

Original Article

Design and characterization of solid dispersion based fast dissolving tablet of Cetirizine hydrochloride

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ABSTRACT

The aim of present investigation was to prepare fast dissolving tablets (FDT) of an antiallergic drug Cetirizine hydrochloride to increase its clinical effects and bioavailability through pre-gastric absorption. The solubility of this poorly soluble drug was enhanced by preparing its solid dispersions with colloidal Silicon dioxide in various ratios. The surface morphology (SEM) of solid dispersion revealed its amorphous form compared to needle shape crystals of pure drug. The optimized batch of solid dispersions (SD3) were characterized by DSC and XRD studies and further developed into FDT by using different concentration of super disintegrants like Sodium starch glycolate and Crosscarmellose sodium via direct compression method. The pre-compression and post-compressive parameters for the designed tablets were evaluated. All formulations showed desired pre and post-compressive characteristics. FTIR study revealed that there was no drug excipient interaction. Formulation (F3) was selected as the best formulation with maximum amount of drug release i.e. $99.98 \pm 0.14\%$ in 6 min and minimum disintegration time of 2.76 ± 0.1 sec. Stability studies of optimized formulation revealed that formulation is stable. Hence, efficacious allergic treatment anywhere and anytime particularly for geriatric, pediatric, mentally ill, bed ridden and patients who do not have easy access to water could be possible.

1. INTRODUCTION

Allergic disorders are most common worldwide. Cetirizine hydrochloride (CTZ) is an orally active and selective H₁-receptor antagonist used in seasonal allergic rhinitis, perennial allergic rhinitis and chronic urticaria. CTZ is a white, crystalline water soluble drug possessing bitter taste properties [1]. Patients, particularly pediatric and geriatric patients, have difficulty in swallowing solid dosage forms. These patients are unwilling to take these solid preparations due to a fear of choking. In order to assist these patients, several fast dissolving drug delivery systems has been developed. Mouth fast dissolving tablets undergo disaggregation in the mouth when in contact with the saliva in less than few seconds forming a suspension which is easy to swallow. The desired criteria for the FDT they should have a pleasing mouth feel, Leave minimal or no residue in the mouth after oral administration and not require water to swallow,

but it should dissolve or disintegrate in the mouth in a matter of seconds [2].

Solid dispersion represents a useful pharmaceutical technique for increasing the dissolution, absorption and therapeutic efficacy of drugs in dosage forms. The formulation of poorly soluble compounds for oral delivery now presents one of the greatest and most frequent challenges to formulation scientists in the pharmaceutical industry [3]. The use of solid dispersions of drugs in water soluble carriers, in which the drugs are highly soluble; to increase the dissolution rate and bioavailability of poorly soluble drugs have been studied extensively. This technique provides a means of reducing particle size to nearly a molecular level. As the soluble carrier dissolves, the insoluble drug is exposed to the dissolution medium as very fine particles for quick dissolution and absorption [4].

The purpose of this research was to design Cetirizine hydrochloride fast dissolving tablets by using solid dispersion of Cetrizine HCL and colloidal silicon dioxide which is a hydrophilic carrier. Solid dispersion were formulated to increase the solubility, dissolution rate, bioavailability, mask the bitter taste of Cetirizine hydrochloride and to improve patient compliance especially pediatric and geriatric patients.

2. MATERIAL AND METHODS

Cetirizine hydrochloride was a gift sample from Vitthal Pharmaceuticals Ltd., Agra, India. Colloidal Silicon dioxide, Microcrystalline cellulose, Croscarmellose sodium, Sodium saccharin, Sodium stearyl fumarate were purchased from S.D. Fine Chemicals, Mumbai, India. All other chemicals, solvents and reagents were used of either pharmacopoeial or analytical grade.

2.1 Preparation of solid dispersion

Solid dispersion of cetirizine hydrochloride was prepared by solvent evaporation method using carrier such as colloidal silicon dioxide in different ratio 1:1, 1:2 and 1:3 (Table 1). The weighed quantity of drug and colloidal silicon dioxide was taken in china dish and ethanol was added. The solvent was removed under vacuum at 40°C in a rotary flash evaporator at 45 rpm for 2 hrs. Solid residue was dried in a vacuum oven for 24 hours at room temperature to remove the residual solvent, pulverized and sieved using sieve # 80. Powder samples were stored in a closed container away from light and humidity in a dessicator until use [5, 6].

Table 1. Composition of Cetirizine HCl solid dispersions

Formulation code	Composition ratio (Cetirizine HCl : colloidal silicon dioxide)
SD1	1:1
SD2	1:2
SD3	1:3

2.2 Evaluation of Solid Dispersions

2.2.1 Estimation of drug content

The solid dispersion equivalent to 10 mg of cetirizine hydrochloride was weighed and transferred to volumetric flask containing 0.1 N HCl buffer. The flask was sonicated for 10 min, the content of each flasks were then filtered through 0.45 µm membrane filters. The sample was diluted and analyzed spectrophotometrically at 233 nm [7].

2.2.2 Dissolution studies

The quantity of solid dispersion, which will theoretically contain a drug content of 10 mg of drug, was calculated from each drug

loaded batch. The in vitro dissolution studies were done to compare the rate of dissolution of solid dispersions with that of pure drug Cetirizine HCL (CTZ) and physical mixtures of drug and carrier (PM). The test was performed in USP II apparatus using 900ml phosphate buffer solution at pH 6.8, 50 rpm and temperature 37± 1°C. The drug content was analyzed by UV Spectrophotometer at 230 nm. The change in amount of drug release after formation of solid dispersion and physical mixture of the drug and carrier were compared [8].

2.2.3 Scanning Electron Microscopy (SEM)

The SEM analysis was carried out using scanning electron microscope (S3400, Hitachi, JAPAN). Prior to examination, samples were mounted on an aluminum stub using a double sided adhesive tape and then making it electrically conductive by coating with a thin layer of gold (approximately 24 nm) in vacuum. The scanning electron microscope was operated at an acceleration voltage of 15 KV. The surface morphology of pure drug and optimised solid dispersion was examined [9].

2.2.4 Differential Scanning Calorimetry (DSC)

DSC analysis was performed for pure drug, physical mixture and optimised solid dispersion using METTLER DSC 30S, Mettler Toledo India Pvt. Ltd., Switzerland, using crucible Al 40µL, at of 100C /min heating rate, under nitrogen environment. The temperature range used was 0 – 400°C [10].

2.2.5 Powder X-ray Diffraction

Samples of pure drug and optimised solid dispersion were evaluated using a Kristalloflex 810 Siemens diffractometer. The samples were radiated using Ni filtered CuKa radiation operated at 40 kV and 30 mA. The samples were scanned from 5° to 45° (2θ) at scanning speed of 0.5 θ/min [11].

2.3 Preparations of fast dissolving tablets of optimised solid dispersion

Fast dissolving tablets (FDT's) of optimized solid dispersion were prepared by direct compression method according to formula given in Table 2. All the ingredients such as microcrystalline cellulose, DC-mannitol, were passed through mesh # 40. Superdisintegrants i.e sodium starch glycolate and Croscarmellose sodium was mixed by taking small portion of it in ascending order and blended to get a uniform mixture in a mortar. Blends were directly compressed on a 16- station single rotary tableting press (Type – CMD3 – 16. Cadmach Machinery Pvt. Ltd., Ahemdabad) using an 8-mm standard flat punch by direct compression technique. Dwell time was set at 30 ms and the compaction force varied from 4 to 12 kN [12-14].

Table 2. Composition of FDT of optimised solid dispersion of Cetirizine hydrochloride

Ingredients (weight in mg)	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)
Solid dispersion (SD3)	25	25	25	25	25	25
Sodium starch glycolate	20	25	30	-	-	-
Crosscarmellose sodium	-	-	-	20	25	30
Sodium saccharin	10	10	10	10	10	10
Sodium stearyl fumarate	10	10	10	10	10	10
DC-Mannitol	15	15	15	15	15	15
Purified talc	10	10	10	10	10	10
Avicel PH 102 (Microcrystalline cellulose)	qs	qs	qs	qs	qs	qs

2.4 Evaluation of prepared fast dissolving tablets

2.4.1 Pre compression parameters

Characteristics like tapped density, bulk density, carr's index, hausner's ratio were studied for powder blend of formulations which are ready to compress into tablets [15, 16].

2.4.2 Post compression Parameters

2.4.2.1 Weight variation

Twenty tablets were selected at random and weighed and the average weight was determined by using a digital balance. Then individual tablets were weighed and compared with the average weight. Not more than two of the individual weights deviate from the average weight by more than the 7.5% [17].

2.4.2.2 Thickness

Ten tablets from each formulation were taken randomly and their thickness was measured with a digital screw gauge micrometer. The mean SD values were calculated [18].

2.4.2.3 Hardness and friability

Hardness or crushing strength of the tested orally fast dissolving tablet formulations was measured using the tablet hardness tester (Monsanto type). The friability of a sample of 20 orally fast dissolving tablets was measured utilizing a USP-type Roche friabilator (Camp-bell Electronics, Mumbai). Pre-weighed tablets were placed in a plastic chambered friabilator attached to a motor evolving at a speed of 25 rpm for 4 min. The tablets were then de-dusted, reweighed, and percentage weight loss (friability) was calculated [19, 20].

$$\% \text{ Friability} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \dots (1)$$

2.4.2.4 Wetting time

Five circular tissue papers were placed in a Petri dish of 10 cm diameter. Ten milliliters of water containing 0.5% eosin, a water-soluble dye, was added to the petri dish. The dye solution was used to identify complete wetting of the tablet surface. A tablet was carefully placed on the surface of the tissue paper in the petri dish at 25°C. The time required for water to reach the upper surface of the tablets and to completely wet them was noted as the wetting time. These measurements were carried out in replicate of six. Wetting time was recorded using a stopwatch [21, 22].

2.4.2.5 Drug content

All the formulations were assayed for drug content. Ten tablets were randomly selected from each formulation and pulverized to a fine powder. Weighed aliquots containing an amount of powder equivalent to a single dose were taken in triplicate and assayed for the drug content utilizing a UV-VIS spectrophotometer (Model UV/Visible 1700 double beam Spectrophotometer, Shimadzu, Japan) at a wavelength of 230 nm [23].

2.4.2.6 In vitro disintegration time

The in vitro disintegration of tablets was performed by placing one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using pH 6.8 (simulated saliva fluid) maintained at 37±2°C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per min in the pH 6.8 maintained at 37±2°C. The time taken for the complete disintegration of the tablet with no palpable mass remaining in the basket was measured and recorded [24].

2.4.2.7 In vitro dissolution studies

In Vitro release studies of Cetirizine from all formulations were performed according to USP XVIII apparatus II, paddle method (Dissolution testapparatus-TDT-06T, Electro lab, Mumbai, India). Paddle speed was maintained at 50 rpm and 900 ml of pH 6.8 phosphate buffers was used as the dissolution medium. Samples (10 ml) were collected at predetermined time intervals and replaced with equal volume of fresh medium, filtered and analyzed with a UV-Visible spectrophotometer (Shimadzu, Japan) at $\lambda = 230$ nm. Drug concentration was calculated from a standard calibration plot and expressed as cumulative % drug dissolved [25].

2.4.2.8 Drug excipients compatibility studies

These studies were performed in order to confirm the drug-excipient interaction. These studies mainly include FTIR spectroscopy. FTIR spectra of pure drugs, optimised solid dispersion and formulated FDT containing optimised solid dispersion were recorded on FTIR spectrophotometer (Bruker, USA). The scanning range was from 4000 to 600 cm^{-1} , and the resolution was 1 cm^{-1} . The scans were evaluated for presence of principal peaks of drug, shifting and masking of drug peaks, and appearance of new peaks due to excipient interaction. This spectral analysis was employed to check the compatibility of drugs with the excipients used [26].

2.5 Stability studies

The optimized formulation was subjected for stability studies at accelerated conditions of a Temperature 40°C and a relative humidity of 75% and analyzed at 0, 10, 20 and 30 days for their physical appearance, hardness, disintegration time, wetting time and friability [27].

3. RESULT AND DISCUSSION

3.1 Preparation of solid dispersion

The solid dispersions of Cetirizine HCL with colloidal silicon dioxide in 1:1, 1:2 and 1:3 weight ratios were prepared by solvent evaporation method. All the dispersions prepared were found to be fine and free flowing.

3.2 Characterization of solid dispersion

3.2.1 Estimation of drug content

Drug content of the solid dispersions was found to be between 91 % and 98.8 %. All the solid dispersions showed the presence of high drug content. It indicates that the drug is uniformly dispersed in the powder formulation. Therefore, the method used in this study appears to be reproducible for preparation of solid dispersion.

3.2.2 Dissolution Studies

To compare the release profile of various batches of the solid dispersion and physical mixture of drug and carrier, the *in vitro* release study was carried out on all the batches by using USP II type apparatus. The results of drug release from solid dispersion and physical mixtures of drug and carrier and pure drug are shown in Fig. 1 (Table 3). The formulation SD 3 showed maximum drug release i.e. 99.81% drug release in 20 minutes whereas the physical mixtures of same formulation released

mixture, the dissolution was found to increase in the following order - Pure drug < Physical mixture < Solid Dispersion. This may be due to the presence of polymer, which increases wetting, dissolution of the drug by decreasing the drug particle size in the course of the solid dispersion preparation, polymorphic transformation of drug crystals and chemical interactions between drug and carrier.

Table 3. Cumulative % drug release of various solid dispersion formulations

S. No.	Formulation code	Cumulative % drug release			
		5 min	10 min	15 min	20 min
1.	Solid dispersion (SD1) (1:1)	14.28	39.61	59.87	86.11
2.	Solid dispersion (SD2) (1:2)	26.33	45.92	83.02	92.05
3.	Solid dispersion (SD3) (1:3)	34.01	59.03	87.01	99.81
4.	Physical mixture (PM)	12.73	35.41	60.08	70.24
5.	Pure drug (CTZ)	7.35	15.46	28.72	39.21

3.2.3 Scanning Electron Microscopy (SEM)

The surface morphology of optimized solid dispersion (SD3) and pure drug were examined by SEM analysis (Fig. 2). The pure drug crystals appeared as fine needles with smooth surfaces, partially agglomerated in bundles, whereas in case solid dispersion, particles were in almost amorphous form. These observations provided the evidence of solid dispersion formation because crystalline drug is converted into amorphous form with reduced particle size.

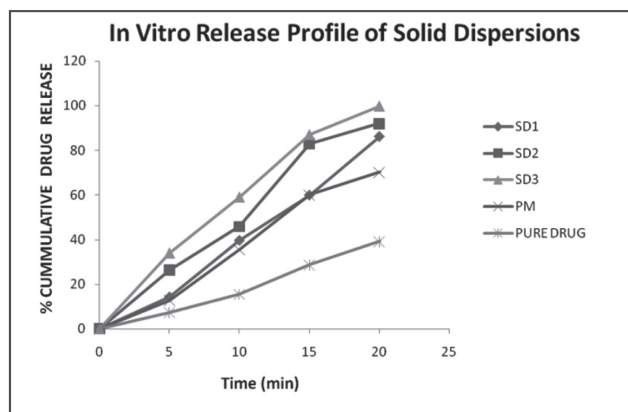
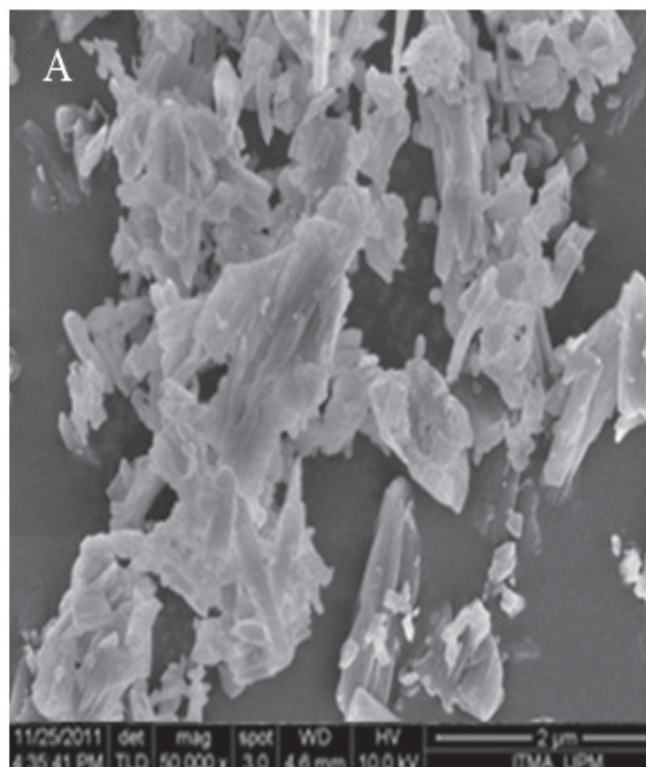


Fig. 1. *In-vitro* release profile of pure drug, solid dispersion (SD) of drug, physical mixture of drug and carrier.

70.24 % in 20 minutes, pure drug released 39.21 % of the drug in 20 minutes. The dissolution rate of cetirizine hcl in solid dispersions was strongly dependent upon the concentration of the drug to carrier ratio. Compared with the pure drug and physical



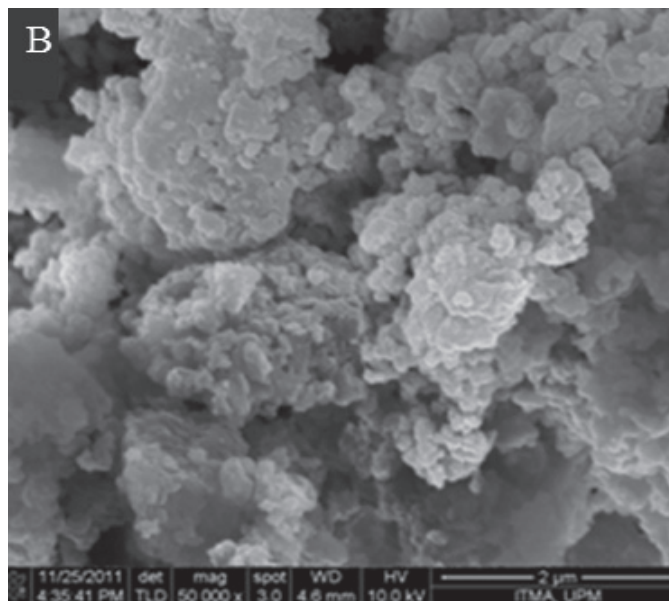


Fig. 2. SEM images of pure drug (A) and optimized solid dispersion (B).

3.2.4 Differential Scanning Calorimetric Studies (DSC)

Differential scanning calorimetry enables the quantitative detection of all processes in which energy is required or produced (i.e., endothermic and exothermic phase transformations). The thermal behavior was studied using differential scanning calorimetry in order to confirm the formation of solid dispersions. The thermograms for pure drug, optimised solid dispersion (SD3) and physical mixture are presented in Fig. 3. DSC scan of cetirizine hydrochloride indicated sharp endothermic peak indicating melting at 220.4°C. The DSC scan of physical mixture (PM) indicated endothermic peak at 83.5°C followed by further decomposition. The endothermic peak corresponding to cetirizine hydrochloride was absent in PM. Solid dispersion (SD3) showed peak at 61.1°C. Reduction in intensity and shifting of sharp melting peak of drug in solid dispersion indicates that the degree of crystallinity is considerably reduced and the drug is present in an amorphous form.

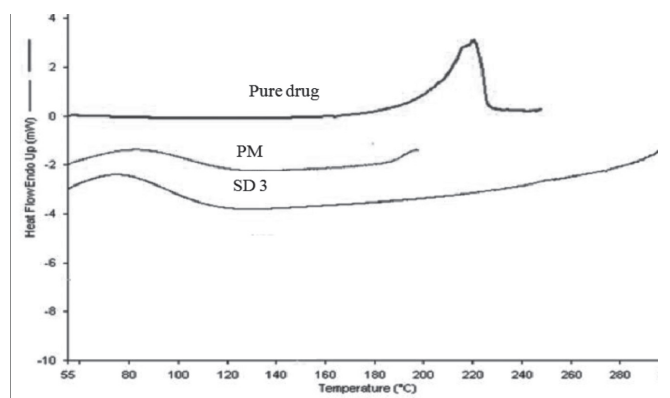


Fig. 3. DSC thermograms for pure drug, solid dispersion (SD3) and physical mixture.

3.2.5 Powder X-Ray Diffraction studies

XRD analysis was performed to confirm the results of DSC studies. The X-ray diffractograms of pure drug, physical mixture and solid dispersion are shown in Fig. 4. XRD of Cetirizine hydrochloride (CTZ) showed sharp peaks at 8.3°, 18.29°, 18.79°, 23.97°, 25° and 33.16° 2θ positions indicating crystalline nature of the drug. XRD of physical mixture (PM) indicates significant decrease in intensity of peaks of cetirizine hydrochloride indicating transformation to amorphous state. XRD of SD3 indicated complete absence of sharp peaks of cetirizine hydrochloride which indicated transformation to amorphous state.

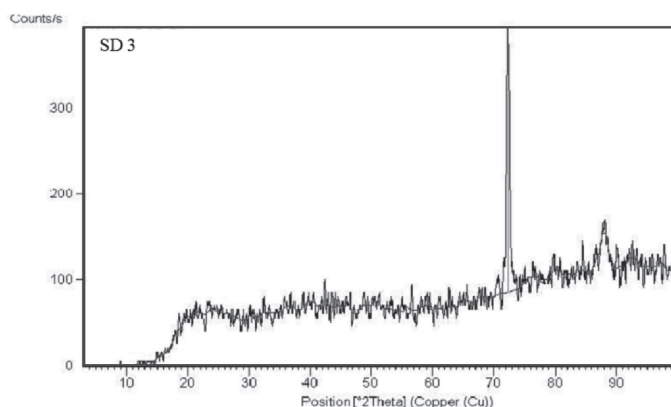


Fig. 4. Powder X-ray diffraction pattern of pure drug (CTZ), Physical mixture (PM) and Solid dispersion (SD3).

3.3 Development of fast dissolving tablet

Fast dissolving tablet of optimized solid dispersion (SD3) was prepared by direct compression method by varying the quantity of superdisintegrants sodium starch glycolate in formulation F1, F2, F3 and Crosscarmellose sodium in F4, F5, F6. Avicel PH 102 was included in the formulation as a disintegrant and a binder. This grade of microcrystalline cellulose is granular in nature and thus displays excellent flow properties. To impart pleasant taste and improve mouth feel, sodium saccharin was included as sweetening agent. Sodium stearyl fumarate was employed as a lubricant instead of magnesium stearate not only because of the metallic taste of the latter, but also due to its water solubility and directly compressible features. The batch flowability and compressibility properties were attributed to the presence of micro crystalline cellulose, MCC, (Avicel 102), which is an excellent filler/ flow-aid for direct compression (average particle size, 90 μm).

3.4 Evaluation of developed fast dissolving tablet

3.4.1 Pre compression parameters

The Bulk density of all the formulations were within the range of 0.52±0.004 to 0.55±0.02 g/ml and tapped density was found to be in the range of 0.59±0.01 to 0.65 ± 0.02 g/ml (good flow property). The Angle of repose of powder blends of all formulation was found to be in the range of 19.23 ± 0.33 to 29.52° ± 0.7 (good flow property). The calculated Carr's index of all formulations was found to within the range of 12.84 ±

0.15 to 17.48% ± 0.33 (good flow property). The calculated Hausner's ratio of all the formulations was found to be in the range of 1.105 ± 0.08 to 1.23 ± 0.06 (good flow property). The values of precompressional parameters evaluated were within the prescribed limits and indicated good free flowing properties.

3.4.2 Post compression parameters

The post compression parameters of all batches were studied and shown in Table 4. The loss of percentage of weight in friability was found to be in the range of 0.45±0.01 to 0.84±0.01 which is less than 1% and hardness was in the range of 3.07±0.14 to 3.50±0.27 which indicated that tablets had good mechanical

resistance. The thickness of prepared tablets was found to be in the range of 3.1±0.05 to 3.8±0.11 mm. The wetting time of all formulations was found to be in the range of 16±0.1 to 24±0.3 sec. Wetting time of all the formulation were less than 24 sec, due to rapid water absorbing nature of sodium starch glycolate and Crosscarmellose sodium via capillary and swelling mechanisms. The weight variation of all formulations was found to be in the range of 90.05±0.02 to 92.3±0.06 mg. All the formulation passes the drug content assay. Uniformity of drug contents was more than 98% in all the formulations. The disintegration time of all formulations was found to be in the range of 2.76±0.1 to 6.01±0.04 sec.

Table 4. Evaluation of all post compression characteristics of developed FDT

Formulation code	Hardness (kg/cm ²)± sd (n=3)	Friability (%w/w) ± sd (n=3)	Thickness (mm) ± sd (n=6)	Weight variation (mg) ± sd (n=3)	Wetting time (sec.) ± sd (n=6)	Drug content (%)± sd (n=6)	Disintegration time (sec.) ± sd (n=6)	Taste / mouth feel
F1	3.12±0.15	0.45±0.01	3.2±0.01	92.3±0.06	20±0.1	98.7±0.02	3.35±0.4	palatable
F2	3.28±0.04	0.62±0.15	3.7±0.04	90.1±0.01	18±0.2	99.2±0.23	4.11±0.03	palatable
F3	3.50±0.27	0.81±0.22	3.3±0.02	90.4±0.04	16±0.1	99.5±0.06	2.76±0.1	palatable
F4	3.16±0.00	0.58±0.13	3.8±0.11	91.2±0.05	21±0.3	100.2±0.1	5.38±0.07	palatable
F5	3.07±0.14	0.84±0.01	3.1±0.05	90.11±0.01	24±0.3	99.1±0.01	6.01±0.04	palatable
F6	3.08±0.01	0.81±0.12	3.3±0.06	90.05±0.02	17±0.2	98.4±0.4	4.46±0.01	palatable

3.4.3 In vitro dissolution studies

The *in-vitro* dissolution study was carried out in the USP dissolution test apparatus II, paddle method (Dissolution

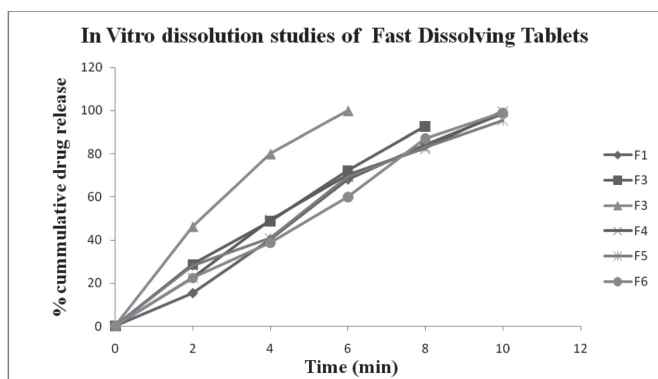


Fig. 5. *In-vitro* dissolution studies of developed fast dissolving tablets (F1-F6).

test apparatus-TDT-06T, Electro lab, Mumbai, India). Paddle speed was maintained at 50 rpm and 900 ml of pH 6.8 phosphate buffers was used as the dissolution medium maintained at 37 ± 0.5°C. All the formulation released more than 90% of the drug within 10 minutes. The rapid drug dissolution might be due to

easy breakdown of particle by superdisintegrant action. From the result F3 was selected as best formulation since it showed 99.98± 0.14% drug release in 6min (Fig. 5).

3.4.4 Compatibility Studies

The FTIR spectrum of Cetirizine hydrochloride (Fig. 6a) showed characteristic peaks at 3444.97 and 3291.18 (3300-3500) (N-H), 2922.37 (2850 – 3000) (C-H), 2854.79 and 2796.22 (3300 - 2500) (O-H), 1442.66 and 1368.13 (1350 –1550) (N=O), 1123.61 (1220 -1020) (C-N), 1287.13, 1240.80 and 1006.79 (1000 – 1300) (C-O) (Fig. 1). Whereas the FTIR spectrum of physical mixture (Fig. 6b) and FDT'S (Fig. 6c) showed characteristic peaks at 3402.09 (3300-3500) (N-H), 2910.50 (2850 – 3000) 2910.50 (CH), (3300 - 2500) (O-H), 1427.36, 1283.08 (1350 –1550) (N=O), 1161.61 and 1081.98 (1220 -1020) (CN) and 1020.53 (1000 –1300) (C-O) (Fig. 2). This indicates the characteristic peaks of Cetirizine hydrochloride were present even in formulated Cetirizine hydrochloride tablets, indicates that the drug was found to be compatible with the polymers used. Based on the FTIR studies, there appears to be no possibility of interaction between Cetirizine and excipients used in the study as no change or shifts in the characteristic peaks of drug was noticed.

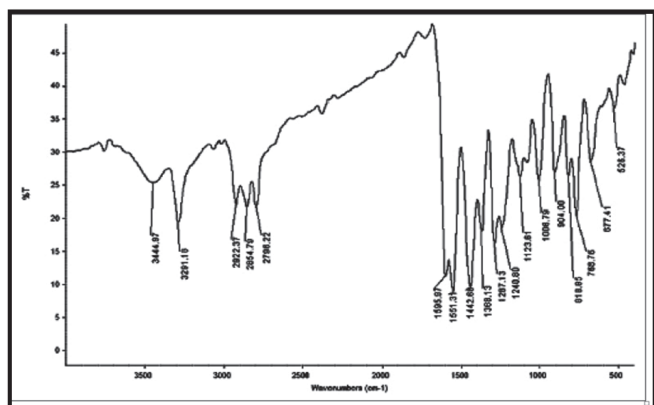


Fig. 6 (a). FTIR spectra of pure Cetirizine Hydrochloride powder.

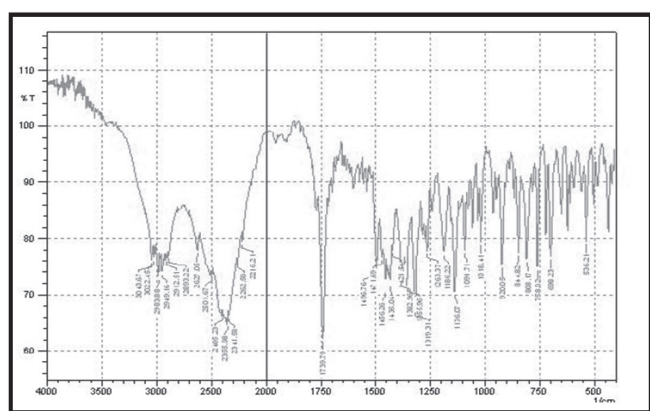


Fig. 6 (b). FTIR spectra of physical mixture.

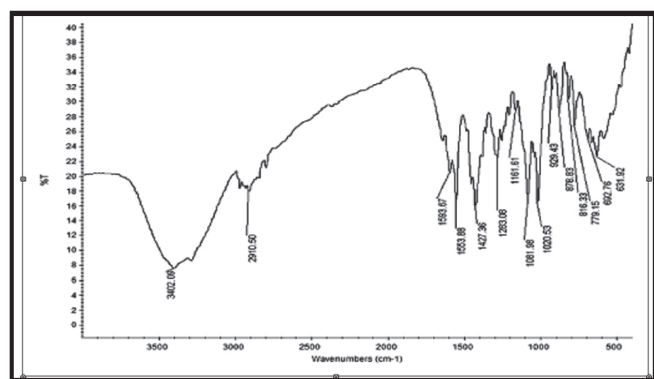


Fig. 6 (c). FTIR spectra of fast dissolving tablet formulation.

3.5 Stability Studies

The stability studies of the optimized formulation (F6) were conducted to assess its stability with respect to its physical appearance, hardness, DT, wetting time and friability. The results are given in Table 5. The results of the stability study indicated that the tablets showed no change in physical appearance during the study period. There were no observed differences in hardness, DT, wetting time and friability before and after the storage period. This indicates that the optimized formulation is fairly stable.

Table 5. Stability study of optimised formulation (F3)

Duration of test (days)	Hardness (kg/cm ²)	Disintegration time (sec)	Wetting time (sec)	Friability (%)
0	3.50 ± 0.27	2.76 ± 0.1	16 ± 0.1	0.81 ± 0.22
10	3.51 ± 0.02	2.76 ± 0.06	16 ± 0.04	0.80 ± 0.11
20	3.50 ± 0.04	2.77 ± 0.02	17 ± 0.06	0.81 ± 0.04
30	3.51 ± 0.03	2.77 ± 0.01	16 ± 0.3	0.81 ± 0.02

4. CONCLUSION

Fast disintegrating tablet is a promising approach with a view of obtaining faster action of the drug and would be advantageous in comparison to currently available conventional dosage forms. The goal of this research work had been achieved by preparing fast dissolving tablet from optimized solid dispersion of Cetirizine HCL and colloidal silicon dioxide. Solid dispersion of drug in a hydrophilic carrier is one of the promising techniques of increasing dissolution rate of drug. The developed fast dissolving tablet proved to have easy portability, rapid onset of action, accuracy of dosage, administration without water and an ideal dosage form for paediatric and geriatric patients.

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