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Original Article

Formulation and Evaluation of Fast Disintegrating Tablets of Antihistamine Drug Using Natural Super Disintegrants

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ABSTRACT

Background: Fast Disintegrating Tablets (FDTs) are crucial in pharmaceuticals for rapid drug onset and improved patient compliance, particularly for those who have difficulty swallowing. Chlorpheniramine Maleate (CPM), an antihistamine used for allergy relief, is the focus of this study to develop FDTs. The rapid onset of action is advantageous in treating allergic reactions, providing quick relief from symptoms like sneezing, runny nose, and itching. By exploring this innovative approach, the present study aims to enhance the convenience, effectiveness, and patient acceptance of oral drug delivery. **Materials and Methods:** Tablets were formulated by direct compression, incorporating three superdisintegrants: Tulasi powder, *Isabgol* mucilage, and Croscarmellose sodium. Various pre- and post-compression parameters were examined, including flow properties, hardness, wetting time, water absorption ratio, disintegration time, in-vitro dissolution studies, and accelerated stability studies. **Results:** Pre-compression parameters showed good compressibility and flow properties. Post-compression parameters met specified limits, with formulation F6, containing 14 mg *Isabgol* mucilage, demonstrating the lowest disintegration time (7 sec) and highest cumulative drug release (98.85%). Accelerated stability testing confirmed the stability of formulation F6 over three months under elevated temperature and humidity conditions. **Conclusion:** *Isabgol* mucilage proved to be the optimal superdisintegrant, exhibiting the fastest disintegration time, highest drug release, and favorable flow properties offering a reliable solution for patients with swallowing difficulties and ensuring rapid relief. This study highlights the potential of *Isabgol* mucilage in enhancing the performance of FDTs, paving the way for improved patient outcomes and compliance.

Keywords: Chlorpheniramine maleate, Croscarmellose sodium, Fast disintegrating tablets, *Isabgol* mucilage, Superdisintegrant, Tulasi powder.

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INTRODUCTION

In the domain of oral drug delivery, Fast Disintegrating Tablets (FDTs) have emerged as a groundbreaking solution to tackle challenges associated with conventional tablet formulations. FDTs, also known as orally disintegrating tablets or quick-dissolve tablets, offer a significant advantage by rapidly dissolving or disintegrating within seconds in the oral cavity, thus eliminating the need for water or minimal liquid consumption. This remarkable characteristic has attracted the attention of healthcare professionals, researchers, and patients, especially those who experience difficulties in swallowing conventional tablets.[1-3]

The significance of FDTs lies in their capacity to deliver drugs rapidly and facilitate dissolution in the oral cavity, leading to a quicker onset of action and enhanced bioavailability. Leveraging the advantages of FDTs can result in improved therapeutic efficacy, particularly in situations necessitating immediate relief, such as allergies or acute symptoms. Furthermore, FDTs hold promise for specific patient groups, including the elderly, pediatric patients, and individuals with swallowing difficulties, as they offer a convenient and user-friendly method of drug administration.[4-6]

The present study aims to develop and evaluate fast disintegrating tablets of an antihistamine drug utilizing natural superdisintegrants. Natural superdisintegrants have gained recognition as preferable alternatives to synthetic counterparts due to their biocompatibility, sustainability, and ease of regulatory compliance. Additionally, these natural compounds exhibit

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excellent water absorption and swelling properties, facilitating rapid tablet disintegration and drug release. By integrating natural superdisintegrants into the formulation, we aim to overcome the limitations associated with traditional tablet formulations, ensuring swift disintegration, improved taste, and overall patient acceptance.[7]

The objective of this investigation is to evaluate the feasibility and efficacy of utilizing natural superdisintegrants in the development of FDTs for antihistamine drugs. Through comprehensive formulation and evaluation, we aim to determine the optimal combination of natural superdisintegrants that offer rapid disintegration, efficient drug delivery, and desirable sensory attributes. The findings of this study have the potential to advance oral drug delivery systems, providing a patient-centric approach to medication administration and improving therapeutic outcomes for individuals with allergic conditions.[8]

By exploring this innovative approach, we aim to enhance the convenience, effectiveness, and patient acceptance of oral drug delivery. The outcomes of this study will illuminate the potential of FDTs as a promising alternative to conventional tablets, particularly in the context of antihistamine medications, and pave the way for further advancements in pharmaceutical technology.

MATERIALS AND METHODS

Materials

Chlorpheniramine maleate was provided as a gift sample by Bhavani Pharmaceuticals, Hubli. Tulasi Powder, *Isabgol* Mucilage were obtained from Tippanna Kshatriya Ayurvedic shop, Hubli. Croscarmellose Sodium, Mannitol, Sodium Saccharin, Talc were provided by Vergo pharmaceuticals, Verna. Other reagents and chemicals used were of analytical reagent grade.

Methods

Preparation of Isabgol mucilage

The mucilage extraction process began by soaking *Plantago ovata* seeds in water (20-30 times the volume of seeds) for a minimum of 48 hr. The mixture was then boiled for 2 hr to ensure complete release of mucilage into the water. The mucilage was separated from the seeds by squeezing it through a muslin cloth. To precipitate the mucilage, 3 times the volume of 95% ethanol was added. The mucilage was then dried in an oven at 50-55°C. Once dried, the mucilage was scraped and pulverized using a pestle and mortar. The resulting powder was passed through a 60-mesh sieve to achieve a uniform particle size.[9,10]

Determination of λ_{max} of chlorpheniramine maleate and Preparation of Calibration Curve

A 100 mg sample of the Active Pharmaceutical Ingredient (API) was precisely weighed and dissolved in a small quantity of pH 6.8 phosphate buffer, then diluted to achieve a concentration of 1000 µg/mL (SS-I). From SS-I, 10 mL was further diluted to 100 mL to attain a concentration of 100 µg/mL (SS-II). Aliquots of 0.2, 0.4, 0.6, 0.8, 1.0, and 1.2 mL were pipetted from SS-II into 10 mL volumetric flasks, and the volume was adjusted with pH 6.8 phosphate buffer to achieve concentrations of 2, 4, 6, 8, 10, and 12 µg/mL, respectively. The absorbance of each concentration was measured at 261 nm against a blank.[11,12]

Determination of Drug-Polymer Compatibility

Fourier Transform Infrared (FTIR) Spectroscopy

A physical mixture of the API and excipients in a 1:1 ratio was stored in amber-colored bottles. These bottles were then placed in a stability chamber set to 40°C±2°C and 75%±5% relative humidity for 1 month. After this period, samples were analyzed using an FTIR-8400S instrument (Shimadzu, Japan) with a scanning range of 400 to 4400 cm^{-1}.[12]

Characterization of Superdisintegrants

Swelling index

To determine the swelling index, 1 g of mucilage was added to a 25 mL glass-stoppered measuring cylinder along with 25 mL of water. The initial volume occupied by the dry husk was measured as V1. The mixture was agitated every 10 min for 1 hr and then left to stand for 3 hr at room temperature. After this period, the volume occupied by the mucilage (V2) was measured. The mean value of V2 was calculated from three samples to determine the swelling index. This process was repeated thrice to obtain the average and variation for the swelling index.[13]

$$\text{Swelling index} = (V2 - V1)/V1 \times 100$$

Formulation of chlorpheniramine maleate Fast Disintegrating Tablets

Eighty tablets were manufactured using the direct compression method, with each tablet comprising 100 mg of CPM. The formulation codes and compositions for the various tablet formulations are detailed in Table 1. All materials used in the formulations were sieved through an 80# sieve and thoroughly mixed. The blend was then compressed into tablets using 9.5 mm flat round punches on a 12-station tablet compression apparatus (Rimex MINI press, Karnavathi Engineering Pvt. Ltd., Gujarat, India).[14]

Physicochemical Evaluation of Fast Disintegrating Tablets

Weigh Variation

Twenty tablets were randomLy selected from each batch and individually weighed to assess weight variation. The percentage deviation allowed conforms to the standards set by the United States Pharmacopeia (USP).[15]

Thickness

The tablet thickness of 10 tablets was measured using Vernier calipers.[16]

Hardness

Monsanto Hardness Tester was used to determine the hardness of tablets.[17]

Friability

Twenty tablets were accurately weighed and placed in the Roche Friabilator and undergo 100 revolutions. The percentage of friability is then calculated using the difference between the initial and final weights.[18]

$$\% F = (\text{Initial wt.} - \text{Final wt.} / \text{Initial wt.}) \times 100$$

Disintegration time

The disintegration test, per IP standards, involved immersing tablets in simulated saliva fluid (pH 6.8) at 37°C within a basket apparatus. Tablets are assessed for complete disintegration, with time recorded in seconds.[19]

Wetting Time and Water Absorption Ratio

The wetting time of tablets was determined by placing them on folded tissue paper in a Petri dish filled with water and amaranth red dye. The water absorption ratio was calculated by weighing the tablets before (Wb) and after water absorption (Wa) using the following formula.[20]

$$R=100\times Wa-Wb/Wb$$

In vitro drug release

Six tablets from each formulation were introduced into the LABINDIA dissolution test apparatus (DS8000). The dissolution medium consisted of 900 mL of phosphate buffer at pH 6.8 maintained at 37±0.5°C, and agitated at 50 rpm. Samples were withdrawn at 2-min intervals for subsequent analysis.[21,22]

RESULTS

Determination of Absorption Maxima and Standard Calibration Curve of chlorpheniramine maleate

The UV absorption spectrum of chlorpheniramine malate in phosphate buffer with a pH of 6.8 exhibited a maximum wavelength of 261 nm, as depicted in Figure 1. A linear relationship between absorbance and concentration was observed within the concentration range of 100 µg/mL.[22]

Determination of Drug Polymer Compatibility Studies

FTIR analysis indicated that combining the drug with different superdisintegrants did not cause notable changes in the functional groups' peak values. Tulasi, peaks were observed at 1704.38 cm^{-1} for C=C stretching, 1704.38 cm^{-1} for C=N stretching, 1355.79 cm^{-1} for C-N stretching, 862.91 cm^{-1} for C-Cl bending, and 2451.57 cm^{-1} for COOH. Similarly, combining the drug with *Isabgol* resulted in peaks at 1700.10 cm^{-1} for C=C stretching, 1700.10 cm^{-1} for C=N stretching, 1355.79 cm^{-1} for C-N stretching, 862.91 cm^{-1} for C-Cl bending, and 2423.00 cm^{-1} for COOH. This suggests compatibility between the drug and the superdisintegrants (Figure 2a and 2b).

Swelling Index of Superdisintegrants

The swelling index of Tulasi powder was found to be 300±1.48, whereas the swelling index of *Isabgol* mucilage was determined to be 1900±3.64.

Pre-compression Parameters

The flow properties of the powder blend were evaluated through various tests. The angle of repose ranged from 30˚.72' to 34˚.10', indicating favorable flow properties. Bulk density measurements ranged between 0.43 and 0.47 g/mL, suggesting good flow characteristics. Tapped density values were between 0.49 and 0.53 g/mL, further confirming favorable flow properties. The compressibility index varied from 9.98% to 15.78%, indicating satisfactory compressibility and flow properties. Additionally, Hausner's ratio values ranged from 1.11 to 1.18, further indicating

Table 1: Formulated Composition of different Batches of FDT of CPM.

Sl. No.	Ingredients (mg/Tablet)	Formulation Code								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Chlorpheniramine Maleate	4	4	4	4	4	4	4	4	4
2	Tulasi powder	8	12	14						
3	*Isabgol* Mucilage				8	12	14			
4	Croscarmellose sodium							8	12	14
5	Mannitol	82	78	76	82	78	76	82	78	76
6	Sodium saccharin	2	2	2	2	2	2	2	2	2
7	Purified talc	4	4	4	4	4	4	4	4	4

*(mg-Milligram).

satisfactory flow properties. Overall, the formulations exhibited favorable flow properties, as summarized in Table 2.

Evaluation of Compressed chlorpheniramine maleate Tablets

Thickness

The tablets across all formulations exhibited consistent thickness, ranging from 2.40±0.01 to 2.43±0.11 mm.

Weight variation

The weight variation among tablets was minimal, with values ranging from 99.43±0.1 to 106.2±0.2 mg. Tablet weights remained within the acceptable range as per pharmacopoeia specifications, falling below the 15% deviation limit.[22]

Hardness

The tablets exhibited uniform hardness ranging from 3.5±0.1 to 3.4±0.1 kg/cm², reflecting consistent compression force application.

Friability

The tablets showed good mechanical resistance with friability ranging from 0.202 ± 0.06 to 0.403 ± 0.10%, well below the acceptable limit of 1%. This indicates that the fast-disintegrating tablets maintained acceptable quality standards.

Drug Content of chlorpheniramine maleate

The assay method was used to evaluate tablets, yielding drug content that was within the acceptable range. The amount found was 97.06±0.5-99.36±0.1%w/w, matching the requirements of I.P

Disintegration time

The Disintegration Times (DT) for formulations containing Tulasi powder, *Isabgol* Mucilage, and Croscarmellose sodium were evaluated. For formulations with Tulasi powder (F1-F3), the disintegration times ranged from 44±0.3 sec to 35±0.2 sec. In contrast, formulations containing *Isabgol* Mucilage (F4-F6) exhibited disintegration times ranging from 27±0.1 sec to 7±0.1 sec. Finally, formulations containing Croscarmellose sodium (F7-F9) showed disintegration times varying from 37±0.3 sec to 33±0.3 sec. These results demonstrate the effect of different superdisintegrants on the disintegration profile of the tablets. The disintegration profiles for all formulations are illustrated in Figure 3.

Wetting time and Water absorption ratio

The wetting times for the nine formulations varied from 15.3±0.5 to 40.3±1.5 sec. *Isabgol* mucilage demonstrated the quickest wetting time, followed by Croscarmellose sodium and Tulasi powder. The water absorption ratio ranged between 61.6±0.8 and 102.6±0.5%. Higher concentrations of *Isabgol* mucilage, CCS, and Tulasi powder resulted in higher water absorption ratios. Notably, *Isabgol* mucilage showed the highest absorption ratio of 102.6±0.5% for formulation F6, contributing to its rapid disintegration (Table 3).

In vitro release studies

The results of the *in vitro* drug release studies for FDTs of chlorpheniramine maleate are presented in Table 4 and Figure 4. All formulations exhibited a drug release exceeding 90% within 14 min.

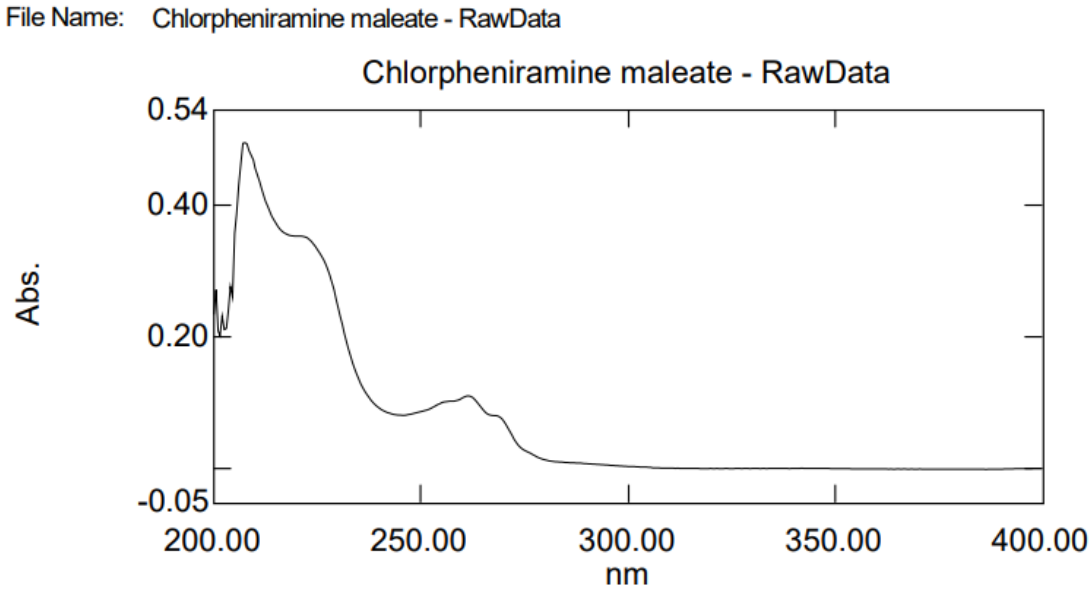

Figure 1: UV spectra of chlorpheniramine maleate in Phosphate buffer pH 6.8.

Table 2: Evaluation of powder blends of chlorpheniramine maleate.

Formulation Code	Angle of repose	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	32.92°±0.002	0.47±0.002	0.52±0.006	10.76±0.004	1.12±0.002
F5	32.38°±0.003	0.44±0.004	0.50±0.004	11.14±0.001	1.12±0.003
F6	30.42°±0.002	0.43±0.003	0.51±0.002	15.32±0.003	1.18±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

*(g/mL-Gram/milliliter).

Table 3: Evaluation of compressed chlorpheniramine maleate tablets.

Code	Thickness (mm)	Weight variation	Hardness (kg/cm²)	Friability (%)	Disintegrate time (s)	Wetting time (s)	Water absorption ratio (%)	Drug content (%w/w)
F1	2.43± 0.05	100.18±0.4	3.4±0.1	0.350±0.05	44±0.3	40.3± 1.5	67± 0.8	97.82 ± 0.3
F2	2.43± 0.05	99.9±0.2	3.4±0.05	0.402±0.15	37±0.1	35.1± 0.5	70.6± 0.7	97.65 ± 0.3
F3	2.43± 0.05	104.9±0.1	3.4±0.1	0.301±0.1	35±0.2	27.8± 1	78± 3.7	97.94 ± 0.4
F4	2.43± 0.05	106.2±0.2	3.5±0.05	0.252±0.13	27±0.1	22.1± 0.9	89.3± 0.7	97.25 ± 0.2
F5	2.43± 0.05	99.43±0.1	3.5±0.1	0.302±0.07	13±0.3	17.5± 1.5	96.6± 0.5	98.82 ± 0.3
F6	2.43± 0.11	100.15±0.3	3.5±0.05	0.352±0.09	7±0.1	15.3± 0.5	102.6± 0.5	99.04 ± 0.3
F7	2.40± 0.01	101.55±0.4	3.4±0.05	0.202±0.06	37±0.3	38.6± 1	61.6± 0.8	98.25 ± 0.4
F8	2.43± 0.05	99.99±0.1	3.4±0.05	0.403±0.10	35±0.2	32.13± 1.5	62.3± 0.7	99.36 ± 0.1
F9	2.43± 0.05	100.00±0.	3.4±0.06	0.351±0.11	33±0.3	24.2± 0.5	68.7± 0.8	97.06 ± 0.5

All values are expressed as mean± SE, n=3. *(mm-Millimeters, kg/cm²-Kilogram per Square Centimeter, %-Percent, s-Seconds, %w/w-Percent weight by weight).

Effect of Superdisintegrant on Drug Release

Formulations F1, F2, and F3, containing 8 mg, 12 mg, and 14 mg of Tulasi powder as a superdisintegrant, showed cumulative drug release percentages of 92.91%, 93.39%, and 94.28%, respectively, at 14 min. Formulations F4, F5, and F6, with 8 mg, 12 mg, and 14 mg of *Isabgol* mucilage, exhibited cumulative drug release percentages of 93.21%, 95.01%, and 99.05%, respectively. Formulations F7, F8, and F9, containing varying concentrations of 8 mg, 12 mg, and 14 mg of Croscarmellose sodium, also demonstrated high drug release. Notably, the formulation containing *Isabgol* mucilage (14 mg) as a superdisintegrant exhibited the highest drug release.

Stability Studies

After subjecting the tablets to accelerated stability conditions (40°C±2°C and 75%±5% relative humidity) for three months, no significant changes were observed in the disintegration time, release characteristics, or physical-chemical properties of the tablets. This suggests that the formulated fast-disintegrating tablets remained stable under these conditions. Further studies

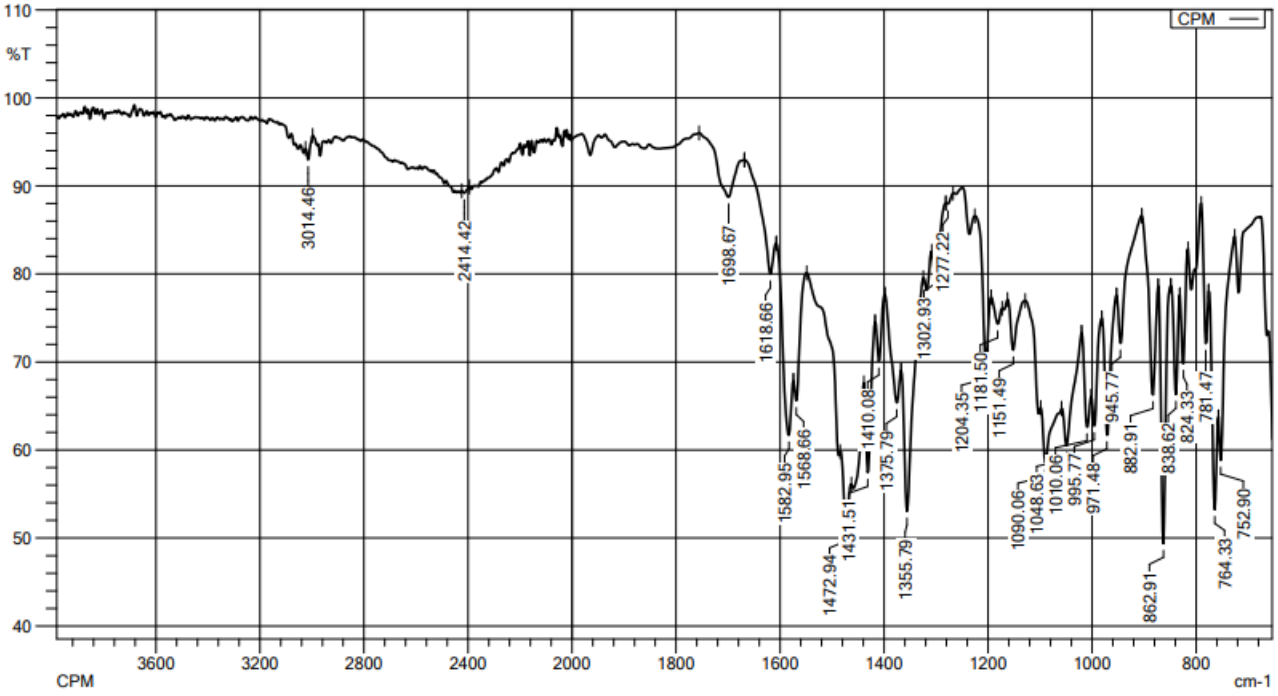

Figure 2a: FTIR spectrum of chlorpheniramine maleate.

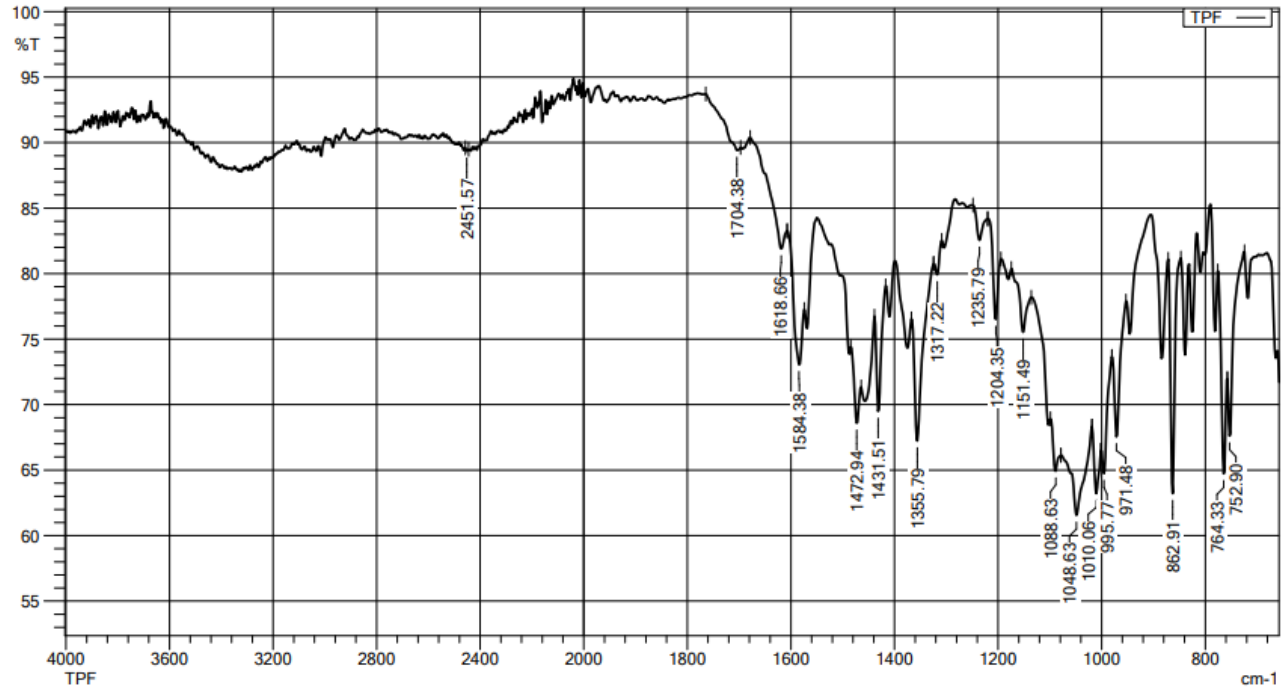

Figure 2b : FTIR spectrum of chlorpheniramine maleate+ Tulasi powder.

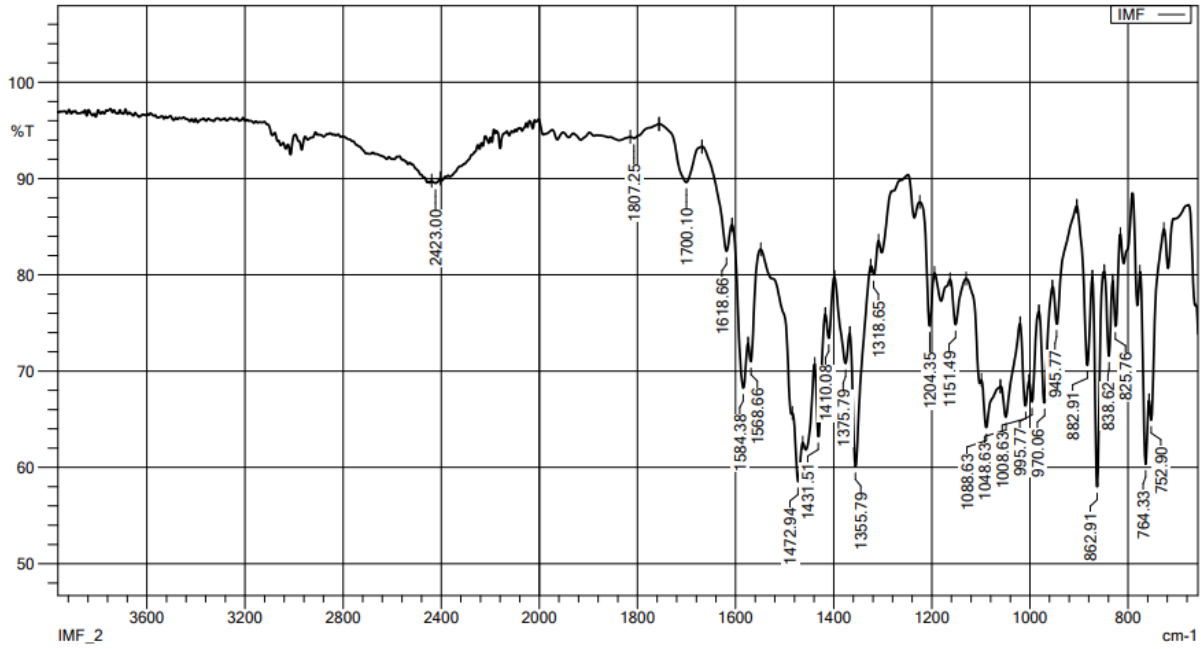

Figure 2c: FTIR spectrum of chlorpheniramine maleate+*Isabgol* mucilage.

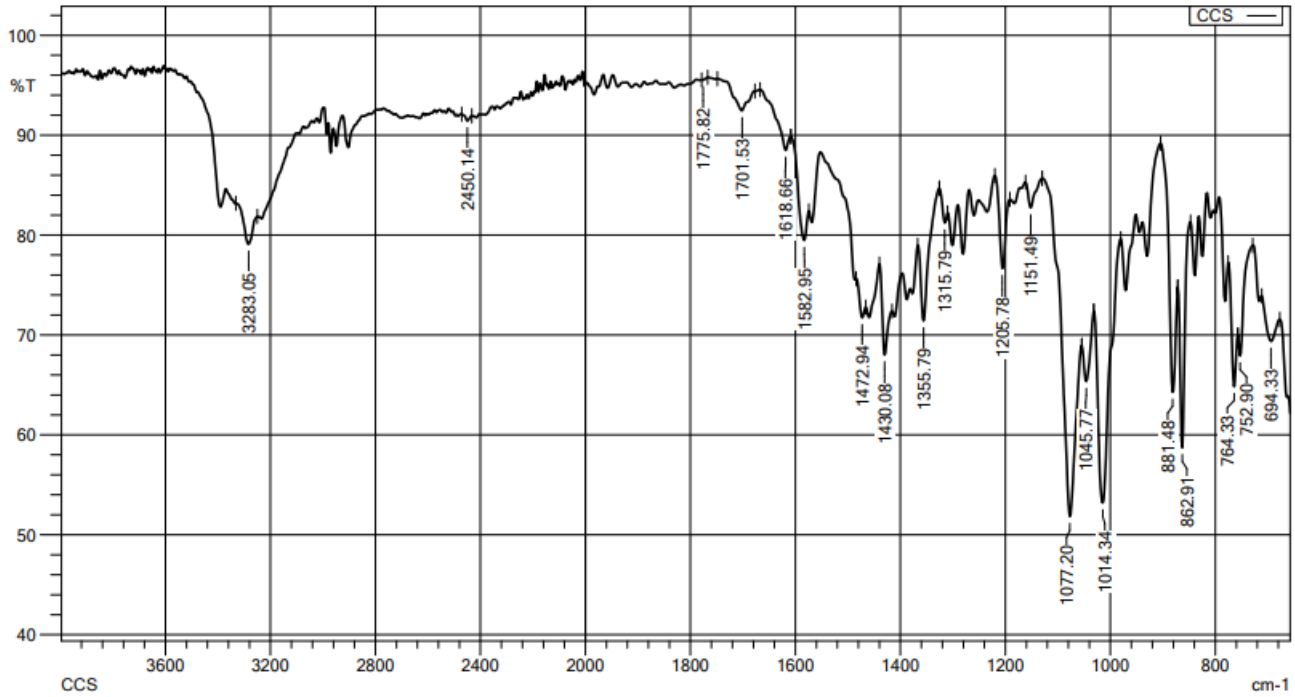

Figure 2d : FTIR spectrum of chlorpheniramine maleate+Croscarmellose sodium.

following ICH guidelines are necessary to confirm the product's shelf-life.[22]

DISCUSSION

The evaluation of fast-disintegrating tablets of chlorpheniramine maleate included several critical tests to determine their effectiveness and stability. This discussion highlights the findings from various analyses, focusing on their implications for tablet performance.

The UV absorption spectrum of chlorpheniramine maleate exhibited a maximum wavelength at 261 nm, confirming its suitability for analysis. The linear relationship between absorbance and concentration within the studied range ensured accurate drug quantification. This linearity is essential for reliable measurement of drug content in the formulations, underpinning the overall accuracy of dosage.[11]

FTIR analysis was conducted to assess potential chemical interactions between chlorpheniramine maleate and the

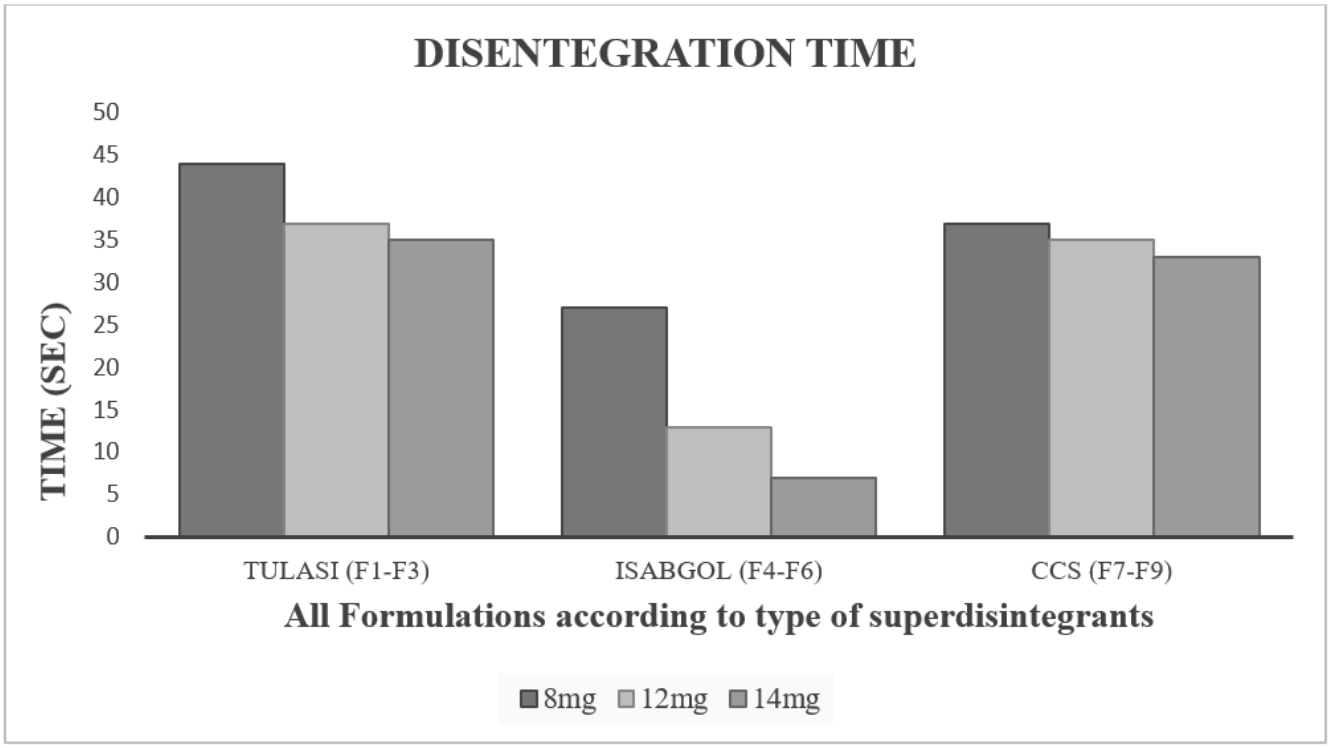

Figure 3: Disintegrate profile of chlorpheniramine maleate tablets (F1-F9).

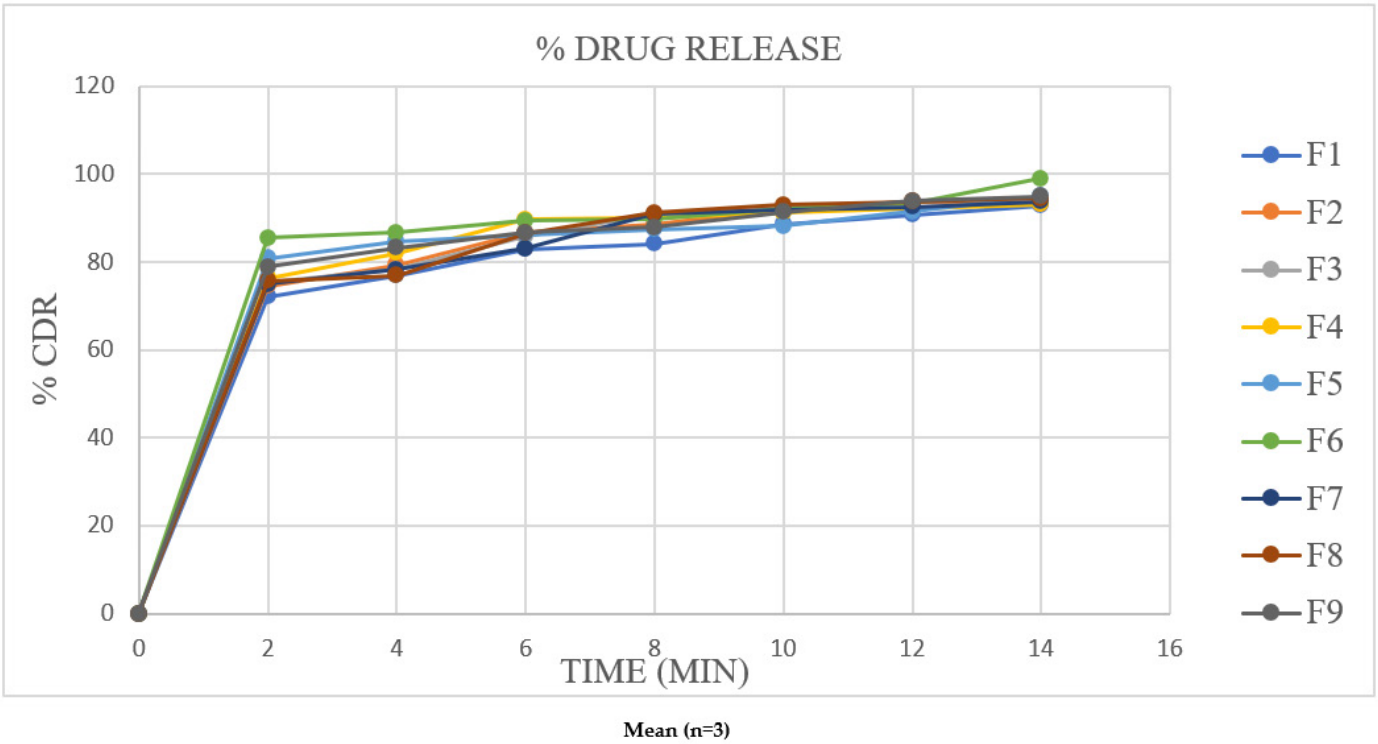

Figure 4: Cumulative % drug release profile of formulation F1–F9.

Table 4: *In vitro* cumulative percent of drug release of F1 to F9.

Time (m)	Cumulative percent of drug release from all formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	72.15±0.01	74.61±0.01	75.50±0.01	76.42±0.02	80.88±0.03	85.55±0.01	75.05±0.02	75.73±0.02	78.86±0.08
4	76.92±0.05	79.39±0.07	78.27±0.03	82.08±0.04	84.76±0.04	86.76±0.02	78.27±0.04	76.93±0.02	83.19±0.07
6	82.91±0.01	86.72±0.05	85.83±0.08	89.64±0.07	86.19±0.05	89.41±0.08	83.14±0.07	86.50±0.04	86.73±0.01
8	84.12±0.03	88.61±0.03	90.84±0.01	90.19±0.06	87.41±0.05	89.9±0.06	90.84±0.06	91.29±0.05	87.95±0.03
10	88.69±0.03	92.06±0.02	92.51±0.04	91.18±0.05	88.29±0.01	92.08±0.04	91.83±0.01	92.96±0.06	91.40±0.05
12	90.80±0.04	93.73±0.01	93.73±0.06	92.3±0.02	91.51±0.01	93.3±0.01	92.61±0.04	93.73±0.08	93.96±0.03
14	92.91±0.05	93.39±0.03	94.28±0.05	93.21±0.03	95.01±0.08	99.05±0.02	93.83±0.02	94.50±0.07	94.96±0.04

*(m-Minutes), Mean (n=3).

superdisintegrants (Tulasi powder, *Isabgol* mucilage, and Croscarmellose sodium). The results revealed no significant changes in the principal peaks of the drug when combined with these superdisintegrants. This indicates chemical compatibility, suggesting that the drug and the excipients do not interact adversely. Such compatibility is crucial for maintaining the stability and efficacy of the formulations, ensuring that the therapeutic effectiveness of the drug is not compromised.[12]

The swelling index of the superdisintegrants plays a pivotal role in their performance. *Isabgol* mucilage exhibited a significantly higher swelling index compared to Tulasi powder. This higher swelling capacity indicates a greater potential for rapid tablet disintegration and enhanced drug release. The ability of *Isabgol* mucilage to swell extensively suggests it can effectively facilitate the breakdown of tablets in the digestive tract, leading to faster drug availability.[13]

The pre-compression parameters of the powder blend, including angle of repose, bulk density, tapped density, compressibility index, and Hausner's ratio, all indicated favorable flow properties. These results confirm that the powder blend has good flowability and compressibility, which are essential for uniform tablet formation and consistent dosing. Good flow properties ensure that the powder can be processed efficiently during manufacturing, reducing the risk of production issues and ensuring uniform tablet weights and drug content.[14-16]

The physical evaluation of the compressed tablets showed consistent thickness across all formulations, with minimal weight variation, acceptable hardness, and low friability. The consistent thickness indicates uniform die fill during the compression process. Minimal weight variation and acceptable hardness ensure that each tablet contains the correct amount of drug and can withstand handling without breaking. Low friability further indicates good mechanical resistance, meaning the tablets are durable and less likely to crumble during packaging and transportation.[16-18]

Disintegration times were assessed for tablets containing different superdisintegrants. Tablets with *Isabgol* mucilage disintegrated the fastest, followed by those with Croscarmellose sodium and Tulasi powder. The faster disintegration times of *Isabgol* mucilage-containing tablets indicate its superior disintegration properties. Rapid disintegration is crucial for fast-dissolving tablets as it ensures quick release of the active ingredient, enhancing the onset of action.[19]

Wetting times and water absorption ratios were critical parameters in evaluating the effectiveness of the superdisintegrants. Wetting times were quickest with *Isabgol* mucilage, followed by Croscarmellose sodium and Tulasi powder. Higher concentrations of superdisintegrants generally resulted in quicker wetting times and higher water absorption ratios. *Isabgol* mucilage showed the highest water absorption, which correlates with its rapid disintegration. The ability to quickly absorb water and swell is essential for superdisintegrants, as it facilitates the rapid breakup of the tablet matrix, leading to faster drug release.[20]

in vitro drug release studies demonstrated that all formulations achieved over 90% drug release within 14 min. The release rate was highest with *Isabgol* mucilage, followed by Croscarmellose sodium and Tulasi powder. This rapid drug release is likely due to the efficient disintegration and high-water absorption capacity of *Isabgol* mucilage. The effectiveness of *Isabgol* mucilage in ensuring rapid and complete drug release makes it an excellent choice for fast-disintegrating tablets, providing quick relief to patients.[21]

Stability studies under accelerated conditions showed no significant changes in disintegration time, release characteristics, or physical-chemical properties of the tablets. This indicates that the tablets remain stable, maintaining their effectiveness over time. Stability under such conditions suggests that the tablets will have a reasonable shelf life, although further studies following ICH guidelines are necessary to confirm this.[23]

CONCLUSION

The current study provides conclusive evidence *Isabgol* mucilage proved to be an effective Superdisintegrant for chlorpheniramine maleate fast-disintegrating tablets, demonstrating superior swelling, rapid disintegration, and efficient drug release compared to Tulasi powder and Croscarmellose sodium. Pre-compression parameters indicated favorable flow properties, while the tablets exhibited consistent thickness, minimal weight variation, and satisfactory mechanical properties. *in vitro* studies confirmed over 90% drug release within 14 min, with *Isabgol* mucilage formulations showing the highest release rates. Stability studies suggested that the tablets remained stable under accelerated conditions. Overall, *Isabgol* mucilage enhances FDT performance, potentially improving patient compliance and therapeutic outcomes. Further research is needed to confirm long-term stability and commercial scalability.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

Abs: Absorbance Conc Concentration; **CDR:** Cumulative drug release; **g:** Gram; **hr:** Hour; **Kg:** Kilogram; **mg:** Milligram; **min:** Minutes; **mL:** Milliliter; **mm:** Millimeter; **mcg/µg:** Microgram nm Nanometer; **pH:** Potential of hydrogen; **SD:** Standard deviation; **sec:** Seconds; **UV:** Ultraviolet; **w/v:** Weight per volume; **w/w:** Weight per weight; **Wt:** Weight; **λ_{max}:** Absorption maxima; **%:** Percentage; **°C:** Degree Celsius.

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