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Original Article

CEFPODOXIME PROXETIL FAST DISSOLVING TABLETS: COMPARATIVE STUDY

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ABSTRACT

Objective: In the present investigation, fast dissolving tablets of cefpodoxime proxetil were formulated using superdisintegrants to impart fast disintegration.

Methods: In the current study, 12 formulations of fast dissolving tablets of cefpodoxime proxetil were formulated using two different approaches *viz.,* direct compression and sublimation. Three different superdisintegrants viz., croscarmellose sodium, sodium starch glycolate, and crospovidone were used in a different concentration in all the respective formulations. The final powder blend was subjected for the pre-compression evaluation and all the formulations were evaluated for post-compression parameters. Stability studies were also evaluated for the best formulations as per ICH guidelines. Finally, results were statistically analyzed by the application of one way ANOVA test and t-test.

Results: Among all the formulations of different approaches, formulation cefpodoxime proxetil 4 (CP4) containing 6% crospovidone as a super disintegrant was showed the best results. *In vitro* dissolution data revealed that formulation CP4 prepared by direct compression method showed 99.387±0.270% drug release within 15 min whereas the percentage release by formulation prepared by using sublimation showed 83.927±0.735% release. The optimized formulation was further subjected to comparative *in vitro* study with two marketed formulation of different brands.

Conclusion: All the data of all formulations is shows that direct compression approach is the best approach for developing the fast dissolving tablets to enhance the onset of action and bioavailability.

Keywords: Cefpodoxime proxetil, Cross caramellose sodium, Fast dissolving tablet, Sublimation method

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INTRODUCTION

The most suitable and widely acceptable delivery system for drug administration is the oral drug delivery system because of its self-administration; compactness and easy manufacturing [1]. More than 75% of drugs are given in orally. Oral drug delivery system is becoming important day by day due to its fine characteristics; no invasion, no pain, easy to handle and patient compliance [2]. Due to its great importance, it also left some of the drawbacks, in which the major drawback is dysphagia [3]. Pediatrics and geriatrics patients suffer a lot from the dysphagia (difficulty in swallowing) which leads to poor patient compliance [4]. Therefore, to improvise such issues novel drug delivery system is come in existence called fast dissolving tablets (FDTs).

The demands of the development of FDTs are increased enormously as it has a great impact on patient compliance. Fast disintegrating tablets (FDTs) are gaining more popularity because drug gets dissolved or easily disintegrated in the mouth within a sec without the need of water [5].

Nowadays, fast dissolving tablets are very important to increase the bioavailability of the drug and onset of action in comparison with conventional tablets which have low bioavailability, low solubility and the large onset of action. Basic considerations of FDTs are to improve the aqueous solubility, permeability, mechanical strength etc. therefore drugs which have low aqueous solubility and low permeability (Class III drugs of BCS System) are considered important [6, 7].

Cefpodoxime proxetil (CP) is a broad spectrum third-generation cephalosporin, which shows effective antibacterial activity against both gram-positive and gram-negative bacteria. Cefpodoxime proxetil having the low aqueous solubility and also having the low oral bioavailability up to 50% that may have a negative impact on its sub-therapeutic plasma drug levels leading to therapeutic failure [8, 9].

Consequently, to improve the aqueous solubility and bioavailability of cefpodoxime proxetil, FDTs of cefpodoxime proxetil will be in consideration. Therefore, it is hypothesized that fast dissolving tablets of cefpodoxime proxetil will provide enhanced bioavailability and better patient compliance.

In the present study fast dissolving tablets of cefpodoxime proxetil was achieved by using two different methods *viz.,* direct compression and sublimation method in-order to improve the disintegration time and dissolution rate which may further improve bioavailability and faster onset of action of drug.

MATERIALS AND METHODS

Cefpodoxime proxetil was obtained as gift sample from INOVA CAPTAB UNIT-II Baddi, HP, India, sodium starch glycolate, microcrystalline cellulose, croscarmellose sodium were obtained as a gift sample from Maple Biotech Pvt. Ltd. Pune, India. All other ingredients and chemicals used were of analytical grade.

Preformulation studies

All the preformulation parameters were carried out effectively.

Differential scanning calorimetry

Differential scanning calorimetry (DSC) analysis was performed using Perkin-Elmer Series 7 DSC on 2 to 8 mg samples pure cefpodoxime proxetil [10].

Compatibility studies

A perfectly dried sample of the pure drug (with excipients) was mixed with dried potassium bromide (KBr) powder. The mixture was then subjected to KBr press to obtain the mixture pellet. The pressure for preparing the palate was between 10000 to 12000 psi. The prepared drug pellet was scanned between 4000 to 400 cm^{-1} at a resolution of 4 cm^{-1}. The spectrum was recorded and interpreted for the confirmation of the drug purity [11, 12].

Determination of absorption maxima (λmax)

Known concentrations of cefpodoxime proxetil were prepared in different solvents viz., glycine buffer of pH 3.0. Concentrations were then scanned in UV spectrum mode in the range of 400-200 nm against similarly treated blank [13].

Calibration curve

Accurately weighed, 100 mg of cefpodoxime proxetil was dissolved in 50 ml of glycine buffer pH 3.0 in 100 ml of the pre-calibrated volumetric flask. The solution was shaken for few minutes until a clear solution was obtained and volume was makeup with methanol which gives a standard solution of 1000 μg/ml. Different dilutions of known concentration were prepared from the standard solution ranging between 20-32 μg/ml. Absorption was measured at 257 nm using glycine buffer pH 3.0 as blank.

Determination of qualitative solubility of cefpodoxime proxetil in different solvents

The solubility of cefpodoxime proxetil was determined in various solvents viz., methanol, water, phosphate buffer pH 6.8, and glycine buffer pH 3.0, 0.1N HCl. Solubility was done by Higuchi conner method [13]. Active drug was added in different solvents in 10 ml of the volumetric flask. All volumetric flasks were placed in digital water bath shaker for 72 h continuous shaking at ambient temperature. After that, the solution was filtered using Whatman filter paper (No. 42). The filtrate solution was then further diluted and absorption was measured by UV-VIS spectrophotometer against similarly treated blank.

Preparation of fast dissolving tablets (FDTs)

FDTs were prepared by two different techniques viz; direct compression and sublimation technique using different superdisintegrants at a different level of concentrations. The entire ingredients were weighed carefully and were sieved through sieve no. 60 [14, 15].

The blend was mixed thoroughly and was directly subjected to compression into 200 mg tablets using tablet punching machine. Then compressed tablets of the sublimation technique were allowed to sublime by placing them in a hot air oven for 6 h at a temperature of 60±1 °C [16, 17]. All the prepared formulations were then subjected for further evaluations.

Table 1: Composition of fast dissolving tablets CP1-C12

Ingredients (mg)	Direct compression method (CP1-CP6)						Sublimation method (CP7-CP12)					
	CP1	CP2	CP3	CP4	CP5	CP6	CP7	CP8	CP9	CP 10	CP 11	CP 12
CP	50	50	50	50	50	50	50	50	50	50	50	50
SSG	–	–	–	–	8	12	8	12	–	–	–	–
CCS	8	12	–	–	–	–	–	–	8	12	–	–
Crospovidone	–	–	8	12	–	–	–	–	–	–	8	12
Camphor	–	–	–	–	–	–	6	6	6	6	6	6
Mg. stearate	6	6	6	6	6	6	6	6	6	6	6	6
Talc	6	6	6	6	6	6	6	6	6	6	6	6
MCC	124	120	124	120	124	120	119	115	119	115	119	115
SLS	1	1	1	1	1	1	1	1	1	1	1	1
Aspartame	4	4	4	4	4	4	4	4	4	4	4	4
Menthol	1	1	1	1	1	1	–	–	–	–	–	–
Net weight (mg)	200	200	200	200	200	200	200	200	200	200	200	200

*CP = cefpodoxime proxetil, SSG = sodium starch glycolate, CCS = cross caramellose sodium, MCC = micro crystalline sodium, SLS = sodium lauryl sodium

Evaluation of tablets

Pre-compression evaluation

Pre-compression method of powder blend was evaluated effectively which includes bulk density, tapped density, hauser's ratio, carr's index and angle of repose (θ) [18-21].

Post-compression evaluation

All the prepared formulations were subjected to post-compression evaluations.

Hardness

The hardness of the tablets was evaluated by monsanto hardness tester. 6 tablets of each batch were taken randomly for hardness and average hardness was calculated [22].

Thickness

20 tablets of each batch were selected randomly and the thickness was determined by digital vernier calliper. Average of the thickness was then calculated [23].

Uniformity of the weights

Randomly, 20 tablets were taken from each batch and accurately weighed individually by digital weighing balance and the average weight of each batches tablets were calculated. Weight variation of the individual tablet was calculated and compared with the standard limits as per Indian Pharmacopoeia (IP) [24].

Friability

Friability of the tablets was determined by using the friability test apparatus. Accurately pre-weighed 20 tablets were taken and placed onto the digital friabilator [25]. The friabilator was rotated to 100 revolutions for 4 min. The loss of weight of the tablets was measured and friability was calculated.

Uniformity of the drug content

Six tablets of each batch were taken and crushed to form a fine powder and powder was weighed equivalent to 50 mg of the drug. A weighed amount of powder was dissolved in small amount glycine buffer pH 3.0 which was freshly prepared into the 100 ml volumetric flask. Make up the volume after sonication was done for 25 min. The mixture was then filtered by using whatman filter paper (No. 42). 1 ml of the solution was taken and make up the volume up to the mark (100 ml). The final solution was analyzed in UV-VIS spectrophotometer at 257 nm wavelength against similarly treated blank [26, 27].

***In vitro* disintegration time**

Six tablets were taken from all formulations and maintaining the water temperature at 37.0±0.5 °C. Time taken for complete the disintegration of tablets was recorded by stopwatch. For accuracy, an average of six tablets was taken [28].

Wetting time

10 cm diameter five tissue papers were placed in a dry petri plate. 2 ml of amaranth dye solution was added to the petri plate along with 10 ml of simulated saliva solution. Tablets were put on the tissue paper and the time for complete wetting was measured by a stopwatch. Average three tablets of each batch were measured [29].

Water absorption ratio

10 cm diameter five tissue papers were placed in a dry Petri plate. 2 ml of amaranth dye solution was added to the Petri plate along with 10 ml of simulated saliva solution. Tablets which were pre-weighed were put

on the paper. When the tablets were wet in all sides, then tablets were re-weighed and water absorption ratio was calculated [30].

In vitro dissolution studies

USP Type-II (paddle type) dissolution apparatus were used for *in vitro* dissolution. Three tablets of each batch were used for determination of dissolution studies. Glycine buffer pH 3.0 (900 ml) was used as dissolution media which was maintained at 37.0±0.5 °C and speed of the paddle were adjusted at 75 rpm. 10 ml sample was withdrawn at the different time of interval and diluted adequately. All samples were analyzed at 257 nm wavelength in UV-VIS spectrophotometer using similarly treated blank. From the raw dissolution data, the total amount of drug release profile was calculated at a different interval of time [31]. The kinetic studies for all formulations were also done. Further, the optimized formulation was subjected to comparative *in vitro* studies with the marketed formulation of two different brands.

Statistical analysis

Statistical analysis of selected formulation and marketed formulations was done using graph pad prism 7.0 software. Statistical analysis is important to check the formulation that the selected formulation is significant or not significant [32].

Short-term stability studies of optimized batch

In the present study, selected batch in aluminum foil pack was placed in a stability chamber for stability studies at 40.0±2.0 °C/ 75.0±5.0 % RH for 3 mo. Samples were collected after 3 mo interval and evaluated for physical appearance, disintegration time wetting time, drug content and *in vitro* dissolution [33].

RESULTS AND DISCUSSION

Pre-formulation parameters

Cefpodoxime proxetil was observed for organoleptic properties like physical appearance, odor, and melting point. The drug was identified with the help of UV and FTIR and exhibited absorption maxima at 257 nm when methanol was used as a solvent as mentioned in the literature (fig. 1). The Beer's Lambert range was found to be 24-32µg/ml and the standard curve has shown R^2 value of 0.996 with the euqtion of linearity as y=0.11x+0.002 as shown in fig. 2.

Differential scanning calorimeter shows endothermic fusion peak at 110.45 °C, which was corresponding to the melting point of cefpodoxime proxetil (fig. 3).

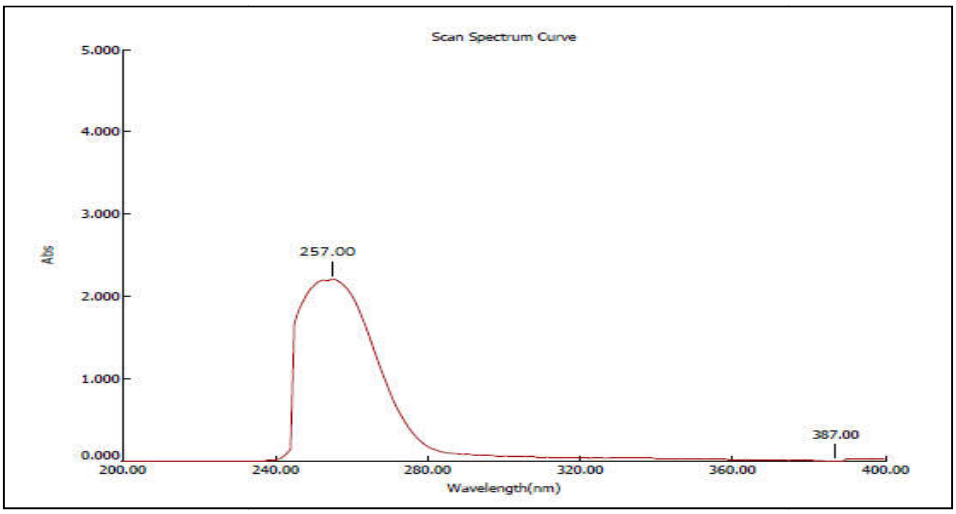

Fig. 1: Absorption spectra of pure drug

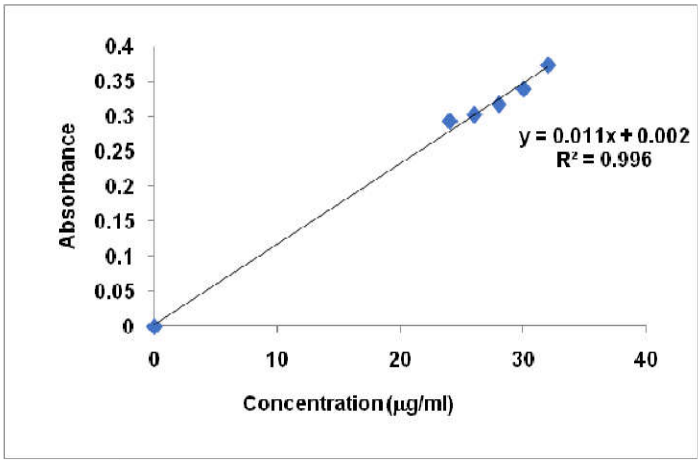

Fig. 2: Cefpodoxime proxetil calibration curve in glycine buffer pH 3.0

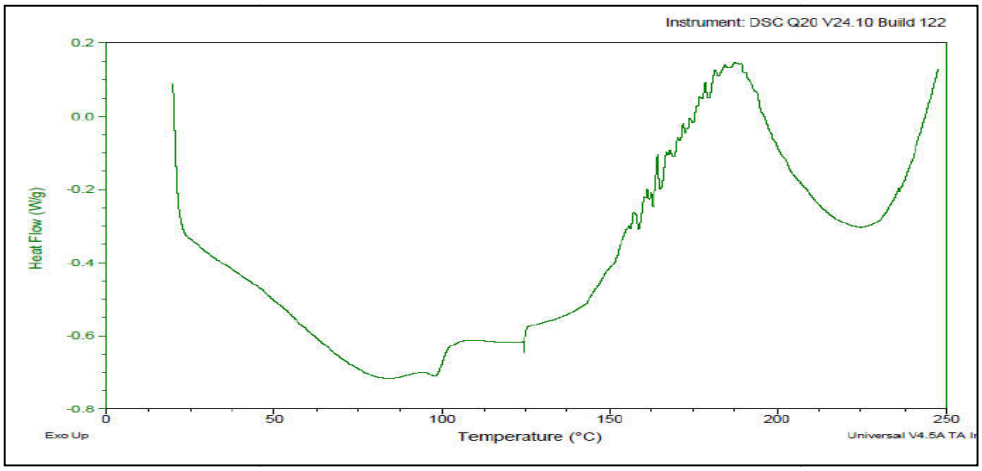

Fig. 3: DSC thermogram of cefpodoxime proxetil

Solubility studies of the drug was performed and it was found that drug was slightly soluble in water with solubility of 0.90±0.021 mg/ml whereas drug was highly soluble in methanol with solubility of 735.56±0.104 mg/ml

Table 2: Solubility studies of cefpodoxime proxetil in different solvents

S. No.	Solvent used	Solubility (mg/ml)	Solubility profile
1	Methanol	735.56±0.021	Freely soluble
2	Ethanol	198.23±0.002	Freely soluble
3	Water (pH 7.0)	0.900±0.104	Very slightly soluble
4	Phosphate buffer pH 6.8	1.580±0.011	Sparingly soluble
5	Glycine buffer pH 3.0	2.032±0.014	Sparingly soluble
6	0.1N HCl	0.276±0.011	Slightly soluble

Compatibilities studies

Compatibility studies of the powered pure drug were done with different excipients like crospovidone, sodium starch glycolate and cross caramellose sodium. All spectrums were subjected to interpretation with a comparison of individual standard FTIR spectra's. Comparisons of the peak of functional groups observed in FTIR spectra of compatibility studies is shown in table 3.

Table 3: Comparison of the peak of functional groups observed in FTIR spectra of compatibility studies

IR spectra	The peak of functional groups (Wave length (cm^{-1}))				
	OH from H_2O and amide NH stretch	S–C–H	β-lactam C=O stretch	Amide C=O stretch	Carboxylate stretching C–O
Standard spectra	3500–3000 (broad band)	2985.94, 2939.64	1760.00	1674.00	1275
Cefpodoxime proxetil	3200.04-3319.63	2985.94, 2939.64	1761.08	1674.28	1275.00
Cefpodoxime proxetil+CCS	3020.34-3506.74	2985.94, 2940.61	1758.19	1674.28	1275.00
Cefpodoxime proxetil+crospovidone	3122.89-3506.74	2985.94, 2940.61	1758.19	1673.32	1275.00
Cefpodoxime proxetil+SSG	3122.89-3525.06	2985.94, 2939.64	1761.08	1674.28	1275.00

*CCS = cross caramellose sodium, SSG = sodium starch glycolate

Table 4: Evaluation of powder blend

Code	Bulk density (g/ml)	Tapped density (g/ml)	Hausner ratio	Carr's index (%)	Angle of repose
CP1	0.651±0.016	0.757±0.015	1.162±0.007	14.006±0.562	26.353±0.416
CP2	0.444±0.022	0.503±0.029	1.133±0.010	12.380±0.272	24.253±0.605
CP3	0.610±0.015	0.703±0.012	1.152±0.009	13.129±0.663	22.513±0.546
CP3	0.673±0.022	0.715±0.028	1.110±0.007	9.962±0.580	22.764±0.716
CP5	0.518±0.015	0.580±0.014	1.118±0.007	10.670±0.559	27.173±0.830
CP6	0.654±0.021	0.723±0.019	1.117±0.006	10.787±0.716	25.720±0.334
CP7	0.433±0.009	0.495±0.007	1.143±0.009	12.533±0.661	30.893±0.389
CP8	0.621±0.004	0.695±0.008	1.118±0.006	10.673±0.472	26.170±0.306
CP9	0.581±0.022	0.663±0.025	1.141±0.009	12.357±0.734	27.067±0.801
CP10	0.610±0.015	0.706±0.011	1.157±0.011	13.560±0.874	30.143±0.300
CP11	0.472±0.010	0.554±0.016	1.174±0.013	14.480±0.944	29.293±0.480
CP12	0.541±0.046	0.628±0.052	1.161±0.003	13.917±0.242	28.420±0.700

*mean±SD, n = 3, SD = standard deviation

Pre-compression evaluations

All formulations were evaluated effectively for pre-compression evaluations. Data is represented in table 4.

Post-compression evaluations

Post-compression evaluations of all formulations were carried out successfully and data are tabulated table 5 and table 6 respectively [27].

In vitro dissolution studies were conducted for all the formulations via USP type-II dissolution apparatus, using glycine buffer pH 3.0 as a dissolution medium. It was observed that more than 90 % drug was released within 15 min in direct compression method formulations (CP1-CP6). Tablets formulated by the sublimation method showed more than 80 % of the drug release within 15 min. Formulation CP4 that containing 6 % of crospovidone revealed maximum drug release profile up to 99.387±0.270 % within 15 min, whereas formulation CP12 showed 83.927±0.735 % drug release (fig. 4).

Table 5: Post compression evaluations of prepared formulations CP1-CP12

Code	Hardness (kg/cm^2)	Thickness (mm) (n=20)	Weight variation	Friability (%)	Drug content (%)
CP1	3.867±0.306	3.376±0.053	Pass	0.668±0.005	97.14±0.275
CP2	4.067±0.416	3.390±0.047	Pass	0.605±0.015	98.35±0.550
CP3	3.733±0.306	3.392±0.040	Pass	0.349±0.017	101.74±0.386
CP4	3.733±0.306	3.367±0.026	Pass	0.349±0.089	100.89±0.964
CP5	4.133±0.416	3.418±0.059	Pass	0.428±0.033	98.35±0.550
CP6	4.167±0.252	3.369±0.040	Pass	0.578±0.42	100.77±0.862
CP7	3.387±0.416	3.546±0.069	Pass	0.790±0.035	99.227±0.985
CP8	3.200±0.600	3.569±0.068	Pass	0.811±0.19	98.860±0.788
CP9	2.967±0.603	3.464±0.053	Pass	0.667±0.050	98.887±0.870
CP10	3.833±0.208	3.552±0.045	Pass	0.790±0.035	100.067±0.162
CP11	2.567±0.252	3.425±0.034	Pass	0.811±0.019	99.793±0.657
CP12	2.267±0.115	3.457±0.038	Pass	0.667±0.050	98.693±0.949

*mean±SD, n = 3, SD = standard deviation, n = number of treatments

Table 6: Post compression evaluations of prepared formulations CP1-CP12

Code	Disintegration time (sec)	Wetting time (sec)	Water absorption ratio (%)
CP1	59.433±0.666	41.02±0.517	80.087±0.522
CP2	45.900±0.300	57.953±0.170	85.577±0.534
CP3	11.730±0.676	22.150±0.692	67.090±0.225
CP4	8.333±0.577	12.343±0.612	78.037±0.423
CP5	43.797±0.469	38.707±0.564	64.793±0.647
CP6	19.727±0.636	28.647±0.605	71.317±0.146
CP7	61.067±0.777	90.967±0.872	101.810±0.326
CP8	54.467±0.551	81.967±0.950	90.940±0.830
CP9	59.067±0.611	84.633±0.603	77.507±0.805
CP10	45.933±0.416	77.837±0.729	85.153±0.329
CP11	38.100±0.985	63.633±0.603	78.200±0.680
CP12	23.000±0.600	47.100±0.361	80.740±0.609

*mean±SD, n = 3, SD = standard deviation

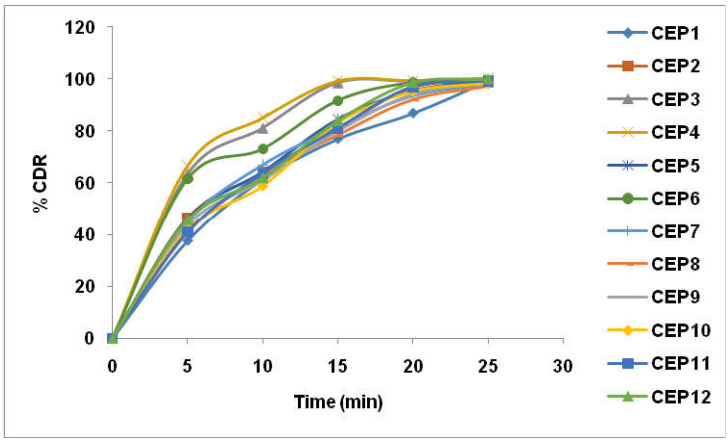

Fig. 4: Comparative *in vitro* drug release profile of all formulations (CP1-CP12)

Hence, the release profile revealed that tablets containing super disintegrants were better in term of drug release, further crospovidone resulting in faster drug release 99.387±0.270 % within 15 min, when compared with other super disintegrants [28]. The Formulation CP4 prepared by direct compression method also showed better dissolution when compared with formulations

prepared by sublimation. Therefore, CP4 formulation was optimized as best formulation and further subjected for comparative *in vitro* drug release with two marketed formulation of different brands. The marketed formulations showed 88.907±0.566 % and 92.627±0.719 % drug release in 15 min (Figure5). The percent drug release is tabulated in table 10 and fig. 5 respectively.

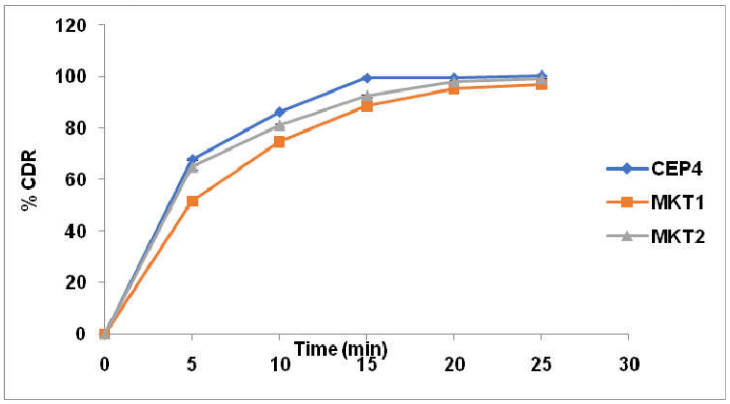

Fig. 5: Comparative *in vitro* drug release profile of CP4, MKT1, and MKT2

The *in vitro* release data were subjected to various mathematical release models *viz.,* zero order, first order, Higuchi and Pappas and best-fit model were decided by the highest R^2 value. On the basis of maximum regression value, Higuchi Model for drug release kinetics was found to be the best fit model for most of the formulations (table 7).

Table 7: Curve Fitting Data of the release rate profile of formulations CP1 to CP12

Formulation code	Models				
	Zero oder (R^2)	1st Order (R^2)	Higuchi (R^2)	Pappas (R^2)	Best fit model
CP1	0.933	0.821	0.994	0.914	*Higuchi*
CP2	0.899	0.929	0.994	0.886	*Higuchi*
CP3	0.735	0.950	0.940	0.843	*1st Order*
CP4	0.707	0.899	0.926	0.832	*Higuchi*
CP5	0.894	0.934	0.993	0.868	*Higuchi*
CP6	0.781	0.927	0.961	0.849	*Higuchi*
CP7	0.887	0.621	0.995	0.898	*Higuchi*
CP8	0.913	0.621	0.995	0.885	*Higuchi*
CP9	0.914	0.584	0.995	0.893	*Higuchi*
CP10	0.915	0.967	0.987	0.899	*Higuchi*
CP11	0.908	0.960	0.989	0.901	*Higuchi*
CP12	0.908	0.863	0.989	0.890	*Higuchi*

Statistical analysis of selected formulation and marketed formulations were calculated by graph pad prism 7.0. Applying, one way ANOVA, it was found that there is no significant difference in all twelve formulations. Using t-test for comparison of the selected formulation with marketed formulations, formulation CP4 and MKT1 showed that there was no significant difference.

Thus, above studies indicate that formulation CP4, MKT1, and MKT2 is having an almost similar profile, but CP4 will provide improved onset of action and bioavailability as indicated by its dissolution rate.

Short-term stability study of the optimized formulation

A sample withdrew after three months shown no more drastic change in *in vitro* drug release profile. All the data showed the good similarity of dissolution profile before and after stability studies (table 8). Results of the stability study had shown no remarkable change in the release profile of the cefpodoxime proxetil FDTs after the stability. Stability study of selected formulation CP4 was found to be stable and complies with pharmacopeial standards.

Table 8: Short-term stability study of optimized formulation (CP4)

Time (min)	% CDR (Initial)	% CDR (After storage of 3 mo)
0	0	0
5	67.927±0.542	66.400±0.704
10	86.337±0.205	84.000±0.771
15	99.110±0.645	99.030±0.085
20	99.743±0.025	99.390±0.329
25	100.437±0.127	100.000±0.714
Drug content (%)	100.898±0.964	100.090±0.293
Disintegration Time (sec)	8.333±0.577	9.600±0.529
Wetting Time (sec)	12.343±0.612	12.833±0.764

*mean±SD, n = 3, SD = standard deviation, CDR = cumulative drug release

CONCLUSION

Fast dissolving tablets were prepared in two different approaches to direct compression and sublimation. Pre-formulations parameters like the physical characterization of the drug were evaluated. All the formulations were passed the pre-compression and post-compression parameters. Formulation CP4 that contained 6 % of crospovidone showed the fastest drug release of 99.387±0.270 % within 15 min which was the optimized formulation. Thus, it was concluded that fast dissolving tablets of cefpodoxime proxetil can be successfully prepared using direct compression technique and it will enhance the drug dissolution which will further increase absorption and bioavailability of the drug.

FUNDING

Nil

AUTHORS CONTRIBUTIONS

All the author has contributed equally.

CONFLICT OF INTERESTS

Declare none

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