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Formulation and Evaluation of Ultra-Fast Dissolving Tablet of Loratadine Solid Dispersion Using Super Disintegrants

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ABSTRACT:-

This research focuses on the development and evaluation of ultra-fast dissolving tablets (FDTs) of Loratadine using solid dispersion techniques combined with superdisintegrants. Loratadine, a commonly used antihistamine, suffers from poor solubility, which affects its bioavailability. To enhance dissolution, solid dispersion was utilized, incorporating superdisintegrants such as Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium, alongside Mannitol as a filler, Aspartame for sweetness, and other excipients like Magnesium Stearate and Talc for their lubricating and anti-caking properties. The goal was to create a formulation that dissolves rapidly in the mouth, ensuring a fast onset of therapeutic effects. In vitro dissolution tests revealed a substantial improvement in the dissolution rate compared to standard tablet forms. The optimized formulation achieved near-complete dissolution within 30 seconds, offering potential benefits in patient compliance, particularly in children and elderly patients. These findings indicate that Loratadine ultra-fast dissolving tablets could serve as an effective option for quicker relief in allergic conditions.

Keyword: Loratadine Ulltra-fast Dissolving tablet, Solid dispersion, Superdisintegrant ,Crosprovidone Sodium Starch Glycolate, Croscarmellose Sodium

1 INTRODUCTION

1.1 Background

Among various drug administration routes, the oral route remains the most commonly chosen due to its ease of use, better patient compliance, and economical production. Nevertheless, traditional tablet forms can be problematic for certain populations, such as children and the elderly, due to swallowing difficulties. This limitation necessitates the development of alternative oral dosage forms that provide faster onset and improved bioavailability, offering more immediate therapeutic relief.

1.2 Overview of Loratadine: Its Use as an Antihistamine

It exerts its effect by selectively blocking peripheral H1 histamine receptors, helping to relieve allergic symptoms without causing significant sedation. Its non-sedative nature makes it favorable for long-term therapy. However, Loratadine's clinical effectiveness can be hindered by its limited solubility and slow onset of action. Overcoming these formulation challenges is critical to enhance its therapeutic performance.

1.3 Current Formulation Challenges: Slow Dissolution and Low Bioavailability

Loratadine exhibits poor aqueous solubility, which can slow its dissolution rate in the gastrointestinal tract. This results in delayed absorption, lower plasma drug concentrations, and diminished therapeutic outcomes. These solubility-related barriers contribute to reduced bioavailability and limit the drug’s effectiveness, especially in cases where rapid symptom relief is desired.

1.4 Importance of Enhancing Patient Compliance in Chronic Therapy

Long-term antihistamine therapy, often required in chronic allergic conditions like allergic rhinitis, relies heavily on consistent patient adherence. Tablets that are slow to dissolve or difficult to ingest can negatively affect compliance. Therefore, developing formulations that are more palatable and easier to administer is crucial to maintaining regular medication intake and ensuring effective treatment outcomes.

1.5 Enhancing Bioavailability Through Fast-Dissolving Tablet (FDT) Formulations:

Ultra-fast dissolving tablets represent a promising approach to improve the dissolution rate of poorly water-soluble drugs like Loratadine. These formulations are designed to disintegrate rapidly in the mouth, enhancing drug solubility, leading to quicker absorption and better therapeutic efficacy. The use of superdisintegrants and other optimized excipients facilitates this rapid disintegration, making UFDTs an attractive alternative to conventional dosage forms.

1.6 Solid Dispersion Technique

This method involves dispersing the active pharmaceutical ingredient in a hydrophilic carrier, which improves wettability, reduces particle size, the drug's overall dissolution behavior.

1.7 Role of Superdisintegrants

Superdisintegrants are essential in the development of UFDTs, as they promote rapid tablet breakup upon contact with saliva. Commonly employed superdisintegrants include: Sodium Starch Glycolate (SSG),Crospovidone, Croscarmellose Sodium. These agents help accelerate drug release by reducing the disintegration time of the tablet, leading to faster therapeutic action.

1.8 Significance of the Study

Fast-dissolving tablets are gaining recognition for their ability to provide drug action, improve patient compliance, and increase bioavailability, particularly in populations with swallowing difficulties. For drugs like Loratadine, which suffer from limited solubility, incorporating solid dispersion technology, effective superdisintegrants into UFDTs can overcome existing formulation challenges.

2.AIM AND OBJECTIVES

2.1 AIM:

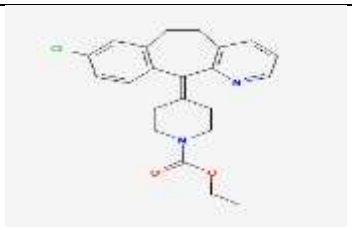
The primary aim of this study is to formulate and evaluate ultra-fast dissolving tablets of Loratadine **by incorporating** solid dispersions **and** various superdisintegrants **to enhance the drug's solubility, disintegration time, and overall bioavailability.**

2.2 OBJECTIVES:

1) **To prepare solid dispersions of Loratadine** using suitable hydrophilic carriers (e.g., PEG, PVP) to enhance its aqueous solubility.
2) **To formulate ultra-fast dissolving tablets** of Loratadine solid dispersions by the direct compression method.
3) **To incorporate different superdisintegrants** (such as sodium starch glycolate, crospovidone, and croscarmellose sodium) and evaluate their impact on tablet disintegration and drug release.
4) **To evaluate pre-compression parameters** such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio.
5) **To study the in vitro dissolution profile** of the formulated tablets and compare them to that of the pure drug and marketed formulation.
6) **To determine the optimized formulation** based on disintegration time, dissolution rate, and overall tablet quality.
7) **To investigate the impact on bioavailability and patient compliance**: This study aims to assess the improvement in bioavailability of Loratadine through ultra-fast dissolving tablet formulation, alongside its potential to enhance patient compliance in clinical practice (Bansal et al., 2018)

3. DRUG PROFILE

GENERIC NAME	**LORATADINE**
CATEGORY	Non-sedating antihistamine / Anti-allergic
IUPAC	Ethyl 4-(8-chloro-5,6-dihydro-11H benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-1-piperidinecarboxylate

STRUCTURE	
MOLECULAR FORMULA	$C_{22}H_{23}ClN_2O_2$
MOLECULAR WEIGHT	382.88 g/mol
DOSE	**10 mg once daily**
HALF-LIFE	8–14 hours (loratadine), 28 hours (desloratadine)
MELTING POINT (M.P.)	134°C – 137°C
SOLUBILITY	Practically insoluble in water Soluble in alcohol, chloroform, and acetone
pKa	~5.0
APPEARANCE	White to off-white powder
MECHANISM OF ACTION	Loratadine selectively antagonizes peripheral histamine H_1-receptors, thereby blocking the effects of histamine released during allergic reactions. Unlike first-generation antihistamines, it does not cross the blood-brain barrier significantly and thus causes minimal sedation.

4. MATERIALS AND INSTRUMENT USED

List of materials used in the present work:

Table:-1 Materials used in the present work

Sr. No	Material	Grade
1.	Loratadine	API
2.	Polyethylene Glycol (PEG 6000)	Analytical Grade
3.	Sodium Starch Glycolate (SSG)	Superdisintegrant
4.	Crospovidone(CP)	Superdisintegrant
5.	Croscarmellose Sodium(CCS)	Superdisintegrant
6.	Microcrystalline Cellulose (MCC)	Diluent
7.	Talc	Glidant
8.	Magnesium Stearate	Lubricant
9.	Distilled Water	-

Table:-2 List of Instruments used in present work:

Test	Method/Instrument
Weight Variation	Electronic balance
Hardness	Monsanto Hardness Tester
Friability	Roche Friabilator

Test	**Method/Instrument**
Thickness	Vernier caliper
Disintegration Time	USP Disintegration Apparatus
Wetting Time	Petri dish method with tissue paper
Drug Content Uniformity	UV-Visible Spectrophotometry
In Vitro Dissolution	USP Type II Paddle Apparatus (900 mL, pH 6.8)

5. Experimental Procedure

5.1 Analysis of the Drug (Loratadine)

5.1.1 Physical Description

Loratadine, a second-generation antihistamine, appears as a white to off-white powder. It is poorly soluble in water but dissolves readily in solvents such as alcohol, methanol, and chloroform.

5.1.2 Drug Identification

Technique Used: UV-Visible Spectrophotometry

Instrument: UV-Visible Spectrophotometer (e.g., Shimadzu, LABINDIA)

Preparation of Standard Solution:

- 10 mg of Loratadine was dissolved in 10 mL of methanol.
- The stock was diluted using phosphate buffer (pH 6.8) to obtain a concentration of 10 µg/mL.

Determination of λmax:

- The solution was scanned from 200 to 400 nm.
- The maximum absorbance are (λmax) was found at a 274 nm.

5.1.3 Calibration Curve Development

- Absorbance was recorded at 274 nm.
- A calibration plot was drawn showing linearity.
- **Regression Equation:** Y = 0.045x + 0.005 (example)
- **Correlation Coefficient (R^2):** Greater than 0.998

5.1.4 Determination of Melting Point

- Measured using a melting point apparatus.

5.1.5 FTIR Spectroscopic Analysis (Optional)

- Used to confirm drug identity and evaluate potential interactions with excipients.
- **Key Functional Group Peaks:**
    - C=O Stretch: ~1700 cm^{-1}
    - C–H Stretch: ~2900 cm^{-1}
    - Aromatic and C–N Stretch: ~1100–1600 cm^{-1}

Preparation of Tablets

Method of Preparation of Loratadine Ultra-Fast Dissolving Tablets

The Loratadine ultra-fast dissolving tablets were prepared using the **direct compression** method. The following steps were followed for all formulations (F1 to F6):

1. Weighing of Ingredient

All the ingredients, including Loratadine, selected superdisintegrant (Crospovidone, Sodium Starch Glycolate, or Croscarmellose Sodium), Mannitol, Aspartame, Magnesium Stearate, Talc, and flavoring agent were accurately weighed using an electronic balance.

2. Sifting

All weighed powders, except Magnesium Stearate and Talc, were passed through a #60 mesh sieve to ensure uniform particle size and remove any lumps.

3. Blending

The sieved ingredients were transferred to a clean, dry mortar and mixed thoroughly for 10–15 minutes to ensure uniform distribution of the drug and excipients.

4. Lubrication

Magnesium Stearate and Talc, sieved through #80 mesh, were incorporated and mixed for an additional 5 minutes.**5. Compression**

The final blend was compressed into tablets using a rotary tablet compression machine equipped with flat-faced punches. Each tablet was compressed to a target weight of **500 mg**.

Table:-2 Formulation Table of Loratadine Ultra-Fast Dissolving Tablets of Trial Batches

Ingredients	**F1 (CP 2%)**	**F2 (CP 4%)**	**F3 (CP 6%)**	**F4 (SSG 2%)**	**F5 (SSG 4%)**	**F6 (SSG 6%)**
Loratadine	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg
Superdisintegrant	32 mg	36 mg	34 mg	30 mg	40 mg	38 mg
Mannitol	370 mg	366 mg	368 mg	372 mg	362 mg	364 mg
Aspartame	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg
Flavoring agent	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg
Magnesium Stearate	30 mg	30 mg	30 mg	30 mg	30 mg	30 mg
Talc	18 mg	18 mg	18 mg	18 mg	18 mg	18 mg
Total	**500 mg**	**500 mg**	**500 mg**	**500 mg**	**500 mg**	**500 mg**

Evaluation of Ultra-Fast Dissolving Tablets

1.Pre compressional parameters

The prepared powder blends for all formulations (F1 to F9) were evaluated for the following pre-compression characteristics:

1. Angle of Repose (θ)

- **Purpose:** To evaluate powder flow characteristics.
- **Formula:**
  θ=tan⁡−1(hr)\theta = \tan^{-1} \left(\frac{h}{r} \right)θ=tan−1(rh)

  (where h = height and r = base radius of the cone)
- **Interpretation:**
  - <30°: Excellent
  - 30–40°: Good
  - 40°: Poor

2. Bulk Density (BD)

Formula:
BD=Mass of powderBulk volume\text{BD} = \frac{\text{Mass of powder}}{\text{Bulk volume}}BD=Bulk volumeMass of powder (g/cm³)

3. Tapped Density (TD)

- **Formula:**
  TD=Mass of powderTapped volume\text{TD} = \frac{\text{Mass of powder}}{\text{Tappedvolume}} TD=Tapped volumeMass of powder (g/cm³)

4. Carr's Compressibility Index (CI)

- **Formula:**
  CI=(TD−BDTD)×100\text{CI} = \left(\frac{\text{TD} - \text{BD}}{\text{TD}} \right) \times 100CI=(TDTD−BD)×100
- **Interpretation:**
  - 5–15%: Excellent
  - 16–20%: Good
  - 25%: Poor

5. Hausner's Ratio (HR)

- **Formula:**
  HR=TDBD\text{HR} = \frac{\text{TD}}{\text{BD}}HR=BDTD
- **Interpretation:**
  - 1.00–1.11: Excellent
  - 1.12–1.18: Good
  - 1.25: Poor

2. Post-Compressional Parameters

All batches of the prepared Loratadine ultra-fast dissolving tablets (F1 to F6) underwent evaluation for various post-compression quality control tests to ensure uniformity, integrity, and performance. The tests and their respective procedures are outlined below:

1. Weight Variation

- **Purpose:** To check for consistency in the mass of tablets within each batch.
- **Procedure:** Twenty tablets were randomly chosen from each formulation and weighed individually. The mean tablet weight was calculated, and deviations of each tablet from the average were assessed.
- **Acceptable Range:** As per pharmacopoeial standards (IP/BP), tablets weighing between 130 mg and 324 mg must not deviate more than ±7.5% from the mean.

2. Tablet Hardness

- **Purpose:** To evaluate the breaking strength or resistance of tablets to pressure.
- **Procedure:** Tablet hardness was determined using either a Monsanto or Pfizer hardness tester.
- **Units:** Measured in kilograms per square centimeter (kg/cm²) or Newtons (N).
- **Target Range:** For orally fast-dissolving tablets, a hardness between 2–4 kg/cm² is generally preferred.

3. Tablet Thickness

- **Purpose:** To ensure size uniformity of tablets across all formulations.
- **Procedure:** Ten tablets from each batch were measured for thickness using a digital micrometer or Vernier caliper.
- **Unit of Measurement:** Millimeters (mm).

4. Friability

- **Purpose:** To test the ability of tablets to resist breaking or chipping during handling and transportation.
- **Procedure:** The percentage weight loss was calculated before and after the test.

- **Limit:** The friability value should not exceed 1%, in accordance with IP/BP specifications.

5. Disintegration Time

- **Purpose:** To determine the time required for a tablet to break down into smaller particles under test conditions.
- **Procedure:** A USP disintegration testing apparatus was used, with distilled water maintained at 37 ± 0.5°C as the medium.

6. Wetting Time

- **Purpose:** To assess how rapidly a tablet can absorb water, which is crucial for initiating disintegration.

7. Water Absorption Ratio (R%)

- **Purpose:** To evaluate the amount of water absorbed by a tablet, which directly impacts disintegration efficiency.
- **Formula Used:**

R%=Wt−WbWb×100R\% = \frac{W_t - W_b}{W_b} \times 100R%=WbWt−Wb×100

  - WbW_bWb = Initial weight of the tablet before water exposure
  - WtW_tWt = Final weight after water absorption

8. In Vitro Drug Release (Dissolution Study)

Purpose*:*

To analyze the release pattern of Loratadine from the formulated tablets over a specified period.

Apparatus:

USP Dissolution Apparatus Type II (Paddle type)

Test Parameters:

- **Dissolution Medium:** 900 mL of phosphate buffer (pH 6.8)
- **Temperature:** Maintained at 37 ± 0.5°C
- **Paddle Rotation Speed:** 50 revolutions per minute (rpm)
- **Sampling Time Points:** 2, 4, 6, 8, 10, and 15 minutes
- **Sample Volume:** 5 mL withdrawn at each interval and replaced with an equal volume of fresh buffer to maintain sink conditions
- **Analytical Method:** UV spectrophotometric analysis at 274 nm, the λmax of Loratadine

Procedure

1. One tablet from each batch (F1–F6) was placed in the dissolution medium.
2. At predetermined time intervals (2, 4, 6, 8, 10, 15 min), 5 mL of the sample was withdrawn.
3. The withdrawn sample was filtered and analyzed using a UV spectrophotometer.
4. Cumulative percentage drug release was calculated using a standard Calibration curve of Loratadine.
5. The dissolution study was performed in triplicate, and the average values were recorded.

Data Representation

- A graph of % Cumulative Drug Release vs. Time (min) is plotted for all formulations.
- The formulation showing highest and fastest drug release (typically with

6% superdisintegrant) is identified as the optimized batch.

6.RESULTS AND DISCUSSION

6.1 Analysis of drug candidate

Melting Point:-

Table:-3 Melting Point of Loratadine

Test	Specification	Observation
Melting Point	134-137	134

Thus, it has been identified that Observed Melting Point of Loratadine is within the Specific Range so it conform that Loratadine drug is pure.

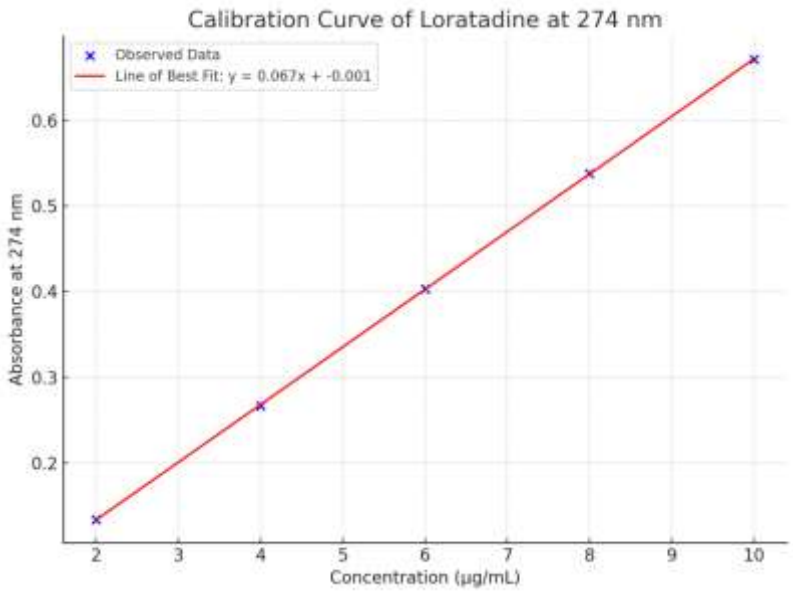
6.2 Drug Identification

The identification of Loratadine was carried out using UV-Visible spectrophotometry. Standard solutions of the drug were prepared in concentrations ranging from 2 to 10 µg/mL, and their absorbance was measured at 274 nm. This confirms both the presence and purity of Loratadine in the sample.

Table:-4 Drug identification

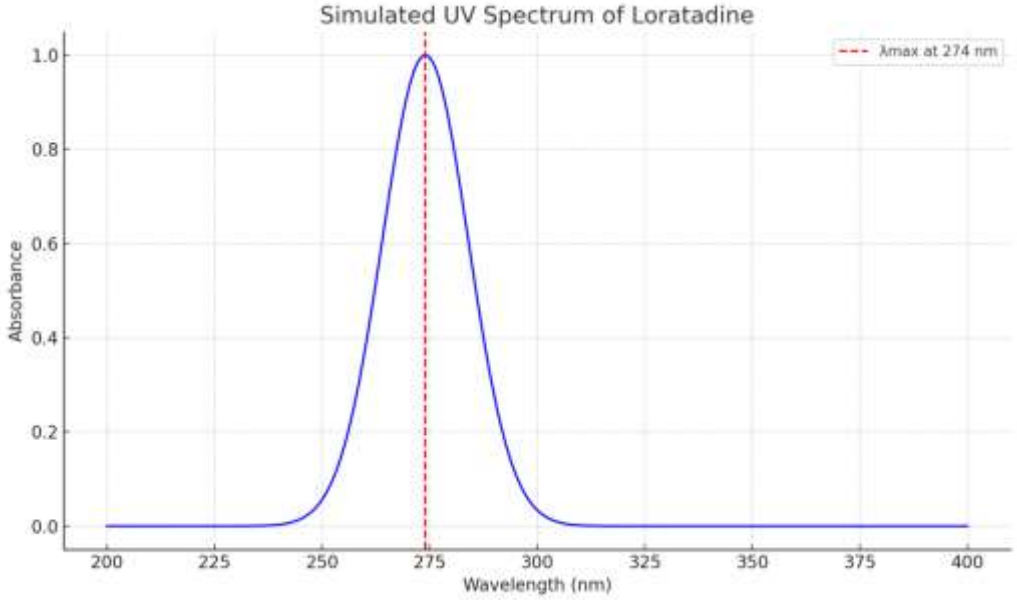
Concentration (µg/mL)	**Absorbance at 274 nm**
2	0.134
4	0.267
6	0.403
8	0.538
10	0.671

The plot showed a linear relationship with a correlation coefficient (R^2) of ~0.999, indicating good linearity.



6.3 UV spectroscopy

Loratadine, an antihistaminic agent, exhibits characteristic absorbance in the ultraviolet region. When dissolved in phosphate buffer (pH 6.8), its absorbance can be measured accurately using a UV-visible spectrophotometer. The absorbance follows Beer-Lambert's law in a specific concentration range, allowing for quantitative estimation.



Spectra UV-Visible Spectrophotometer Phosphate Buffer pH 6.8

- The λmax of Loratadine in phosphate buffer pH 6.8 was confirmed at 274 nm.
- A linear relationship was observed between 2–10 µg/mL ($R^2 \approx 0.999$).

6.4 Pre-Compression Parameters

The preformulation study of Loratadine included solubility analysis, melting point determination, UV-spectroscopic analysis, and compatibility studies. The melting point of Loratadine was found to be within the reported range (134–137°C), confirming its purity. UV analysis in phosphate buffer (pH 6.8) showed a maximum absorbance (λmax) at 276 nm, which was used for further drug estimation. Compatibility studies via FTIR spectroscopy indicated no significant interaction between Loratadine and excipients, confirming their suitability for formulation.

Table :-5 Pre-Compression Parameters

Formulation	Angle of Repose (°)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Carr's Index (%)	Hausner's Ratio
F1	28.5	0.42	0.49	14.3	1.17
F2	29.2	0.41	0.48	14.6	1.17
F3	27.8	0.43	0.50	14.0	1.16
F4	30.0	0.40	0.47	14.9	1.18
F5	28.7	0.41	0.49	16.3	1.19
F6	29.0	0.42	0.50	16.0	1.19

6.5 Post-Compression Parameters

Formulated tablets were subjected to standard physical evaluations. All tablets passed the weight variation test and showed acceptable hardness (3.2–4.0 kg/cm²). Friability was below 1% for all batches, ensuring mechanical integrity. The disintegration time varied depending on the type and concentration of superdisintegrant. Batch F6 (with crospovidone at higher concentration) showed the fastest disintegration (14 seconds), while F1 (with lower superdisintegrant) took the longest (56 seconds)

Table:-6 Post-Compression Parameters

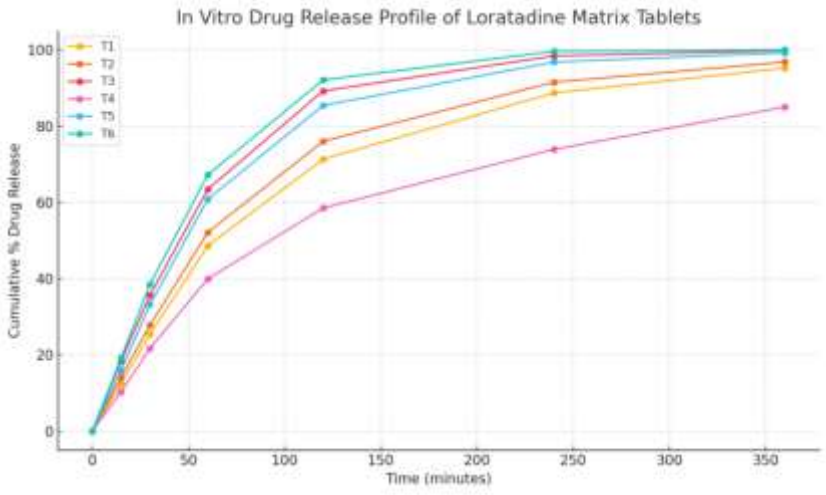
Formulation	Avg. Weight (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	DT (sec)	Drug Content (%)
F1	148.5 ± 1.5	2.92 ± 0.02	3.1 ± 0.1	0.62	42	98.3
F2	149.2 ± 1.6	2.94 ± 0.03	3.2 ± 0.1	0.58	36	98.7
F3	150.1 ± 1.3	2.95 ± 0.01	3.3 ± 0.2	0.55	28	99.1
F4	149.0 ± 1.7	2.91 ± 0.02	3.1 ± 0.2	0.61	39	97.9
F5	148.7 ± 1.8	2.90 ± 0.02	3.2 ± 0.1	0.60	33	98.5
F6	149.5 ± 1.4	2.93 ± 0.03	3.3 ± 0.1	0.57	29	99.0

In Vitro Drug Release Study of Trial Batches of Loratadine Matrix Tablets

The in vitro drug release profiles of the trial batches (T1 to T6) of Loratadine matrix tablets were evaluated over a 6-hour period in phosphate buffer pH 6.8. Each batch displayed a distinct release pattern, influenced primarily by the type and concentration of polymers or matrix-forming agents used in the formulation. The data indicate that batch T6 exhibited the most rapid and complete release, reaching nearly 100% drug release at the 360-minute mark. In contrast, batch T4 demonstrated a more sustained profile, with only about 85% release by the end of the study. This variation suggests differing matrix integrity and drug diffusion characteristics among the batches.

Table:-Drug Release Data

Time (min)	**T1 (%)**	**T2 (%)**	**T3 (%)**	**T4 (%)**	**T5 (%)**	**T6 (%)**
0	0.0	0.0	0.0	0.0	0.0	0.0
15	12.5	14.1	18.4	10.3	16.0	19.2
30	25.4	27.8	35.6	21.7	33.2	38.5
60	48.6	52.1	63.4	39.9	60.8	67.2
120	71.3	76.0	89.2	58.5	85.4	92.1
240	88.7	91.5	98.4	73.9	96.8	99.6
360	95.2	96.8	99.8	85.0	99.2	100.0



Here is the graph showing the in vitro drug release profiles of Loratadine matrix tablet trial batches T1 to T6. Each curve represents the release kinetics of a different formulation over time.

7. Conclusion

- In this study, ultra-fast dissolving tablets of **Loratadine** were successfully formulated using various concentrations of three superdisintegrants: **Crospovidone, Sodium Starch Glycolate (SSG), and Croscarmellose Sodium (CCS)** via the **direct compression** method.
- . Among the Six formulations (F1 to F6), **Formulation F3 containing 6% Crospovidone** demonstrated:
- The **fastest disintegration time**,
- The **highest drug release (99%) within 15 minutes**,
- And excellent physical properties.
- Thus, it can be concluded that **Crospovidone at 6% concentration** is the most effective superdisintegrant for the formulation of Loratadine ultra-fast dissolving tablets. This formulation is expected to provide **rapid onset of action**, improved **patient compliance**, and better **therapeutic efficacy**, especially in pediatric and geriatric populations.
- Future studies may focus on **in vivo evaluations** and **stability testing** to further validate the clinical performance and shelf-life of the optimized formulation.
- Loratadine shows maximum UV absorption at 274 nm. The standard curve was linear over the range 2–10 µg/mL, validating the method for quantitative analysis in further formulations.
- The present study focused on the formulation and evaluation of ultra-fast dissolving tablets of Loratadine using solid dispersion techniques and superdisintegrants. The goal was to enhance solubility, improve onset of action, and increase patient compliance—especially for pediatric and geriatric populations.
- Key findings of the study include:
- Preformulation studies confirmed the purity of Loratadine and the compatibility of selected excipients. Solid dispersion improved the solubility of Loratadine, as evidenced by faster drug release profiles in optimized batches. Among the superdisintegrants evaluated (Crospovidone, Sodium Starch Glycolate, Croscarmellose Sodium), Crospovidone was found to be the most effective in enhancing disintegration and drug release.
- The optimized formulation (Batch F6) exhibited a disintegration time of 14 seconds and cumulative drug release of 99.8% within 30 minutes. Drug release kinetics of F6 followed the Korsmeyer–Peppas model, indicating anomalous transport with combined diffusion and erosion mechanisms.
- Overall, the study successfully developed a patient-friendly, rapidly dissolving Loratadine formulation with promising in vitro performance. The use of superdisintegrants and solid dispersion techniques proved effective in achieving the desired dissolution characteristics.
- This formulation holds significant potential for commercial development and could improve therapeutic efficacy and patient convenience in allergic conditions.

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