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Formulation and evaluation of third-generation Cefpodoxime proxetil as an Oro-dispersible tablets for treating infections

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ABSTRACT

The main problems to humans include the infection caused in the respiratory tract and urinary tract, namely respiratory tract infection (RTI) and urinary tract infection (UTI). Cefpodoxime Proxetil drug is available in the market that has a problem with drug release profile and flows property. To overcome this problem, the compacted powder form made into a micro-ionized form for its better flow property and drug release by using a direct compression technique. The study was based on the aim to evaluate and formulate oro-dispersible tablets as an effective approach via orally for the treatment of RTI & UTI prepared by direct compression technique. FTIR and DSC showed no incompatibility between drugs and excipients. The pure drug Cefpodoxime Proxetil and the excipients were blended using an octagonal blender. The Pre-formulation study was performed for this blend and pure drug. Further, the blend was made compressed into a tablet by direct compression technique. Two factorial design was implemented. Prepared tablets were evaluated for drug content, hardness, thickness, uniformity in the weight, friability, disintegration test, dispersion time, *in-vitro* studies, release kinetics, and also stability studies. The optimized formulation A6 found to have good flow property. The evaluation results of optimized formula A6 showed 99.60% drug content, 390mg average weight, 0.91% weight uniformity, 3.80 kg/cm2 hardness, 0.67%, friability, 23.70sec, disintegration time, 16 sec dispersion time and 95.5% drug release than the other formulation batch. The current study showed that the optimized formula A6 exhibited good disintegration time, drug release, and friability than marketed product X and other batches.

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INTRODUCTION

Cefpodoxime Proxetil is a broad-spectrum cephalosporin antibiotic and which belongs to the BCS class IV have been mainly used for the treatment of skin infection, upper-lower respiratory tract infection, and urinary tract infection. Pro-drug, which is present in the dosage form, will activate the non-specific esterase enzyme in the intestine. It is not able to elicit the required pharmacological action that lowers the solubility and bioavailability (47%). In order to reach the systemic circulation, it fails to elicit its action (Budhwaar and Nanda, 2012). The solubility is much important factor for the therapeutic site to improve

the solubility. Because of this, the challenges have been present to

improve this for the poorly soluble drug. There are reports mentioned in different literature to enhance the solubility of the drug and also bioavailability by different methods like to reduce particle size, for the dispersion of tablets in water, complexation (Kumar *et al.*, 2011; Mohanachandran *et al.*, 2010).

One of the best techniques used for carriers is solid dispersion for low soluble drugs and a reduction in particle size (Chowdary *et al.*, 2011). The fair form can only absorb when drugs are administered orally (Chaulang *et al.*, 2008). Different pharmaceutical techniques have been used for the novel dosage form for the tablets of oral dispersible. These are placed in the mouth and left aside to dissolve without the use of water and show faster action (Paul *et al.*, 2011). The bio availability has been increased when the drug travels down from mouth, pharynx to the esophagus as saliva moves down. It is a suitable route for the patients, usually bedridden. During traveling and no access to water these conditions, it is very useful (Prasad *et al.*, 2013).

In this present study of research work, the tablets are prepared by the process of direct compression method by using a different concentration of super disintegrating agents such as croscarmellose sodium (CCS). CCS swells of quickly around 4–8 times than its original volume using water for the burst release of drug and the polymers. The formulation was optimized, and the release takes place immediately ad causes the dissolution of Cefpodoxime Proxetil.

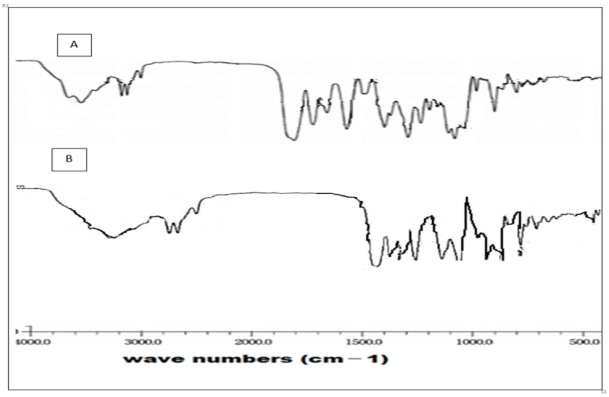


Figure 1: Overlain FTIR Spectra of (A) Cefpodoxime proxetil Drug & (B) Physical mixture

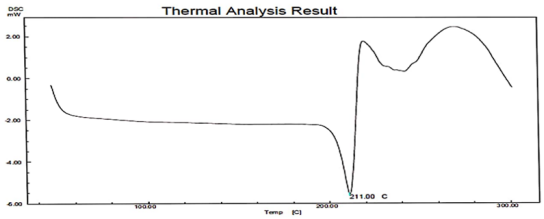


Figure 2: DSC of a reference sample

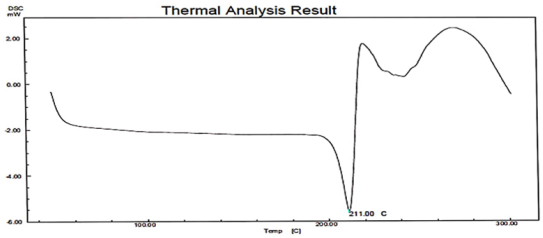


Figure 3: DSC of sample Cefpodoxime proxetil

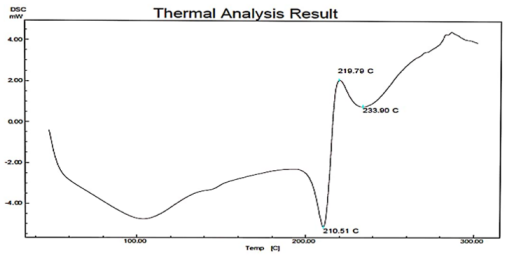


Figure 4: DSC of Physical Mixture

MATERIALS AND METHODS

Materials used

Cefpodoxime Proxetil**,** Croscarmellose Sodium, and Crospovidone were obtained from Microlabs Ltd, Bommasandra, Bangalore-560099.

Solubility

The required amount of drug was added and dissolved in different solvents to define the solubility of the crude drug by the visual inspection method. The excess quantity of the drug was weighed and dropped in a flask containing 10 mL of solvent, and it is then kept on the water bath shaker for 72 hours at 37^{o}C. The filtered solution was analyzed spectro photometrically at 235 nm (Kaushik *et al.*, 2004).

Fourier-transform infrared spectroscopy

KBR pellet method is used at the range of 4000 to 400 cm^{-1}, the IR spectra of the pure drug were identified by using FTIR Spectrophotometer (8400S, Shimadzu, Kyoto, Japan) by KBr pellet method using KBr press (Techno search Instruments, Mumbai, India). (8400S, Shimadzu, Kyoto, Japan).

Differential scanning calorimetry

Differential scanning calorimeter (DSC-60, Shimadzu) was used to perform on pure drug and the excipients to check its compatibility. The samples are airtight in a container of temperature ranging

Table 1: Composition of Cefpodoxime proxetil Oro-dispersible Tablets

Sl.No	Formulation	A1 2.5%	A2 5%	A3 7.5%	A4 2.5%	A5 5%	A6 7.5%	A7 2.5%+2.5%
1	Cefpodoxime proxetil	161	161	161	161	161	161	161
2	Cross Carmellose Sodium	10	20	30	-	-	-	10
3	Crospovidone	-	-	-	10	20	30	10
4	Colloidal Silicon Dioxide	12	12	12	12	12	12	12
5	Micro Crystalline Cellulose	181	171	161	181	171	161	171
6	Sodium Lauryl Sulfate	8	8	8	8	8	8	8
7	Aspartame	8	8	8	8	8	8	8
8	Flavoring Agent	8	8	8	8	8	8	8
9	Magnesium Stearate	4	4	4	4	4	4	4

Table 2: Solubility of Cefpodoxime proxetil drug

Solvent	Solubility (mg/ml)
Water	0.11 ±0.02
Methanol	14.32±0.11
Ethanol	11.21±0.05
Chloroform	0.12±0.03
PBS 1.2	0.263±0.008
PBS 6.8	0.343±0.011
PBS 7.4	0.318±0.012

Table 3: Interpretation of theFT-IR spectrum of drug and physical mixture

The peak observed (cm^{-1})	Interpretation
3448.06.	N - H Stretching
2928.80.	C - H Stretching
1655.16.	C = O Stretching
1292.52.	C - N Stretching
3404.14	O - H Stretching
1326.01	C - O Stretching

from 40 to 300^{o}C at 20^{o}C/min rate. Nitrogen gas was purged continuously (Kaushik *et al.*, 2004).

Pre-formulation studies of pure drug and excipients

Bulk Density

It is known as the untapped volume and which is expressed as gm. / cm3 divides the weight of the sample. Apparent bulk density is determined by taking a weighed quantity of the powder (W) in a measuring cylinder, and volume (Bv) was measured by using the below formula (Akiladevi, 2018).

$$BD = \frac{W}{Bv} \quad (1)$$

Where,

BD =Bulk Density

W = Sample weight

Bv = untapped or bulk volume

Tap Density

The weighed amount of the sample powder was discharged in the measuring cylinder, and then the volume was measured. It is tapped for 100 times on a hard surface at the height of 10cm till the volume of difference was reduced, and then the final reading was measured and denoted by Tv. It is expressed in g/ml (Akiladevi, 2018).

$$D = \frac{W}{Tv} \tag{2}$$

Where,

W- Powder weight

Tv- Tapped volume

Angle of repose

It is the measurement of the friction between the particles. The powder consists of individual particles of different sizes and shapes. It is considered in the flow of the powder during the mixing of powders, the flow of the powder in the hopper, flow between the dying cavity and punches. It is the angle between the horizontal plane and the freestanding surface of the powder. The low value of the angle of repose means the flow of the particles, or the friction between them is high (Akiladevi, 2018).

$$Tan\ \theta = \frac{h}{r} \tag{3}$$

Where,

θ = the angle of repose,

h = height of the cone

r = Radius of the cone base

Carr's Compressibility Index

It indicates the flow properties of the powder. It is expressed in %.

$$C.\ I = \frac{TD - BD \times 100\%}{TD} \tag{4}$$

Where,

TD is tapped density

BD is bulk density

Hausner's Ratio

It defines the flow property of powder that is measured by the ratio of tapped and bulk density. It shows good flow if the value is less than 1.25.

$$HR = \frac{TD}{BD} \tag{5}$$

Where, TD- Tapped Density

BD -Bulk Density

Optimization Study by Two Factorial Designs

Design Expert software was used for this illustration. Obtained data were used for prepared dispersible tablets was used. Two factors that were selected were the Cross carmellose sodium (factor A), crospovidone (factor B) to analyze their response on disintegration time, dispersion time, and % drug release. ANOVA response was quantified in two factorial designs.

Formulation of Cefpodoxime proxetil dispersible Tablets

161 mg of pure drug Cefpodoxime proxetil was weighed accurately for each batch of the tablet, and then it was mixed with super disintegrating agents such as Croscarmellose sodium and Crospovidone. This prepared powder mixture was passed through sieve number #22, and then it is blended using an octagonal blender machine. The prepared blend was converted into a tablet by direct compression technique using a rotary tablet compression machine**.** Further, the prepared tablets were stored in the close tightened container, and certain parameters are evaluated, as shown inTable 1.

Evaluation Studies

Drug content

Weighed accurately 10 prepared tablets and powdered it. Take 100mg of powdered Cefpodoxime proxetil drug and dissolved into 100ml of methanol. Further, it was serially diluted with methanol, and the absorbance was measured at 235nm. The drug content of Cefpodoxime proxetil was determined using the equation given below (Singh and Sharma, 2018)

$$\%\ Assay = \frac{Abs(test)}{Abs(std)} \times 100 \tag{6}$$

Thickness

Vernier caliper scale was used to measure tablet thickness, which gives accurate results (Singh and Sharma, 2018).

Hardness test

The study of the hardness of the tablet from each batch was checked with Pfizer hardness tester by keeping a tablet between the tester and then a force is applied to break the tablet. The limit for the hardness of the uncoated tablet was 3-6 kg/cm^2. The result was expressed in Newton. (Bhupendra *et al.*, 2012)

Friability test

This test was done in the Electro lab Friabilator apparatus and where we take the weight of 10 whole

Table 4: Pre-Compression parameter results of pure drug Cefpodoxime proxetil

Sl.No	Parameter	Result
1. 1.	Bulk Density	1. 0.51
1. 2.	Tapped Density	0.59 g/ml
1. 3.	Angle of Repose	22.450
1. 4.	Carr's Index	13.55%
1. 5.	Hausner Ratio	1.156

Table 5: Comparison of Pre-compression parameter results of Batches A1-A7

Batch code	Angle of repose (θ)	Bulk density (Db) (g/ml)	Tapped density(Dt)(g/ml)	Carr's index (%)	Hausner ratio
A1	28.84	0.54	0.65	16.923	1.203
A2	26.51	0.55	0.638	13.793	1.16
A3	24.93	0.55	0.645	14.728	1.172
A4	24.93	0.55	0.646	14.860	1.174
A5	24.68	0.56	0.643	12.908	1.148
A6	23.99	0.53	0.614	13.680	1.158
A7	25.39	0.585	0.683	14.348	1.167

tablets, note down the weight of tablets, and perform the friability using Friabilator and report the weight of the tablet after 100 revolutions at 25 RPM. The limit for weight loss of conventional compressed tablets was 0.5 to 1.0 % (Velmurugan and Vinushitha, 2010).

$$\%Friability = 1 - \frac{(Final\ weight)}{(Initial\ weight)} \times 100 \quad (7)$$

Disintegration test

To check disintegration time for uncoated tablets was done in the 6 glass tube rack of basket USP disintegration apparatus. In each tube, one tablet was introduced, and this basket rack was positioned with one liter of water or simulated intestinal fluid at body temperature 37±2°C. Further, this assembly was positioned in the beaker containing 0.1N HCL and in which each tube contains a disc. Further, to move this basket assembly, a standard motor device was used at the frequency of 28-32 cycles per minute. To meet USP standards, the tablet should disintegrate, and all particles must pass through mesh size 10 in a mentioned time. Then the result of the disintegration time of all batches was recorded. The fast releasing tablets must disintegrate within 3 mins.

Average Weight

Weigh 20 tablets individually, and record the weights, calculate the average weight per tablet using the following calculation. (Mehta *et al.*, 2010).

Average wt. / tablet =

$$Total\ wt.\ of\ 20\ Tablets\ in\ gram \times \frac{1000}{20} \quad (8)$$

Dispersibility test

This test was done to check the time required for the tablet to disperse into the water. It was done by dropping the tablet into the 100ml of water. Further, visually observe for complete dispersion of tablets in water and note down the time taken. For dispersible tablets, according to IP, the dispersible time was not more than 3 min (Schiermeier and Schmidt, 2002).

Dissolution studies

This study was done in type II USP apparatus (paddle type) by using dissolution medium such as Phosphate buffer saline (PBS) of pH 6.8 at a maintained temperature 37 ± 0.5°C and rotation speed of 75 rpm. 5 ml Aliquots were withdrawn at intervals of 5, 10, 15, 20, 25, 30, 35, 40 min, and sink condition was maintained by replacing an equal volume of fresh medium. Then samples were filtered using a Whatman filter paper, and it was analyzed by using U.V. spectrophotometer at 235 nm. A total of 3 mean numbers trail was taken (Kuchekar *et al.*, 2009).

Release kinetic studies

The cumulative drug release obtained from the formulation was used to obtain release kinetics using mathematical models such as Zero-order, First-order, Higuchi, and Korsmeyer-Peppas model using BCP Software (Damodharan *et al.*, 2009).

Similarity Studies

The dissolution study for Oro-dispersible tablets was performed in PBS pH 6.8. The data obtained from dissolution studies were statistically analyzed by calculating $f1$ value and $f2$ value using BCP Software (Anupama *et al.*, 2011).

Stability Studies

Aluminum foil was used to pack the selected formulations and maintained in the stability chamber at 40○C ± 2○C/75% RH ± 5% for about six months. Their preformulation studies, drug content, and *in vitro* disintegration time at intervals of 2 months has been evaluated (Wagh *et al.*, 2010).

RESULTS AND DISCUSSION

Solubility

The obtained result of Cefpodoxime proxetil drug is highly soluble in methanol & ethanol and insoluble in water & chloroform. The studies were carried out using different buffer solutions. The drug is slightly soluble in all buffers but has shown maximum solubility in PBS 6.8 (0.343 mg/ml) and was selected as a dissolution medium for *in vitro* dissolution study, as shown in Table 2.

Fourier-transform infrared spectroscopy

FTIR spectra of pure drug and physical mixture of drugs and polymer were determined. The Functional groups obtained for the physical mixture of drugs and polymer were found to be in correlation with pure drug mixture peaks. As shown in Figure 1 and Table 3, the prominent peaks of physical mixture 3420 cm-1 (N-H Stretching); 3290cm-1(O-H Symmetric Stretching); 1500-1800cm-1(C=O, C=N, C-H Stretching) bending were noticed in the physical mixture. FT-IR spectroscopic interpretation results showed no interactions between drug mixture and polymer occurred because no change in the peaks was seen. Hence drug mixture and selected polymer were compatible with each other.

Differential scanning calorimetry

DSC curves obtained for pure Cefpodoxime proxetil, Croscarmellose, and Crospovidone showed in Figures 2, 3 and 4. The DSC thermograms of pure drug Cefpodoxime proxetil have shown a melting point sharp at 210ºC, and powder mixture of drug and excipients has shown the melting peak at 210ºC. Therefore, the endothermic peak of pure drug Cefpodoxime proxetil and physical mixture showed peaks identically at a specified range of temperature, which indicates all excipients are compatible with each other.

Pre-formulation studies

Pre-formulation study of the pure drug (Cefpodoxime proxetil)

The pre-formulation study was carried out for pure drug Cefpodoxime proxetil and final blent, which showed good flow property and met the pharmacopeia specifications, as shown in Table 4 and Table 5. Cefpodoxime proxetil in powder form was investigated for various physical parameters. The result revealed that it has better flow property, tapped density, bulk density, Carr's index, and Hausner ratio thereof confirmed its better flow property. Cefpodoxime proxetil and excipients in the blend state had evaluated for its Preformulation property as it has a great role in the preparation of the tablets. They showed better flow property, compressibility, and Hausner ratio that showed its better suitability for the direct compression.

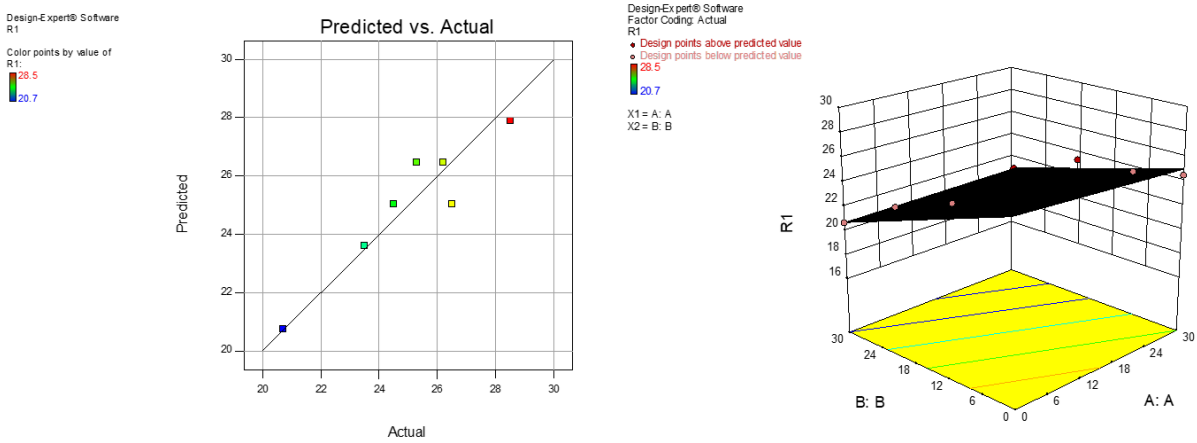
Optimization study by Two Factorial Designs: Evaluation ofthequantitative effects of the factors

ANOVA study is done with multiple regression analysis by using the software. It was calculated for the response that has been for statistical analyses of orodispersible tablets are implemented. The assessed factors' effects with p-values on the responses are shown in Table 6. It was found that factors A and B showed significant effects on responses with less than 0.05 P-value. It was noted that responses showed a significant effect on dispersible tablets, as shown in Figures 5, 6 and 7.

Evaluation Studies

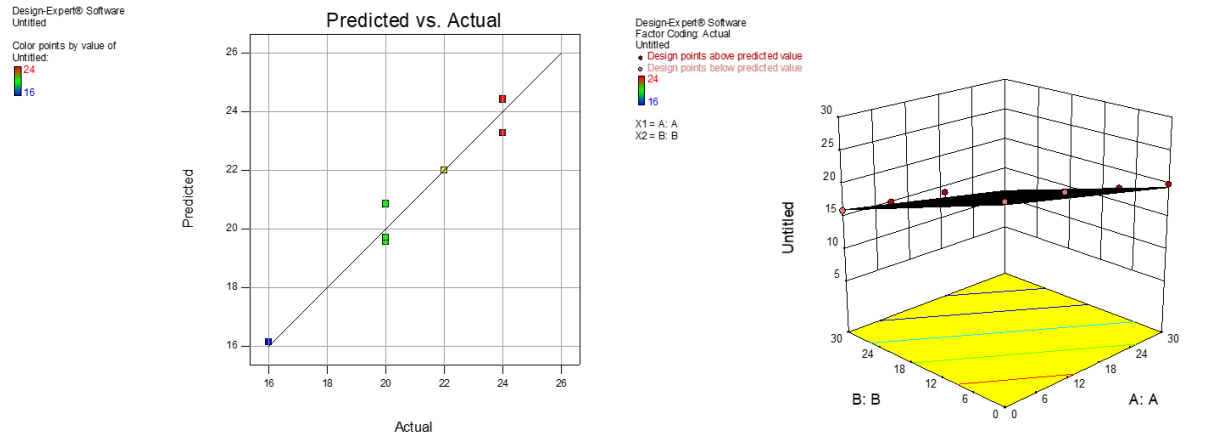
Drug content

The prepared tablet was tested for drug content.



(A) Predicted vs. actual (B) 3D surface plots of R1

Figure 5: R1 Disintegration time

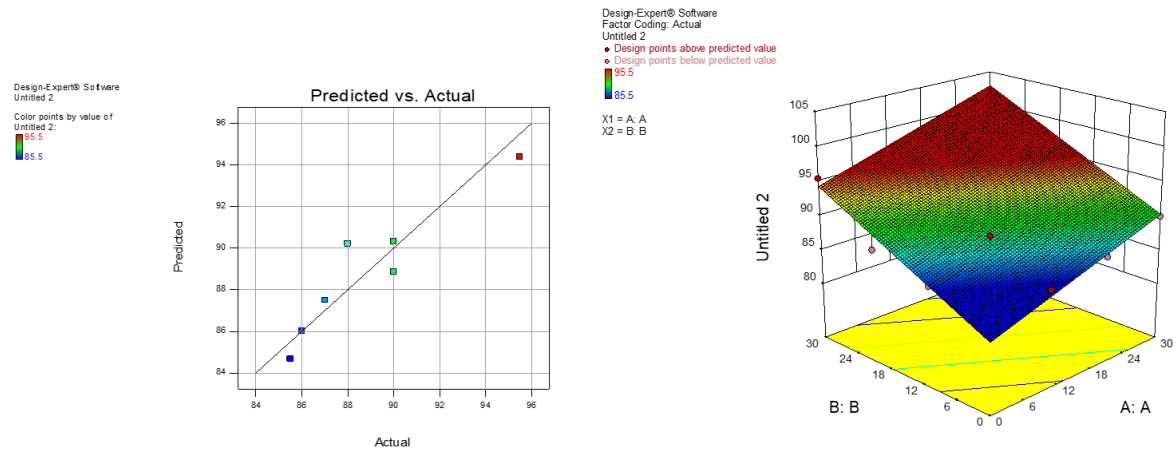


(A) Predicted vs. actual (B) 3D surface plots of R2

Figure 6: R2 Dispersion time

Table 6: 2^3 full factorial design layout and responses noted for tablet formulations

Formulation Run	Factor 1 A: A	Factor 2 B: B	Response 1	Response 2	Response 3
1	10	0	28.5	24	85.5
2	20	0	26.2	22	87
3	30	0	24.5	20	90
4	0	10	25.3	24	86
5	0	20	23.5	20	88
6	0	30	20.7	16	95.5
7	10	10	26.5	20	90



(A) Predicted vs. actual (B) 3D surface plots of R3

Figure 7: R3 % Drug release

The optimized formula A6 was found to be 99.60% and was within the range of 85-115%, which compiles the Pharmacopoeia specifications, as shown in Table 7.

Thickness

Thickness was measured for each tablet in a batch. The A6 thickness was found to be 3.31 mm that compiles the pharmacopeia specifications within ± 5%, as shown in Table 7.

Hardness test

The hardness was measured for the prepared tablets, and the hardness of the optimized formula A6 was found to be 3.80 kg. The hardness was within the optimum range of 3-6kg. Hence, the tablets passed hardness test, as shown in Table 7.

Friability test

The friability was measured for all the tablets. The friability for optimized formula A6 was found to be 0.67. Hence, the tablets passed the friability test, as shown in Table 7.

Disintegration test

The DT was measured for the optimized formulation. The DT was found to be 23.70 sec, complied with pharmacopeia specifications, as shown in Table 7.

Average weight

The average weight of optimized formula A6 was found to be 390 mg and, therefore, which compiles the limits, as shown in Table 7.

Dispersibility test

The dispersion time was measured for the optimized formulation A6, and it was found to be 16 sec, which was complied with pharmacopeia specifications, as shown in Table 7.

Wetting time and water absorption ratio

The water absorption ratio of all the formulations is depicted in Table 3, and the optimized formula A6 was found to be 90, as shown in Table 7.

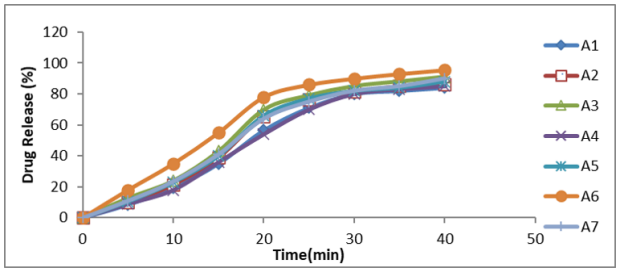


Figure 8: % Drug Release profile

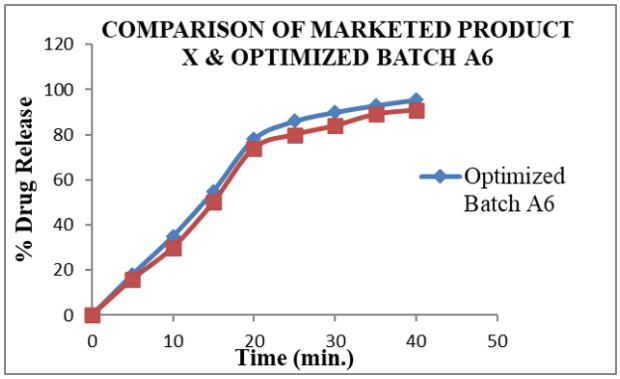


Figure 9: % Drug release resultof Optimized Batch A6 & Marketed Product X

Dissolution studies

Dissolution studies were performed in PBS 6.8 to

Table 7: Comparing the results of the post-compression parameter of all batches

Batch Code	A 1	A 2	A 3	A 4	A 5	A 6	A 7
Drug content	97.53	98.63	98.87	96.52	97.73	99.60	97.23
Thickness (mm)	3.35	3.39	3.31	3.45	3.37	3.31	3.33
Hardness (kg/cm^2)	4.50	4.20	3.80	3.50	4.20	3.80	4.60
Friability (%)	0.79	0.62	0.90	0.71	0.44	0.67	0.85
Disintegration Test (Sec)	31.90	25.20	29.25	25.30	27.0	23.70	28.80
Average weight(mg)	390	389	391	390	388	390	391
Dispersion time (sec)	24	22	20	24	20	16	20
Water absorption ratio	76.5	82.6	89.50	78.00	85.50	90.00	81.00

compare the dissolution profile of the pure drug Cefpodoxime Proxetil with marketed formulation (X). From the graph Figures 8 and 9, it was shown that CP tablets of optimized formula batch A6 and X had shown 95.50 % and 91.0 % release of drug in 40 minutes, respectively. Form this, it is clear that A6 shows better dissolution, and further studies can be carried out at the targeted site for bioavailability. The tablets containing Crospovidone 7.5% showed well *in vitro* disintegration, and that improved bioavailability of the drug, as shown in Tables 8 and 9. Moreover, the prepared tablets A6 have extra advantages like fast relief from infection, improved patient compliance, and quick onset of action.

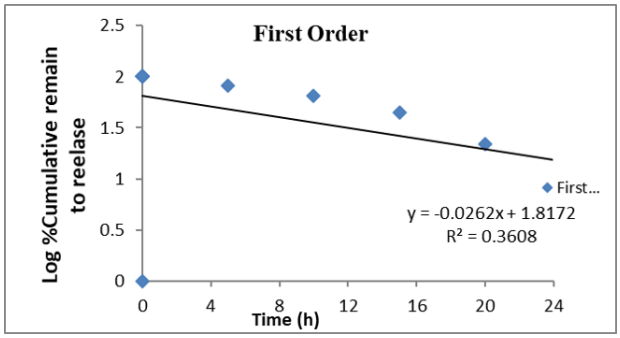


Figure 10: First-order kinetics plot of A6 formulation

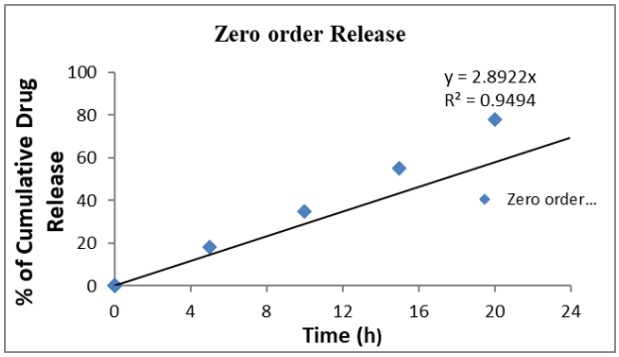


Figure 11: Zero-order kinetics plot of A6 formulation

Release kinetic studies

The optimized formula A6 in this study demonstrated good drug release over the remaining formulation. A6 formulation was further studied to check the drug release behavior. The solubility of the prepared formulation was enhanced due to its formulation procedure as the tablet is targeted to show better release in PBS 6.8 pH. Data obtained for dissolution in PBS 6.8 pH was further was applied to BCP software, and results were obtained. The optimized formulation A6 shows first-order kinetics, followed by a diffusion mechanism. To study the kinetic studies of A6 formulation, the values obtained from the *in-vitro* dissolution studies were fitted into various models, and results are shown in Table 10 and Figures 10, 11, 12 and 13. This overall observation shows that Optimized formulation A6 obeys first-order kinetics

Similarity studies

The result of the A6 formula and the marketed product X revealed to be similar from Table 11 and Figure 14 by using BCP Software.

Stability studies

The Optimized A6 formulation was kept at 40 ± 2°C with 75 ± 5% RH for about a period of 6 months. The different studies carried out for the tablets at the end of 2, 4, and 6 months. The A6 optimized

Table 8: Percentage of drugrelease profile

Time (min)	Percentage Drug Release (%)						
	A1	A2	A3	A4	A5	A6	A7
0	0	0	0	0	0	0	0
5	8.5±0.01	9.8±0.03	12.8±0.01	9±0.01	10.5±0.02	18±0.01	11±0.02
10	19.5±0.02	21.5±0.04	24±0.02	18±0.08	23±0.03	35±0.02	23.5±0.05
15	35±0.3	39±0.05	43±0.01	36±0.09	40±0.01	55±0.01	41±0.04
20	56.5±0.2	65.5±0.6	69.8±0.03	54±0.04	66±0.01	78±0.11	64±0.14
25	71±0.1	76.5±0.03	79±0.04	70±0.04	77±0.02	86±0.5	75±0.05
30	80±0.6	81.5±0.2	85±0.05	80±0.05	82±0.11	90±0.6	82±0.06
35	82±0.4	85±0.03	88±0.01	83±0.06	84±0.01	93±0.06	85±0.03
40	84±0.5	86±0.2	91±0.02	85±0.04	88±0.02	95.5±0.04	90±0.04

Table 9: % Drug Release result of Optimized Batch A6 & Marketed Product X

Time (mins)	% Drug Release	
	Optimized Batch A6	Marketed Product X
0	0	0
5	18	16
10	35	30
15	55	50
20	78	74
25	86	80
30	90	84
35	93	89
40	95.5	91

Table 10: Kinetics release studies of A6 optimized formula

Kinetic model	First-order kinetics	Zero-order kinetics	Higuchi model	Korsmeyer – Peppas model
R2	0.9494	0.3608	0.86	0.987

Table 11: Data on Similarity Studies

Time	Reference	Test	Rt-Tt	(Rt-Tt)2	|Rt-Tt|
0	0	0	0	0	0
5	16	18	-2	4	2
10	30	35	-5	25	5
15	50	55	-5	25	5
20	74	78	-4	16	4
25	80	86	-6	36	6
30	84	90	-6	36	6
35	89	93	-2.2	4.84	2.2
40	91	95.5	-1.5	2.25	1.5
			0	0	0
			0	0	0
N=9	Rt sum=514			(Rt-Tt)2sum= 149.09	|Rt-Tt|sum=31.07
Similarity factor(50-100)= 68.88345 (F2); Difference factor (0-15)= 6.167315(F1)					

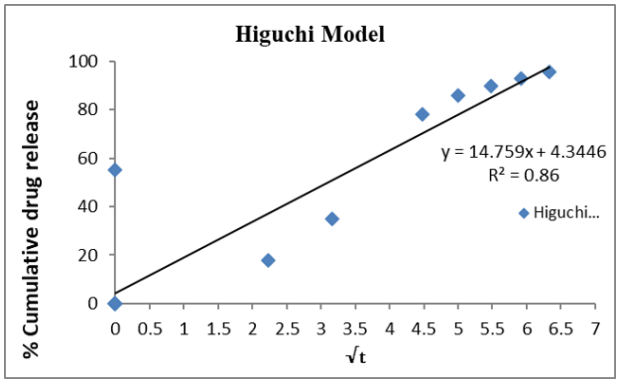


Figure 12: Plot of the Higuchi model of A6 formulation

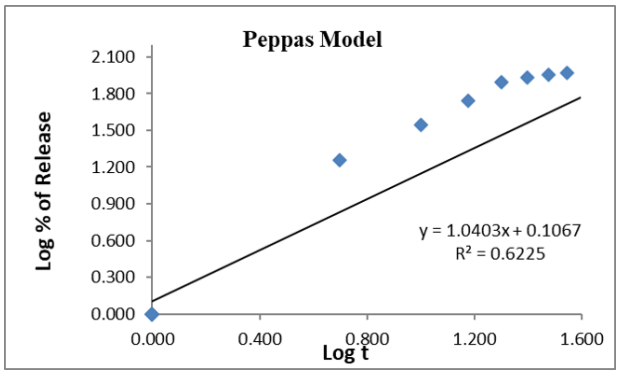


Figure 13: Plot of Peppas model of A6 formulation

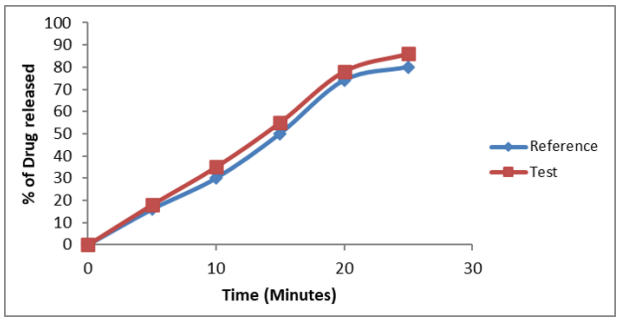


Figure 14: Graph of Similarity Factors Study

formulations were found to be physically and chemically stable for 6 months at stability conditions.

CONCLUSIONS

In the research work, Cefpodoxime Proxetil dispersible tablet was formulated using different concentrations of super disintegrants by direct compression technique, which passes all the precompression parameters such as bulk density, angle of repose, tap density, Carr's index, Hausner ratio and showed good flow property and compatibility. All the evaluation parameters were found to be within the range of Pharmacopoeia specifications. From the similarity data, results were found to be similar between A6 formulation and the marketed product X.

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Conflicts of Interest

The author confirms that this article content has no conflicts of interest.

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