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COMPARATIVE EVALUATION OF DIFFERENT BRANDS OF CEFIXIME TRIHYDRATE 100 MG DISPERSIBLE TABLETS IP

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Abstract:

Objective: *The objective of the study was to carry out the evaluation tests and compare evaluation parameters for different marketed brands of Cefixime as Trihydrate 100 mg dispersible tablets IP.* ***Methods:*** *Five different brands were randomly selected for this study, which were coded as brand A, brand B, brand C, brand D and brand E. different evaluation tests were performed and compared. The tests for Hardness, friability, weight variation, wetting time, test for uniformity of dispersion and In-vitro Disintegration test, were performed and compared.* ***Results:*** *The important criteria for dispersible tablet to comply with regulatory requirements are to pass in the disintegration test and test for uniformity of dispersion. Based on the study, all the selected brands passed the disintegration test. However among the five brands brands A, B & D passed for test for uniformity of dispersion, whereas rest of brands i.e., C & E did not pass for test for uniformity of dispersion.* ***Conclusion:*** *Based on evaluation parameters data, brand D was found to be the best and superior among the selected brands of Cefixime Trihydrate 100 mg dispersible tablets, if price of tablets also considered then brand B be the best at low price among all brands with specified qualities.*

Key words: *Brands, Dispersible Tablets, Cefixime Trihydrate, Disintegration Test and Uniformity of Dispersion*

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INTRODUCTION:

Oral drug delivery is the most favored route for the administration of various medications and tablets are the most widely accepted dosage form. In recent days tablets become the most favorable dosage form as compared to other available dosage forms. The popularity of this dosage form is because of advantages such as ease of manufacturing, convenience in administration, and high accuracy in dosage, stability and safety. Despite all the advantages, conventional tablets generally do not prove useful in certain situations. The elderly face difficulties in taking conventional oral dosage forms because of hand tremors and dysphasia. Swallowing is also a common problem in the young individuals because of their under developed muscular and skeletal system (1). According to one review dispersible tablet formulation is one of among 51 new pediatric oral formulations which belong to Formulations requiring manipulation category. (2)

Dispersible tablet delivery system is characterized by fast disintegration, quick dissolving, rapid release and improved patient compliance. Dispersible tablets are uncoated tablets or film-coated tablets intended to be dispersed in water before administration giving a homogeneous dispersion. Dispersible tablets as defined in European Pharmacopoeia are uncoated or film coated tablets intended to be dispersed in water before administration giving a homogeneous dispersion. Typically a dispersible tablet is dispersed in about 5 to 15 ml of water (e.g. in a tablespoonful or a glass of water) and the resulting dispersion is administered to the patient. United States Food and Drug Administration (FDA) defined fast dissolving tablets as a "solid dosage forms containing medicinal substances or active ingredients which disintegrate rapidly usually within a matter of seconds when placed in water. (3, 4).

Cefixime is a third generation antibiotic, which is bacteriostatic, used in the treatment of urinary tract infections, lower respiratory tract infections such as bronchitis, pharyngitis, and gonorrhea in children and elderly patients (4).Only 40-50% of an oral dose of Cefixime is absorbed from the gastrointestinal tract. Cefixime is better absorbed from oral suspension than from tablets, therefore a dispersible tablet dissolved in water before administration gives better absorption Cefixime trihydrate is available in oral tablet and oral suspension forms in the market. Tablets which contain 100mg and 200mg of cefixime trihydrate are available in market. (3, 5, 6)

Choice of excipients especially disintegrants can phenomenally affect the tablet's quality attributes like disintegration time. The type of fillers or diluents and lubricants may also affect tablet disintegration time. Manufacturing environmental conditions and process parameters need to be optimized as they have significant effect on disintegration of tablet. Important examples are the method of granulation (which will affect the physical properties of granules), mixing condition during addition of lubricants & anti-adherents, the applied punch force during tableting and punch force time relationship. Although hardness of the tablet increases with increase in compaction force but it may either increase or decrease disintegration time or give complex relationship with maximum and minimum disintegration time. Superdisintegrants are prerequisite in dispersible tablets to ensure that these tablets are rapidly broken down into the primary particles to facilitate the dissolution or release of the active ingredients within specified time. (7)

The aim of this study is to evaluate and compare the different marketed brands of Cefixime as Trihydrate 100 mg dispersible tablets IP**.**

MATERIALS AND METHODS:

Materials: Five different brands of Cefixime Trihydrate IP 100 mg dispersible tablets purchased from pharmacy shops, Electronic balance, Roche friability tester, disintegration test apparatus, sieve no. 22, Monsanto Hardness tester, purified water and 100 mL beaker, petri plate.

Methods:

Weight variation test:

Twenty tablets were taken and average weight was calculated. Then individual tablets were weighed and the individual weight was compared with an average weight. IP limit for weight variation in case of tablets weighing 130 – 324 mg ± 7.5 % and more than 324 mg ± 5 %.(5, 8)

Tablet hardness test: The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of each batch of tablet was checked by using "Monsanto hardness tester". The hardness was measured in terms of kg/cm^2. 5 tablets were chosen randomly and tested for hardness. The average hardness of 5 determinations was recorded. (6)

Friability:

Friability test was done by Roche friabilator. Ten tablets were weighed and were subjected to combined effect of attrition and shock by utilizing a plastic chamber that resolve at 25 rpm dropping the tablets at

distance of 6 inch with each revolution. Operated for 100 revolutions, the tablets were dusted and reweighed. The percentage friability was calculated. Limit- less than 1% (5, 9, 10)

$$\text{Friability} = \frac{\text{Initial weight - Final weight}}{\text{Initial weight}} \times 100$$

Wetting time:
Wetting time of dosage form is related to the contact angle. It needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. For this purpose, A filter paper folded twice was placed in a small petri-dish (Internal diameter = 6 cm) containing 6 ml of water at 25ºC. A tablet was placed on the filter paper and the time required for the complete wetting of the Tablet was recorded as a wetting time. The mean of three determinations was used. (3, 11)

Uniformity (Fineness) of dispersion:
2 tablets were placed in 100 ml of purified water and stirred gently until both the tablets are completely dispersed. A smooth dispersion was obtained which was passed through sieve screen with a nominal mesh aperture of 710 µm (sieve number 22). The tablets will consider passing the test if no residue remained on the screen. (4, 5, 7, 10, 12)

Disintegration Time:
The test was carried out on 6 tablets using the apparatus specified in I.P.-1996, distilled water at 37ºC ± 0.5ºC was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured in seconds. To be complied with the Pharmacopoeial standards, dispersible tablets must disintegrate within 3 min when examined by the disintegration test for tablets. Average disintegration time of six tablets was determined. (5, 9, 11, 13)

RESULTS AND DISUSSION:

In the present study, different brands of Cefixime Trihydrate dispersible (100mg) tablets were evaluated through weight variation, hardness, friability, wetting time disintegration time and uniformity of dispersion. It helps to recognize the comparative difference of parameters of dispersible tablets and to report the best one and it can also helps to find out the effect of these differences may related to price.

Price fluctuation:
As the variation in the price has been observed from as much as 53 to 72.45 rupees per 10 tablets (table 1) while there was no significant variation in the quality of the tested brands.

Table:1

S.NO	FORMULATION CODE	B.NO	PRICE PER 10 TAB	DIRECTION FOR USE
1	A	018I038	65.5	Disperse in 15 ml of boiled & cooled water immediately before use
2	B	X55052	53	Disperse one tablet in teaspoonful of water immediately before use
3	C	31171429	54.05	The tablet should be dispersed in water immediately before use.
4	D	EI80278	72.45	Disperse the tablet in a tea spoonful of boiled & cooled water immediately before administration
5	E	LAB811A	57	Disperse the tablet in a 5 ml of boiled & cooled water immediately before administration

Weight Variation:
It was found that the different brand tablets were of an average weight of 250mg to 500mg ± 10%. Table.2 indicated that brands C weighed 503 mg that is highest and brand B 247.75 mg is the lowest weight but the drug Cefixime trihydrate dose is 100 mg in all brands. The weight difference is may be due to difference in additives used in different brands and different methods by different companies.

Hardness:
All the formulations have an average hardness in between 4 to 6.4 kg/cm^2 which was found to be acceptable; because these formulations have to be disintegrated within in 3 minutes.

Friability:
The average percentage friability for all the brands was between 0.43% to 0.85%, which was found to be within the limit (i.e. maximum 1%). So the maximum friability was 0.85% of brand A and the minimum friability 0.43% OF brand D

Wetting Time:
The average wetting time for all the formulations was in the range of 16.33 to 113 seconds. The maximum wetting time of 113 seconds and minimum wetting time of 16.33 seconds were shown by E and D respectively.

***In-vitro* disintegration time:**
The in-vitro disintegration time for all the brands were in the range of was 15 seconds to 55 seconds which is well within the Pharmacopoeial standards. (BP 2011, 3 minutes and IP 2007. 3 minutes). Table.2 indicates that product E has shown a maximum disintegration time about 55 sec and product D has shown minimum disintegration time about 15 sec. and it observed that there is no relation between hardness, friability and disintegration time of these dispersible tablets. Superdisintegrants play a major role in the dissolution and disintegration of the tablets. Superdisintegrants provide rapid disintegration due to combined effect of swelling and water absorption by the formulation.

Uniformity of dispersion:
Brands A, B and D passed the test for uniformity of dispersion as per specifications given in BP 2011 and IP 2007. Brands C & E failed test for uniformity of dispersion as few particles mass observed to be retained on 22 no sieve as depicted in figures 2 & 3 respectively. The failures of brand C and E with respect to test for uniformity of dispersion may be due to, Poor choice or selection of super disintegrant or due to higher concentration of binder or due to tablet hardness.

Along with all these tests it was also tested that the dispersion of tablet in specified amount (mentioned in direction for use on label of tablet strips) of freshly boiled and cooled water. All the tablets dispersed within 2 minutes in specified amount of freshly boiled and cooled water.

Table: 2

BRAND	WEIGHT VARIATION (AV.Wt. mg±SD)*	HARDNESS (kg/cm2± SD)**	FRIABILITY (%)	WETTING TIME (SEC± SD)***	DISINTE-GRATION TIME (SEC)	UNIFORMITY OF DISPERSION
A	350.25±3.43	4±0.22	0.85	65±1	38	PASS
B	247.75±6.41	4.9±0.22	0.81	53.66±1.53	30	PASS
C	503.00±8.49	6.4±0.22	0.56	35.66±2.08	25	FAIL
D	298.50±7.05	5.8 ±0.27	0.43	16.33±1.15	15	PASS
E	402.50±4.73	5.2 ±0.27	0.61	113±2.64	55	FAIL

* Average of 20 determinations. ** Average of 5 determinations, *** Average of 3 determinations

Fig.1,Seive no 22 (enlarged view) before study

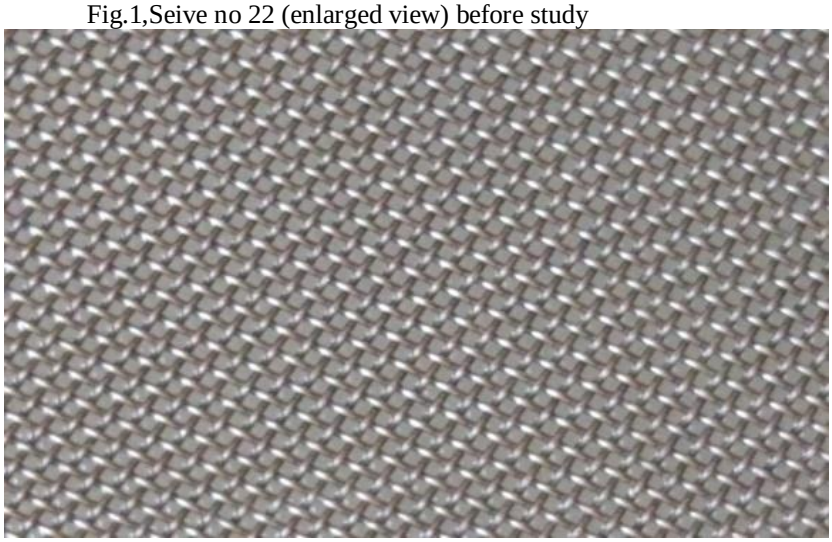


Fig.2 ,seive no 22 (enlarged view) brand C

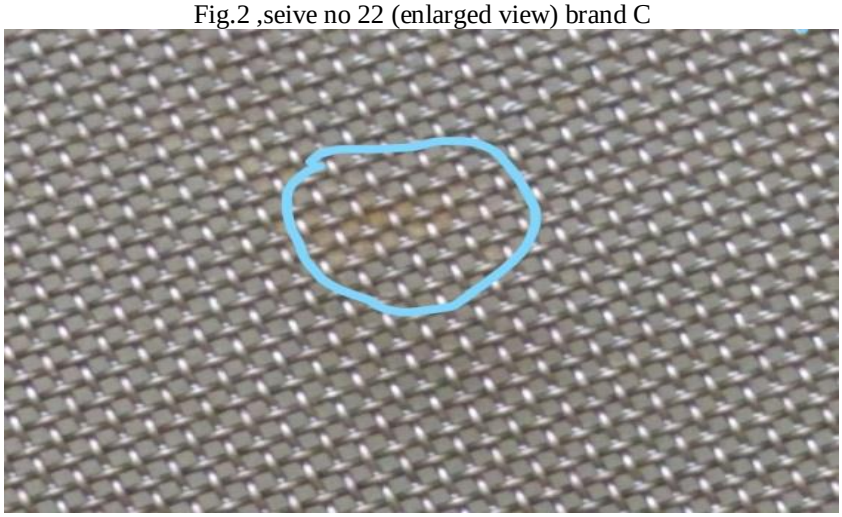
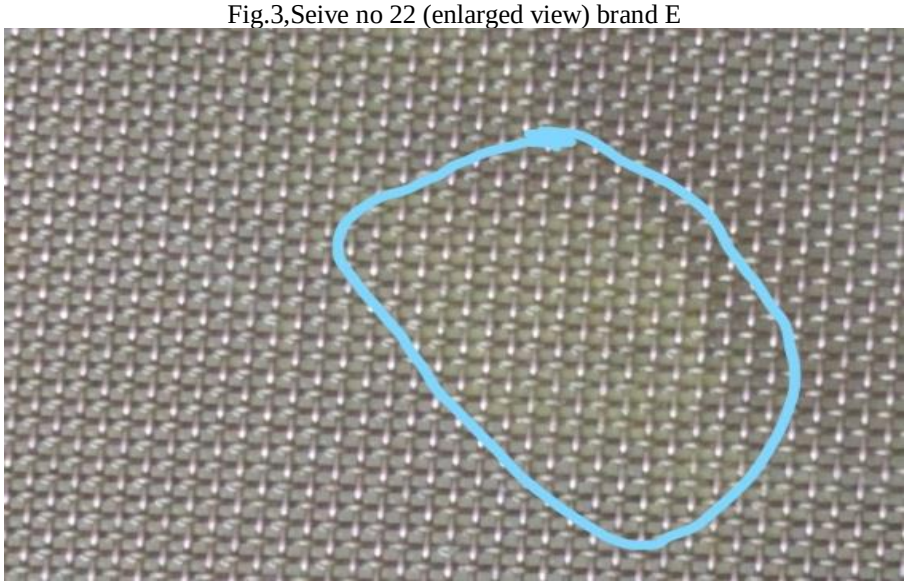


Fig.3,Seive no 22 (enlarged view) brand E



CONCLUSION:

All the brands selected for study, passed the test for weight variation, hardness, friability and disintegration, as per IP. Brand D was found to be the best with respect to its disintegration time as it disintegrated by 15 seconds, passed all the tests which performed, but the cost of this brand is highest (Rs. 72.45/10) among all selected brands. Brand B with lowest cost (Rs.53/10) among five brands passed all the tests with disintegration time 30 seconds. C and E failed the test for uniformity of dispersion. Among the brand A, B and D, brand D was found to be superior with respect to hardness, friability and disintegration test and test for uniformity of dispersion and brand B was found to be most economical with low average weight and with all specified qualities, which will always preferable over costlier brands. To sum up, disintegration time and uniformity of dispersion of dispersible tablets depends mainly on the careful selection of super disintegrant in the formulation, proper addition of suitable binder and maintaining optimum hardness during compression process.

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