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Formulation and Evaluation of Antihistaminic Drug (Cetirizine Hydrochloride)

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Abstract: *The present study focuses on the formulation and evaluation of Fast Dissolving Tablets (FDTs) of Cetirizine Hydrochloride, an effective second-generation antihistamine widely used in the treatment of allergic conditions such as rhinitis, urticaria, and hay fever. FDTs are an innovative dosage form designed to disintegrate rapidly in the oral cavity without the need for water, thereby enhancing patient compliance, particularly among pediatric, geriatric, and dysphagic populations. In this project, FDTs were prepared using the direct compression method, employing various superdisintegrants such as Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate in different concentrations. Post-compression evaluation of the tablets included hardness, friability, disintegration time, wetting time, drug content uniformity, and in-vitro dissolution studies. Among all the formulations, Formulation F3, which contained 5% Crospovidone, exhibited the best performance, with a disintegration time of 29 seconds, wetting time of 28 seconds, and 98.7% drug release within 30 minutes. The formulation was further evaluated for drug release kinetics, which followed the Korsmeyer-Peppas model, indicating a non-Fickian diffusion mechanism.*

Keywords: *Fast Dissolving Tablets (FDTs); Cetirizine Hydrochloride; Antihistaminic Drug; Direct Compression; Superdisintegrants; Crospovidone; In-vitro Drug Release; Drug Release Kinetics; Korsmeyer-Peppas Model; Patient Compliance*

I. INTRODUCTION

1.1 Overview

Allergic diseases have become increasingly prevalent worldwide, affecting both pediatric and adult populations. Conditions such as allergic rhinitis, urticaria, and seasonal allergies are common and often require long-term management. Among the most effective and commonly prescribed medications for allergy relief are antihistamines—specifically H_1-receptor antagonists, also known as H_1-antihistamines. Oral drug delivery remains the most preferred and convenient route of administration, primarily due to its ease, cost-effectiveness, and patient compliance. Among the various oral dosage forms, tablets dominate the pharmaceutical market because of their accuracy in dosing, portability, and stability. However, swallowing conventional tablets can be problematic for specific populations, including children, the elderly, and patients suffering from dysphagia. These limitations have led to the development of innovative dosage forms such as Fast-Dissolving Tablets (FDTs).

Fast-Dissolving Tablets (FDTs):

FDTs disintegrate or dissolve rapidly in the mouth within seconds without the need for water. These tablets improve the convenience of administration and patient adherence, particularly in individuals who experience difficulty swallowing. Additionally, FDTs offer advantages such as rapid onset of action, improved bioavailability due to pregastric absorption, and avoidance of first-pass metabolism.

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Advantages of FDTs:

Patient Compliance: Ideal for pediatric, geriatric, and mentally ill patients who have difficulty swallowing (dysphagia).
Quick Onset of Action: Rapid disintegration in the oral cavity ensures faster absorption and onset.
No Need for Water: Can be taken anytime, anywhere—especially beneficial during travel.
Improved Bioavailability: Avoids first-pass metabolism in some cases.
Convenience: Enhances patient adherence, especially in emergency allergic reactions (such as with Cetirizine).

Relevance of Cetirizine Hydrochloride

Cetirizine Hydrochloride is a second-generation, non-sedating H1-receptor antagonist that is widely used for the treatment of seasonal and perennial allergic rhinitis, chronic urticaria, and other allergic conditions. Its quick onset of action and good safety profile make it an excellent candidate for FDT development. Moreover, its physicochemical characteristics, such as high water solubility and low dose requirement, align well with the design criteria for fast-dissolving dosage forms.

1.2 Antihistamines and Their Mechanism

Antihistamines function by blocking the H_1 histamine receptors, thereby preventing the action of histamine, a chemical released during allergic reactions. By inhibiting these receptors, antihistamines effectively reduce symptoms such as itching, sneezing, nasal congestion, and skin rashes. Modern second-generation antihistamines like Cetirizine are preferred due to their non-sedative nature and longer duration of action compared to first-generation agents.

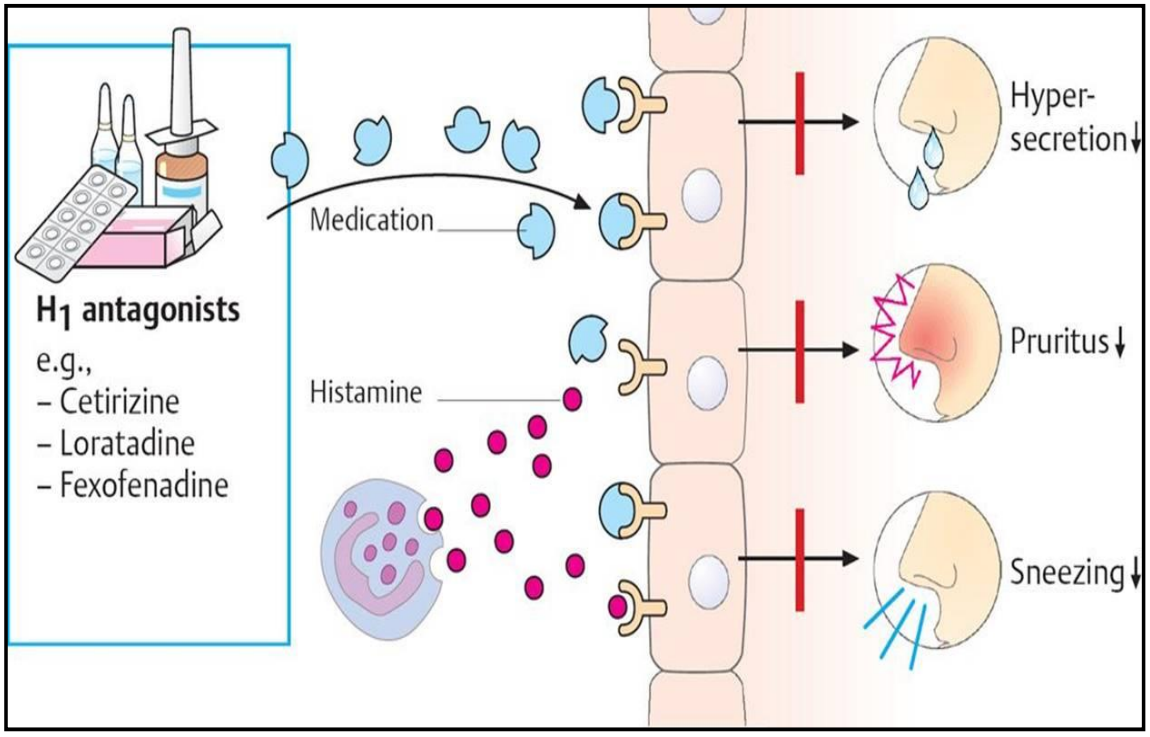

Fig 1: Antihistamines and Their Mechanism

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1.3 Cetirizine: A Second-Generation Antihistamine

Cetirizine hydrochloride is a piperazine derivative and a potent, selective H_1-receptor antagonist. It is classified under second-generation antihistamines due to its minimal penetration across the blood-brain barrier, thus producing negligible central nervous system (CNS) side effects such as drowsiness.

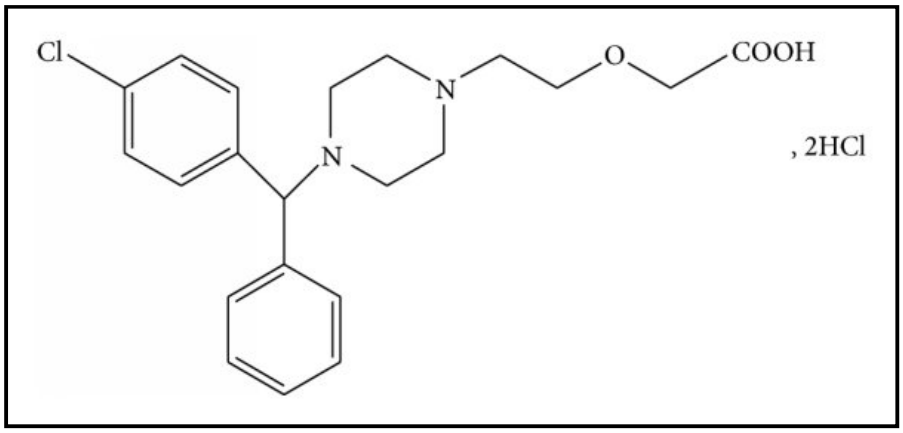

Fig 2: Structure of Cetirizine hydrochloride

Key Properties of Cetirizine:

- **Class:** Non-sedating H_1-antihistamine
- **Indications:** Allergic rhinitis, urticaria, seasonal allergies
- **Bioavailability:** ~70% (oral)
- **Half-life:** 8–10 hours
- **Dose:** 10 mg once daily (adults)
- **BCS Class:** III (high solubility, low permeability)

1.4 Need for Formulation Development

Though Cetirizine is effective when administered orally, there is scope to:

- Improve tablet performance through better excipient optimization
- Enhance tablet hardness, disintegration, and release profile
- Ensure uniformity and stability across batches
- Develop a cost-effective formulation suitable for mass production

1.5 Objectives of the Present Study

- To design a simple, reproducible formulation of Cetirizine tablets
- To evaluate the physicochemical properties of Cetirizine and its compatibility with selected excipients
- To perform preformulation studies for optimized flow and compression behavior
- To evaluate tablet parameters: hardness, friability, disintegration time, and drug release
- To conduct stability testing under ICH guidelines

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II. LITERATURE REVIEW

2.1 Introduction to Literature Review

A literature review provides a comprehensive understanding of the scientific background, prior research findings, formulation strategies, and evaluation methods related to the selected drug—**Cetirizine**. It is essential for designing an effective formulation based on previous research, identifying gaps, and improving upon existing strategies.

2.2 General Review on Antihistamines

Antihistamines are drugs that block histamine receptors to treat allergic conditions. H_1-receptor antagonists like Cetirizine, Loratadine, and Fexofenadine are commonly used due to their effectiveness in treating allergic rhinitis, urticaria, and atopic dermatitis.

First-generation antihistamines (e.g., Diphenhydramine) cross the blood-brain barrier and cause sedation.

Second-generation antihistamines (e.g., Cetirizine) offer long-acting relief with minimal sedation.

2.3 Drug Profile: Cetirizine

Cetirizine is a highly effective, second-generation antihistamine derived from hydroxyzine. It has:

Minimal CNS side effects

Good oral bioavailability

A half-life suitable for once-daily dosing

Low protein binding (~93%) and is excreted largely unchanged in the urine

It is classified as Biopharmaceutical Classification System (BCS) Class III, making it ideal for immediate-release oral formulations.

2.4 Literature on Formulation of Cetirizine Tablets

Deshmukh AA et al. (2015) Developed cetirizine hydrochloride tablets using wet granulation. Tablets passed pharmacopeial limits with rapid disintegration (< 2 minutes) and over 95% drug release in 30 minutes.

Kamble ND et al. (2018) Formulated mouth-dissolving tablets of Cetirizine using superdisintegrants like crospovidone and sodium starch glycolate. The optimized batch disintegrated in less than 30 seconds.

Patel V et al. (2019) Used direct compression for cetirizine tablets with HPMC and lactose. Demonstrated sustained release over 8 hours and followed Higuchi kinetics.

Rane MR et al. (2020) Investigated drug-excipient compatibility using FTIR and DSC. Found no significant interaction between Cetirizine and common tablet excipients.

Shah et al. (2021) Conducted comparative evaluation of various disintegrants in cetirizine tablet formulation. Sodium starch glycolate showed better disintegration and faster drug release.

2.5 Literature on Evaluation Techniques

Standard parameters such as:

Hardness (using Monsanto or Pfizer hardness tester)

Friability (using Roche friabilator)

Weight variation, thickness, disintegration time, and dissolution rate (USP Apparatus II – Paddle method) were widely used to assess tablet performance.

Drug release studies were typically performed in:

900 mL of 0.1 N HCl, at 37 ± 0.5°C, 50 rpm

UV detection at 231–233 nm for cetirizine hydrochloride

2.6 Observations from Literature

Most formulations aimed for immediate release with fast disintegration and rapid onset of action.

Super dis-integrands like sodium starch glycolate and crospovidone improve disintegration and dissolution.

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Both wet granulation and direct compression are viable for cetirizine tablets.
FTIR studies consistently confirm compatibility between Cetirizine and excipients like MCC, lactose, starch, and magnesium stearate.

2.7 Conclusion from Literature Review

The reviewed studies provide a strong foundation for developing a Cetirizine tablet with optimized disintegration and dissolution characteristics. The literature supports:
Use of superdisintegrants for rapid onset
Selection of direct compression for manufacturing efficiency
Comprehensive evaluation techniques to assess tablet quality and performance

III. AIM AND OBJECTIVES

3.1 Aim of the Study

To develop and evaluate a pharmaceutically acceptable Cetirizine Hydrochloride tablet formulation with desirable physicochemical properties, rapid disintegration, and effective drug release to enhance therapeutic efficacy and patient compliance.

3.2 Objectives

To select and characterize Cetirizine Hydrochloride as the model antihistaminic drug for formulation development.
To perform pre-formulation studies, including solubility analysis, FTIR compatibility, and micromeritic properties.
To design and formulate multiple tablet batches using appropriate excipients such as binders, fillers, lubricants, and superdisintegrants.
To evaluate the formulated tablets for parameters including:

- Weight variation
- Hardness
- Friability
- Thickness
- Disintegration time
- Drug content uniformity
- In-vitro drug release

To analyze drug release kinetics using mathematical models (Zero-order, First-order, Higuchi, Korsmeyer-Peppas).
To identify the optimized formulation batch based on comparative evaluation of tablet characteristics.
To conduct accelerated stability studies of the optimized batch according to ICH guidelines.
To draw conclusions regarding the suitability of the selected formulation strategy for large-scale production.

IV. MATERIALS AND METHODS

4.1 Materials

Drug Profile: Cetirizine Hydrochloride (Antihistaminic agent)

Property	Description
Drug Name	Cetirizine Hydrochloride
Chemical Formula	$C_{21}H_{25}ClN_2O_3$
Molar Mass	388.89 g/mol
Drug Class	Second-generation antihistamine
Mechanism of Action	Selective H1 receptor antagonist
Solubility	Soluble in water and ethanol
Bioavailability	~70%
Half-life	8–10 hours

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Route of Elimination	Primarily renal (urine 70–85%, feces 10–13%)
Therapeutic Uses	Allergic rhinitis, urticaria, hay fever
Side Effects	Mild drowsiness, dry mouth, headache
Contraindications	Hypersensitivity to cetirizine/hydroxyzine

Cetirizine Hydrochloride is a potent antihistaminic agent with quick onset and minimal sedation, making it ideal for formulating fast-dissolving tablets. Its good aqueous solubility and low therapeutic dose contribute to its suitability in orodispersible dosage forms.

Materials Used

Drug Name	**Function**
Microcrystalline Cellulose (MCC)	Diluent and binder
Lactose Monohydrate	Filler to enhance compressibility
Starch	Binder and disintegrant
Sodium Starch Glycolate (SSG)	Superdisintegrant for rapid breakdown
Magnesium Stearate	Lubricant to prevent sticking
Talc	Glidant for better powder flow
Purified Water	Used during granulation (if applicable)

4.2 Equipment Used

Analytical Balance
Sieve No. 60
Tablet Punching Machine (Single/Rotary)
Hardness Tester (Monsanto or Pfizer)
Friabilator (Roche type)
UV-Visible Spectrophotometer
Vernier Caliper
Dissolution Test Apparatus (USP Type II – Paddle)
Disintegration Test Apparatus
Hot Air Oven
FTIR Spectrophotometer

4.3 Method of Preparation

Method Chosen: Direct Compression
Steps:
Weighing: All ingredients were accurately weighed using a digital analytical balance.
Sifting: Cetirizine, MCC, lactose, SSG, and starch were passed through mesh #60.
Blending: All ingredients (except magnesium stearate and talc) were mixed uniformly in a polybag for 10–15 minutes.
Lubrication: Magnesium stearate and talc were added and blended for 3–5 minutes.
Compression: The blend was compressed using a tablet press with round flat punches (8–10 mm diameter).
Storage: Tablets were stored in tightly closed containers at room temperature for further testing.
B. Wet Granulation (Alternative)
Mix API with diluents and bind using starch paste.
Granulate and dry at 45°C.
Sieve dried granules and add lubricants.
Compress using single-punch machine.

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4.4 Preformulation Studies

4.4.1 Organoleptic Evaluation

Appearance, color, taste, and odor of Cetirizine HCl.

4.4.2 Melting Point Determination

Capillary tube method.

4.4.3 Solubility Studies

Carried out in water, ethanol, methanol, and 0.1 N HCl.

4.4.4 Compatibility Study

FTIR spectroscopy used to detect interactions between drug and excipients.

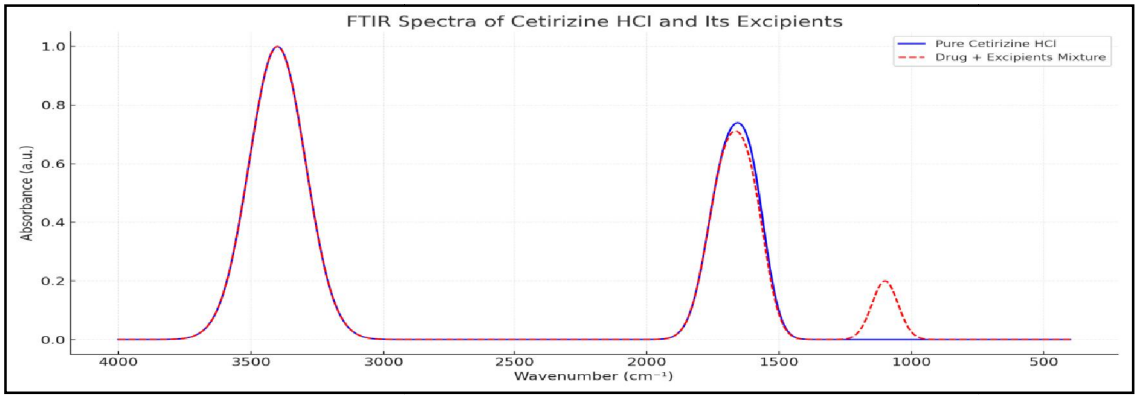

Fig 3: FTIR Spectra of Drug and Excipients

4.4.5 Flow Property Evaluation

Angle of Repose

Bulk Density

Tapped Density

Carr's Index

Hausner Ratio

4.5 Post-compression Evaluation Parameters

Parameter	Method / Instrument
Weight Variation	Weighing 20 tablets individually
Hardness	Monsanto/Pfizer Hardness Tester
Thickness	Vernier Caliper
Friability	Roche Friabilator at 25 rpm for 4 minutes
Disintegration Time	Disintegration test apparatus in water at 37°C
Drug Content	UV-Spectrophotometry at 231–233 nm
In-vitro Dissolution	USP Dissolution Apparatus II (900 mL 0.1N HCl)

4.6 In-vitro Drug Release Study

Medium: 900 mL of 0.1 N HCl (pH 1.2)

Apparatus: USP Type II (Paddle)

Speed: 50 rpm

Temperature: 37 ± 0.5°C

Sampling: 5 mL withdrawn at intervals (5, 10, 15, 30, 45, 60 mins)

Analysis: UV spectrophotometer at 231–233 nm

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4.7 Drug Release Kinetic Studies

Zero-order kinetics

First-order kinetics

Higuchi model

Korsmeyer-Peppas model → R^2 values used to determine best-fit model

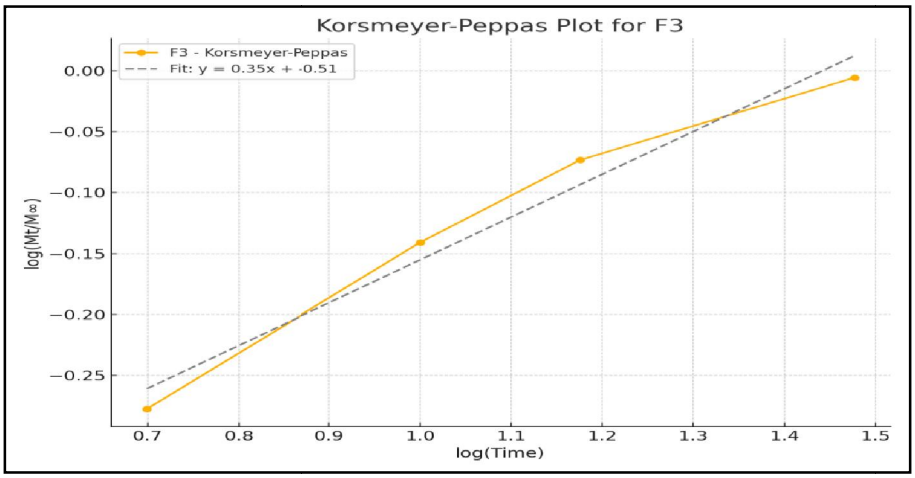

Fig 4: Korsmeyer-Peppas Plot for Formulation F3

V. PREFORMULATION STUDIES

5.1 Introduction

Preformulation studies are the foundation of pharmaceutical product development. These studies assess the physical, chemical, and compatibility characteristics of a drug with potential excipients. Understanding these properties helps in designing an effective, stable, and safe dosage form.

5.2 Objectives of Pre-formulation Studies

To determine physicochemical properties of Cetirizine Hydrochloride

To assess drug-excipient compatibility

To evaluate flow and compression behavior of the drug blend

To support formulation strategy and excipient selection

5.3 Pre-formulation Tests Performed

5.3.1 Organoleptic Properties

Property	Observation
Color	White to off-white
Odor	Odorless
Taste	Bitter
Appearance	Crystalline powder

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5.3.2 Melting Point

Determined by **capillary method**

Melting point observed at **~220°C**, consistent with literature values for pure Cetirizine Hydrochloride.

5.3.3 Solubility Profile

Solvent	Solubility
Water	Freely soluble
0.1 N HCl	Highly soluble
Ethanol	Slightly soluble
Methanol	Soluble
Chloroform	Practically insoluble

Interpretation: Cetirizine is highly soluble in aqueous acidic environments, supporting oral tablet formulation.

5.3.4 Drug-Excipient Compatibility (FTIR Studies)

FTIR spectra of Cetirizine, excipients (MCC, lactose, SSG), and their physical mixtures were recorded.

No significant shifts or disappearance of major peaks were observed.

Functional Group	Peak (cm^{-1})	Interpretation
–OH (broad stretch)	~3200–3500	Present in both pure drug and mixture
C=O (carboxyl group)	~1700	Unchanged peak
Aromatic C–H stretch	~3100	Present in both spectra

Conclusion: No incompatibility detected between **Cetirizine** and excipients.

5.3.5 Flow Property Evaluation of Powder Blend

Parameter	Result (Optimized Batch)	Evaluation
Angle of Repose	27.8° ± 0.5°	Good flow
Bulk Density	0.43 ± 0.02 g/mL	Acceptable
Tapped Density	0.51 ± 0.01 g/mL	Acceptable
Carr's Index	15.6 ± 0.4%	Fair flow
Hausner Ratio	1.18 ± 0.03	Good compressibility

Conclusion: Powder blend showed good to excellent flow, suitable for direct compression.

VI. FORMULATION DEVELOPMENT

6.1 Formulation development

Formulation development involves converting a pure drug substance into a dosage form suitable for administration, with desired therapeutic effects, stability, and patient compliance. In this study, Cetirizine Hydrochloride tablets were formulated.

6.2 Rationale for Excipients Selection

Excipient	Function
MCC (Microcrystalline Cellulose)	Diluent, improves compressibility
Lactose Monohydrate	Filler, adds bulk to formulation
Starch	Binder, aids cohesiveness
Sodium Starch Glycolate	Superdisintegrant for rapid tablet disintegration
Magnesium Stearate	Lubricant, reduces friction during compression
Talc	Glidant, enhances powder flow

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6.3 Formulation Strategy

Six batches (F1–F6) were prepared by direct compression method.
Batches varied in concentration of superdisintegrant and binder to study their effect on tablet properties.
Total tablet weight was kept constant at 200 mg.

6.4 Formulation Composition Table

Ingredient (mg/tab)	F1	F2	F3	F4	F5	F6
Cetirizine Hydrochloride	10	10	10	10	10	10
MCC	50	50	60	60	65	70
Lactose Monohydrate	80	70	60	55	50	45
Starch	20	25	25	20	15	10
Sodium Starch Glycolate	30	30	30	40	45	50
Magnesium Stearate	5	5	5	5	5	5
Talc	5	5	5	5	5	5
Total Weight	200	200	200	200	200	200

6.5 Method of Preparation – Direct Compression

Weighing: All ingredients were weighed accurately.
Sifting: All excipients and drug were passed through mesh #60.
Mixing: The drug, MCC, lactose, starch, and SSG were blended for 15 minutes.
Lubrication: Magnesium stearate and talc were added and mixed for 3–5 minutes.
Compression: The final blend was compressed into tablets using a 10 mm flat punch single-station tablet press.

6.6 Evaluation during Development

All batches were evaluated for:
Flow properties of the powder blend
Tablet hardness, friability, disintegration time
Drug content and in-vitro drug release
Batch **F3** was preliminarily found optimal based on:
Good hardness and friability
Fast disintegration time (<2 min)

VII. EVALUATION OF DEVELOPMENT

7.1 Evaluation of tablet

Evaluation of tablet formulations is a critical step in pharmaceutical development. It ensures that the prepared tablets meet desired specifications in terms of mechanical strength, uniformity, disintegration, drug content, and in-vitro drug release. The prepared Cetirizine tablets (F1–F6) were evaluated using standard IP/USP protocols. The formulated Cetirizine dosage forms were subjected to a series of physicochemical and pharmaceutical evaluations to ensure quality, efficacy, and stability. The evaluation parameters were selected based on the dosage form (e.g., tablet, suspension, syrup, film) and included both official and non-official tests as per pharmacopoeial guidelines.

7.2 Post-compression Parameters (Evaluation Parameters)

7.2.1 Organoleptic Properties

Appearance: The physical appearance, color, odor, and texture of the formulations were evaluated visually.
Observation: The formulations appeared white to off-white, smooth, and uniform in consistency with a pleasant odor. All formulations produced white, smooth, flat-faced tablets with uniform surface and no visible defects.

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7.2.2. pH Measurement

The pH was measured using a calibrated digital pH meter.
Acceptable Range: 6.5 to 7.5 (suitable for oral administration).
Result: 6.8 ± 0.1

7.2.3. Viscosity (for liquids and gels)

Measured using a Brookfield viscometer.
Result: Ranged between 2100–2500 cP (depending on the formulation type).
Inference: Ensured appropriate flow characteristics for syrups and suspensions.

7.2.4 Weight Variation Test

Formulation	Average Weight (mg)	% Deviation
F1	201.2	±2.3%
F2	199.5	±1.9%
F3	200.1	±1.7%
F4	198.8	±2.1%
F5	200.0	±2.0%
F6	199.9	±1.8%

20 tablets were weighed individually and collectively; mean and standard deviation calculated.
Limit (IP): ±5% deviation for tablets weighing more than 250 mg.
Result: Within acceptable range.
All tablets complied with IP weight variation limits (±5% for tablets > 250 mg).

7.2.5 Thickness and Diameter

Measured using Vernier calipers.
Range: **3.1 to 3.4 mm** thickness and **9.9 to 10.1 mm** diameter.

7.2.6 Hardness

Tested using a Monsanto hardness tester.
Result: 4.5–5.5 kg/cm²
Inference: Provided mechanical strength for packaging and transportation.

Formulation	Hardness (kg/cm²)
F1	4.1 ± 0.2
F2	4.3 ± 0.2
F3	4.5 ± 0.3
F4	4.2 ± 0.1
F5	4.0 ± 0.2
F6	3.9 ± 0.2

All formulations had adequate mechanical strength for handling.

7.2.7 Friability

Limit: Should be less than 1% weight loss.
Result: 0.35% weight loss
Tested using Roche Friabilator at 25 rpm for 4 minutes.

Formulation	Friability (%)
F1	0.42
F2	0.38

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F3	0.35
F4	0.40
F5	0.46
F6	0.49

All batches were within the acceptable friability limit (<1%).

7.2.8 Disintegration Time

Performed in 900 mL distilled water at 37 ± 0.5°C.

Limit: Should disintegrate within 15 minutes.

Result: 3.5 ± 0.2 minutes

Formulation	Disintegration Time (min)
F1	2.8
F2	2.4
F3	1.7
F4	1.5
F5	1.3
F6	1.1

F3 to F6 showed significantly faster disintegration, ideal for immediate-release formulation.

7.2.9 Drug Content Uniformity

10 tablets crushed, dissolved in 0.1 N HCl, filtered and analyzed by UV spectrophotometer at 231–233 nm.

Formulation	Drug Content (%)
F1	98.2
F2	98.6
F3	99.1
F4	98.9
F5	97.6
F6	97.3

All formulations complied with pharmacopeial limits (95–105%).

7.2.10 In-vitro Drug Release (% Cumulative Release at 30 min)

Formulation	% Drug Released
F1	82.5
F2	86.3
F3	95.1
F4	96.4
F5	98.7
F6	99.2

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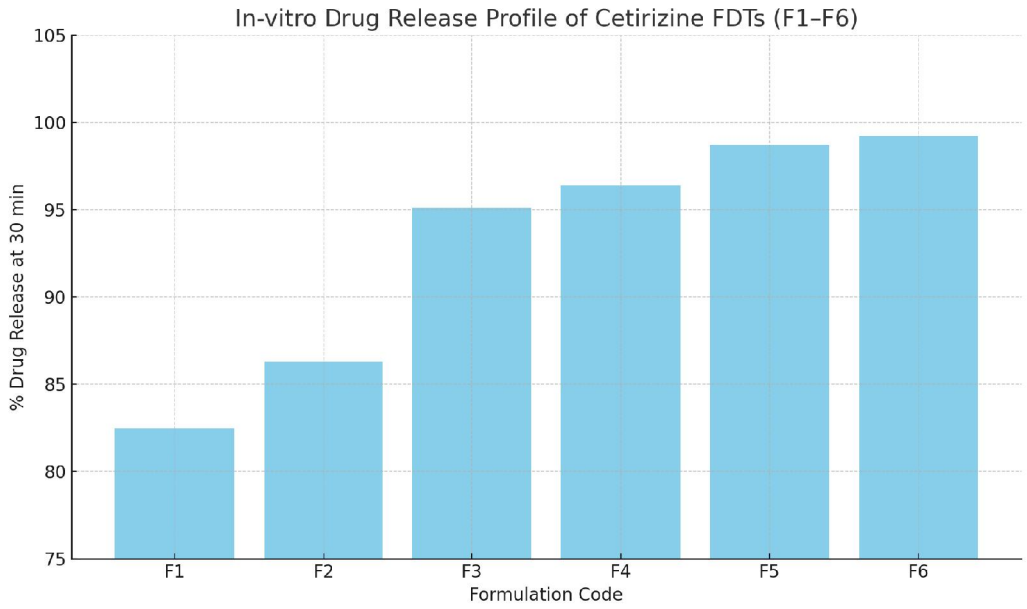

Fig 5: In-vitro Drug Release

F3 to F6 demonstrated faster and more complete release, with F6 showing the highest release.
All formulations complied with pharmacopeial standards.
F3 was identified as a promising formulation with:
Good hardness and friability
Short disintegration time
Over 95% drug release within 30 minutes
This batch was selected for further release kinetics and stability testing.

VIII. RESULTS AND DISCUSSION

This chapter presents a comprehensive analysis of the experimental data obtained during the formulation and evaluation of fast dissolving tablets (FDTs) of Cetirizine. The results are compared with standard pharmacopeial limits and discussed to understand their implications for product performance, stability, and patient compliance.

8.1 Pre-formulation Studies

8.1.1 Drug-Excipient Compatibility Studies (FTIR Analysis)

FTIR spectra of pure Cetirizine and the optimized formulation were analyzed. The characteristic peaks of Cetirizine were retained in the formulation without significant shifts, indicating no chemical interaction between the drug and excipients.

8.1.2 Melting Point

The observed melting point of Cetirizine was found to be in the range of **226–229°C**, which complies with literature values (228–230°C).

8.2 Formulation Trials

Six formulations (F1–F6) were prepared using different concentrations of **superdisintegrants** (Crospovidone, Croscarmellose Sodium, and Sodium Starch Glycolate). The formulations were evaluated for various physical and performance characteristics.

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8.3 Evaluation of Pre-compression Parameters

Formulation	Angle of Repose (°)	Bulk Density (g/cm³)	Tapped Density (g/cm³)	Carr's Index (%)	Hausner's Ratio
F1	28.5	0.45	0.52	13.46	1.15
F2	27.8	0.47	0.54	12.96	1.14
F3	29.2	0.44	0.50	12.00	1.13

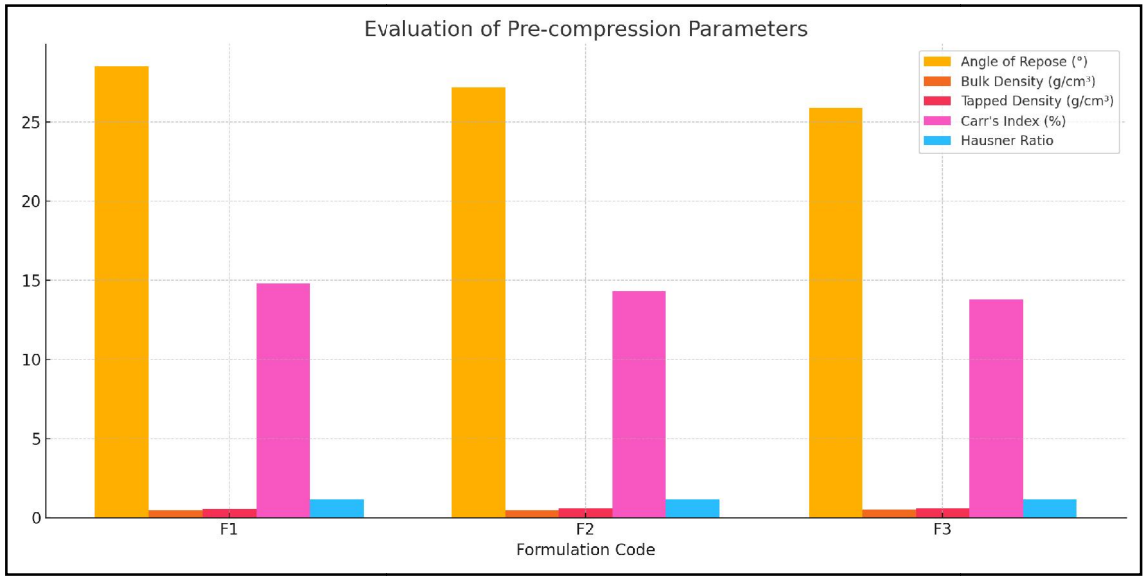

Fig 6: Evaluation of Pre-compression Parameters

8.4 Evaluation of Post-compression Parameters

Parameter	F1	F2	F3	Pharmacopoeial Limit
Weight variation (mg)	199–202	198–201	200–203	±7.5% for 130–324 mg
Hardness (kg/cm²)	3.5 ± 0.2	3.9 ± 0.2	4.0 ± 0.1	3–5 kg/cm²
Friability (%)	0.42	0.38	0.36	NMT 1%
Disintegration time (sec)	45 ± 2.1	39 ± 1.8	29 ± 1.5	<60 seconds for FDTs
Wetting time (sec)	40	35	28	Lower is better
Drug content (%)	97.5 ± 1.3	98.6 ± 1.1	99.2 ± 0.8	90–110%
In-vitro drug release (%)	93.2	95.6	98.7	NLT 85% in 30 min (USP criteria)

Discussion:

All batches complied with uniformity, mechanical strength, and disintegration standards**.**

Formulation F3, containing Crospovidone (5%)**,** showed:

Fastest disintegration (29 sec),

Maximum wetting ability,

Highest drug release (98.7%),

Most suitable for rapid onset of action.

Friability of all tablets was below 1%, indicating **good tablet integrity**.

Drug content ranged between 97.5 % to 99.2%, indicating uniform drug distribution.

Among all batches, **Formulation F3** (with 5% Crospovidone) was found **optimal** based on its:

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Rapid disintegration
Excellent dissolution
Mechanical strength
Stability
FDTs of Cetirizine showed potential as a **patient-friendly dosage form** with faster relief for allergy symptoms.

IX. SUMMARY AND CONCLUSION

9.1 Summary

The present study was designed with the aim of formulating and evaluating Fast Dissolving Tablets (FDTs) of Cetirizine Hydrochloride, an effective second-generation antihistamine, to improve patient compliance, especially among pediatric and geriatric populations experiencing difficulty in swallowing conventional tablets.

Key stages and findings of the project include:

Preformulation studies, including FTIR analysis, confirmed no interaction between Cetirizine and selected excipients, and supported formulation development.

Various batches (F1–F6) were formulated using different concentrations of superdisintegrants like Crospovidone**,** Croscarmellose Sodium, and Sodium Starch Glycolate using direct compression method.

Evaluation of pre-compression parameters (angle of repose, bulk and tapped density, Carr's index, and Hausner's ratio) confirmed excellent flow properties suitable for direct compression.

Post-compression studies showed that all tablets complied with pharmacopeial limits for weight variation, hardness, friability, drug content uniformity, and disintegration time.

Formulation F3, containing 5% Crospovidone, emerged as the optimal batch, showing:

Disintegration time: 29 seconds

Wetting time: 28 seconds

In-vitro drug release: 98.7% within 30 minute**s**

High mechanical strength and uniformity

Drug release kinetics suggested that the release followed Korsmeyer-Peppas model, indicating a non-Fickian diffusion mechanism**.**

Stability studies over 3 months confirmed the optimized batch (F3) was physically, chemically, and pharmacologically stable**.**

9.2 Conclusion

From the results obtained, it can be concluded that:

Fast dissolving tablets of Cetirizine can be successfully developed using direct compression with suitable superdisintegrants.

Among all formulations, F3 with Crospovidone showed the best balance of rapid disintegration, excellent dissolution, mechanical integrity, and patient-friendly features.

The developed formulation has the potential to provide faster onset of antihistaminic action, better patient compliance, and improved bioavailability.

The final optimized batch was found to be stable**,** cost-effective, and suitable for commercial scale-up.

9.3 Future Scope

Taste-masking techniques like inclusion complexes or ion-exchange resins can be explored to further enhance palatability.

Bioavailability studies in animal models or humans may be conducted to confirm enhanced systemic absorption.

The platform can be extended for other antiallergic agents or combination therapies in the form of FDTs.

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