Amount Dissolved) and this is compared to the reference compound or standard for the dosage form being dissolved[24].

The objective of this study is to carry out a qualitative and quantitative evaluation on seventeen brands of ciprofloxacin hydrochloride tablets, with a view to ascertaining whether they complied with pharmacopoeia standards. Physicochemical methods such as friability test, disintegration test, weight uniformity, dissolution test were carried out. Ultraviolet/visible spectrophotometry method was developed for the quantitative analysis.

Method

Fifteen brands of ciprofloxacin hydrochloride were purchased from Mushin market in Lagos state, Nigeria. All the brands were coded. Ciprofloxacin reference standard (99.97%) was kindly supplied by May and Baker Nigeria PLC, Ikeja, Lagos.

All the reagents used were of analytical grade.

Procedure

Weight uniformity: The British Pharmacopoeia method was adopted. Ten tablets of each brand were used. Each tablet was weighed one after the other on the analytical balance. The weight of each tablet was recorded and the mean and standard deviation was calculated[25,27].

Friability test: The weight of 10 tablets of a particular brand was taken using an analytical balance. These tablets were placed in the drum of Erweka® Type TA friabilator (NV52970) which was switched on and operated at a speed of 30 revolutions per minute for 4 minutes. The tablets were dusted and their weight taken again to ascertain the percentage friability[24,27].

Disintegration time test: Distilled water, 400ml, was poured into a beaker in the large compartment of the Copley® disintegration machine (Erweka(R) Model TT2, NV53434, Fab. no. 8346662, Manufactured by Heusenstamm, Federal Republic of Germany), the temperature of the apparatus was regulated at 37°C with the aid of a thermostated heater attached to the apparatus. Six tablets of each brand were collected, one tablet was placed into each of the six tubes of the disintegration basket before it was placed into the beaker containing the disintegration medium and hung on the metal holder. The machine was put on and the basket oscillated in an up and down manner until the drug disappeared. The time taken for each tablets of the drug to disappear was then recorded[27].

Dissolution test: Deionised water, 900ml, was poured into a round bottom beaker in the dissolution machine (Dissolution tester USP, Model TDT – 08L, Manufactured by Electrolab, ETC-11L). The whole set up was carried out at a temperature of 37°C. The agitator switch was turned on and this was set to a speed of 50 revolutions per minutes. The medium, 5ml, was taken with the aid of a syringe just as a tablet of a brand of ciprofloxacin was dropped into the medium and filtered with a millipore filter (0.45μm) as it was transferred into a sample bottle; consequently, 5.0 ml of distilled water was quickly replaced into beaker so as to maintain the constant volume needed. This procedure was repeated at 30min, 45min, 60min and 90min and their concentrations determined using the ultraviolet spectrophotometer[27].

Ultraviolet Spectrophotometry: A 100.0 ml containing 100 μg/ml stock solution of Ciprofloxacin hydrochloride reference standard (kindly supplied by May and Baker Nigeria PLC) was prepared. Serial dilutions of 1-10μg/ml were prepared from the stock solution in triplicates and their absorbances were taken at 276nm using deionized water as the blank. T80 + UV Spectrophotometer, Multicell, double beam (Version 3.3) manufactured by PG Instruments Limited, was used.
A calibration curve was plotted and the regression equation was obtained[25]. (Fig.) A 5.0 μg/ml concentration of the test samples was prepared in triplicates and the average absorbances were obtained. The concentration of the test samples were obtained from the regression equation.

Result

All the ciprofloxacin hydrochloride tablet samples analysed passed the uniformity of weight test, friability test, disintegration test and dissolution ▶

tests when compared with the official specifications. The average disintegration test result obtained for the samples ranged from 1.0 minutes 21seconds ± 0.12 to 6 minutes 49 seconds ± 0.41. The ciprofloxacin hydrochloride tablet samples passed the friability tests with an average range of 0.00 to 0.31%. (Table 1)

Based on the U.S.P. specification 73.33% of the brands analysed passed the quantitative assay, 26.67% failed (6.67% were below the U.S.P. range and 20.00% were above the range).

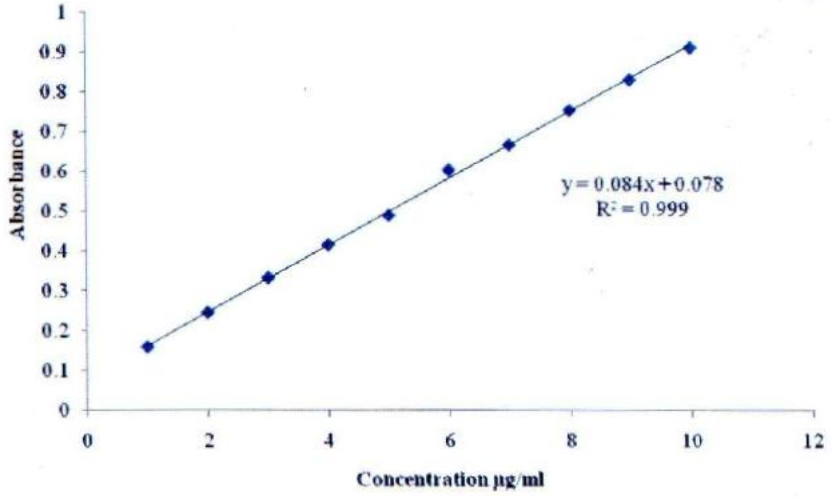

Figure 1: Calibration Curve for Ciprofloxacin hydrochloride Standard

Table I: The physicochemical and quantitative results obtained for fifteen brands of ciprofloxacin hydrochloride (SO= Standard Deviation)

Code of brand	Average weight/Per tablet in gm ± SD	Friability (%)	Disintegration test (minutes) ± SD	% Dissolution in 30minutes±SD	% Purity ± SD
AA	0.6579 ± 0.0079	0.03	4min3sec ±0.83	110.94±30.53	88.76 ± 0.00
AB	0.6811 ± 0.0083	0.03	6min49sec ±0.41	87.86±0.00	103.57 ± 0.19
AC	1.0258 ± 0.0109	0.14	1min37sec ±0.29	115.29±5.53	109.35 ± 0.12
AD	0.7732 ± 0.0073	0.03	2min36sec ±0.65	87.97±0.21	120.42 ± 0.12
AE	0.7631 ± 0.0097	0.03	2min8sec ±0.68	97.55±10.68	108.10 ± 0.00
AF	0.7632 ± 0.0065	0.05	5min11sec ±0.48	88.61±17.99	106.25 ± 0.12
AG	0.7749 ± 0.0125	0.03	4min ±0.95	112.66±25.99	106.96 ± 0.12
AH	0.8377 ± 0.0191	0.02	2min20sec ±0.23	88.18±19.79	119.52 ± 0.00
AI	0.6542 ± 0.0147	0.02	5min56sec ±0.91	108.7±24.64	110.77 ± 0.12
AJ	0.9417 ± 0.0086	0.02	1min22sec ±0.41	93.31±11.34	99.05 ± 0.00
AK	0.9954 ± 0.0126	0.03	1min21sec ±0.12	128.00±30.65	108.39 ± 0.12
AL	0.6453 ± 0.0102	0.02	2min1sec ±0.33	125.55±5.86	102.62 ± 0.00
AM	0.6402 ± 0.0067	0.03	1min49sec ±0.22	117.65±19.16	145.18 ± 0.12
AN	0.6902 ± 0.0158	0.00	4min28sec ±1.34	112.66±19.04	98.45 ± 0.24
AO	0.9679 ± 0.0118	0.03	5min24sec ±0.48	90.96±3.78	105.24 ± 0.19

Discussion

For a dosage form of drug to be efficacious, it is important that it contains the required amount of active ingredient that would exert a pharmacological response, thus, analysis of drugs is of paramount importance. In this work, ciprofloxacin hydrochloride tablets were analysed using physicochemical analytical methods: friability test, disintegration time test, dissolution test, weight uniformity and quantitative assay.

According to the British Pharmacopoeia (BP) 2005, the permissible deviation in weight for tablets greater that 250mg in weight is 5%[25]. From the results obtained all the 15 brands analysed conformed to standard specification.

The results obtained for the disintegration time test for all the brands conformed to the specification of the disintegration test in the B.P 2005 which stated that tablets must disintegrate within 15 minutes[25].

The United State Pharmacopoeia (USP) 27th edition stated that the percentage friability of tablets should not be more than 1%[27]. From the results obtained, all the 15 brands that were subjected to this test conformed to the official specification which is an indication that they can withstand wear and tear.

Official specification for dissolution test according to USP, 27th edition states that at 30 min, 80% or more of the concentration of the tablet should be released. From the results obtained all the brands met the official specification.

The permissible range of purity for ciprofloxacin hydrochloride tablets according to the USP 27th edition is 90-110%[27]. From the result obtained, 73.33% of the brands analysed passed the quantitative assay, 26.67% failed (6.67% were below the U.S.P. range and 20.00% ▶

were above the range).

Conclusion

Fifteen brands of ciprofloxacin hydrochloride tablets were analysed. The results of the physicochemical tests showed that all the 15 brands met the official specifications.
Determination of the percentage purity showed that 73.33% of the brands met the official specification while 26.67% failed (6.67% were below the U.S.P. range and 20.00% were above the range).

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