



Development And Characterization Of Fast Dissolving Tablets

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Abstract:

The aim of this investigation was to develop fast dissolving tablets containing Cyproheptadine Hydrochloride, with the goal of achieving a high onset of action. Fast dissolving tablet of Cyproheptadine hydrochloride was prepared by using direct compression method, there were nine batches were prepared of fast dissolving tablets, by using super disintegrant as croscopolvidone, croscarmellose and SSG.

The fast dissolving tablets are evaluated for various parameters, the FDT of Cyproheptadine HCL containing croscopolvidone showed faster disintegration time at concentrations 5% as compare to other. Hence from all nine formulation batch B3 showed better result like drug content, disintegrating time, drug release hence this is our optimized batch. Also, B3 was found stable during the stability study for 2 months. Hence prepared Fast dissolving tablet was stable in all conditions.

Keywords: Fast Dissolving Tablets, Cyproheptadine, Direct compression

Introduction:

Fast dissolving Tablets

Fast dispersible tablets (FDTs) are the novel dosage form that quickly disintegrates in the mouth (1-3 min) without chewing upon oral administration and without the need for water, different other conventional oral solid dosage forms. The best time for a Fast-dissolving tablet to get separated is measured to be less than a minute. Mostly the disintegration times vary from 5 to 30 seconds and are prepared to recount; direct compression, solid dispersion, lyophilization, or molding techniques. FDTs are recognized by the addition of super disintegrants like cross-linked cellulose imitative; carboxymethyl cellulose, sodium starch glycolate, and polyvinylpyrrolidone, which provides rush breakdown when gets in exchange with water or salivary

secretions^[1-5]. The bioavailability of drugs may rise due to oral and pre-gastric absorption, reducing the first-pass metabolism in the gastrointestinal tract^[6-8].

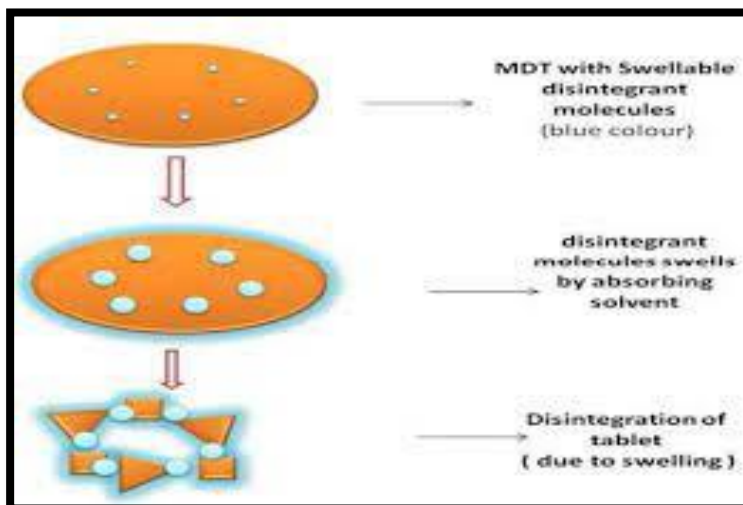


Figure 1. Mechanism of action of Fast dissolving tablet

1.2. Advantage of fast dissolving tablets (FDTs)

Fast-dissolving tablet shows the following advantages^[9-11].

- Improved stability.
- Suitable for controlled/sustained Offers improved compliance and convenience to patients and prescribers.
- It improves patient adherence and reduces the development of resistance in the case of antimicrobials.
- For Rapid drug delivery, FDTs are considered to be the preferred dosage form.
- The drug is released quickly from this dosage form and gets dissolved in the GIT tract without getting into the stomach, increased bioavailability can be achieved.
- FDTs are very convenient for administering to various classes of patients from the disabled, travelers, and busy people, who do not always have access to water.
- Some drugs are absorbed from the pharynx and esophagus as the saliva passes down into the stomach; in such cases, the bioavailability of drugs is increased.
- No water needed.
- No chewing needs
- Release actives
- Allow high drug loading

1.3 Limitations of fast dissolving tablets (FDTs) [9-10, 12-14]

- Rapid drug therapy intervention is not possible
- Sometimes may require more frequency of administration
- Dose dumping may occur
- Reduced potential for accurate dose adjustment
- For proper stabilization and safety of the stable product, FDT requires special packaging
- Leave unpleasant taste and/or grittiness in the mouth if not formatted properly.

MATERIALS

Drug: Cyproheptadine hydrochloride

Table 1. Details of Active Pharmaceutical Drugs Used

Sr. No	Name of drug	Sample Supplier	Potency
1.	Cyproheptadine hydrochloride	Tagoor Laboratories.	99.99%

Excipients:**Table 2.** Details of Excipients Used in Formulation

Sr. No	Excipients Name	Suppliers
1	Lactose	Aarti Chemicals. Mumbai
2	Magnesium stearate	Aarti Chemicals. Mumbai
3	Crospovidone	Aarti Chemicals. Mumbai
4	Polyethylene glycol 6000	Aarti Chemicals. Mumbai
5	Croscarmellose sodium	Aarti Chemicals. Mumbai
6	Talc	Aarti Chemicals. Mumbai
7	SODIUM STARCH GLYCOLATE(SSG)	Aarti Chemicals. Mumbai
8	MCC	Aarti Chemicals. Mumbai

RESULT & DISCUSSION: -**Preformulation studies:**

Preliminary physicochemical properties of Cyproheptadine hydrochloride powder were investigated by performing tests for the organoleptic properties of the drug, Test purity, and flowability test. The result of characterizations of pure drugs is shown in

Table 3. Organoleptic properties of Cyproheptadine hydrochloride powder

Sr. No	Parameters	Observation/Result
1	Colour	White- light yellow Powder
2	Odour	Odorless

Table 4. Solubility of Cyproheptadine hydrochloride powder

Sr. No	Solubility	Observation/Result
1	Water	Insoluble
2	Methanol	Soluble
3	Phosphate buffer pH-6.8	Soluble

Table 5. Melting point of Cyproheptadine hydrochloride powder

Sr. No	Melting point	Observation/Result
1	Cyproheptadine hydrochloride powder	165°C

DISCUSSION

Based on the above physical characterization of Cyproheptadine hydrochloride, after observation

the solubility of the drug and melting point matches with the reference data which confirms the purity of the drug. But the drug is belonging BCS –II class and hence shows very poor water solubility that's the way to enhance the solubility of a drug in water using the solubility enhancement method by preparing solid dispersion of the drug.

λ_{\max} determination of Cyproheptadine hydrochloride

In buffer pH 6.8 Cyproheptadine hydrochloride gives maximum absorbance (λ_{\max}) at 252nm shown in **Figure 2**.

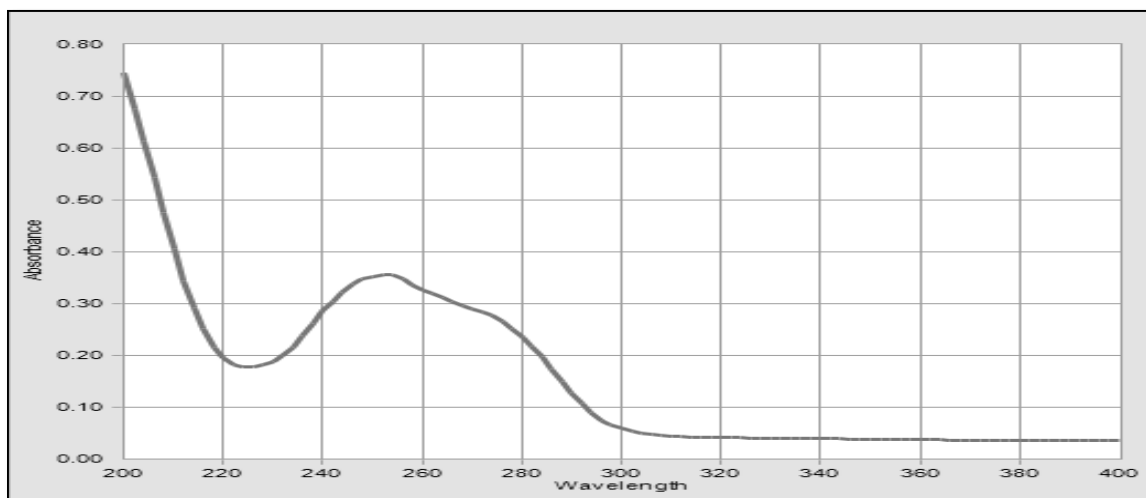


Figure 2. λ_{\max} of Cyproheptadine hydrochloride

The absorption maximum (λ_{\max}) was observed at 252 and the absorbance of a series of solutions (1-30 $\mu\text{g ml}$) was recorded at that λ_{\max} . The standard curve and calibration date of Cyproheptadine hydrochloride are shown in **Figure 2** and **Table 6**.

Calibration curves of Cyproheptadine hydrochloride

Table 6. Calibration data of drug at 252nm

Sr.no	Concentration(($\mu\text{g/mL}$)	Absorbance
1	0	0
2	5	0.126
3	10	0.305
4	15	0.448
5	20	0.605
6	25	0.713
7	30	0.912
Slope	0.030	
R ²	0.997	
Equation	$y = 0.030x - 0.006$	

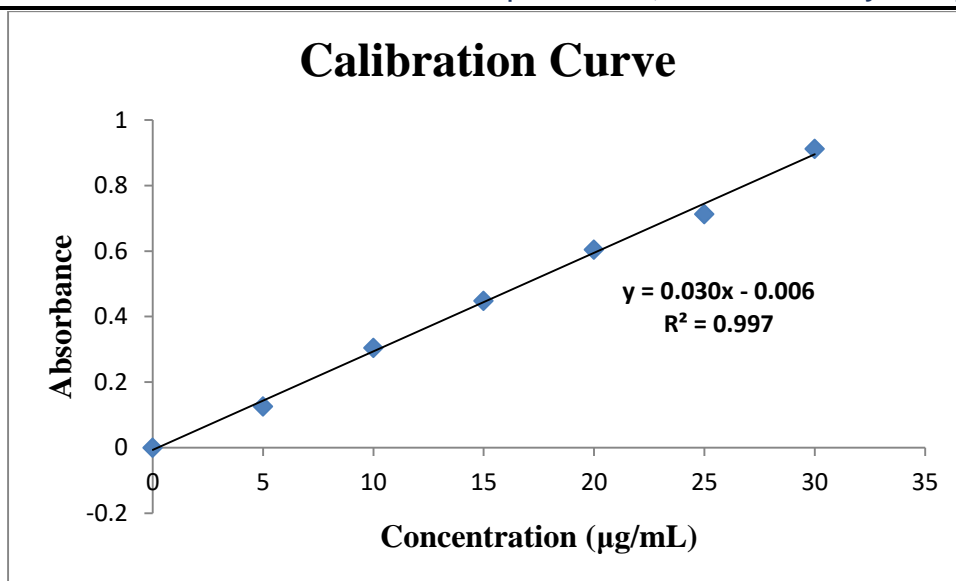


Figure 3. Calibration curve of Cyproheptadine hydrochloride in 6.8 Phosphate buffer at 252 nm

DISCUSSION:

In calibration curves the r^2 & the regression equation (y) for Cyproheptadine hydrochloride were calculated indicating the capability of the developed method to estimate both the drugs over the desired concentration range. The mean regression equations were found as $y = 0.030x - 0.006$ the intercept, slope, and regression coefficient (R²) were found to be 0.003 and 0.006, respectively. The result shows that there is an excellent correlation between the peak area ratios and the concentrations of drugs in the range tested.

Drug Excipient Compatibility Study

Fourier Transmission Infra-Red (FT-IR) Studies

Before formulation, preformulation study was carried out by comparing FT-IR spectra of pure Lamivudine and its physical mixture with super-disintegrants using Fourier Transmission Infrared spectrophotometer. There was no difference in their spectra. It was observed that the drug remained intact in the presence of Superdisintegrants.

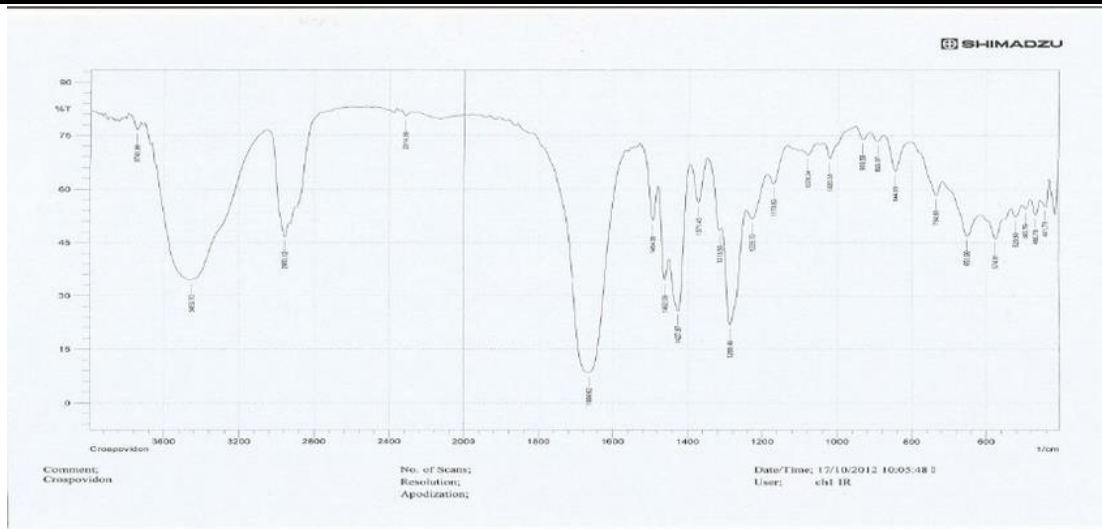


Figure 4. FTIR Spectra of Crosspovidone

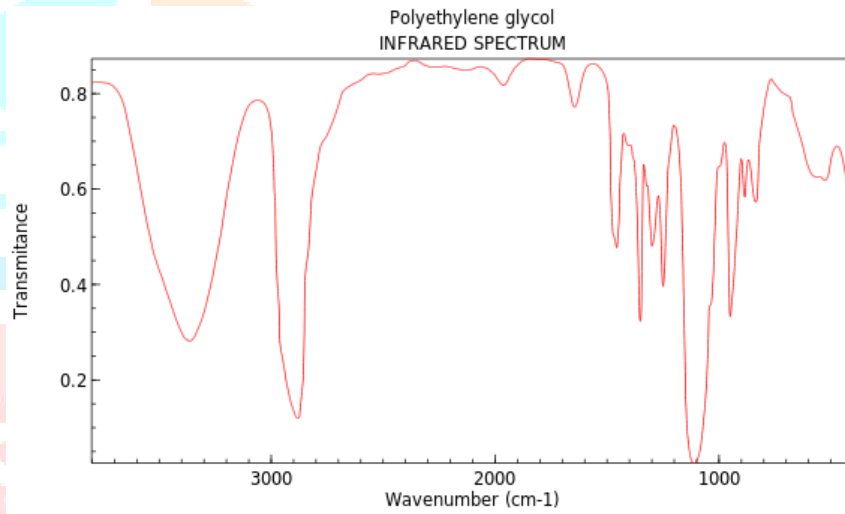


Figure 5. FTIR Spectra of PEG 6000

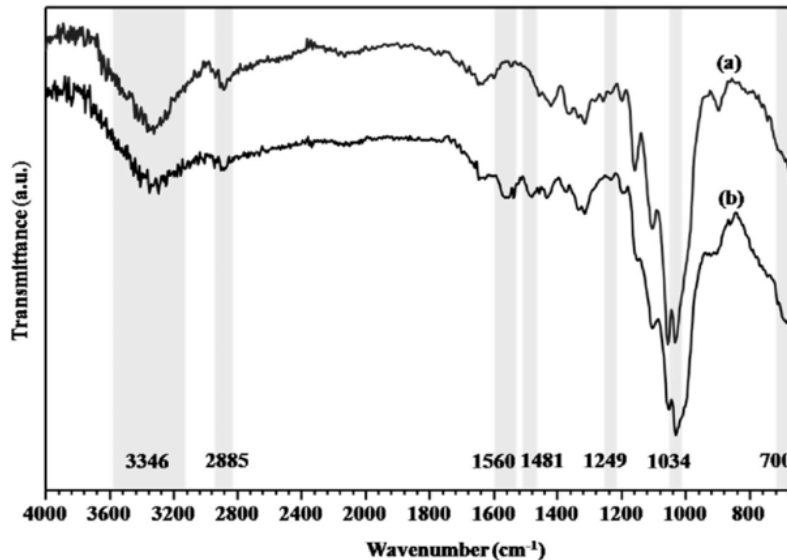


Figure 6. FTIR Spectrum of (a) MCC and (b) MMCC

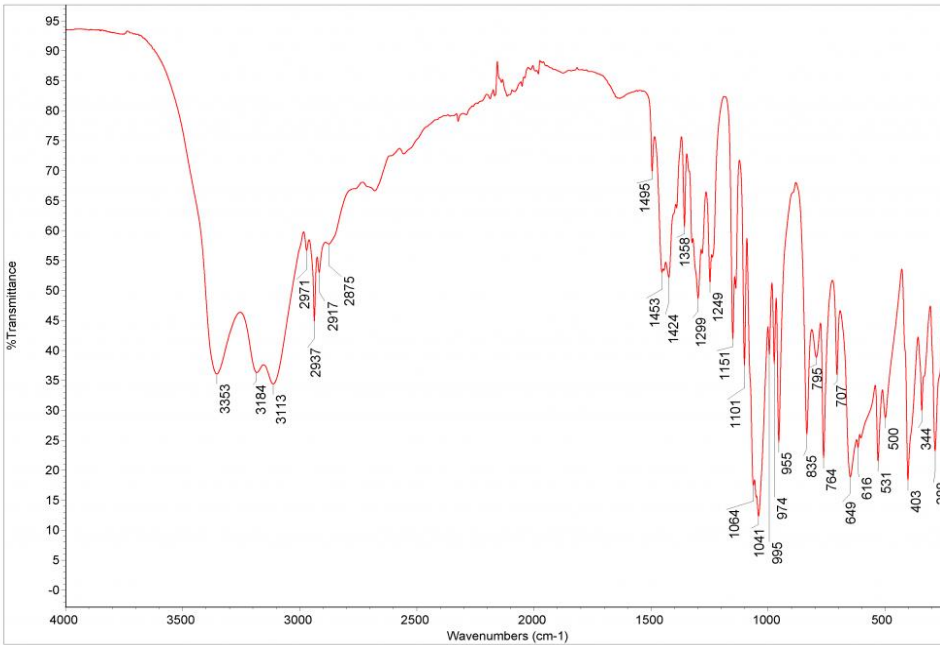


Figure 7. FTIR of Lactose

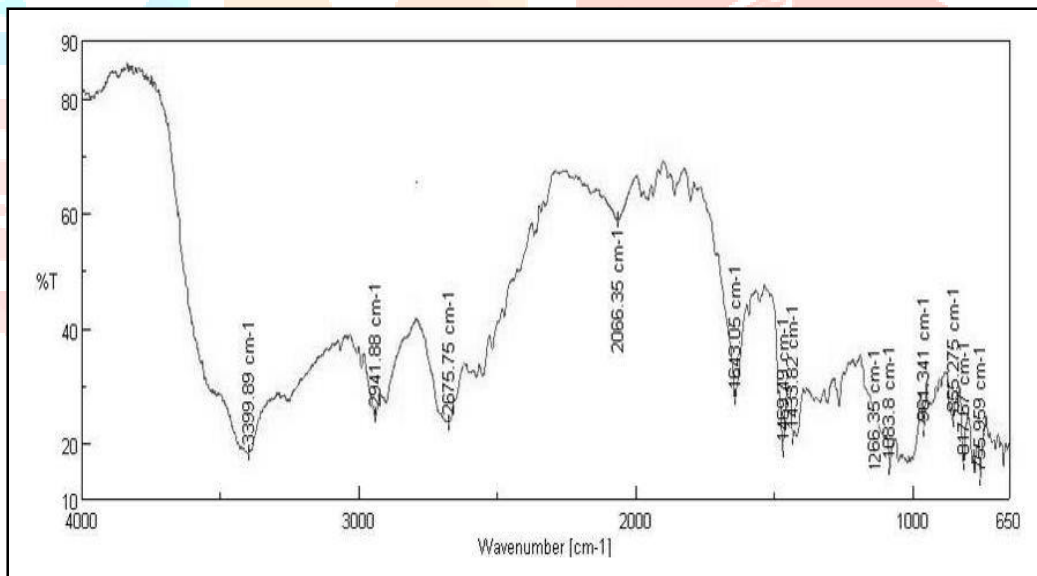


Figure 8. FTIR Spectra of Solid Dispersion

Table 7. FTIR spectra observation of Cyproheptadine hydrochloride and Physical mixture

Stretching	Drug peak (cm ⁻¹)	physical mixture peak(cm ⁻¹)
N-H	3398.92 cm ⁻¹	3399.89 cm ⁻¹
Aromatic Phenyl	1591.5 cm ⁻¹	1592.0cm ⁻¹
C-N stretch	1267 cm ⁻¹	1267 cm ⁻¹
C-H stretch	1082.83 cm ⁻¹	1083.8 cm ⁻¹

From the table it was observed that the group present in pure drug like N-H, Aromatic phenyl, C-N, C-H these similar group are present in FTIR spectra of physical mixture (drug+polymer). Hence concluded that there is no interaction between drug and polymer they are compatible to each other.

Evaluation of Solid Dispersion of Cyproheptadine hydrochloride

Solubility study of Solid Dispersion

Enhancement of solubility of Cyproheptadine hydrochloride was performed by solid dispersion method by preparing solid dispersion of Cyproheptadine hydrochloride and PEG 6000 was taken in the ratio of, 1:0.5, 1:0.75, and 1:1.

The evaluation of the prepared solid dispersion physical appearance, and % Drug Content and In vitro dissolution study was performed. The result of all tests summarized in **Table 8**.

Table 8. Evaluation data of prepared solid dispersion

Sr .no	Solid dispersion	Water Solubility (Mg/mL)
1	Drug	0.039
2	SD1	0.052
3	SD2	0.084
4	SD3	0.95

Water solubility of pure drug was found to be 0.039mg/ml and solid dispersion were found to be 0.052, 0.084, 0.95. Solid dispersion ratio 1:1 showed highest water solubility hence this ratio is selected for further preparation of fast dissolving tablet.

Dissolution study of Solid Dispersion and Pure Drug

% drug release from pure drug and both three SD1, SD2, and SD3 were performed for different times 10, 20, 30, 40, 50, and 60 min. The observation data are given in **Table 9**.

Table 9. %Drug release study of Cyproheptadine Hydrochloride Solid Dispersion

Time(min)	PURE DRUG	SD1	SD2	SD3
0	0	0	0	0
10	6.34	15.07	19.76	28.88
20	15.12	30.44	37.11	40.15
30	19.54	38.23	48.53	55.56
40	25.03	44.76	55.78	66.35
50	30.00	48.98	65.89	76.88
60	39.67	80.60	89.90	97.09

Evaluation parameters of Cyproheptadine hydrochloride solid dispersion checked and concluded that in all ratio solid dispersion, the white color mixture obtained which have drug content range 95.8%-98.7%. Solid dispersions of Cyproheptadine hydrochloride with PEG 6000 in different ratios showed an enhancement in the drug dissolution rate, Also the dissolution data shows that compare to pure drug and other ratios 1:1 ratio of Cyproheptadine hydrochloride and PEG 6000 give satisfactory drug release, so it was concluded that 1:1 ratio of solid dispersion was optimized for further development. Drug release of pure drug within 60min showed 39.67% and solid dispersion showed 80.60,89.90,97.09 %drug drug release .

Pre-Compression Evaluationsof Tablet Blend

The results of the pre-compression parameters evaluated were within limits and indicated good free-flowing property which is described in **Table 7.9**.

Table 10. Pre-compression evaluation data of tablet powder

Formulation Batches	Angle of repose(θ) \pm SD (n=3)	Bulk Density \pm SD (n=3) gm/cc	Tapped Density \pm SD (n=3) gm/cc	Compressibility \pm SD (n=3) gm/cc	Hausner's ratio \pm SD (n=3) gm/cc
B1	30.6 \pm 04	0.452 \pm 0.01	0.536 \pm 0.07	15.67 \pm 1.9	1.19 \pm 0.8
B2	27.6 \pm 8.0	0.438 \pm 0.02	0.570 \pm 0.01	17.51 \pm 0.9	1.21 \pm 0.4
B3	28.9 \pm 01	0.465 \pm 0.07	0.530 \pm 0.01	18.47 \pm 0.9	1.23 \pm 0.1

B4	25.8±1.8	0.436±0.04	0.531±0.05	17.89±09	1.22±0.4
B5	29.5±1.9	0.429±0.08	0.571±0.05	16.29±08	1.24±0.6
B6	30.37±0.27	0.39±0.26	0.52±0.35	23.57 ±07	1.18±0.2
B7	30.63±0.34	0.41±0.34	0.49±0.29	22.32 ±03	1.17±0.1
B8	31.93±0.34	0.43±0.24	0.51±0.18	21.27 ±05	1.24±0.7
B9	30.56±0.34	0.42±0.29	0.52±0.21	19.34±06	1.18±04

DISCUSSION

Pre-compression parameters of tablet blends were checked to confirm the flow properties from the results of pre-compression parameters it can conclude that the blend flow was good enough to help the compression.

- A. **Angle of Repose:** The angle repose of all the formulations ranges from 25 to 30'. It was evident from the results, that the powder blends of all formulations possess good flow properties. The results of angle of repose for all the formulations are shown in Table - 7.9
- B. **Bulk Density:** The bulk density of all formulations ranges from 0.39±0.26g/cm² to 0.46±0.07g/cm'. The results indicate that the powder blends of all formulations were having good flow properties. The results are shown in Table-7.9
- C. **Tapped Density:** The tapped density of all the formulations ranges from 0.49±0.29g/cm³ to 0.57±0.05g/cm from the results, it was inferred that the powder blend of all formulations possesses good flow properties. The results of all the formulations are shown in Table -7.9
- D. **Compressibility Index:** The compressibility index of all the formulations ranges from 15.67±19 to 23.57±07. The results indicate that the powder blend of all formulations possess good flow properties. The results of all formulations are shown in Table - 7.9
- E. **Hausner's Ratio:** The Hausner's ratio for powder blends of all formulations ranges from 1.17±0.1 to 1.24±0.7 however from the results that the powder blends of all formulations have good flow properties partier except. The results are shown in Table 7.9 >1.25-poor flow property <1.25-Good flow >1.25-poor flow property

It was evident from the results of the pre-compression studies, that the powder blends of all nine formulations possess good flow properties, which were within the standard limits and were qualified for compression into Tablets.

Post Compression Evaluation Parameters:

Tablets were subjected to post-evaluation parameters like weight variation test, thickness, hardness, friability, wetting time, water absorption test, drug content, disintegration test, and dissolution. The results were recorded for all the evaluation parameters shown in **Table 7.10**.

Table 11. Post-compression evaluation data of tablet

Formulation	Average weight tablet(mg) \pm SD	Thickness (mm)	Hardness (Kg/cm ²) \pm SD	Friability %
B1	100 \pm 0.19	3.24	3.14 \pm 0.25	0.53
B2	101 \pm 1.16	3.12	3.69 \pm 0.25	0.45
B3	100 \pm 0.11	3.20	3.12 \pm 0.27	0.41
B4	100 \pm 1.18	3.32	3.20 \pm 0.25	0.59
B5	98 \pm 1.04	3.23	3.47 \pm 0.27	0.84
B6	100 \pm 0.78	3.21	3.51 \pm 0.25	0.81
B7	100 \pm 1.81	3.32	3.12 \pm 0.27	0.72
B8	99 \pm 1.89	3.13	3.20 \pm 0.25	0.64
B9	98 \pm 1.99	3.36	3.50 \pm 0.27	0.73

Hardness

The hardness for tablets of all the nine formulations was found to be 3.12-3.232 kg/cm².

Weight Variation Test

The weight variation for tablets of all formulations was found to be within the limit as per IP. The results indicate that all tablets of each formulation were of uniform weight.

% friability

The friability for tablets of all the nine formulations was found to be 0.41 % to 0.84%.

All the formulations among that B3 optimized batch containing super disintegrating agents crosspovidone .

The friability of B3 formulation was found to be 0.41%.

Friability below 1% was an indication of good mechanical resistance. The results indicate that the friability for tablets of all formulations were below 1% and hence pass the test.

Thickness

The thickness for all nine formulation was found to be 3mm the result indicate that the tablet of all formulation were of uniform size.

% Drug Content, Wetting time, and Disintegration time:

% Drug Content for all batches checked and found well within acceptable limits. As the MCC was in formulation, the ratio was good in all batches. Wetting time and Disintegration time both parameters were important for FDT formulation. Both the parameters were evaluated given in **Table 12**.

Table 12. Post-compression evaluation data of tablet

Formulation	Drug content (%)	Wetting time (sec)	Disintegration time (sec)
B1	96.8	49	67
B2	97.2	41	60
B3	99.7	40	48
B4	96.9	64	76
B5	98.1	62	70
B6	95.54	60	68
B7	96.98	71	85
B8	96.99	69	80
B9	97.01	65	78

Drug Content

The drug content for batches of all the nine formulations was found to be 95.54% to 99.7. The results are shown in Table-. The highest drug content was found in batch B3 formulation was found to be 99.7.this is our optimized batch.

Wetting time

The wetting time for all the nine formulation was found to be 40 to 71 sec due to highest concn.of super disintegrant croscopolidone batch B3 showed less wetting time 48 sec .

Disintegration time

The disintegration time for tablets of all the nine formulations was found between 48 to 85 sec. The results of disintegration time reveal that the amount of Croscopolidone significantly affects Disintegration times. It also

shows that the amount of Crospovidone in the formulation was an optimum impact up to 5mg. After that, the DT time was increased. The formulated batch B3 among all batches, less DT time which contains 5mg of Crospovidone.

In-vitro % Drug Release

In-vitro dissolution studies for all the formulated tablets of Cyproheptadine hydrochloride were carried the result were shown in **Table 7.12**.

Table 7.12: Drug release study of Cyproheptadine hydrochloride Fast dissolving tablet

Time (min)	B 1	B2	B3	B4	B5	B6	B7	B8	B9
0	0	0	0	0	0	0	0	0	0
2	11.65	20.6	25.9	15.3	15.76	19.1	11.3	11.9	15.6
4	30.98	29.4	41.5	25.54	33.76	36.8	31.6	30.09	35.9
6	43.87	45.6	56.9	40.65	45.87	49.6	55.9	56.87	59.6
8	50.26	59.7	62.98	50.98	54.98	57.98	65.7	68.12	71.9
10	62.87	67.5	69.98	60.54	67.98	72.8	72.5	73.65	76.8
12	70.98	74.9	73.78	70.80	74.76	76.09	78.9	79.98	81.5
14	76.98	77.21	79.8	77.78	79.32	81.87	82.5	84.21	86.9
16	79.72	81.98	85.6	80.65	83.76	88.98	86.1	87.6	89.98
18	89.09	84.6	91.9	83.98	91.98	95.1	88.2	90.6	91.87
20	91.87	96.98	98.9	89.09	94.76	97.57	92.1	93.5	95.4

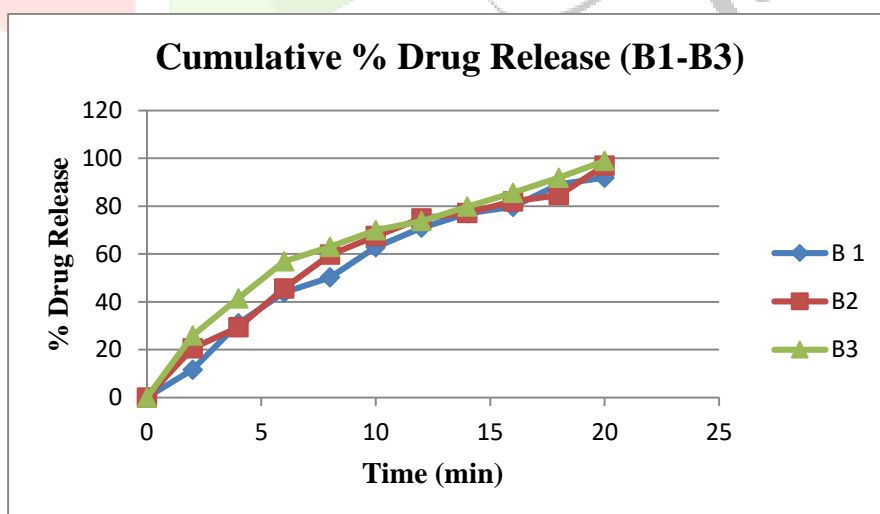


Figure 7.5 (a): Drug release study of Cyproheptadine hydrochloride fast-dissolving tablet (B1-B3)

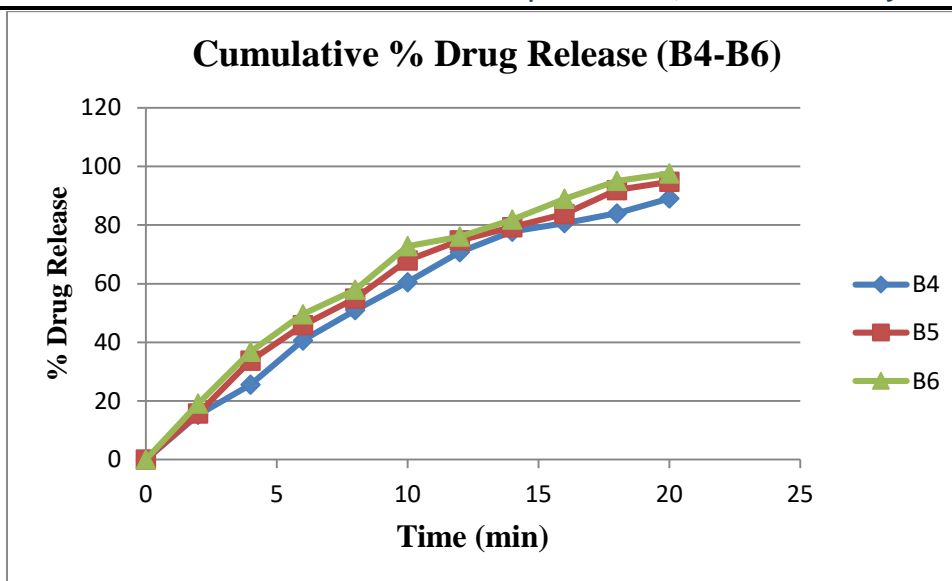


Figure 7.5 (b) : Drug release study of Cyproheptadine hydrochloride fast-dissolving tablet (B4-B6)

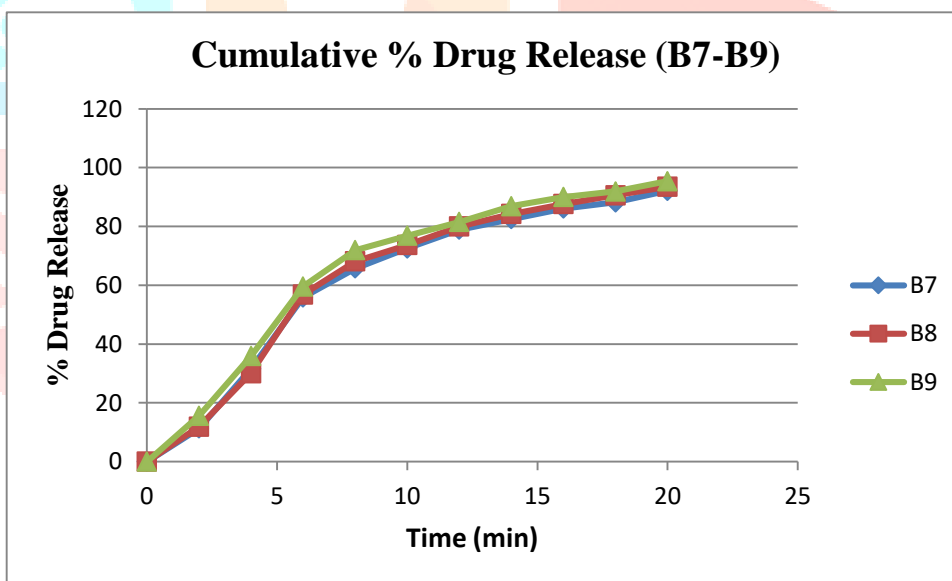


Figure 7.5 (c): Drug release study of Cyproheptadine hydrochloride fast-dissolving tablet (B7-B9)

DISCUSSION:

Dissolution study of all batches performed. The drug release shows the clear impact of Crospovidone. Additionally, the higher the amount of Crospovidone the drug release was faster as the DT time is low. Hence batch B3 which contains 5 mg Crospovidone and 2 mg binder released in 20min more than 98.9% of the drug. Hence the Batch B 3 batch was selected as an optimized batch.

Stability Studies

Optimized batch B3 taken for a 2-month stability study at **40°C and 75% RH**. Initial results and after 2-month results were compared for any loss or change during stability. The results of the initial and after 2months were recorded which was given in **Table 7.13**.

Table.7.13. Stability study of optimized batch B3

Parameter	At 0 month	At 1 month	At 2 month
Appearance	White color round tablet	White color round tablet	White color round tablet
Average Weight (mg)	103 ± 3	103 ± 2	103 ± 2
Disintegration time(sec)	48 sec	49 sec	49sec
% Drug Content	96.9	96.7	96.7
% Drug release after 20 min	99.9	99.8	99.8

DISCUSSION: Batch B3 was found stable after 2 month and results were found satisfactory hence prepared fast-dissolving tablet was stable in all conditions.

CONCLUSION

Fast dissolving tablet of cyproheptadine hydrochloride was prepared by using direct compression method the evaluation parameter showed all batches were lies within the official standard limit. The fast dissolving tablet by using super disintergerant as crosspovidone ,croscarmellose,SSG showed better result.

The FDT of cyproheptadine HCL by using crosspovidone showed faster dis intergration time at

concentrations 5% as compare to other. Hence from all nine formulation batch B3 showed better result like drug content, disintegrating time, drug release hence this is our optimized batch. Also, B3 was found stable during the stability study for 2 months. Hence prepared Fast dissolving tablet was stable in all conditions.

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