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COMPARITIVE STUDIES ON THE PHYSICOCHEMICAL PROPERTIES AND DISSOLUTION OF MARKETED CIPROFLOXACIN TABLETS

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Abstract

Ciprofloxacin is a second generation fluoroquinolone derivative acts by inhibiting bacterial DNA gyrase (TopoisomeraseII) used for the treatment of bacterial gastroenteritis, respiratory tract infections, controlling bronchitis and pneumonia caused by Gram negative bacteria.

In this study the physicochemical properties and dissolution was carried out for three brands of marketed ciprofloxacin tablets. The present work is comparing the physiochemical evaluation (Weight variation, Hardness, Thickness and Diameter, Friability, Disintegration and Dissolution), release characteristics of manufactured Ciprofloxacin tablets. Here we enclosed the comparison results of three brands of marketed Ciprofloxacin tablets and Trend charts.

Key words: *Ciprofloxacin, physicochemical properties, dissolution, Trend charts.*

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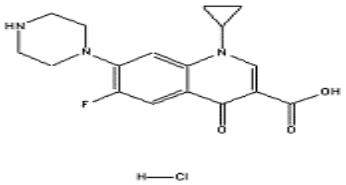
INTRODUCTION TO DRUG PROFILE

Ciprofloxacin Hydrochloride

Chemical Name 1-cyclopropyl-6-fluoro-1, 4dihydro-4, 7-(1-piperazinyl)-3-quinoline carboxylic acid hydrochloride monohydrate.

Structure



Molecular Formula: $C_{17}H_{18}FN_3O_3.HCl$

Molecular Weight: 367.84 (anhydrous)

Category

Ciprofloxacin is a second generation fluoroquinolone derivative. The presence of a fluorine atom at position six extends the antibacterial activity and piperazinyl ring at position seven confers potent antipseudomonal activity. Ciprofloxacin has cyclopropane ring at N- position which makes it the most potent amongst the various quinolone derivatives.

Pharmacokinetic Properties

Oral administration of 500mg dose of Ciprofloxacin produces a peak plasma concentration of about 2.5mcg/ml after 1-2 hours. The half life of Ciprofloxacin is about 3.5-4.5 hours. About 30-50% of an oral dose of Ciprofloxacin is excreted in the urine within 24 hours as unchanged drug and as biologically active metabolites. Peak urinary concentration ranging from about 300-500 mcg/ml have been achieved after a 500 mg dose given orally. Normally 19-43% of Ciprofloxacin is bound to serum proteins. Antacids reduce the bioavailability of Ciprofloxacin.

Mode of Action

Inhibit bacterial DNA gyrase (Topoisomerase II), the enzyme responsible for introducing negative super coils into the bacterial DNA. This leads to disruption of DNA structure and death of bacteria.

Storage Should be stored in dry place and protected from heat and direct sunlight.

Available as

Tablets : 250 and 500 mg/tablet
Eye drops, Ear drops : 0.3%w/v
Eye ointment : 0.3%w/v

Table no 1: Some Commercial Orally Disintegrating Tablet Products

Product	ODT company/partner
Floxip Tab	Abbott
Ciprofloxacin Tab	IDPL
Neocip Tab	Cipla
Alcipro Tab	Sppl
Baycip Tab	Bayer
Bicipro Tab	Kee pharma
C-Flox Tab	Prem pharma
Cebran Tab	Blue cross
Ceepro Tab	Lincolin
Cifran Tab	Ranbaxy
Ciplox Tab	Cipla
Ciprazol Tab	Mankind
Orpic Tab	Dey's Medical
Penquin Tab	Hindusthan Ab's
Repcip Tab	Replica Remedies

MATERIALS AND METHODS

Table no: 2 Instruments list

Instruments	Supplier/Manufacturer
Balances	Citizen scale pvt. Limited, Thane
Disintegration apparatus	Electro lab, Mumbai
Dissolution apparatus	Electro lab, Mumbai
UV Spectrophotometer	Elico SL 159
Hardness tester	Dr.Schleuniger pharmatron,U S A
Thickness Tester	Vernier calipers
Friabilator	Electrolab, Mumbai

Materials Used:

- Ciprofloxacin (standard drug)
- Ciprofloxacin tablets different brands
- Phosphate buffer

Weight Variation Test:

Method: 20 tablets were randomly selected from each formulation and their average weight was calculated using digital balance (Denver, Germany). Individual weight of each tablet was also calculated using the same and compared with the average weight.

Hardness:

Schluenzier hardness tester was used for the determination of the hardness of tablets. Place the tablets between the jaws, for each measurement orient the tablet in the same way with respect to the direction of the application of the force. Carryout the measurement on 6 tablets, taking care that all fragments of the tablets have been removed before each determination.

Thickness and Diameter:

The thickness and diameter of 6 tablets were recorded by using Vernier calipers.

Friability:

Accurately weigh not less than 6.5 grams of tablets and place the tablets in the drum. Rotate the drum 100 times and remove the tablets. Remove any loose dust from the tablets as before, if no tablets are cracked split or broken, weigh the tablets to the nearest milligram

The tablets that loose less than 1% weight were considered to be compliant

Expression of results:

The friability is expressed as the loss of weight and it is calculated as a percentage of the initial weight.

% Friability = (A-B/B) X 100

A=Initial weight of tablets used, B=Weight of tablets after 100 revolutions

Disintegration Test:

Place 1 tablet in each of the 6 tubes and add a disc to each tube. Maintain the temperature of the disintegration media at 37±2ºC as specified in the individual monographs. At the end of time limit specified lift the basket from the fluid and observe the tablets. All of the tablets have disintegrated completely. [7]

Dissolution Test:

The in vitro dissolution study was carried out in the USP dissolution test apparatus (Electro lab Dissolution tester USP) ODTs of desired formulation were taken and placed in the vessels of dissolution apparatus.

Samples were collected from the vessels at different time intervals, replenished with same volume of the blank solution and analyzed using UV – Visible spectrophotometer at λ_{max} of the drug. Drug concentration was calculated from the standard graph and expressed as % of drug dissolved or released. The release studies were performed in 6 replicates and mean values were taken. [9]

Dissolution conditions:

Medium : Phosphate buffer 900 ml at 37 ± 0.5 ^{0}C
Apparatus : apparatus II as per USP, paddles
Rpm : 50
Time intervals : 5,10,15,30
Sampling volume : 10 ml
Wavelength : 268

Test solution:

Place six tablets in each of six dissolution flasks containing 900 ml of dissolution medium previously maintained at 37 ±0.5oC and run the apparatus for 10 minutes. After 10 min withdrawn 10 ml of sample and filter the solution through 0.45micron filter.

Procedure:

Measure the absorbance of the above resulting solution by using dissolution medium as blank solution. Calculate the quantity of Ciprofloxacin dissolved in the medium by the formula and by using UV Spectrophotometer at 268 nm. [11]

RESULTS AND DISCUSSION

The present work is comparing the physiochemical evaluation, release characteristics of manufactured Ciprofloxacin tablets.

Uniformity of weight:

From the table-3, the uniformity of the weight test of all three different brands of tablets was carried out from thus brand-B shows more deviation than other different brands results were shown in table 3 and figure 2 .

Thickness:

From table-4, the thickness of brand-B shows less deviation compared to the brand-A and brand-C shown in table 4 and figure 3.

Hardness:

From the table-5 and figure 4, the hardness test was carried out by using Monsanto hardness tester. From observations brand-A shows more deviation than other brands. Brand-B shows less hardness when compared with other brands.

Friability:

From table-6, the Friability of brand-A shows more deviation compared to the brand-B and brand-C.

Disintegration:

From table-7, the Disintegrating Time of brand-B shows more deviation compared to the brand-A and brand-C.

Dissolution:

The release character of brand-A and C showed the same type of release at the end of the 30 min and brand-B showed maximum release at end of 45 min which takes more time than other 2 brands comparatively results were shown in table 8 and figure 5.

CONCLUSION

The demand for orally disintegrating tablets has enormously increased during the last decade. Particularly for geriatric and pediatric patients who have difficulty in swallowing, conventional tablets and capsules. Oral administration of the drugs is difficult in patients having concomitant vomiting or diarrhea. Fast dissolving or fast disintegrating dosage forms are meant to disintegrate immediately upon contact with the saliva leading to faster release of drug in the oral cavity. Because administrating the fast disintegrating dosage forms, absorption of the drugs occurs through buccal mucosa and it may reduce the first pass metabolism leading to better efficacy of the drug.

Ciprofloxacin is a second generation fluoroquinolone derivative acts by inhibiting bacterial DNA gyrase (TopoisomeraseII) used for the treatment of bacterial gastroenteritis, respiratory tract infections, controlling bronchitis and pneumonia caused by Gram negative bacteria.

All the above brands were satisfactory in respect of weight variation, hardness, friability, thickness, Disintegration and dissolution profile of brand A and C. From the proceeding results and discussions the in vitro evaluations of different brands of marketed Ciprofloxacin showed in significant differences due to the process factor and formation varies from manufacturer to manufacturer.

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Table no: 3 Individual Weight Variations

S.NO	INDIVIDUAL WEIGHT VARIATION(mg)		
	Brand-A	Brand-B	Brand-C
1	710	730	690
2	700	740	710
3	690	730	700
4	700	735	700
5	710	730	720
6	712	740	685
7	708	742	690
8	705	740	695
9	700	736	696
10	700	730	710
11	710	728	720
12	715	728	700
13	704	730	712
14	702	735	704
15	700	730	698
16	710	740	696
17	710	735	700
18	715	730	702
19	710	735	704
20	700	730	715
MEAN	705.55	733.7	702.35

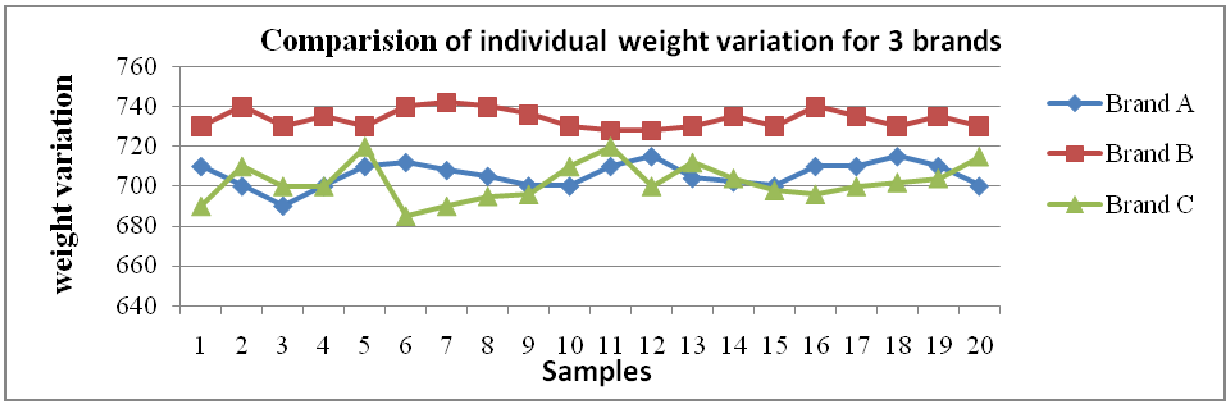

Fig. no 2 Trend chart for individual weight variations

Table no: 4 Thickness Studies For Three Brands

S.NO	THICKNESS(mm)		
	Brand A	Brand B	Brand C
1	3.51	4.02	3.53
2	3.48	3.99	3.47
3	3.47	4.00	3.53
4	3.53	4.01	3.51
5	3.50	3.99	3.50
6	3.48	3.98	3.51
MEAN	3.49	3.99	3.50

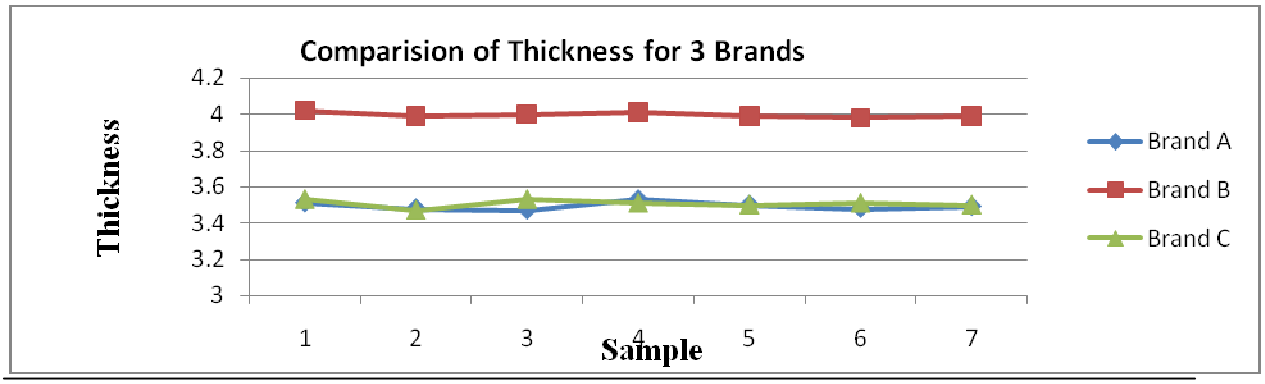

Fig. no 3 Trend chart for thickness:

Table no: 5 Hardness Studies For Three Brands

S.NO	HARDNESS(kg/cm²)		
	Brand A	Brand B	Brand C
1	4.5	3.1	3.1
2	5.2	3.0	3.2
3	4.7	3.2	3.0
4	4.5	3.0	3.3
5	4.9	3.2	3.1
6	4.7	3.0	3.2
MEAN	4.75	3.08	3.08

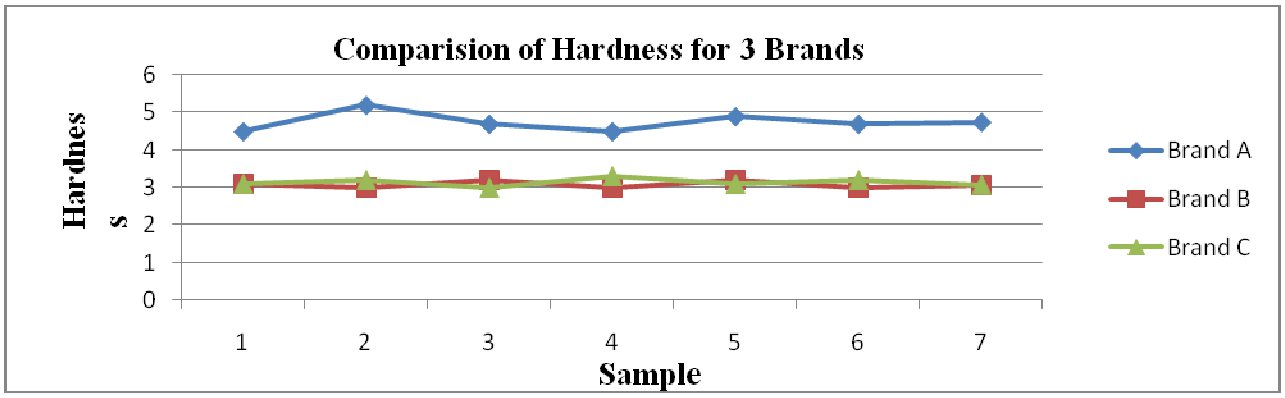

Fig no 4: Trend chart for hardness

Table no: 6 Friability Studies For Three Brands

S.NO.	BRANDS	FRIABILILTY
1	Brand-A	0.6
2	Brand-B	0.8
3	Brand-C	0.7

Table No 7: Disintegrating Test For Three Brands

S.NO.	BRANDS	DISINTEGRATING TIME
1	Brand-A	3 Min
2	Brand-B	9 Min
3	Brand-C	4 Min

.

Table No 8: Dissolution Study

Sampling time	CUMULATIVE PERCENT OF DRUG RELEASE		
	Brand-A	Brand-B	Brand-C
5	96.24	92.54	93.06
10	96.65	94.08	95.67
15	97.00	95.51	96.05
30	97.48	96.12	97.40

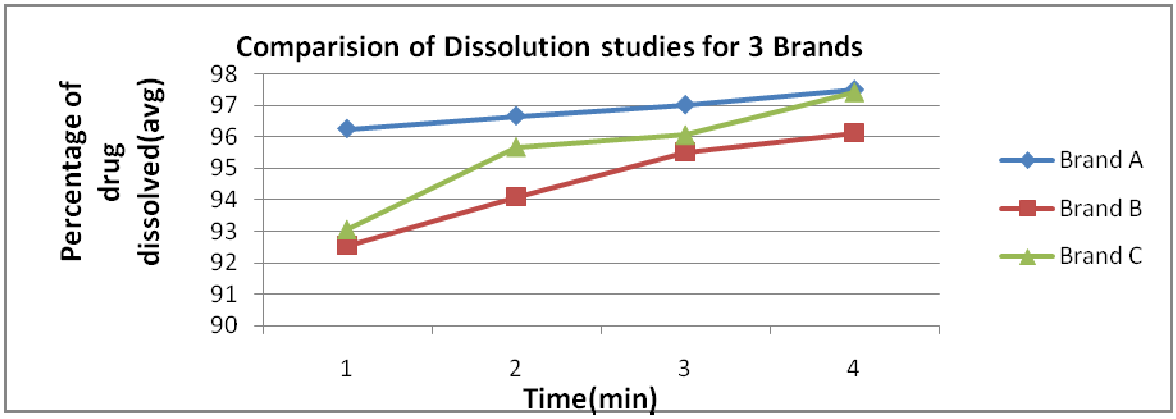

Fig No 5 Trend chart for dissolution

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