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FORMULATION AND EVALUATION OF FAST DISINTEGRATING TABLET OF LORATADINE BY USING ISPAGHULA MUCILAGE

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Direct compression method, Superdisintegrant, Ispaghula mucilage, *In-vitro* dissolution, Loratadine, Water absorption ratio

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ABSTRACT: Aim and Objective: The main aim of the research work is to formulate and evaluate fast disintegrating tablets of Loratadine by incorporating Ispaghula Mucilage as a Superdisintegrant. **Materials and Methods:** Tablets were produced utilizing the direct compression technique, incorporating three distinct synthetic superdisintegrants and a natural superdisintegrant (Ispaghula mucilage) at varying concentrations. The primary objective was to reduce disintegration time and enhance the bioavailability of Loratadine. **Result:** The pre-compression characteristics suggested that the compressibility and flow qualities were favourable. After compression, the tablets exhibited acceptable values for hardness (ranging from 3.4 ± 0.1 to 3.5 ± 0.1 kg/cm²), wetting time (ranging from 15.3 ± 0.5 to 45.6 ± 1.5 seconds), and water absorption ratio, all well within the specified limits. Given that the tablets are meant for oral disintegration, our primary focus was on *in-vitro* dissolution studies and disintegration time. Among all the formulations, F12 shows shortest disintegration time, merely 8 seconds, and the highest cumulative percent of drug release, reaching 98.67%, to its content of 30mg of Ispaghula mucilage. The accelerated stability test, conducted following the ICH guidelines, demonstrated the stability of the optimized F12 formulation at Relative humidity of 75%+5% and temperature of 40°C+2°C and were recorded throughout three months duration. **Conclusion:** Ispaghula mucilage proved to be the optimized formulation. It exhibited the fastest disintegration time, highest drug release, and favorable flow properties, making it a promising choice for the development of Fast disintegrating tablets of Loratadine.

INTRODUCTION: In the field of oral drug delivery, fast disintegrating tablets (FDTs) have revolutionized conventional tablet formulations by providing an innovative solution to various challenges.

Also referred to as orally disintegrating tablets or quick-dissolve tablets, FDTs possess a remarkable advantage: they quickly dissolve or disintegrate within seconds in the mouth, eliminating the requirement for water or minimal liquid intake.

This unique attribute has garnered significant interest from healthcare experts, researchers, and patients, especially those who face difficulties in swallowing standard tablets¹. Fast disintegrating tablets (FDTs) hold great significance due to their capacity to swiftly deliver and dissolve drugs in the mouth, resulting in faster onset of action and

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improved bioavailability. Leveraging the benefits of FDTs can lead to heightened therapeutic effectiveness, particularly in situations necessitating immediate relief, such as allergies or acute symptoms. Additionally, FDTs show promise in catering to specific patient groups, such as the elderly, pediatric patients, and those with swallowing challenges, as they provide a convenient and user-friendly approach to drug administration².

In this study, the primary objective is to develop and assess orally dissolving tablets containing an antihistamine drug, utilizing natural superdisintegrants³⁻⁵. Furthermore, these natural compounds exhibit remarkable water absorption and swelling properties, facilitating rapid tablet disintegration and drug release. Through the incorporation of natural superdisintegrants in the formulation, we aim to overcome the limitations associated with conventional tablet preparations, ensuring swift disintegration, improved taste, and overall patient acceptance^{6,7}.

This research aims to explore the viability and effectiveness of employing natural superdisintegrants in creating fast disintegrating tablets (FDTs) for antihistamine drugs. Through extensive formulation and evaluation, we aim to identify the most suitable combination of natural superdisintegrants that ensure rapid tablet disintegration, efficient drug delivery, and favorable sensory qualities. The outcomes of this investigation hold the promise of advancing oral drug delivery systems, providing a patient-centered approach to medication administration, and enhancing therapeutic results for individuals suffering from allergic conditions. The primary focus of this research is to investigate the development and assessment of fast disintegrating tablets (FDTs) that incorporate an antihistamine drug and utilize the benefits of natural superdisintegrants⁸. Through this innovative approach, our goal is to improve the convenience, efficacy, and patient satisfaction associated with oral drug delivery. The findings from this study will provide valuable insights into the potential of FDTs as a promising alternative to traditional tablets, especially in the context of antihistamine medications, and pave the path for future advancements in pharmaceutical technology.

MATERIALS AND METHODS:

Materials: Loratadine was provided as a gift sample by Bhavani Pharmaceuticals, Hubli, Ispaghula Mucilage were obtained from Tippanna Kshatriya Ayurvedic shop, Hubli. Crospovidone, Croscarmellose Sodium, Sodiumstarchglycolate, Microcrystalline cellulose, Mannitol, Sodium Starch glycolate, Aerosil, Sodium starch fumerate, Vanilla flavour, Aspartame were provided by Vergo pharmaceuticals, Verna. Other reagents and chemicals were used of analytical reagent grade.

Preparation of Ispaghula: The mucilage was obtained from *Plantago ovata* seeds by immersing them in water (20-30 times the volume of seeds) for a minimum of 48 hours. Subsequently, the mixture was boiled for 2 hours. The mucilage was then separated from the seeds by squeezing it out through a muslin cloth. To precipitate the collected mucilage, 3 times the volume of 95% ethanol was added. The resulting mucilage was dried in an oven at temperature ranging from 50 to 55 °C. Once dried, the mucilage was scraped and pulverized using a pestle and mortar. The resulting powder was sieved through a mesh with a size of number 60# to obtain a uniform particle size^{9,10}.

Preformulation Study:

Analytical methods:

Preparation of 0.1N HCL: To make 0.1 N HCl, take 2.1 ml of concentrated HCl and mix it with distilled water in a 250 ml volumetric flask to make a solution of 250 ml.

Determination of Absorption Maxima: In order to create a solution of 100 µg/ml (SS-II), 10 ml of a 1000 µg/ml solution (SS-I) was taken from a 100mg sample of the API dissolved in a small volume of 0.1 N HCl and diluted with water to a total volume of 100 ml.

Standard Calibration Curve of Loratadine: To prepare the calibration curve, six different volumes (0.2 to 1.2 ml) of SS-II were transferred into 10 ml volumetric flasks and adjusted with 0.1 N HCl to concentrations from 2-12 µg/ml, respectively and measured at 275 nm against a blank. This entire process was performed three times to ensure accuracy and reliability, and the standard deviation was determined^{11,12}.

Assessing the Compatibility of the Drug with the Polymer:

Characterization of Superdisintegrants:

Swelling Index: The swelling index of a material, often a hydrogel or polymer, is determined by measuring the percentage increase in weight or volume after immersing the material in a liquid, typically distilled water, for a set time.

The process involves measuring the initial dry mass, immersing the material, removing excess liquid, and measuring the final swollen mass. This index reflects the material's liquid absorption capacity, offering insights into its swelling

behavior and applications in biomaterials, drug delivery, and environmental sensing¹³.

$$S I = (\text{Final mass} - \text{Initial mass}) / \text{Initial mass} \times 100$$

Formulation of Loratadine: We prepared a total of 80 tablets, each containing 100mg of Loratadine^{14, 15}, using the direct compression method. The formulation codes and compositions are listed in **Table 1**. We sieved the materials used in the formulation through an 80# sieve and thoroughly mixed them. Subsequently, we compressed the blend into tablets with 12.5mm flat round punches on a 12 station tablet compression machine.

Formulation of Loratadine Fast Disintegrating Tablets:

TABLE 1: FORMULATED COMPOSITION OF DIFFERENT BATCHES OF FDT OF LORATADINE

S. no.	Ingredients (MG/TAB)	Formulation Code											
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	Loratadine	10	10	10	10	10	10	10	10	10	10	10	10
2	Croscarmellose sodium	10	20	30									
3	Crosspovidone				10	20	30						
4	Sodium starch glycolate							10	20	30			
5	Isabgol Mucilage										10	20	30
6	Microcrystalline cellulose	80	80	80	80	80	80	80	80	80	80	80	80
7	Mannitol	78	68	58	78	68	58	78	68	58	78	68	58
8	Aerosil	8	8	8	8	8	8	8	8	8	8	8	8
9	Sodium starch fumerate	2	2	2	2	2	2	2	2	2	2	2	2
10	Vanilla flavour	4	4	4	4	4	4	4	4	4	4	4	4
11	Aspartame	8	8	8	8	8	8	8	8	8	8	8	8

*(mg-milligram)

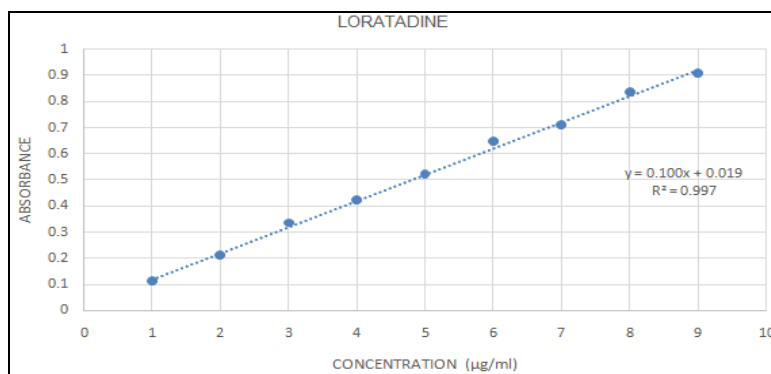


FIG. 1: CALIBRATION CURVE FOR LORATADINE IN 0.1N HCL

RESULT AND DISCUSSION: In this study, Loratadine formulations were prepared using natural superdisintegrants like Ispaghula, as well as synthetic superdisintegrants such as CCS, SSG and CP, in order to compare their effects.

Characterization of drug:

Determination of Organoleptic Properties: The substance exhibits a powdered form, characterized by a white color and an absence of Odour.

Analytical Methods:

Determination of λ_{max} and Standard Calibration Curve of Loratadine: The UV absorption spectrum of Loratadine in 0.1N HCl showed a peak at 275nm at a concentration of 100µg/ml. Where a linear relationship was found between absorbance and concentration^{16, 17}.

Determination of Drug Polymer Compatibility Studies: The Fourier Transform Infrared (FTIR)

peak matching technique was used to assess the drug's compatibility with the superdisintegrants. The analysis revealed that the primary peaks of the drug and physical mixture remained constant which indicates that API is compatible with superdisintegrants¹⁸.

Swelling Characteristics of Superdisintegrants:

Swelling index of Ispaghula mucilage was determined to be 1900 ± 3.64 .

Evaluation of powder blends of Loratadine:

Pre-Compression Parameters: Various tests were conducted to evaluate the flow properties of the powder blend. Angle of repose was found to $30^\circ.42$

to $34^\circ.92$, indicating good flow properties for all formulations. Bulk density measurements yielded values between 0.43-0.49 g/ml, further confirming favorable flow characteristics¹⁹⁻²¹.

Tapped density values fell within the range of 0.49-0.53g/ml, providing additional evidence of good flow properties. The compressibility index ranged from 10.76-15.32%, indicating good compressibility and flow properties. Hausner's ratio values ranged from 1.10-1.18, signifying satisfactory flow properties. In conclusion, the formulations exhibited desirable flow properties, as summarized in **Table 2**.

TABLE 2: EVALUATION OF POWDER BLENDS OF LORATADINE

Formulation Code	Angle of repose * (Θ)	Bulk density* (g/ml)	Tapped density* (g/ml)	Carr's index* (%)	Hausner's ratio*
F1	32.91 ± 0.002	0.46 ± 0.002	0.52 ± 0.001	10.87 ± 0.002	1.12 ± 0.008
F2	33.11 ± 0.001	0.44 ± 0.006	0.50 ± 0.003	12.16 ± 0.007	1.14 ± 0.004
F3	34.10 ± 0.004	0.43 ± 0.003	0.49 ± 0.002	12.74 ± 0.004	1.14 ± 0.002
F4	34.92 ± 0.002	0.49 ± 0.002	0.52 ± 0.006	12.76 ± 0.004	1.10 ± 0.002
F5	33.38 ± 0.003	0.46 ± 0.004	0.51 ± 0.004	13.14 ± 0.001	1.12 ± 0.003
F6	32.42 ± 0.002	0.46 ± 0.003	0.51 ± 0.002	14.32 ± 0.003	1.14 ± 0.006
F7	31.85 ± 0.002	0.45 ± 0.001	0.52 ± 0.009	12.23 ± 0.002	1.13 ± 0.005
F8	33.12 ± 0.001	0.45 ± 0.005	0.53 ± 0.005	15.05 ± 0.004	1.17 ± 0.004
F9	34.09 ± 0.004	0.44 ± 0.002	0.52 ± 0.002	13.78 ± 0.005	1.15 ± 0.003
F10	32.92 ± 0.002	0.47 ± 0.002	0.52 ± 0.006	10.76 ± 0.004	1.12 ± 0.002
F11	32.38 ± 0.003	0.44 ± 0.004	0.50 ± 0.004	11.14 ± 0.001	1.12 ± 0.003
F12	30.42 ± 0.002	0.43 ± 0.003	0.51 ± 0.002	15.32 ± 0.003	1.18 ± 0.006

*(g/ml-gram/milliliter)

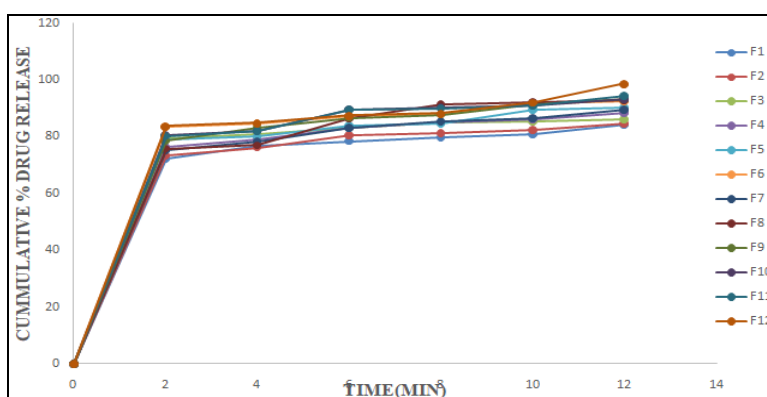


FIG. 2: CUMULATIVE % DRUG RELEASE PROFILE OF FORMULATION F1–F12

Evaluation of Compressed Loratadine Tablets:

Thickness: The thickness of the tablets from all formulations was consistent, from 3.68 ± 0.01 mm to 3.69 ± 0.11 mm, with minimal variations that suggested uniform die fill during compression process²².

Weight Variation: Where direct compression method is used to formulate the tablets. The

material flowed freely, leading to consistent die fill. The weight variation was within acceptable range according to the Pharmacopoeia guidelines, with no deviation greater than 15% (according to standard values).

Hardness: Results from the Monsanto Hardness tester showed a uniform hardness range of 3.4 ± 0.1 to 3.5 ± 0.1 kg/cm², indicating that the tablets are

robust and can handle physical and mechanical stresses well due to the even compression force applied.

Friability: The tablets were evaluated using a Roche Friabilator, and the outcomes demonstrated good mechanical resistance, with friability ranging from 0.202 ± 0.06 to 0.403 ± 0.10 (less than 1%). These results indicated that the fast-disintegrating tablets met the required quality standards and were deemed acceptable.

Drug Content of Loratadine: The assay method was employed to assess the tablets, and the drug content fell within the acceptable range, with values ranging from $97.06 \pm 0.5\%$ w/w to $99.51 \pm 0.2\%$ w/w. The findings complied with the Indian Pharmacopoeia (I.P.) standards.

Disintegration time: The disintegration time of 12 formulations were found to be in the range of 8 ± 0.4 to 44 ± 0.8 seconds. Where the Ispaghula Mucilage containing formulations showing quicker disintegration rates.

This is because of immediate water uptake, swelling, and bursting properties of Ispaghula Mucilage. The most efficient formulation, F12 with

the highest concentration of Ispaghula Mucilage had the shortest disintegration time.

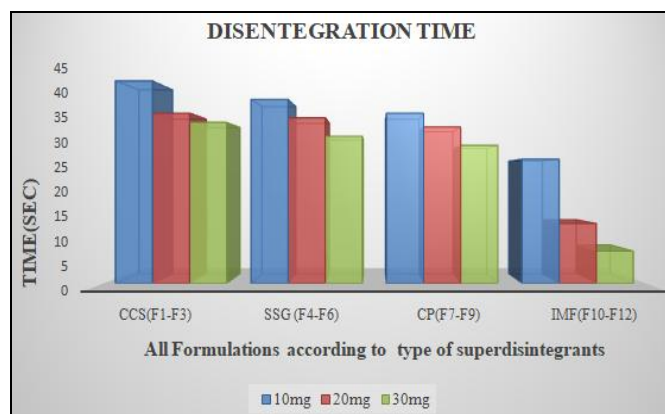


FIG. 3: DISINTEGRATE PROFILE OF LORATADINE TABLETS (F1 -F12)

Wetting time: The wetting times for the 12 formulations was found to be in the range of 15.3 ± 0.5 to 45.6 ± 1.5 seconds.

Water Absorption Ratio: The water absorption ratio was assessed and was found to be between 60.6 ± 0.8 and $102.6 \pm 0.5\%$. Ispaghula mucilage revealed the quickest wetting time and the greatest absorption ratio²³. A summary of the post-compression parameters can be seen in **Table 3**.

TABLE 3: EVALUATION OF COMPRESSED LORATADINE TABLETS

For mula tion code	Appeara nce	Thickness (mm)	Weight variation	Hardness (kg/cm ²)	Friability (%)	Drug content (%w/w)	Disinte grate time (sec)	Wetting time(sec)	Water absorption ratio (%)
F1	White	3.68± 0.05	196.18±0.4	3.4±0.1	0.350±0.05	97.82 ± 0.3	44± 0.8	45.6± 1.5	60.6± 0.8
F2	White	3.68± 0.05	199.9±0.2	3.4±0.05	0.402±0.15	97.65 ± 0.3	37± 0.1	39.13± 1.5	69.3± 0.7
F3	White	3.68± 0.05	198.9±0.1	3.4±0.1	0.301±0.1	97.94 ± 0.4	35± 0.2	34.2± 0.5	74.7± 0.8
F4	White	3.65± 0.05	201.2±0.2	3.5±0.05	0.252±0.13	97.25 ± 0.2	40± 0.4	38.3± 1.5	70± 0.8
F5	White	3.68± 0.05	198.43±0.1	3.5±0.1	0.302±0.07	97.82 ± 0.3	36± 0.2	32.1± 0.5	78.6± 0.7
F6	White	3.68± 0.11	200.15±0.3	3.5±0.05	0.352±0.09	98.04 ± 0.3	32± 0.4	25.8± 1	85± 3.7
F7	White	3.69± 0.01	200.55±0.4	3.4±0.05	0.202±0.06	98.25 ± 0.4	37± 0.1	30± 0.8	80± 1.9
F8	White	3.68± 0.05	199.99±0.1	3.4±0.05	0.403±0.10	99.36 ± 0.1	34± 0.2	26± 1.4	85± 2.8
F9	White	3.68± 0.05	200.00±0.3	3.4±0.06	0.351±0.11	97.06 ± 0.5	30± 0.2	23± 1.1	90± 0.9
F10	Greyish white	3.68± 0.11	198.9±0.1	3.4±0.05	0.242±0.11	97.14 ± 0.2	27± 0.1	22.1± 0.9	89.3± 0.7
F11	Greyish white	3.68± 0.05	200.08±0.3	3.5±0.09	0.292±0.09	98.42 ± 0.3	13± 0.3	17.5± 1.5	96.6± 0.5
F12	Greyish white	3.68± 0.05	199.5±0.7	3.5±0.1	0.342±0.04	99.51 ± 0.3	8± 0.4	15.3± 0.5	102.6± 0.5

All values are expressed as mean ± SE, n=3. *(mm-millimeters, kg/cm²-kilogramper Square Centimeter, %-percent, s-seconds, and % w/w-percent weight by weight).

In-vitro Release Studies: The *in-vitro* drug release studies of Loratadine Tablets (FDT) were shown in **Table 4** and **Fig. 2**. The rate of release was observed to be affected by the type and

concentrations of superdisintegrants used in the formulations. All the 12 formulations had *in-vitro* drug release of at least 80% within 12 minutes²⁴.

TABLE 4: IN-VITRO CUMULATIVE PERCENT OF DRUG RELEASE OF F1 TO F12

Time	Cumulative %drug release of all formulations											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
2	72.15	73.49	79.3	76.4	79.3	83.55	75.05	75.73	78.86	80.42	80.42	83.55
4	76.92	76.25	80.96	78.94	80.29	84.76	78.27	76.93	83.19	82.08	82.08	84.76
6	78.44	80.68	83.15	83.15	83.82	87.41	83.14	86.5	86.73	89.64	89.64	87.41
8	79.64	81.44	84.81	84.8	84.81	88.18	85.25	91.29	87.95	90.19	90.19	88.18
10	80.85	82.42	85.35	86.01	89.6	91.86	86.46	92.06	91.4	91.18	91.18	92.08
12	84.29	84.75	86.12	88.35	90.37	92.63	89.46	92.83	93.41	93.3	95.53	98.67

*(m-minutes)

The Impact of Superdisintegrants on *In-vitro* Drug Release:

The three Formulations (F1, F2, F3) were prepared by using Croscarmellose sodium with a concentrations of 10mg, 20mg, and 30mg. The amount of drug release for F1, F2, and F3 was recorded as 84.29%, 84.75%, and 86.12% at 12 minutes. The highest drug release (86.12%) was observed in F3, containing 30mg of Croscarmellose sodium. Therefore, it can be concluded that the optimal concentration of Croscarmellose sodium was found to be 30mg. Formulations F4, F5, and F6, which included 10mg, 20mg, and 30mg of Sodium starch glycolate as a superdisintegrant, respectively, exhibited cumulative percentages of drug release of 88.35%, 90.37%, and 92.63% at 12 minutes. The highest drug release (92.63%) was observed in formulation F6, containing 30mg of Sodium starch glycolate, and it was obtained at 12 minutes, indicating 30mg of SSG is the optimal Formulation. The next 3 Formulations F7, F8, and F9 were formulated by using Crosspovidone, with 10mg, 20mg and 30mg, respectively. Among them, formulation F9, containing 12mg of Crosspovidone, exhibited the highest amount of drug release (93.41%) at 12 minutes. The finding suggests that the optimal formulation by using Crosspovidone is 30%. Formulations F10, F11, and F12 were prepared with varying concentrations of Ispaghula mucilage as a superdisintegrant, specifically 10mg, 20mg, and 30mg, respectively. The cumulative percentage of drug release for F10, F11 and F12 at 12 minutes were 93.30%, 95.53%,

and 98.67%, respectively. The highest drug release (98.67%) was observed in formulation F12, containing 30mg of Ispaghula mucilage, and it was obtained at 12 minutes, indicating that 30mg of Ispaghula mucilage is the optimal formulation. Based on the obtained values, the cumulative percentage of drug release for all formulation containing 4 different superdisintegrants follows the order:

Ispaghula mucilage > Sodium starch glycolate > Croscarmellose sodium > Crosspovidone. Among 12 formulations tested, the one containing Ispaghula Mucilage (30mg) as a Superdisintegrant demonstrated the highest drug release. This can be attributed to its rapid breakdown in the dissolution medium, leading to maximum drug release. After careful evaluation, it was concluded that formulation F12 is optimal formulation due to its fast disintegration time and highest percentage of drug release.

Stability Studies: The accelerated stability test of the tablets revealed that their disintegration time, release characteristics, and physico-chemical properties remained unaltered after three months of exposure to 40°C ± 2°C and 75% ± 5% RH. Thus, it can be confidently asserted that the formulated FDT'S are stable under these conditions. Nevertheless, further studies are necessary to determine the product's shelf-life according to ICH guidelines.

TABLE 5: STABILITY RESULTS (INITIAL TO 3RD MONTH)

S. no.	Evaluation Parameter	Formulation F12 Observations			
		Initial	First month	Second month	Third month
1	Physical appearance	Greyish white, round, break through, flat tablet	No change	No change	No change
2	Hardness (kg/cm ²)	3.5±0.1	3.48±0.02	3.48±0.631	3.02±0.323
3	Disintegration test(seconds)	8±0.4	7.04±0.6	8.93±0.6	8.33±0.01
4	Dissolution test (%)	98.67	98.62±0.21	97.97±0.42	97.61±0.519
5	Drug content (% w/w)	99.51±0.3	98.71±0.4	98.21±0.18	97.82±0.05

CONCLUSION: Results of this study suggest that formulation F12, which contains Ispaghula mucilage 30 mg as a Superdisintegrant, is an effective method for producing fast-disintegrating Loratadine tablets. These tablets had a disintegration time of 8 ± 0.4 , wetting time of 15.3 ± 0.5 , water absorption ratio 102.6 ± 0.5 , and cumulative % drug release of 98.67 in 12 minutes.

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CONFLICTS OF INTEREST: Nil

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