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A COMPARATIVE STUDY OF DIFFERENT BRANDS OF CETIRIZINE HYDROCHLORIDE TABLETS

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ABSTRACT

Certrizine hydrochloride is an orally administered drug used as anti-histaminic with almost no sedation. The analysis done can conveniently give a general survey of different brands of cetrizine hydrochloride tablets. the difference in parameters tested can relate to difference in bioavailability of drugs. Quality of tablets should full fill certain specifications. This study shows the analysis and evaluation of various pharmaceutical parameters, i.e. weight variation, hardness, thickness, friability, dissolution and disintegration, on different brands of cetrizine hydrochloride tablets available in local markets.

KEYWORDS: Cetirizine hydrochloride tablets, anti-histaminic, quality control.

INTRODUCTION

Cetirizine hydrochloride (CTZ), a human metabolite of the piperazine H1-receptor antagonist hydroxyzine, is used to treat seasonal allergic rhinitis, chronic idiopathic urticaria, perennial allergic rhinitis, allergic asthma. physical urticaria, and atopic dermatitis. Reduced dosage of cetirizine hydrochloride is recommended for patients with hepatic or renal impairment. Many tests are frequently applied to tablet dosage forms to render their optimum therapeutic effects. The technique of optimization is well reported in the literature for the development of tablet formulations. The purpose of carrying out optimization is to select the best possible formulation from a pharmaceutical as well as consumer point of view. The tablet should include the correct dose of the drug (weight uniformity and content uniformity test), the drug should be released from the tablet in a controlled and reproducible way (dissolution test), the tablet should show sufficient mechanical structural fracture and erosion during manufacturing and handling (hardness and friability test), the appearance of the tablet should be elegant with

its weight, size and appearance consistent (visual observation, weight variation, thickness and diameter of the tablet) and the tablet should be packed in a safe manner. The formulation of a tablet is thus designed so that the final tablet has all these essential properties as well as being stable. An important variable in any tablet system is the rate at which the drug substance dissolves; for many solid dosage forms, disintegration precedes drug dissolution. Hence, the proper choice of disintegrants and their consistency of performance are of critical importance to the formulation development of such tablets. In addition to compressional force used to manufacture a tablet, the chemical component in the formula also has shown to prolong disintegration time, which subsequently affects the drug dissolution rate and bioavailabilityCetirizine hydrochloride (CTZ), a human metabolite of the piperazine H1-receptor antagonist hydroxyzine, is used to treat seasonal allergic rhinitis, chronic idiopathic urticaria, perennial allergic rhinitis, allergic asthma. physical urticaria, and atopic dermatitis. Reduced dosage of cetirizine hydrochloride is recommended for patients with hepatic or renal impairment. Many tests are frequently applied to tablet dosage forms to render their optimum therapeutic effects. The technique of optimization is well reported in the literature for the development of tablet formulations. The purpose of carrying out optimization is to select the best possible formulation from a pharmaceutical as well as consumer point of view. The tablet should include the correct dose of the drug (weight uniformity and content uniformity test), the drug should be released from the tablet in a controlled and reproducible way (dissolution test), the tablet should show sufficient mechanical structural fracture and erosion during manufacturing and handling (hardness and friability test), the appearance of the tablet should be elegant with its weight, size and appearance consistent (visual observation, weight variation, thickness and diameter of the tablet) and the tablet should be packed in a safe manner. The formulation of a tablet is thus designed so that the final tablet has all these essential properties as well as being stable. An important variable in any tablet system is the rate at which the drug substance dissolves; for many solid dosage forms, disintegration precedes drug dissolution. Hence, the proper choice of disintegrants and their consistency of performance are of critical importance to the formulation development of such tablets. In addition to compressional force used to manufacture a tablet, the chemical component in the formula also has shown to prolong.

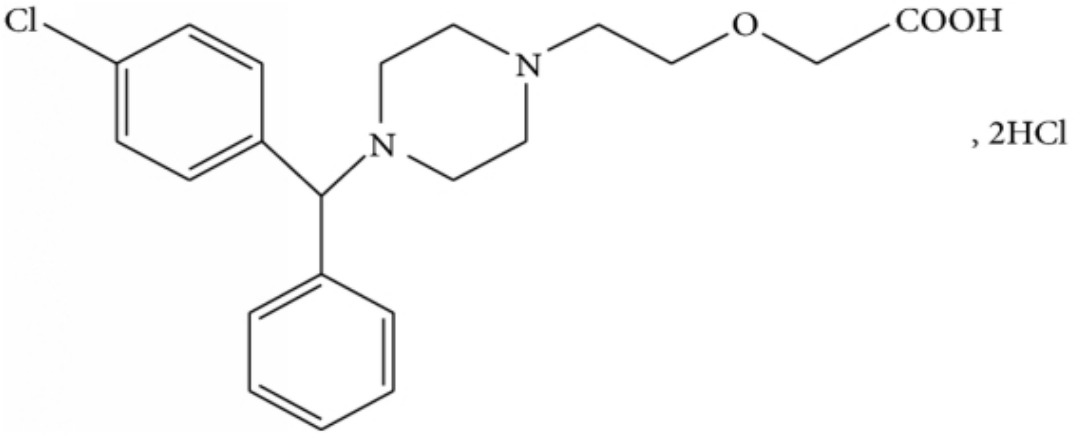


Fig 1: Structure of cetirizine hydrochloride.

MATERIALS AND METHODS

Cetirizine hydrochloride 10 mg tablets from the following three different brands.

- ❖ setride from wockhardt
- ❖ triz from indoco
- ❖ okacet fromCipla

These three brands are evaluated by using these following tests as per required apparatus

- Weight variation test- By using high precision balance
- Hardness- By using Monsanto hardness tester
- Friability- By using Roche friabilator
- Thickness- By using vernier calliper

By the following tests the results are obtained within limits as per I.P. and the tests are explained as.

WEIGHT VARIATION: Weigh individually 20 tablets selected at random and calculate the average weight. Not more than two of the individual weight deviates from the average weight by more than the percentage given in pharmacopeia and none deviates by more than twice that percentage.

I.P/B.P/U.S.P limits for tablet weight variation is given below table no: 1.1

Table no: 1.1.

Weight of tablet	% deviation
80mg	±10%
>80mg -<250mg	±7.5%
250mg or more than	±5%

HARDNES: The tablet should show sufficient mechanical strength to with stand fracture and erosion during manufacture and handling. It is the load required to crush the tablet when placed on its edge. The apparatus used for hardness is Monsanto tester. Normal tablet hardness ranges from 2-4 kg (1kg=10newtons).

FRIABILITY: friability is a property that is related to the hardness of the tablet and also add weight variation, content uniformity problems an instrument is used for friability is called friabilator is used evaluate the ability of tablet to with stand abrasion in packaging, handling and shipping.

Tablet friability apparatus is used for the test remove any loose dust from the tablets and accurately weigh 10 tablets they are placed in a drum which rotate at 25±1rpm rotate the drum 100 times and remove the tablets the sample fails the test if any of the tablets cracked, cleaved or broken is present if the weight loss is more than 1.0% the test is repeated for twice and mean of three tests is calculated the mean not more than 1.0% is considered acceptable according to BP –percentage of friability should not be more than 0.8%. According to the USP- percentage of friability should not be more than 4%.

THICKNES: The appearance of tablet should be elegant and also consistent. It is done by using verniercallipers. Tablet thickness diameter should be controlled with in a 3.5-4mm of a standard value.

DISSOLUTION TEST

Since drug absorption and physiological availability depend on the availability of the drug substance in the dissolution state, having suitable dissolution characteristics is important for a satisfactory tablet. The dissolution test measures the amount of time required for a certain percentage of the drug substance in a tablet to go into solution under a specified set of conditions. It describes a step towards physiological availability of the drug substance, but it is not designed to measure the safety or efficacy of the tablet being tested. It provides an in

vitro control procedure to eliminate variation among production batches. The dissolution medium must be aqueous and the pH of the medium should be controlled and should simulate the biological conditions. Dissolution studies were conducted using a USP apparatus II, paddle type with 50 rpm at 37°±1C. For standard preparation, about 10 mg of cetirizine hydrochloride was placed in a 100 ml volumetric flask and dissolved with 0.1 M hydrochloric acid and then the volume was made up to 100 ml with 0.1 M hydrochloric acid. 2 mll of this solution was transferred to another 100 ml volumetric flask and diluted to 100 ml with the same solvent. For the sample, about 900 ml of 0.1 ml HCl was placed in the dissolution bowl with one tablet and the apparatus was started. The sample was drawn at time intervals of 5, 10, 15, 20, 25 and 30 minutes for each formulation. Absorbance of the sample preparation and that of standard were taken at 220 nm using a 0.1 M hydrochloric acid solution as a blank. Drug concentrations were measured spectrophotometrically.

RESULTS AND DISCUSSION

Three brands of cetirizine hydrochloride 10mg tablets were purchased from apollo pharmacy at Guntur. All the brands of cetirizine hydrochloride tablets used were within their self -life during the study period as given below.

Table no: 1.2.

SAMPLES	BRAND NAME	MFG DATE	EXP DATE	LABELLED STRENGTH	MANUFACTURE
A	SETRIDE	6/2018	5/2020	10mg	Wockhardt
B	TRIZ	9/2018	8/2020	10mg	Indico remedies
C	OKACET	5/2018	4/2020	10mg	Cipla

The evaluation tests of different brands of cetirizine hydrochloride 10mg the results was obtained within limits. The results of evaluation tests are given below table no:1.3.

WEIGHT VARIATION: weight of 10 tablets of different brands.

Table no: 1.3.

Tablet	Setride	Triz	Okacet
1	0.16	0.11	0.18
2	0.16	0.11	0.18
3	0.17	0.12	0.19
4	0.18	0.10	0.18
5	0.15	0.11	0.17
6	0.16	0.10	0.18
7	0.17	0.11	0.19
8	0.16	0.10	0.18

9	0.18	0.10	0.19
10	0.16	0.11	0.18

Statistical weight variations.

Table no: 1.4.

Tablets	Average	Standard deviation
Setride	0.165	0.000215
Triz	0.107	0.0002579
Okacet	1.964	0.132532

Weight variation test

Table no: 1.5.

Tablets	Result)	IP/BP/USP specifications	Deviation frIP/BP/USP
Setride Triz Okacet	0.1595 0.1065 0.1805	Deviation should be ± 7.5%	Within specific limit

HARDNESS TEST: Hardness of 10 tablets from the three different brands

Table no: 2.0.

Tablets	Setride	Triz	Okacet
1	5.0	3.5	4.0
2	5.5	4.0	3.5
3	4.5	4.0	3.5
4	4.0	3.5	4.0
5	5.0	4.0	4.0
6	4.5	4.0	3.5
7	4.0	3.5	3.5
8	5.0	3.5	4.0
9	5.5	4.0	3.5
10	5.0	3.5	4.0

Statistical hardness.

Table no: 2.1.

Tablets	Average(kg)	Standard deviation
Setride	4.9	0.202
Triz	3.75	0.0625
Okacet	3.75	0.0625

FRIABILITY TEST

Table no: 2.2.

Tablets	Result (%)	IP/BP/USP specifications	Deviation from IP/BP/USP specifications
Setride Triz Okacet	0.5 0.93 0.8	Not more than 1%	In specified limit

THICKNESS TEST: Thickness of 10 tablets

Table no: 3.0.

Tablets	Setride	Triz	Okacet
1	1.40	1.38	1.50
2	2.5	2.0	1.90
3	2.16	2.5	2.0
4	2.50	2.16	2.50
5	2.70	2.22	2.30
6	3.0	2.32	3.0
7	2.10	2.42	2.0
8	1.60	2.12	2.22
9	2.30	2.62	2.5
10	2.70	3.12	1.80

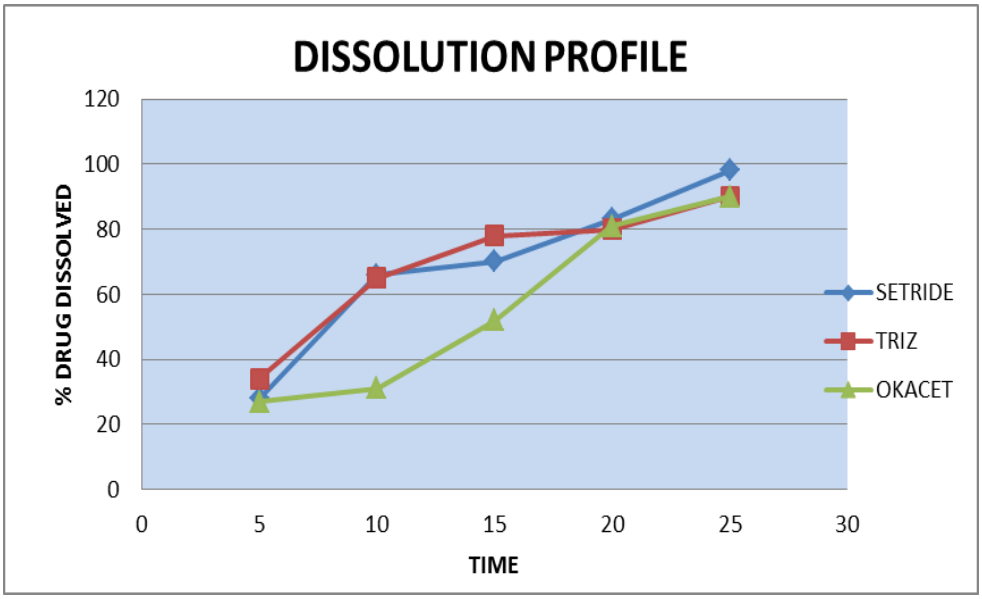
Statistical thickness

Table no: 3.1.

Tablets	Average thickness(mm)	Standard deviation
Setride	2.296	0.2573184
Triz	2.286	0.1822428
Okacet	2.172	0.164856

DISSOLUTION TEST: Test for 10 tablets

Time	Setride	Triz	Okacet
5	28	34	27
10	66	65	31
15	70	78	52
20	83	80	81
25	91	90	90
30	98	96	95



CONCLUSION

Based on the results obtained in this work, all the evaluation tests performed for the three different brands of a cetirizine hydrochloride (Setride, Triz, Okacet) are within the range as per I.P. the amount of active ingredient present in tablets are not meeting the label claim. The best brand was found to be Setride 10mg.

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