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Evaluation of Different Marketed Brands of Ciprofloxacin Hydrochloride Tablets: A Comparative Study

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ABSTRACT

The main objective of the present study was to evaluate the quality of various commercial brands of Ciprofloxacin Hydrochloride Tablets I.P 500mg by performing quality control tests as per the Indian Pharmacopoeia and to determine whether all the formulations used were equivalent or significantly different. For this purpose, 3 brands of Ciprofloxacin500mg tablets were selected and various quality control tests like identification, weight variation, dissolution and drug assay were performed. All the brands met the requirements as per specifications of Indian Pharmacopoeia for tablet formulation. The research work indicated that the three different brands of Ciprofloxacin Hydrochloride Tablets did not shown much difference in their results.

INTRODUCTION:

According to World Health Organization (WHO), the term quality control refers to the sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical. Such procedures may range from the performance of simple chemical experiments which determine the identity and screening for the presence of a particular pharmaceutical substance (thin layer chromatography, infrared spectroscopy, etc.), to more complicated requirements of pharmacopoeial monographs(1). The quality control process is carried out to validate the product quality, to produce medication of superior efficacy, safety, and to provide assurance to the physician, pharmacists and patients as well that given product performs satisfactorily and uniformly(2).

A pharmacopoeia is a lawfully binding collection, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region. There are diverse types of pharmacopoeias in different parts of the world and the role of these pharmacopoeias are to embellish quality specifications for active pharmaceutical ingredients (APIs), finished pharmaceutical products (FPPs) and general requisites, e.g. for dosage forms(3).

Ciprofloxacin belongs to fluoroquinolone group and is the fifth largest generic in the total pharmaceutical market in India and South Asia with continuous growth (4). It is on the World Health Organization's List of Essential Medicines, the most effective and safe medicines needed in a health system (5). The bactericidal action of ciprofloxacin results from inhibition of the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV, which are required for bacterial DNA replication, transcription, repair, strand supercoiling repair, and recombination(6).In the current practices of anti-infective therapy, ciprofloxacin is a very popular fluoroquinolone having a broad spectrum of activity and diverse therapeutic prospects. The reasons for its wide use include multiresistant pathogens susceptible only to ciprofloxacin. The available clinical evidence suggests the potentially enhanced efficacy of this drug in the treatment of various community-acquired and nosocomial infections, e.g. respiratory tract, urinary tract, skin infections and sexually transmitted diseases(7).

MATERIALS AND METHODS:

MATERIALS:

We have purchased three commercial brands of Ciprofloxacin Hydrochloride 500mg tablets from various retail pharmacies located in Guwahati and they are listed in Table 1. The Ciprofloxacin Hydrochloride working standard(WS) used in this study was obtained from M/s Vapi Care.

Table 1: List of Commercial Brands of Ciprofloxacin Hydrochloride Tablets under study

Product code	Batch No	Manufacturer	Mfd Date	Exp Date
A	1501000495	Alembic Pharmaceuticals Ltd. (Baddi, Solan, H.P)	09/2015	08/2018
B	9260	Orissa Drugs & Chemicals Ltd (Mancheswar Ind. Area, Orissa)	03/2016	02/2019
C	GCTT-015	Laborate Pharmaceutical India Ltd (Rajban Road, Paonta Sahib, H.P)	04/2016	03/2019

Instruments:

The test for identification and assay were carried out by High-Performance Liquid Chromatography (Agilent 1260infinity series) equipped with a UV detector and dissolution test was carried out in Dissolution Test Apparatus (Electrolab TDT-08L). A UV-Vis Spectrophotometer (Cary 100, Varian) was used to calculate the percentage release of Ciprofloxacin Hydrochloride tablets.

METHODS:

Quality Control Tests:

The quality control tests were performed according to Indian Pharmacopoeia (I.P). The Indian Pharmacopoeia is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India.

1. Uniformity of weight:

The test was carried out by weighing individually twenty tablets of each brand and their average weights were calculated. Further %weight variations were calculated and compared with the I.P. limits (8).

Table 2: Limits for Uniformity of weight as per I.P.

Dosage form	Average weight	Percentage deviation
Uncoated and film-coated tablets	80 mg or less	10%
	More than 80 mg but less than 250 mg	7.5%
	250 mg or more	5%

2. Identification Test

Reversed-phase High-Performance Liquid Chromatography was used for carrying out the identification test on Agilent 1260 series autosampler integrated with UV detector. The software employed was Chemstation. The test complies with I.P when the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the Ciprofloxacin Hydrochloridereference solution(8).

3. Assay

The determination of assay was done by HPLC. The chromatographic conditions maintained throughout the procedure were a stainless steel column (25cm × 4.6mm ×5µm) packed with octadecylsilane chemically bonded to porous silica. The mobile phase was a mixture of 87 volumes of 0.025M Phosphoric Acid (Merck) which was adjusted with triethylamine (Fischer Scientific) to a pH of 3.0±0.1 and 13 volumes of Acetonitrile (Fischer Scientific). The mobile phase prior to use was filtered and degassed. The flow rate was maintained at 1.5ml per minute with Spectrophotometer wavelength set at 278nm and injection volume of 10µl (8).

Preparation of Reference solution

Ciprofloxacin Hydrochloride working standard (WS) equal to 8mg was accurately weighed and dissolved in 15 ml of 0.01M hydrochloric acid. The prepared solution was sonicated for 10 minutes and finally diluted to 25ml with 0.01M hydrochloric acid.

Preparation of Test solution

Of all the three brands of Ciprofloxacin Hydrochloride 500mg tablets, 20 tablets of each brand were weighed separately and powdered. An accurately weighed powder containing about 1.25g of ciprofloxacin was transferred to a 500ml volumetric flask with the addition of 400ml of 0.01M hydrochloric acid; shook for 20minutes and then diluted to 500ml with 0.01M hydrochloric acid. Filtered the solution, 10ml of the filtrate was diluted to 100ml with 0.01M hydrochloric acid (8).

4. Dissolution

The dissolution test was carried out for all three different brands in USP Type II Apparatus (Paddle) /Apparatus 1 of I.P. (Electrolab, TDT-08L) with six individual units of each brand. To determine drug release 900 ml of water was used as dissolution medium and rotating the paddle at 50 rpm for 30 minutes. A suitable volume of the dissolution medium was withdrawn at the end of analysis and filtered through Whatman filter No.40.The amount of dissolved ciprofloxacin was determined by measuring the absorbance of the filtrate, suitably diluted with water, at the maximum at about 276nm. The content of ciprofloxacin in the medium was calculated from the absorbance obtained by repeating the determination using a solution of known concentration of Ciprofloxacin Hydrochloride WS (8).

Preparation of Reference solution

An accurately weighed quantity of Ciprofloxacin Hydrochloride working standard (WS) was prepared in dissolution medium to obtain a final concentration of 5µg/ml.

Preparation of Test solution

Test solutions were further diluted to obtain a final concentration of 5.56µg/ml.

RESULTS AND DISCUSSION:

1. Weight Variation Test:

Weights of all the tablets of all three brands were found to be within the permissible limit i.e. ±5% deviation.Hence all three brands comply with I.P in weight variation test.Among three brands, the brand with product code C (B No.GCTT-015) has the highest value of the mean as compared to other brands. The results of weight variation test are listed in Table 3.

Table 3: Results of Weight variation of 3 brands.

Sample Code	Average weight	Upper limit	Lower limit	Remarks
A	0.7350	0.7718	0.6982	Complies
B	0.7377	0.7746	0.7008	Complies
C	0.7438	0.7810	0.7066	Complies

2. Identification Test: This test was found to be in compliance with the criteria mentioned in I.P. which states that the principal peak in the chromatogram obtained with test solution in assay corresponds with the peak in the chromatogram obtained with the reference solution.

3. Assay: This was required to confirm that the labeled amount of drug was available in the given dosage form. The results of drug assay of three different brands of Ciprofloxacin tablets showed that amount of Ciprofloxacin available in all these formulations were near to 100 % which means drug was available as per their stated value and the dosage forms were in stable form. Assay of all brands meets standard range mentioned in Indian Pharmacopoeia i.e. 90-110% limit. The results of identification and assay are given in table4.

Table 4: Results of identification and assay of different brands of Ciprofloxacin Hydrochloride tablets

Product Code	Identification (HPLC)	Assay (HPLC)
A	Complies	99.5% Limit (90-110%)
B	Complies	100.0% Limit (90-110%)
C	Complies	99.59% Limit (90-110%)

4. Dissolution: In this study, the different brands were evaluated for their *in-vitro* drug release. The study indicated that although the results varied among the different formulations they were within the acceptance limit of not less than (NLT) 80%. The release rate of the active ingredient of the brand having Product code Cis lower than that observed for other two brands.

The results are listed in table 5.

Table 5: Results of comparative dissolution studies of different brands of Ciprofloxacin Hydrochloride tablets expressed as percentage drug release

Sr. No.	Product Code A	Product Code B	Product Code C
Tablet 1	91.9%	100.7%	97.1%
Tablet 2	96.0%	94.1%	97.0%
Tablet 3	98.9%	96.2%	93.5%
Tablet 4	106.2%	95.4%	89.8%
Tablet 5	95.2%	108.5%	96.8%
Tablet 6	94.3%	96.7%	89.0%
Limit: Not Less Than 80%			

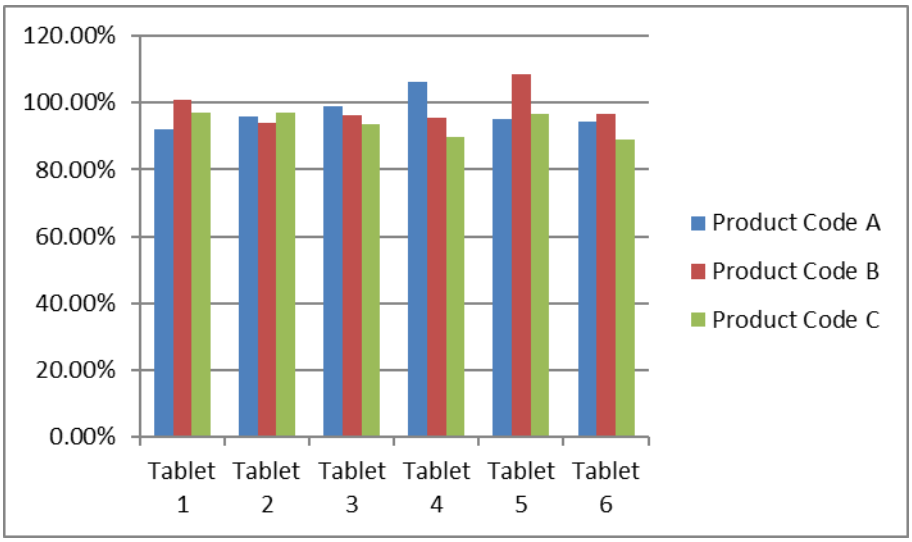

Figure 1: Dissolution profile for different brand

CONCLUSION:

Constant surveillance of marketed drug products within the country is very essential to ensure that the commercially available drugs are dependable, satisfactory and safe.In the present study, different quality control parameters were successfully analyzed for three different brands of Ciprofloxacin Hydrochloride tablets and found that all the brands have passed all official tests prescribed by Indian Pharmacopoeia (IP).The three different brands did not show much difference in their results except for their dissolution profile.This may be due to different excipients used in the tablet; a physical form of the drug used in the tablet or may be due to different manufacturing processes opted by the different manufacturer.From our study, we can conclude that the three brands can be substituted for one another in terms of quality depending upon their availability.

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