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Research Article

FORMULATION OPTIMIZATION AND QUALITY ASSESSMENT OF ORODISPERSIBLE CHEWABLE TABLETS OF LORATADINE

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ABSTRACT

The present study was undertaken to formulate and optimize orodispersible chewable tablets of Loratadine with the objective of improving its solubility, dissolution rate, and oral bioavailability. Loratadine, a poorly water-soluble antihistaminic drug, exhibits limited dissolution characteristics, which may reduce its therapeutic effectiveness. To enhance drug release, super disintegrating agents such as maize starch, mannitol, and croscarmellose sodium were incorporated in varying concentrations to promote rapid disintegration by increasing tablet porosity and facilitating faster penetration of dissolution medium. All formulations were prepared by the direct compression method using an 8 mm punch on an 8-station rotary tablet compression machine. The pre-compression parameters of the powder blends, including angle of repose, bulk density, and tapped density, demonstrated good flow properties, indicating suitability for direct compression. The compressed tablets were evaluated for post-compression parameters such as hardness, thickness, friability, weight variation, drug content uniformity, disintegration time, and in-vitro dissolution studies. All formulations complied with the official limits specified in the Indian Pharmacopoeia. Among the prepared formulations, F6 showed the highest percentage drug release of 94.6% within 45 minutes and was identified as the optimized formulation. The enhanced performance of F6 was attributed to the presence of croscarmellose sodium at a concentration of 60 mg, which significantly improved tablet disintegration and dissolution. The results suggest that optimized orodispersible chewable tablets of Loratadine can be successfully developed to achieve improved drug release characteristics.

Keywords: Loratadine, Orodispersible chewable tablets, Superdisintegrants, Croscarmellose sodium.

INTRODUCTION

Drug Delivery Systems (DDS) have emerged as a strategic approach to enhance therapeutic efficacy, extend product life cycles, and improve patient compliance (Robinson & Lee, 1987). Over the years, significant advancements have been made in novel drug delivery systems (NDDS), focusing on improving physicochemical stability, bioavailability, and targeted drug action (Allen & Cullis, 2004). Despite these innovations, the oral route remains the most preferred method of drug administration due to its convenience, cost-effectiveness, ease of manufacturing, and high patient acceptance (Lachman *et al*., 1991; Banker & Rhodes, 2002). It is estimated that nearly 90% of drugs intended for systemic action are administered orally (Ansel *et al*., 2011). However, conventional solid dosage forms such as tablets and capsules present challenges for patients suffering from dysphagia (difficulty in swallowing), a condition affecting approximately 35% of the general population, particularly pediatric, geriatric, and neurologically impaired patients (Seager, 1998; Sastry *et al*., 2000). Conditions such as Parkinsonism, stroke, unconsciousness, motion sickness, and mental disability further complicate oral drug administration. To overcome these limitations, fast dissolving and chewable tablet technologies were introduced. Chewable tablets are designed to be chewed prior to swallowing and are particularly suitable for children and elderly patients who cannot swallow intact tablets (Banker & Anderson, 1987). These dosage forms provide rapid disintegration, improved dissolution, enhanced bioavailability, and better organoleptic properties when formulated with suitable excipients such as mannitol and superdisintegrants (Shangraw, 1989). Loratadine is a long-acting selective peripheral H1-receptor antagonist widely used in allergic

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rhinitis, urticaria, and other allergic conditions (Sweetman, 2009). Due to its poor aqueous solubility, its dissolution rate becomes a limiting factor for bioavailability. Therefore, formulation of chewable tablets of Loratadine may enhance drug release, improve patient compliance especially in pediatric populations and provide rapid onset of action. The present study focuses on the formulation optimization and evaluation of Loratadine chewable tablets to improve dissolution characteristics and ensure compliance with pharmacopeial quality standards.

MATERIALS AND METHODS

Materials

Loratadine was obtained as a gift sample from NATCO Pharma Pvt. Ltd., India. Ethyl cellulose, maize starch, mannitol, magnesium stearate, talc, and microcrystalline cellulose (MCC) were procured from NATCO Pharma Pvt. Ltd., India. Croscarmellose sodium was used as a superdisintegrant. All other chemicals and reagents used were of analytical grade. Phosphate buffer (pH 7.4) was prepared as per USP specifications and used throughout the study.

Instruments

Electronic balance (Wensar), rotary tablet compression machine (Karnavati, Rimek Mini Press II), Monsanto hardness tester, USP dissolution test apparatus (Lab India DS 8000), USP disintegration test apparatus (Lab India), friability test apparatus (Lab India FT 1020), UV–Visible spectrophotometer (Lab India 3000), hot air oven (VJ Instruments), and digital pH meter (Lab India) were used during the study.

Determination of λmax

A standard solution of Loratadine was prepared in phosphate buffer (pH 7.4) and scanned between 200–400 nm using a UV–Visible spectrophotometer. The maximum absorbance (λmax) was found at 265 nm.

Preparation of Calibration Curve

Accurately weighed 100 mg of Loratadine was dissolved in methanol and diluted up to 100 mL with phosphate buffer (pH 7.4) to obtain the stock solution (1 mg/mL). Serial dilutions were prepared to obtain concentrations ranging from 2–10 µg/mL. Absorbance was measured at 243 nm against phosphate buffer as blank, and the calibration curve was plotted.

Formulation of Loratadine Chewable Tablets

Chewable tablets containing 5 mg of Loratadine were prepared by direct compression technique. All ingredients were weighed accurately, passed through sieve No. 20, and blended uniformly. Magnesium stearate and talc were added as lubricants at the final stage of blending. The powder mixture was compressed using an 8-station rotary tablet compression machine fitted with flat punches. Formulations F1–F9 were prepared by varying the concentration of mannitol, maize starch, and croscarmellose sodium while maintaining a constant tablet weight of 100 mg.

Pre-Compression Evaluation

The powder blends were evaluated for bulk density, tapped density, angle of repose, Carr's index, and Hausner ratio using standard methods to assess flow properties.

Post-Compression Evaluation

The compressed tablets were evaluated for weight variation (as per IP limits), hardness, thickness, friability, and drug content uniformity. Friability was determined using a Roche friabilator at 25 rpm for 100 revolutions.

In-Vitro Dissolution Study

Drug release studies were performed using USP Type II (paddle) dissolution apparatus at 50 rpm in 500 mL phosphate buffer (pH 7.4). Samples were withdrawn at predetermined intervals, filtered, and analyzed spectrophotometrically.

Drug–Excipient Compatibility Study

Fourier Transform Infrared (FT-IR) spectroscopy (Bruker Alpha T, Germany) was performed using the KBr pellet method. Spectra were recorded in the range of 4000–400 cm^{-1} to evaluate possible drug–excipient interactions.

RESULTS AND DISCUSSION

The UV spectrophotometric method developed for the estimation of Loratadine in phosphate buffer (pH 7.4) showed excellent linearity in the concentration range of 2–10 µg/mL with a correlation coefficient (R^2) of 0.999 and regression equation $y = 0.056x - 0.003$, confirming the reliability of the analytical procedure. The pre-compression parameters of all formulations (F1–F9) indicated satisfactory flow properties, with angle of repose values between 25° and 30°, Carr's index ranging from 13.06% to 18.18%, and Hausner's ratio between 1.14 and 1.22, suggesting good compressibility and suitability for direct compression. Post-compression evaluation demonstrated that all tablets complied with Indian Pharmacopoeial limits for weight variation, hardness (2.3–2.7 kg/cm^2), thickness (3.44–3.49 mm), friability (0.30–0.51%), and drug content (95–99%), indicating uniformity and adequate mechanical strength. In-vitro dissolution studies revealed that drug release was significantly influenced by the type and concentration of superdisintegrant, with formulation F6 exhibiting the highest drug release of 94.6% within 45 minutes. The enhanced dissolution profile of F6 may be attributed to improved water uptake and rapid tablet disintegration, resulting in increased surface area for drug release. Furthermore, FT-IR analysis confirmed the absence of significant drug–excipient interactions, demonstrating

compatibility and stability of the optimized formulation. Overall, the results indicate that appropriate optimization of formulation variables significantly improves dissolution performance while maintaining acceptable quality characteristics.

Table 1. Concentration and absorbance obtained for calibration curve of Loratidine in phosphate buffer (pH 7.4**).**

S. No.	Concentration (µg/ml)	Absorbance* (at 265nm)
1	2	0.113
2	4	0.220
3	6	0.337
4	8	0.445
5	10	0.566
Correlation Coefficient = 0.999; Absorbance y = 0.056x -0.003		

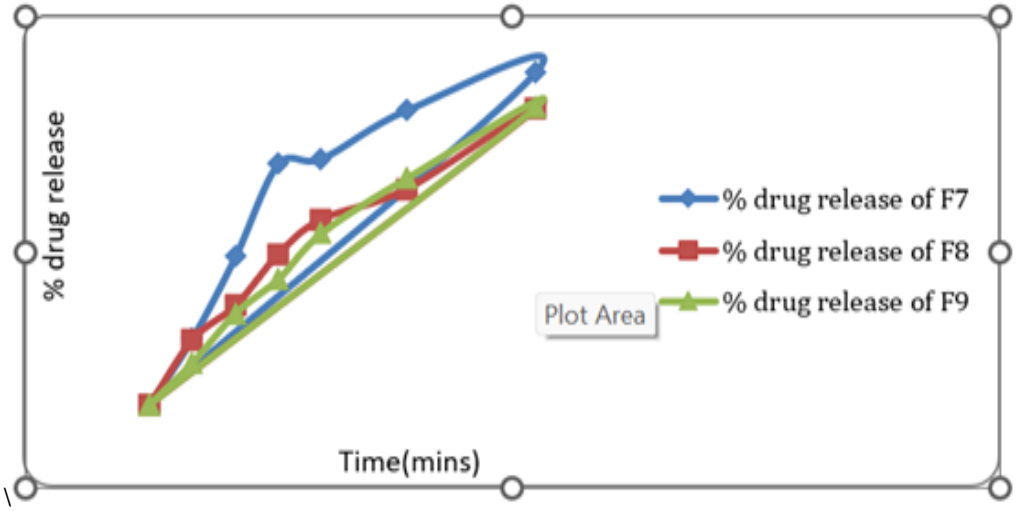

Figure 1. Standard graph of Loratidine in phosphate buffer (pH 7.4).

Table 2. Pre-compression parameters.

Formulations	Bulk Density (gm/cm^2)	Tap Density (gm/cm^2)	Carr's Index (%)	Hausner ratio	Angle of Repose(Ɵ)
F_1	0.40	0.54	17.18	1.20	26.91
F_2	0.50	0.56	15.54	1.18	28.23
F_3	0.50	0.58	13.79	1.19	29.34
F_4	0.46	0.56	16.36	1.19	26.71
F_5	0.44	0.58	13.79	1.16	29.34
F_6	0.48	0.56	14.54	1.17	28.23
F_7	0.49	0.58	16.19	1.18	27.13
F_8	4.51	0.57	13.46	1.16	26.13
F_9	0.54	0.54	15.12	1.15	28.13

Table 3. Post-Compression parameters.

FD	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Assay (%)
F_1	100	2.5	3.49	0.44	96.20
F_2	100	2.6	3.44	0.30	97.15
F_3	102	2.5	3.49	0.43	96.11
F_4	109	2.6	3.48	0.41	99.24
F_5	104	2.3	3.49	0.41	96.26

F_6	101	2.7	3.44	0.44	96.25
F_7	103	2.4	3.45	0.41	96.13
F_8	102	2.6	3.46	0.44	96.58
F_9	101	2.3	3.48	0.42	95.09

Table 4. Dissolution data for all the formulations.

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	98.9	39.5	28.4	48.3	31.7	24.3	17.56	17.27	11.1
10	99.4	76.3	35.2	82.9	34.5	31.6	39.24	26.28	24.19
15	99.2	96.2	48.9	98.7	41.9	49.3	63.86	39.98	33.25
20		99.7	66.8		62.4	58.3	65.19	49.15	45.38
30			78.1		99.5	74.3	78.15	57.26	60.07
45			86.4			94.6	88.15	78.52	78.85

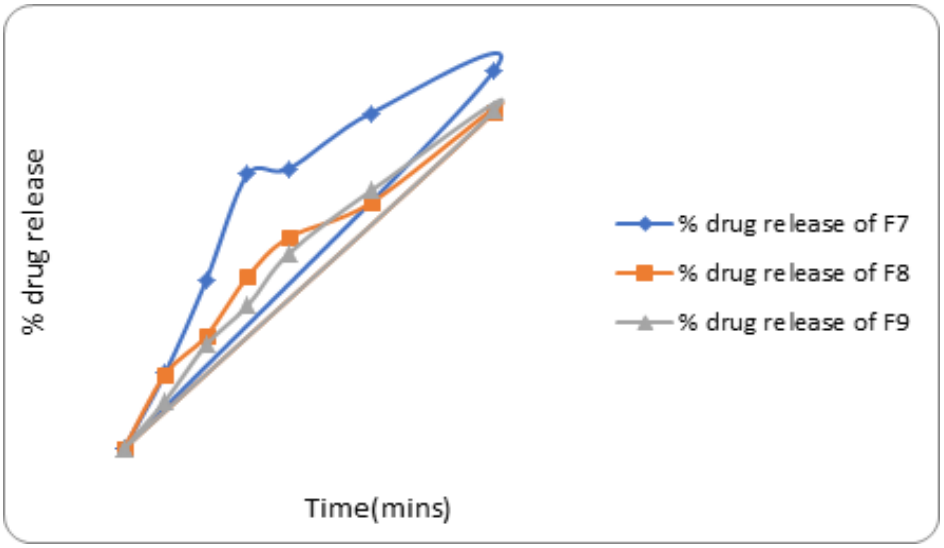

Figure 2. % drug release of the formulation F1-F3.

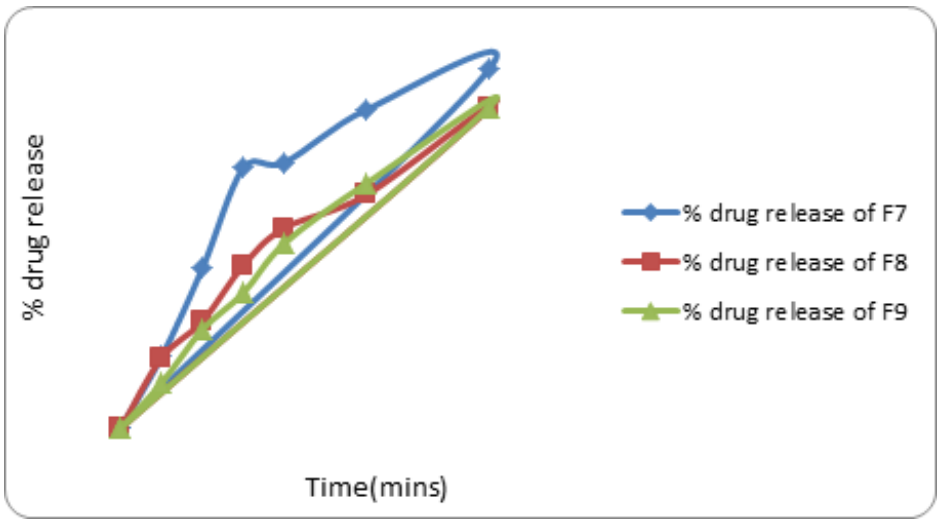

Figure 3. % drug release of the formulation F4-F6.

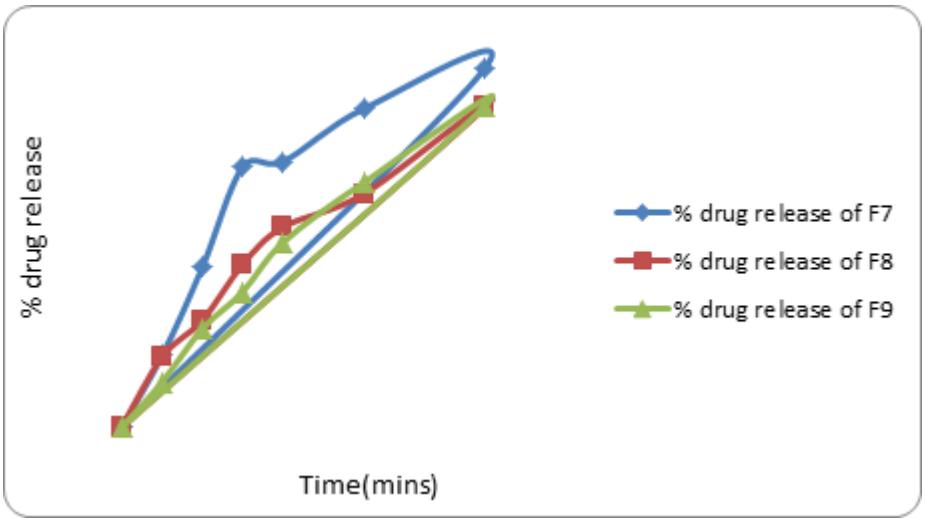

Figure 4. % drug release of the formulation F7-F9.

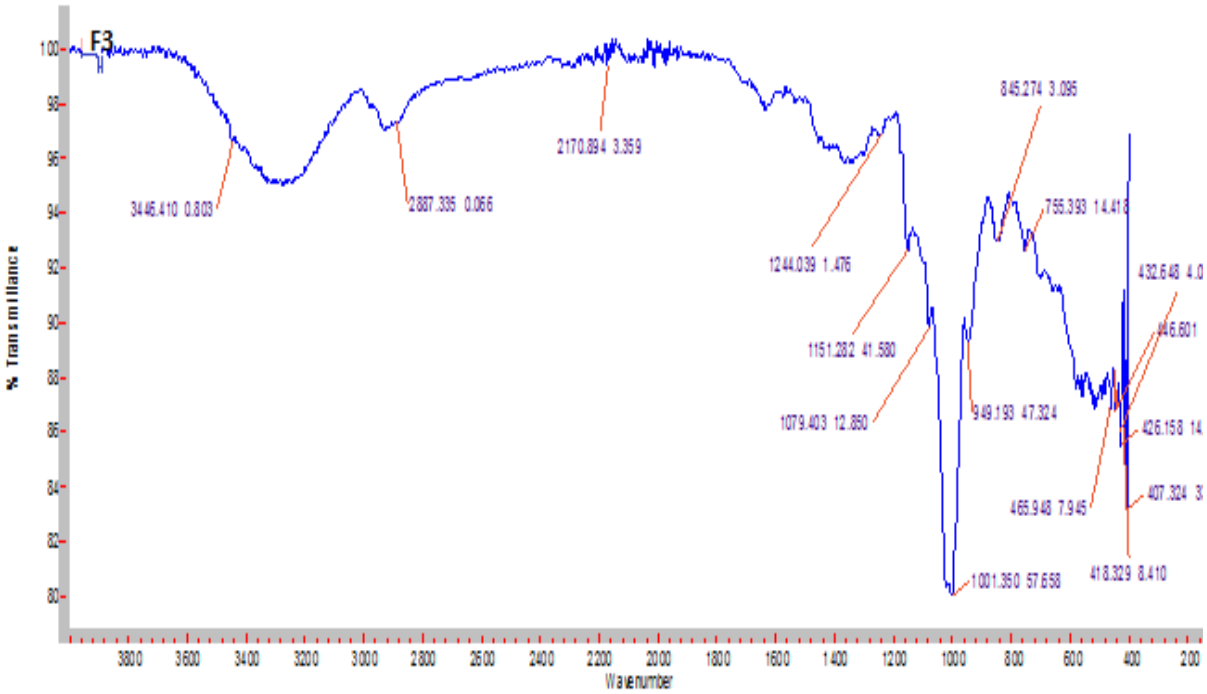

Figure 5. FT-IR Spectrum of Optimized Formulation.

CONCLUSION

The present study successfully demonstrated the formulation and optimization of Loratadine chewable tablets using the direct compression technique with the objective of enhancing solubility, dissolution rate, and patient compliance. Super disintegrants such as maize starch, mannitol, and croscarmellose sodium were incorporated in varying concentrations to evaluate their influence on tablet performance. The powder blends exhibited satisfactory pre-compression characteristics, including acceptable angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio, indicating good flow properties suitable for large-scale tablet manufacturing. All prepared formulations complied with Indian Pharmacopoeial standards for post-compression parameters such as weight variation, hardness, thickness, friability, and drug content uniformity, confirming the mechanical strength and quality of the tablets. In-vitro dissolution studies revealed that drug release was significantly affected by the type and concentration of

superdisintegrant. Among all formulations, F6 exhibited the highest drug release of 94.6% within 45 minutes and was identified as the optimized formulation. The improved dissolution profile of F6 can be attributed to the presence of croscarmellose sodium (60 mg), which enhanced tablet porosity, facilitated rapid penetration of dissolution medium, and promoted faster disintegration. Furthermore, FT-IR studies confirmed the absence of any significant drug–excipient interaction, indicating compatibility and stability of the optimized formulation. Overall, the results suggest that the optimized Loratadine chewable tablet formulation offers improved dissolution characteristics, acceptable physicochemical properties, and enhanced patient compliance, making it a promising alternative to conventional solid oral dosage forms.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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