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Research Article

FORMULATION & DEVELOPMENT OF CEFPODOXIME PROXETIL DISPERSIBLE TABLETS

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Abstract: In present research work, dispersible tablets of Cefpodoxime proxetil were formulated by direct compression technique. Cefpodoxime proxetil is an advanced-generation, broad-spectrum cephalosporin antibiotic approved for the treatment of acute bacterial exacerbation of chronic bronchitis (AECB), group-A beta hemolytic streptococcal pharyngotonsillitis, and uncomplicated skin/skin structure infections in adult and adolescent patients. Cefpodoxime proxetil has slightly bitter taste and has poor water solubility. So in case of acute bacterial exacerbation of chronic bronchitis (AECB) group- A beta-hemolytic streptococcal pharyngotonsillitis, and uncomplicated skin/skin structure infections it require immediate release of drug from the dosage form, which make Cefpodoxime proxetil suitable candidate for dispersible tablets. In the research work, dispersible tablet for Cefpodoxime proxetil was formulated by direct compression Croscarmellose sodium, sodium starch glycollate and Crospovidone were used as a superdisintegrant. It is observed that physical parameters like hardness, thickness has significant effect on the performance of the dispersible tablet, so this parameter are critically maintained or put at their optimum level during the manufacturing of the dispersible tablets to obtain desired properties of dispersible tablets. Formulation F7 shows desired result in comparison with other formulations.

Key**words:** Cefpodoxime proxetil, dispersible tablets, superdisintegrant.

INTRODUCTION

Tablet is solid unit dosage form containing a single dose of one or more active substances. Tablets are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is released [1]. Tablets are most widely used dosage form as it offers several advantages viz. self-administration, compactness and ease in manufacturing, but pediatric and geriatric patients may encounter inconvenience at the time of swallowing. To overcome this problem, in recent years increasing attention has been focused in formulating fast dissolving and dispersible tablets that are intended to dissolve or disintegrate rapidly in the mouth. Tablet disintegration has been considered as the rate limiting step in immediate drug release formulation [2]. Tablets are certainly the most cost-effective and efficient form of dispensing medicines. Tablet provides a versatile, compact, robust and accurate platform for drug delivery. While the functional versatility of the tablet as a dosage form has been appreciated for decades, the design versatility of the tablet has historically been underappreciated. A variety of shapes can provide distinction without compromising manufacturing requirements [3]. Recent advances in Novel Drug Delivery System (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. Tablets are the most widely utilized oral dose format. A novel tablet concept which offers ease of oral administration and benefits of increased patient compliance is the fast dissolving/disintegrating tablet (FDDT)[4]. Dispersible tablets are uncoated/coated tablets intended to be dispersed in water before administration. The tablets must have the ability to form uniform dispersion in water. The chief advantage is quicker absorption and onset of clinical effects. FDDT are generally formulated for geriatric or pediatric patients or for those who are having difficulty in swallowing of tablets. They comprise of totally water soluble excipients and components. Dispersible tablets disintegrate either rapidly in water, to form a stabilized suspension, so, it's preferred for pediatric patients who cannot swallow a solid dosage form and the API is unstable if formulated in liquid formulation, also helpful for patients having prolonged illness who are prone to nauseatic sensations if they have to swallow a tablet. The added advantage of this formulation is faster onset of action as compared to conventional tablets. The properties of the water dispersible tablet, such as porosity, hardness, disintegration time and increase in viscosity after dispersion are necessary to investigate during manufacturing which decides the product performance. Dispersible tablets as defined as 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- 15 ml of water and the resulting dispersion is administered to the patient. The dispersible tablets of the present invention maintain the same advantages as conventional tablets and capsules in terms of their accuracy of dosing and ease of handling. They also possess the advantages of suspensions in terms of better bioavailability and increased compliance with children, elderly and patients who have difficulty in swallowing. These tablets have low friability and therefore are easily transportable. As opposed, to a suspension, no refrigeration is required. The dispersible tablets of the present invention are meant to form a suspension and can also be administered as conventional tablet [5-6].

MATERIALS AND METHODS

Materials

Cefpodoxime proxetil was obtained as gift sample from Shreya Life Sciences Pvt. Ltd. Aurangabad, India. Croscarmellose sodium, Sodium Starch Glycollate, Crospovidone XL 10, SLS, colloidal silicon dioxide, sucralose, orange flavor were of Research grade.

Solubility studies

Solubility studies were carried out in various solvents and it was soluble in methanol , slightly soluble in chloroform , practically insoluble in water and hot water [7].

Table 1. Formulation table Cefpodoxime proxetil dispersible tablets

Sr. No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Cefpodoxime Proxetil	140	140	140	140	140	140	140	140	140
2	Microcrystalline cellulose PH 102	150	-	-	150	50	-	-	75	50
3	Microcrystalline cellulose PH 200	-	150	-	-	100		75		50
4	Xylisorb 300	-	-	150	-	-	150	75	75	50
5	Maize Starch	50	60	70	50	60	70	50	60	70
6	Croscarmellose Sodium	30	20	10	-	-	-	-	-	-
7	Sodium Starch Glycollate	-	-	-	30	20	10	-	-	-
8	Crospovidone XL 10	-	-	-	-	-	-	30	20	10
9	Sodium Lauryl Sulphate	5	5	5	5	5	5	5	5	5
10	Orange Flavor	7	7	7	7	7	7	7	7	7
11	Sucralose	10	10	10	10	10	10	10	10	10
12	Aerosil 200	5	5	5	5	5	5	5	5	5
13	Magnesium Stearate	3	3	3	3	3	3	3	3	3
	Total in mg	400	400	400	400	400	400	400	400	400

EVALUATION TESTS[8-10]

Weight Variation Test

Weigh 20 tablets individually, calculate the average weight, and comparing the individual tablet weight to average weight. Not more than 2 tablets are outside the percentage limit and if no more than two tablets are outside the percentage limit and if no tablet differs by more than two times the percentage limit then the test is passed.

Hardness Test

Tablet requires certain amount of strength or hardness and resistance to friability to with stand

Mechanical shock of handling in manufacture, packaging and shipping. Tablet hardness is defined as the force requires breaking a tablet in diametric compression test and hardness is thus termed as tablet crushing strength. The instruments which are use for the hardness study are known as hardness tester. The examples of hardness tester are Monsento, Pfizer, Strong-cobb, Erweka and Schleunizer. In Pfizer tester the tablet is compressed between a holding anvil and a piston connected to a direct force reading gauge. A reading is obtained with the help of indicator situated on Pfizer hardness tester.

Thickness

Tablet was selected at random from individual formulations and thickness was measured by using Vernier caliper scale, which permits accurate measurement. Tablet thickness should be controlled within a ± 0.5% variation of standard value.

Friability Test

Friability of The tablet was determined using Roche Friability Tester made by Electro lab. Friability for the tablets was determined for 100 revolutions. Friability of the tablets should be less than 1 %.

Disintegration Test

The disintegration test apparatus consist of 6 glass tube that are 3 inches long, open at the top and held against a 10 mesh screen at the bottom end to the basket rack assembly. To test for disintegration time, one tablet is placed in each tube, and the basket rack is positioned in a one liter beaker of water, simulated gastric fluid or simulated intestinal fluid at body temperature such that the tablet remain 2.5 cm below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of beaker. A standard motor device is use to move the basket assembly containing the tablet up and down through a distance of 5-6 cm at a frequency of 28-32 cycles per minute. To be in compliance with USP standards the tablets must disintegrate and all the particles must pass through 10 mesh sieve in the time specified [12].

Table 2.Evalution of Cefpodoxime proxetil dispersible tablets

Formulation	Thickness (mm)	Hardness (Kg/cm^2)	Weight Variation (mg)	Friability (%)	Dispersion Time
F1	3.49±0.35	3.5±0.11	400.23±0.24	0.29±0.08	**40 sec**
F2	3.42±0.22	3.0±0.22	400.50±0.34	0.42±0.05	**34 sec**
F3	3.30±0.32	4.5±0.14	401.56±0.24	0.55±0.23	**46 sec**
F4	3.34±0.41	4.5±0.19	402.69±0.35	0.56±0.9	**50 sec**
F5	3.39±0.34	5.5±0.23	400.67±0.42	0.30±0.01	**65 sec**
F6	3.56±0.45	3.0±0.21	401.89±0.39	0.69±0.03	**45 sec**
F7	3.50±0.25	4.9±0.34	400.15±0.20	0.25±0.02	**25 sec**
F8	3.76±0.45	3.4±0.21	401.79±0.31	0.39±0.02	**35 sec**
F9	3.81±0.45	3.2±0.21	400.19±0.39	0.59±0.03	**40 sec**

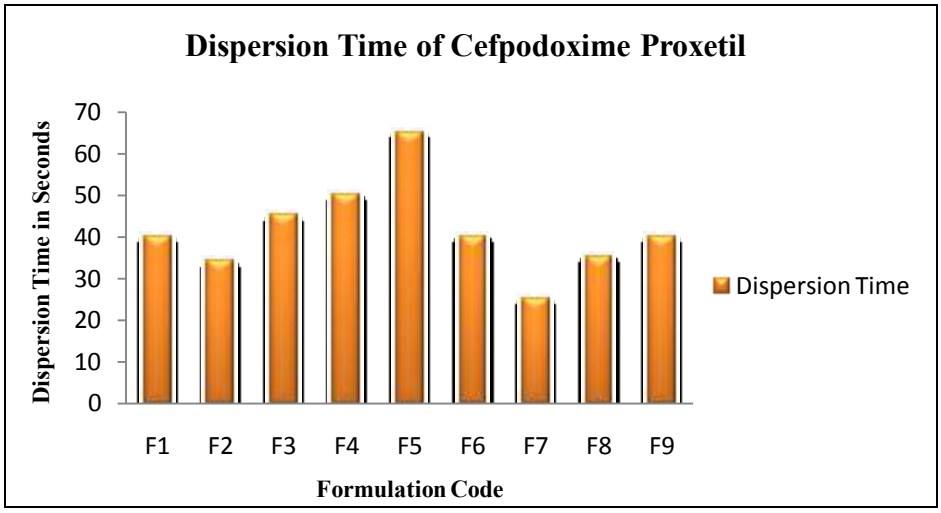

Fig.1 Dispersion Time of Cefpodoxime Proxetil

Dissolution Test

In vitro dissolution study of tablet was conducted using USP apparatus XXII paddle apparatus (Lab India 2000), 900 ml of 0.1 N HCl as dissolution media. Sample was withdrawn upto 30 min. interval, diluted & absorbance was taken at 257 nm[13-14].

Table 3: % cumulative drug release of Cefpodoxime proxetil dispersible tablets

Sl.No	Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	5	28.13	29.09	30.99	34.34	36.25	39.11	40.18	39.90	38.90
2	10	39.57	38.43	42.29	43.06	47.97	49.60	59.53	57.20	55.23
3	15	54.83	63.74	58.64	58.64	69.60	72.08	67.97	64.83	63.90
4	20	68.46	74.36	73.32	69.13	74.85	79.71	80.46	77.32	75.90
5	25	84.04	87.94	82.94	79.80	84.66	86.53	89.85	85.90	84.33
6	30	90.58	93.78	91.25	88.43	91.39	93.29	99.56	96.83	95.21

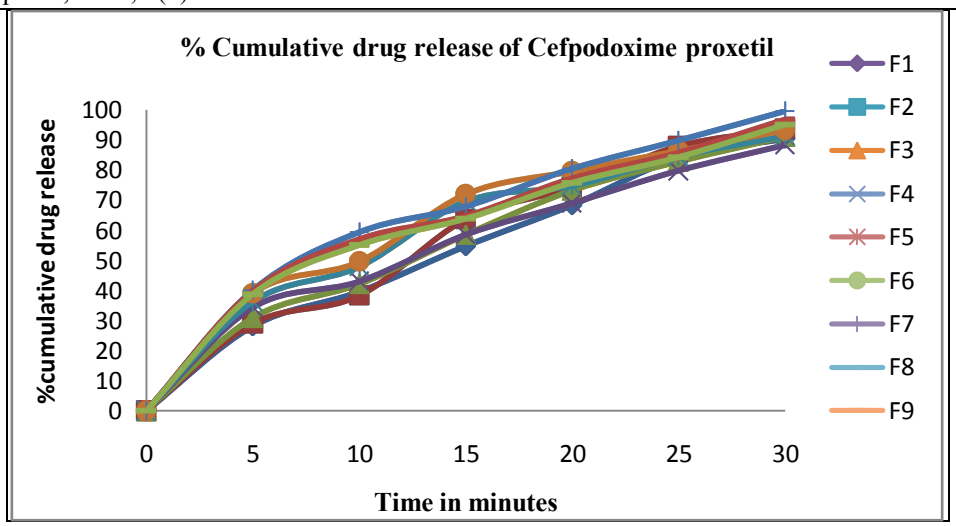

Fig-2: % Cumulative drug release of Cefpodoxime proxetil

CONCLUSION

In present research work, dispersible tablets of Cefpodoxime proxetil were formulated by direct compression technique. The dispersible tablet of Cefpodoxime proxetil was consisting of Croscarmellose sodium, sodium starch glycollate, crospovidone XL 10. From all above study it is concluded that process parameter like hardness, thickness and friability has significantly affect on performance of the dispersible tablet. When tablet hardness is reduced it result in decrease of disintegration time and faster release profile. Thus, all the physical parameter are critically maintained and put at their optimum level during the manufacturing of the dispersible tablets to obtain desired formulation. It was observed that increase in amount of Crospovidone result in lower disintegration time. It was observed that the dispersible tablets of Cefpodoxime proxetil with Crospovidone showed better drug release and disintegration time in comparison to other formulation consisting of Croscarmellose sodium & sodium starch Glycollate. The results of current study clearly indicate that the *in vitro* release of Cefpodoxime proxetil is significantly affected by the amount and concentration of superdisintegrant. As the concentration of superdisintegrant increases the drug release also increased significantly. This indicates that the concentration of superdisintegrant is a one of the major factor in formulation of dispersible tablet. Formulation F7 shows desired result in comparison with other formulation, dispersion time and % cumulative drug release at 30 min. was 25 seconds, 99.56% respectively.

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