WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

REVIEW ARTICLE; FORMULATION AND EVALUATION OF CETIRIZINE TABLET

Mrs. MANISHA P[1], YAZEED.P[2], ASHIQUE HASSAN[3] , ZAINEBATH RAEELA[4]

MALIK DEENAR COLLEGE OF PHARMACY, SEETHANGOLI, P/O BELA,671321

ABSTRACT :

Fast disintegrating tablets (FDTs) offer a promising oral drug delivery method, especially beneficial for populations with swallowing difficulties. This review consolidates and analyzes two independent formulations of Cetirizine Hydrochloride FDTs. Both studies utilized direct compression with superdisintegrants—croscarmellose sodium, crospovidone, and low-substituted hydroxypropyl cellulose (L-HPC). Pre- and post-compression parameters were evaluated alongside drug content, disintegration time, and dissolution profiles. The findings confirm that FDTs formulated with optimized concentrations of superdisintegrants enhance disintegration and release profiles significantly. The comparative study reinforces the suitability of such formulations for improving patient compliance and therapeutic effectiveness in allergic conditions.

Keywords: Cetirizine Hydrochloride, Fast Disintegrating Tablet, Superdisintegrants, Direct Compression, Crospovidone, Croscarmellose Sodium, L-HPC

1. Introduction

The oral route remains the most preferred and widely accepted method for drug administration. However, traditional solid dosage forms such as tablets and capsules often present challenges to certain populations, including the elderly, children, and individuals with dysphagia (difficulty in swallowing). To mitigate these limitations, fast disintegrating tablets (FDTs) have emerged as a favorable alternative. These tablets are designed to disintegrate quickly in the oral cavity, typically within 60 seconds, allowing for rapid absorption without the need for water.

Cetirizine hydrochloride, a second-generation H_1 receptor antagonist, is a widely prescribed antihistamine used for managing seasonal allergic rhinitis, chronic urticaria, and other allergic disorders. Its use in FDT formulations could potentially improve therapeutic onset and compliance.

This review integrates two journal articles that individually explored the formulation of Cetirizine HCl FDTs using direct compression. The focus of both studies was the comparative analysis of different superdisintegrants and their concentrations to determine the optimal formulation for rapid onset and patient acceptability.

2. Aim and Objective

The core objective of this review is to consolidate findings from two independent studies on Cetirizine HCl FDTs to:

- Compare the effectiveness of various superdisintegrants
- Examine pre- and post-compression parameters
- Evaluate drug release profiles and stability
- Propose an optimized formulation strategy

3. Rationale for Fast Disintegrating Tablets

FDTs combine the advantages of solid and liquid formulations. They are particularly suitable for patients who may not have access to water or have compliance issues. Furthermore, some drugs, including cetirizine, benefit from pre-gastric absorption which improves bioavailability and reduces hepatic first-pass metabolism.

Key characteristics of ideal FDTs include:

- Rapid disintegration in saliva
- Pleasant mouthfeel
- Mechanical strength to withstand handling
- Acceptable taste and appearance

4. Materials Used in Formulations

Talc and **Active Ingredient:**

- **Cetirizine Hydrochloride**: Antihistaminic drug with rapid onset requirement

Superdisintegrants:

- **Croscarmellose Sodium** (Study 1)
- **Crospovidone and L-HPC (Low-substituted hydroxypropyl cellulose)** (Study 2)

Other Excipients:

- Microcrystalline cellulose (Avicel PH 102)
- Mannitol
- Aspartame (sweetener)
- magnesium stearate (lubricants)
- Mint flavor (Study 1)

These excipients enhance compressibility, palatability, and disintegration properties.

5. Methodology of Tablet Preparation

Both studies employed **direct compression** as the manufacturing method. This approach involves:

1. Sifting of API and excipients
2. Blending of ingredients in geometric dilution
3. Lubrication with talc and magnesium stearate
4. Compression into tablets using rotary compression machines

Advantages of direct compression include simplicity, lower processing time, and cost-effectiveness.

6. Pre-Compression Evaluation

Both research teams conducted pre-compression tests on the powder blends to ensure suitability for direct compression. Parameters included:

Parameter	Study 1 (Croscarmellose)	Study 2 (Crospovidone/L-HPC)
Bulk Density (g/cm³)	0.402 – 0.417	0.52 – 0.58
Tapped Density (g/cm³)	0.485 – 0.513	0.60 – 0.68
Carr's Index (%)	16.70 – 18.95	12.9 – 16.4
Hausner's Ratio	1.20 – 1.23	1.14 – 1.19
Angle of Repose (°)	26.18 – 32.61	24.68 – 26.3

All values indicated good to excellent flow properties essential for uniform tablet production.

7. Tablet Evaluation Parameters

7.1 Physical Properties

Both studies evaluated:

- **Weight Variation**
- **Hardness**: ~2.6–3.5 kg/cm²
- **Thickness**: 2.5–3.6 mm
- **Friability**: <1%, within IP limits
- **General Appearance**: White, round, and aromatic (Study 1)

7.2 Disintegration and Wetting Time

Formulation	Disintegration Time (sec)	Wetting Time (sec)
Study 1 F3	48	Not stated
Study 2 F3	35.6 ± 1.22	42.4 ± 1.15

Disintegration time decreased as the superdisintegrant concentration increased. Crospovidone exhibited superior performance compared to L-HPC.

8. Drug Content and Uniformity

Both articles reported consistent drug content:

- **Study 1**: 91.98% – 99.94%
- **Study 2**: 96.26% – 99.91%

These values fell within pharmacopeial limits, confirming formulation accuracy.

9. In Vitro Drug Release Studies

Test Conditions:

- **Study 1**: 0.1N HCl, 100 rpm, 37°C
- **Study 2**: pH 6.8 phosphate buffer, 50 rpm, 37°C

Findings:

Formulation	Time to 98%+ Release
Study 1 F3	30 minutes (98.23%)
Study 2 F3	15 minutes (99.60%)

Crospovidone-based formulation (Study 2 F3) demonstrated superior release kinetics, attributed to its high swelling index and capillary action.

10. Stability Studies

Formulation F3 from both studies underwent stability testing at:

- **40°C/75% RH for 3 months**
- **Room and cold temperatures** (Study 1 only)

Both studies reported:

- No significant physical or chemical changes
- Consistent drug content and release profiles

These results confirm the stability of optimized formulations under accelerated conditions.

11. Comparative Analysis of Superdisintegrants

Parameter	Croscarmellose (Study 1)	Crospovidone (Study 2)	L-HPC (Study 2)
Disintegration	Moderate	Fastest	Moderate
Wetting Time	Moderate	Lowest	High
Drug Release Rate	98.23% in 30 min	99.60% in 15 min	~96% in 15 min
Stability	Stable	Stable	Stable

Crospovidone outperformed the other disintegrants in all critical areas, making it the most suitable for FDTs of cetirizine HCl.

12. Discussion

FDTs enhance drug bioavailability, especially for medications like cetirizine requiring rapid onset. Both studies validate the importance of optimizing superdisintegrant type and concentration. Crospovidone was superior due to its high porosity and water-wicking ability, allowing rapid disintegration and dissolution. However, croscarmellose sodium and L-HPC also proved effective to a lesser extent. The role of mannitol, a cooling sweetener, and aspartame further improved mouthfeel and palatability—key aspects for pediatric and geriatric compliance.

Direct compression was efficient and cost-effective, producing tablets with acceptable mechanical strength and rapid performance metrics.

13. Conclusion

The integrated findings confirm that Cetirizine Hydrochloride FDTs, particularly those formulated with crospovidone at optimized concentrations (F3), offer excellent drug release and patient acceptability. The use of direct compression simplifies production, while careful excipient selection enhances performance.

This review demonstrates that crospovidone, among the evaluated superdisintegrants, is most effective for FDTs of cetirizine hydrochloride and supports its broader adoption in formulations targeting allergic conditions requiring fast relief.

14. REFERENCES

[1] Mhaske Nilesh et al., IJPR&A, 2023
[2] Radke RS et al., IJPSRR, 2024
[3] Indian Pharmacopoeia, 2018
[4] USP 30-NF25

[5] Martindale: The Complete Drug Reference
[6] Seager H., J Pharm Pharmacol, 1998
[7] Chang RK et al., Pharm Tech, 2000
[8] Sreenivas SA et al., Indian J Pharm Edu Res, 2005