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Formulation and Evaluation of Oro Dispersible Tablet of Desloratadine

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ABSTRACT

Desloratadine is an antagonist at histamine H1 receptors, and an antagonist at all subtypes of the muscarinic acetylcholine receptor. It has a long-lasting effect and in moderate and low doses, does not cause drowsiness because it does not readily enter the central nervous system. The present study is an attempt to formulate and evaluate the fast dissolving tablets of Desloratadine. Fast dissolving tablets were prepared by direct compression after masking the bitter taste of drug by solid dispersion method with the aid of superdisintegrants. Seven formulations were developed using two different superdisintegrants in varying concentrations in such a way that total weight of the tablet remains the same. The drug-polymer incompatibility was ruled out by *FTIR* studies. All the formulated tablets were subjected for pre and post-compression evaluation parameters. A comparison of *in vitro* drug release of best formulation along with F1 formulation having no superdisintegrants is carried out. All the formulated tablets were shown satisfactory results which complies with official limits. Among the seven formulations, F7 was selected as the best formulation as its wetting time was 33 seconds, disintegration time was 29 seconds and %CDR after 8 minutes was 100.1%. F7 was found to be stable at 25°C ± 2 °C, 60°C ± 5°C and 40 °C ± 2 °C and 75 ± 5 % RH . Formulated tablets containing high concentration of croscarmellose sodium are better and effective than conventional tablets to meet patient compliance, give fast relief from allergy and cost effective.

Keywords: Desloratadine; H1 antagonist; Fast dissolving tablets; ODT; Superdisintegrant, croscarmellose sodium.

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INTRODUCTION

Tablets and capsules are most popular solid dosage form due to ease of ingestion, pain avoidance, versatility and most importantly patient compliance. Also, solid oral delivery systems do not require sterile conditions and therefore, less expensive to manufacture. But the main disadvantage of this dosage form for some patients is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage form. People often experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness and sudden episodes of coughing during the common cold, allergic condition and bronchitis [1]

For these reason, the most desirable formulation for use by the elderly is one that is easy to swallow and easy to handle , tablets which can rapidly dissolve or disintegrate in the oral cavity without water have attracted a great deal of attention. Since such a tablet can disintegrate in only a small amount of water in the oral cavity, it is easy to take for any age patient, regardless of time or place Fast dissolving tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.

Taking these requirements into consideration, attempts have been made to develop a rapid dissolving tablet. For example, it can be taken anywhere at any time by anyone who do not have easy access to water. It is also easy to dose the aged, bed-ridden patients, or infants who have problems swallowing tablets and capsules [2,3].

Desloratadine is a selective, H1 receptor antihistamine drug having bitter in taste. It is the major orally active metabolite of loratadine, approved for allergic rhinitis and/or chronic idiopathic urticaria. Desloratadine is a white to off-white powder that is slightly soluble in water, but very soluble in ethanol and propylene glycol. Receptor binding data indicate that at a concentration of 2–3 ng/mL desloratadine shows significant interaction with the human histamine H1-receptor. Desloratadine inhibited histamine release from human mast cells *in- vitro*. Problems like hand tremors, dysphagia and non co-operative patients, the problems of swallowing is a common phenomenon which leads to poor patient compliance and in effective therapy [4-6]

The main aim of this study is to develop and characterize bitterless fast dissolving of Desloratadine with good mouth feel so as to prepare a “patient-friendly dosage form” which disintegrates in the oral cavity in a matter of second without need of water. This helps in easy swallowing hereby improves clinical effects through pregastric absorption, leading to an increase in bioavailability of the drug and quick onset of pharmacological action can takes place.

MATERIALS AND METHOD

Desloratadine was obtained as gift sample from Shreeji Pharma International, Gujarat. Pearlitol® SD 200, a directly compressible vehicle was purchased from Roquette Pharma, Poly Ethylene Glycol from S.D fine chemicals Pvt Ltd Croscarmellose Sodium (CS), Sodium Starch Glycolate (SSG) was purchased from Gujarat Microvax Pvt Ltd, Aspartame and Sorbitol were from Kawarlal Pharma, Colloidal Silicon Dioxide (aerosil®) from Evonik industries, Magnesium stearate from S.Zhaveri Pharmkem pvt ltd, Strawberry flavour from International flavour fragrance and Talc from Luzenac pharma Pvt Ltd .

Method of preparation

Mouth fast dissolving tablets (MFDT's) were prepared by solid dispersion melting method for masking the taste of desloratadine drug using PEG (1:5) as carrier and the drug was incorporated into the melted PEG 4000 .The (drug: PEG) mixture was cooled and dried, then 80% of pearlitol SD 200 was added into the mixture, then the mixture was coated with remaining 20% of pearlitol SD 200 using distilled water as solvent. The (Pearlitol SD 200 and Distilled Water) solution was coated over the PEG 4000 and the drug blend, this mixture was kept in oven for 3 hours at 60° C, the powder was dried and pulverized with mesh #40. All the ingredients were passed through mesh #40 except magnesium stearate. Magnesium stearate will be passed through mesh #60. Superdisintegrant and other ingredients were weighed and mixed in geometrical order and tablets will be compressed using 8mm round flat punches on a Tablet Compression machine, Rimek minipress-11 mt, karnavati. Batch of 100 tablets each of 150 mg weight were prepared as per the specific master formula [7-9].It is mentioned in Table 1.

In this work, direct compression method with the aid of superdisintegrants were attempted for the formulation development of rapid dissolving tablets of Desloratadine. Dose of 2.5 mg was selected for the present study. Total seven Formulation were prepared (F1 – F7) , among them all contains different concentrations of superdisintegrants except F1 Formulation.

Table 1: Formulation chart of desloratadine fast dissolving tablet.

Ingredients	F1	F2	F3	F4	F5	F6	F7
DRUG (mg)	2.5	2.5	2.5	2.5	2.5	2.5	2.5
PEG 4000(mg)	12.5	12.5	12.5	12.5	12.5	12.5	12.5
SSG(mg)	-	10	12	14	-	-	-
CCS (mg)	-	-	-	-	10	12	14
Mannitol(mg)	75	65	63	61	65	63	61
Sorbitol (mg)	40	40	40	40	40	40	40
Aspartame (mg)	10	10	10	10	10	10	10
Aerosil(mg)	3	3	3	3	3	3	3

Mg. Stearate(mg)	3	3	3	3	3	3	3
Talc(mg)	2	2	2	2	2	2	2
Flavour(mg)	2	2	2	2	2	2	2
Total weight(mg)	150	150	150	150	150	150	150

Preformulation studies:

FT-IR study: [10]

Reagent: Potassium bromide (IR grade)

Procedure:

Few mg of sample was triturated with about 300 mg of potassium bromide. The pellet was prepared and IR-spectrum was recorded at 4000 to 400 cm-1. The spectrum was compared with the reference spectrum of Desloratadine. The drug- polymer compatibility was confirmed by *FTIR* studies, spectrum was shown in Figures 1- 5. *FT-IR* Spectra Data Of Drug + Formulation is shown in Table 2.

EVALUATION

Pre-compression Evaluation:[11-15]

Angle of repose:

Angle of repose was determined using fixed funnel method. The granules were taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of the drug powder. The powder was allowed to flow through the funnel freely onto surface. The height (h) and diameter of the powder cone was measured and angle of repose was calculated by following formula. The data is given in the Table 3.

$$\text{Angle of repose } (\theta) = \tan^{-1}\frac{h}{r}$$

Bulk density:

Loose bulk density (LBD)

LBD was determined by pouring the blend into a graduated cylinder (100ml). The bulk volume and weight of the powder was determined. Loose bulk density was calculated using the formula. The data is given in the Table 3.

$$\text{LBD} = \frac{\text{Mass}}{\text{Volume}}$$

Tapped bulk density (TBD):

The measuring cylinder (100 ml) containing a known mass of blend was tapped 100 times for a fixed time (around 5 min). The minimum volume occupied in the cylinder and the weight of the

blend was measured. The tapped density was calculated using the formula. The data is given in the Table 3.

$$LBD = \frac{\text{Weight of granules}}{\text{Tapped volume}}$$

Compressibility index:

Based on LBD and TBD, the % compressibility of the powder mixture was determined by the following formula: The data is given in the Table 3.

$$\text{Compressibility index} = \frac{\text{TBD - LBD}}{\text{TBD}} \times 100$$

Hausner ratio:

Hausner ratio is an indirect index of ease of powder flow. It is determined by following formula: The data is given in the Table 3.

$$\text{Hausner's ratio} = \frac{\text{TBD}}{\text{LBD}}$$

POST-COMPRESSION EVALUATION[11-15]

Weight variation:

20 tablets were selected randomly from the lot and weighted individually to check for weight variation. The data are given in the **Table 4.**

Tablet thickness and diameter:

Thickness and diameter of tablets was important for uniformity of tablet size. Thickness and diameter was measured by using Vernier callipers on 3 randomly selected samples. The unit is centimetre or millimetre. The data is given in the Table 4.

Hardness test:

Monsanto or Pfizer hardness tester was used for the measurement of hardness. The tablet to be tested was held between a fixed and a moving jaw and reading of the Indicator adjusted to zero. The force applied to the edge of the tablet is gradually increased by moving the screw knob forward until the tablet breaks. The reading is noted from the scale which indicates the pressure required in kg or lb to break tablets. The unit for hardness is kg/cm2 or lb/cm2. The data is given in the Table 4.

Friability test:

Roche friabilator was used for testing the friability of prepared tablets. Twenty tablets were weighed accurately and placed in the friabilator and rotated at 25 rpm for a period of 4 min. Tablets were dedusted using soft muslin cloth and weighed again. Percentage weight loss was determined by using following formula. The weight loss should not be more than 1% to pass the test. The data are given in the Table 4.

$$\% \text{ Friability} = \frac{(\text{Initial wt. of tablets} - \text{Final wt of tablet})}{(\text{Initial wt. of tablet})} \times 100$$

Drug content:

Six tablets were weighed and crushed then 25 mg of powder is dissolved in 100ml of methanol and sonicated for 5-10 min. From that 5 ml was taken in 50ml volumetric flask and make up with 100% methanol. Then drug concentrations were determined by measuring the absorbance at 242 nm using UV-Vis spectrophotometer. The datas are given in the Table 5.

$$\text{Formula} = \frac{\text{Sample Abs}}{\text{Std Abs}} \times \frac{\text{Std dilution}}{\text{Sample dilution}} \times \frac{\text{API purity}}{100} \times 100$$

Wetting time:

A piece of tissue paper folded double was placed in a Petri plate (internal diameter is 6.5 cm) containing 6ml of pH 6.8. The tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. The data is given in the Table 5.

Water Absorption Ratio (R):

A piece of tissue paper folded twice was placed in a small petri dish containing 6ml of water. The weight of the tablet prior to placement in the petri dish was noted (Wb) utilizing a Shimadzu digital balance. The wetted tablet was removed and reweighed (Wa). Water absorption ratio, R, was then determined according to the following equation. The data is given in the Table 5.

$$R = \frac{Wa\text{-}Wb}{Wb} \times 100$$

Where Wb and Wa were tablet weights before and after water absorption, respectively.

***In-vitro* disintegration time:**

The *in-vitro* disintegration time of a tablet was determined using disintegration test apparatus. One tablet was placed in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using phosphate buffer pH 6.8 maintained at 37± 0.5 ºC as the immersion liquid. The time in

seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded. The data is given in the Table 5.

Dissolution test:

In vitro drug release of the samples was carried out using USP – type II dissolution apparatus (paddle type). The dissolution medium, 500 ml of phosphate buffer (pH 6.8) solution, was placed into the dissolution flask maintaining the temperature of 37±0.5ºC and rpm of 50. One tablet was placed in each flask of dissolution apparatus. The apparatus was allowed to run for 10 min. Samples measuring 5 ml were withdrawn after every 2, 4, 6, 8, and 10 min.

Samples were filtered through 10 µm filter. The fresh dissolution medium was replaced every time to maintain sink condition. The collected samples were analysed at 242 nm using dissolution medium as blank. The cumulative percentage drug release was calculated. The values are given in the Table 6.

Stability study:

The fast dissolving tablets were packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines [40 °C ± 2 °C and 75 ± 5 % RH] and at [25 °C ± 2 °C and 60 ± 5 % RH]. The tablets were withdrawn after a period of 30, 60 and 90 days and analyzed for physical characterization (Hardness, Disintegrations and Dissolution, wetting time etc.) and drug content. The data is given in the Table 8,9.

RESULTS AND DISCUSSION

Mouth fast dissolving tablets of Desloratadine were prepared by direct compression method, Pearlitol SD200 is used as a diluents , sodium starch glycolate and croscarmellose sodium were used as superdisintegrants, talc and aerosil is used as flow promoter, magnesium stearate was used as lubricant, aspartame & sorbitol as sweetener and strawberry flavour used to improve mouth feel.

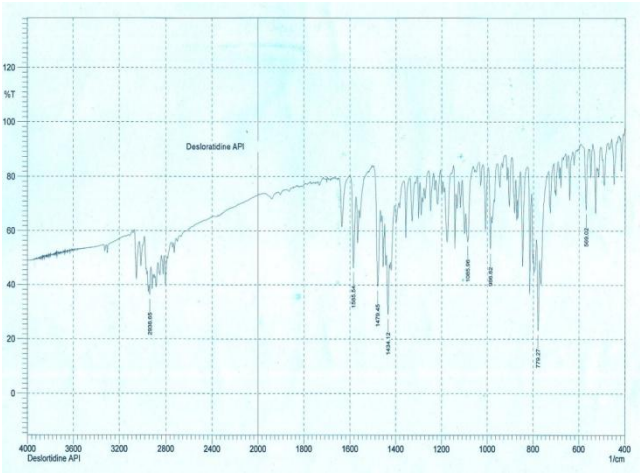

Figure 1: FT-IR spectra of desloratadine.

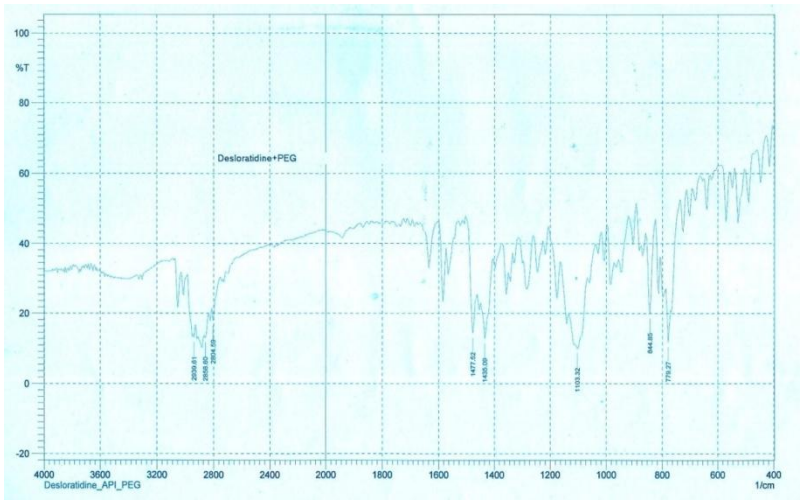

Figure 2: FT-IR spectra of desloratadine + PEG.

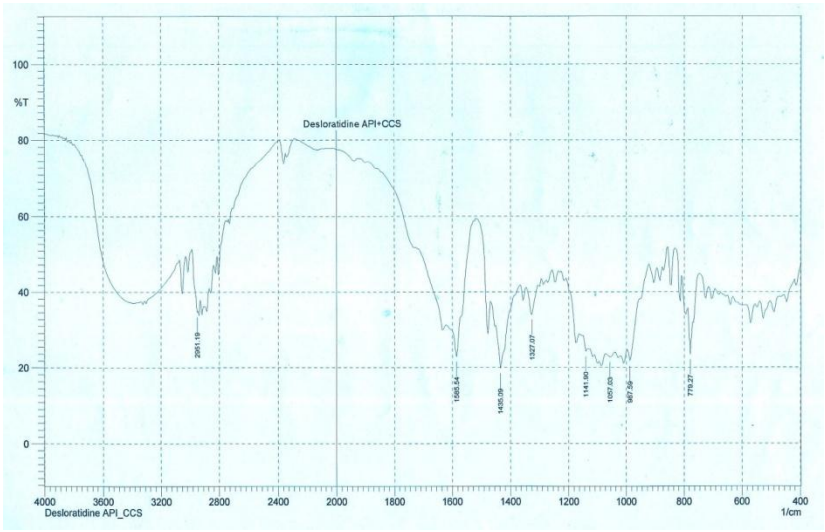

Figure 3: FT-IR spectra of desloratadine + CCS.

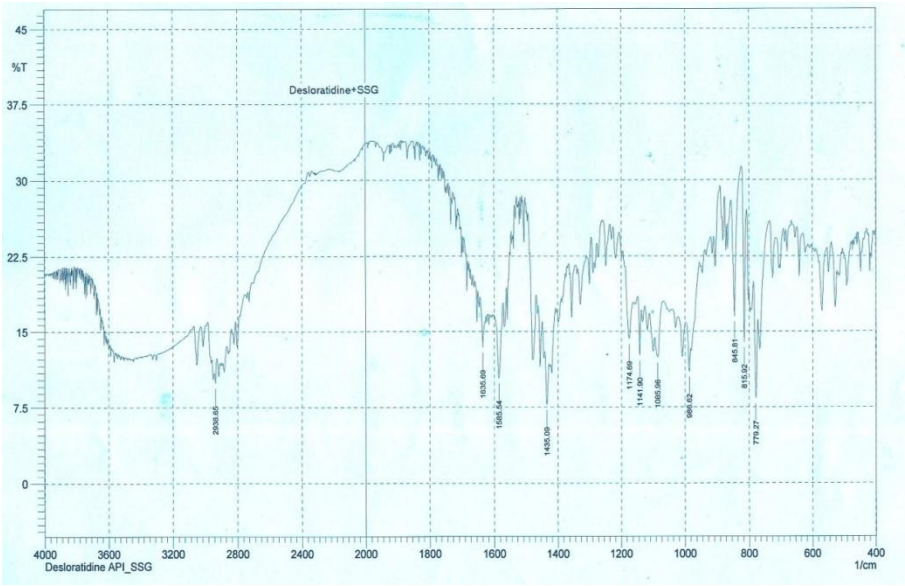

Figure 4: FT-IR spectra of desloratadine + SSG.

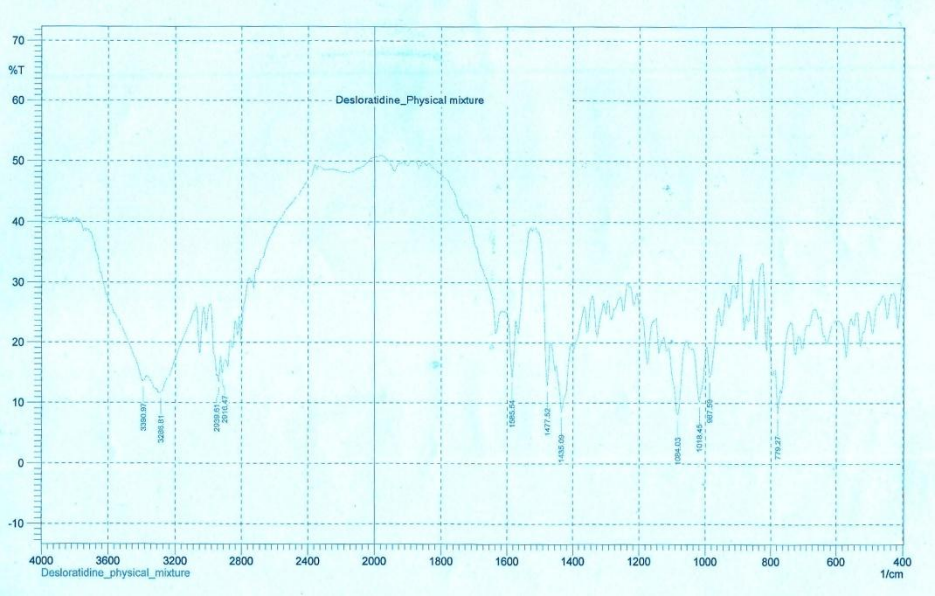

Figure 5: FT-IR spectra of desloratadine + Physical mixture.

Table 2 : *FT-IR* Spectra Data Of Drug + Formulation.

SR. No.	description	Peaks cm±1	Stretching / Deformation
1.	C=C (Aromatic)	1635.69 , 1585.54cm^{-1}	Stretching
2.	C-H	2945.40 , 2989.36cm^{-1}	Stretching
3.	C-N	1084.96 , 1088.03m^{-1}	Stretching
4.	N-H	2938.39 , 2858.52cm^{-1}	Stretching
5.	C-Cl	779.4, 779.3cm^{-1}	Stretching

Solid dispersion method was adopted to mask the bitter taste of the drug and direct compression method was employed to formulate the tablets, because of its cost effectiveness and due to reduced number of manufacturing steps.

The pre-compression parameters like bulk density, tapped density, Carr's index and angle of repose were determined. The final formulation showed acceptable flow properties. The post-compression parameters like the thickness, hardness, friability and *in vitro* dispersion time, wetting time, water absorption ratio and *in vitro* drug release were carried out and the values were found to be within IP, BP limits.

Table 3. Results for preformulation study

Formulation code	Bulk Density (gm/ml)	Tapped Bulk Density (gm/ml)	% compressibility	Hausner's ratio	Angle of repose
F1	0.4317 ± 0.00559	0.5198 ± 0.00453	16.94 %	1.20	25.74°± 1.8071
F2	0.4327 ± 0.00838	0.5557 ± 0.00415	22.13%	1.28	28.60°± 3.8833
F3	0.5047 ± 0.00838	0.6057 ± 0.00415	16.7 %	1.20	28.60°± 3.8833
F4	0.4393 ± 0.00245	0.5169 ± 0.00369	15.10 %	1.18	27.95° ± 2.269

F5	0.3934 ± 0.00372	0.4483 ± 0.00235	12.23 %	1.14	33.57° ±0.3836
F6	0.4211± 0.00287	0.5025 ± 0.00399	16.13%	1.19	35.34°± 0.4503
F7	0.65841 ±0.00554	0.724 ±0.001	10.22%	1.10	1.43°±0.2022

The thickness of the tablet indicates that die fill was uniform. The thickness of the batch from F1-F7 was found to be 2.95 – 3.3 mm and hardness was found to be 3.12-4.31kg/cm^2 and thus tablets were having good mechanical strength. The friability of all the formulated tablets were found to be between 0.21-0.92 % and all the formulated tablets of were shown the % friability within the official limits.(i.e. not more than 1%). Prepared tablets were evaluated for weight variation and percentage deviation from the average weight are reported in Table 5.4 and was found to be within (±7.5) the prescribed official limits. The wetting time of all the formulations (F2-F7) were found to be within 32-61 seconds, which complies with the official specifications. The water absorption ratio of all the formulated batches was found to be 12.6-17.8% which was satisfactory in giving effective and better formulations of rapid dissolving tablets. The drug content of all the formulations (except F1)was found to be within the range of 98.6-100.6 % which was within the limits of BP specifications.

***In vitro* Disintegration time**

All the formulated tablets except F1(without superdisintegrant) have shown *in vitro* Disintegration time of less than 60 seconds, showing that formulated Desloratadine tablets were better and effective for the treatment of allergy than conventional tablets (F1).

Among all the formulations, tablets prepared with croscarmellose sodium were shown less than 40 sec. Disintegration of time. The data's are shown in Table 5.

***In vitro* dissolution study**

The value of dissolution test is mentioned in Table- 6. According to this test, the best formulation with high concentration of CCS (F7) shows maximum drug release within 8 minutes as compared to other formulation.

Table 6: *In-vitro* drug release studies of the selected formulations.

Formulation code	%CDR after 2 minutes	%CDR after 4 minutes	%CDR after 6 minutes	%CDR after 8 minutes	%CDR after 10 minutes
F1	23.2±0.03	39.3±0.68	45.2±0.60	67.7±0.75	78.3±0.86
F2	58.8±0.65	64.9±0.33	81.6±0.24	88.4±0.27	93.9±0.99
F3	68.8±0.65	74.9±0.33	87.6±0.28	95.4±0.24	99.9±0.99
F4	61.3±0.44	68.9±0.68	79.2±0.60	89.7±0.75	95.3±0.86
F5	69.2±0.03	75.3±0.68	88.2±0.60	91.7±0.75	96.3±0.86
F6	78.9±0.45	83.5±0.55	92.5±0.69	99.4±0.50	99.9±0.34
F7	**88.7±0.51**	**98.8±0.65**	**99.2±0.87**	**100.1±0.35**	**100.1±0.23**

*** All values are expressed as mean ± standard deviation (n=3).**

Comparison of dissolution profile of F1 F3 F6 F7. Is shown in Figure 6.

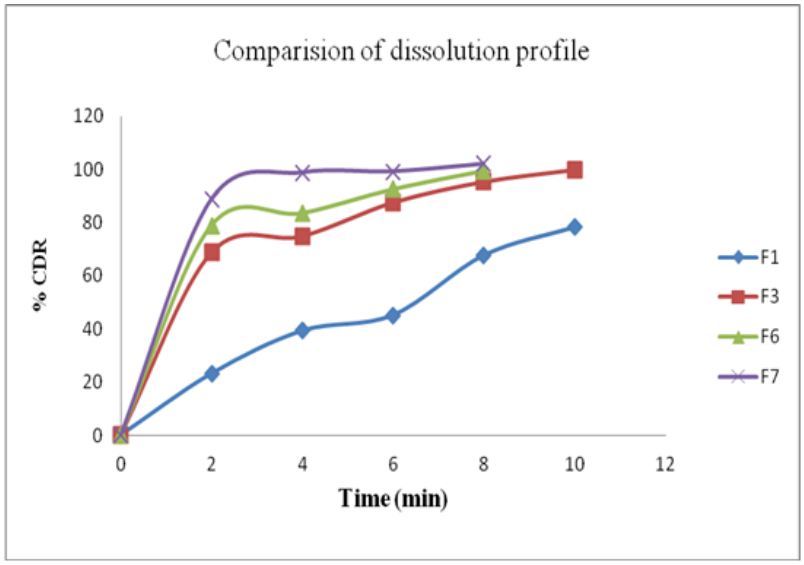

Figure 6: Comparison of dissolution profile of F1 F3 F6 F7.

Table 4: Evaluation parameters of all formulations.

Formulation Code	Hardness (Kg/cm2)	Friability (%)	Weight variation (mg)	Thickness (mm)
F1	3.94 ± 0.567	0.92±0.07	149.7 ±0.56	3.1±0.5
F2	4.14 ± 0.768	0.41±0.08	150 ± 0.23	3.1±0.4
F3	4.31± 0.472	0.91±1.7	153 ± 0.13	3.0±0.6
F4	3.12 ± 0.789	0.21±0.07	150.9 ± 0.19	2.95±0.5
F5	3.56 ± 0.584	0.86±0.04	149.04 ± 0.38	3.15±0.2
F6	3.50 ± 0.873	0.45±1.07	149.5 ± 0.16	3.3±0.3
F7	4.00 ± 0.434	0.23±0.09	150.12 ± 0.23	3.15±0.5

*** All values are expressed as mean ± standard deviation (n=3).**

Table 5: Evaluation parameters of all formulations.

Formulation Code	Wetting time (Sec)	Disintegration time (Sec)	Water absorption ratio (%)	Drug content (%)
F1	178± 1.6	183± 1.5	13.8±0.60	99.7±2.72
F2	61± 0.5	58 ± 1.55	16.8±0.91	98.6±0.12
F3	51 ±1.8	34 ±1 .27	15.4±0.94	99.9±0.36
F4	40 ± 2.5	39 ± 1.44	14.7±0.86	99.2±0.75
F5	43 ± 1.5	46 ± 1.85	13.5±0.26	99.8±1.19
F6	32 ± 1.7	31 ±1.28	17.3±0.31	100.1±0.15
F7	33 ± 1.3	29 ± 1.67	12.6±0.13	100.6±0.40

*** All values are expressed as mean ± standard deviation (n=3).**

Kinetics modeling of drug dissolution profiles: *In vitro* release study data of optimized formulation F7 is fitted into various mathematical models i.e. Zero order, First order, Higuchi model- First order to determine the best-fit model. The release was found to follow First order with regression coefficient value 0.808. The results are shown in Table 7.

Table 7: Kinetics of drug release.

Model	F7 R^2
Peppas	0.828
Higuchi	0.804
First order	0.848
Zero order	0.568

Stability study

The stability of the optimized formulation was studied as shown in Table 8, 9 for three months at accelerated conditions of 40 °C ± 2 °C and 75 ± 5 % RH and at 25 °C ± 2 °C and 60 ± 5 % RH The formulations were found to be stable, with insignificant change in the hardness, disintegration time and drug content and *in vitro* drug release pattern.

Table 8: Stability study of optimized formulation F7at [25°C ± 2 °C, 60°C ± 5%RH]

Evaluation parameter	At 0 days	After 30 days	After 60 days	After 90 days
Hardness test	4.00 kg/cm^2	4.01 kg/cm2	4.0 kg/cm2	4.1 kg/cm2
Drug content	100.6%	99.8%	99.9%	100.4%
Wetting time	33 sec	33 seconds	32 seconds	35seconds
Disintegration time	29 sec	29 seconds	28 seconds	25 seconds
Dissolution (%CDR after 8 min)	100.1%	99.11%	99.61%	100.6%

Table 9: Stability study of optimized formulation F7 at [40 °C ± 2 °C and 75 ± 5 %RH].

Evaluation parameter	At 0 days	After 30 days	After 60 days	After 90 days
Hardness test	4.00 kg/cm^2	4.24 kg/cm^2	3.91 kg/cm^2	4.4 kg/cm^2
Drug content	100.6%	99.3%	99.8%	100.03%
Wetting time	33 sec	33 sec	34 sec	36 sec
Disintegration time	29 sec	29 sec	27 sec	29 sec
Dissolution (%CDR after 10 min)	100.1%	99.51%	99.25%	99.8%

CONCLUSION

The prime objective of the study was to develop desloratadine mouth fast dissolving tablets by using commonly available excipients and conventional technology. From the above study, it was concluded that by employing commonly available pharmaceutical excipients such as superdisintegrants, excipients and proper filler a mouth fast dissolving tablets of desloratadine can be developed which can be commercialized.

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