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Review Article

A Comprehensive Review on Pheniramine Maleate Tablets: Formulation, Characterization, and Therapeutic Applications

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Pheniramine maleate is a first-generation H1-receptor antagonist belonging to the alkylamine class of antihistaminic drugs. It has been used for the symptomatic management of allergic conditions and related manifestations. Conventional oral tablets provide a convenient and stable dosage form; however, difficulty in swallowing conventional tablets can affect patient acceptability and compliance. Orodispersible tablets have therefore emerged as an important alternative for improving convenience of administration. These dosage forms are designed to disintegrate rapidly in the oral cavity with minimal or no requirement for water. Formulation of pheniramine maleate orodispersible tablets requires appropriate selection of diluents, superdisintegrants, lubricants, sweeteners and flavouring agents. Direct compression and effervescent techniques have been investigated for the preparation of pheniramine maleate orodispersible tablets. Superdisintegrants such as crospovidone, croscarmellose sodium, sodium starch glycolate, low-substituted hydroxypropyl cellulose and pregelatinized starch have been investigated to improve tablet disintegration and drug release. Reported studies have demonstrated acceptable physical properties, rapid disintegration and enhanced dissolution of optimized pheniramine maleate orodispersible tablets. This review summarizes the drug profile, pharmacological action, rationale for tablet development, formulation approaches, excipients, manufacturing techniques, evaluation parameters, reported formulation studies, advantages, limitations and future prospects of pheniramine maleate tablets.

Keywords: Pheniramine maleate, antihistamine, H1 receptor antagonist, tablet, orodispersible tablet, superdisintegrant, direct compression, dissolution.

INTRODUCTION

The oral route is one of the most widely accepted routes of drug administration because of its convenience, non-invasive nature, ease of administration and patient acceptability. Tablets are among the most commonly used solid dosage forms because they provide accurate dosing, good physical and chemical stability, ease of packaging and convenient handling [1]. Despite these advantages, conventional tablets may present difficulties for patients who have impaired or difficult swallowing. Pediatric and geriatric patients are particularly important populations in the development of patient-friendly dosage forms. Such limitations have encouraged pharmaceutical scientists to develop alternative oral solid dosage forms capable of rapid disintegration in the oral cavity [2,3]. Orodispersible tablets (ODTs), also known as orally disintegrating, mouth-dissolving or fast-dissolving tablets, are designed to disintegrate rapidly when placed on the tongue in the presence of saliva. They can subsequently be swallowed without the need for administration with water [2,4]. The development of ODTs can improve convenience and may enhance patient compliance, particularly where swallowing conventional tablets is problematic. Pheniramine maleate is an H1-receptor antagonist belonging to the first-generation alkylamine antihistamines. It inhibits

the effects of histamine and has been used for allergic conditions, itching and other histamine-associated symptoms [5]. A published formulation study specifically investigated pheniramine maleate in an orodispersible tablet dosage form using different superdisintegrants [6]. The development of pheniramine maleate tablets is therefore of pharmaceutical interest because an appropriately designed dosage form can combine accurate drug delivery with acceptable mechanical strength, rapid disintegration and satisfactory drug release.

2. Pheniramine Maleate

2.1 General description

Pheniramine is a first-generation antihistamine of the alkylamine class. Pheniramine maleate is the maleate salt form used in pharmaceutical products. It acts mainly by antagonizing histamine H1 receptors and thereby reduces histamine-mediated allergic responses [5,7]. Pheniramine is used for the symptomatic management of allergic manifestations. It has also been associated with the management of conditions involving itching and other histamine-mediated symptoms [5,7].

2.2 Pharmacological action

Histamine plays an important role in allergic reactions. Activation of H1 receptors contributes to vascular permeability and effects on smooth muscle. H1-antihistamines such as pheniramine antagonize these receptor-mediated effects [5]. The reference formulation study describes pheniramine maleate as an H1-receptor antagonist that inhibits the effects of histamine on capillary permeability and vascular, bronchial and other smooth muscles [6]. Its pharmacological activity provides the basis for its use in allergic conditions and associated symptoms.

2.3 Therapeutic applications

Pheniramine has been used as an antihistamine for allergic conditions including symptoms associated with allergic rhinitis and itching. It has also been reported for use in motion sickness and symptoms such as nausea, vomiting and vertigo [5,6].

Because antihistamines may produce central nervous system effects, formulation and administration should be considered in relation to the pharmacological characteristics of first-generation antihistamines [5].

3. Rationale for Pheniramine Maleate Tablet Development

Conventional tablets are convenient, but some patients have difficulty swallowing solid dosage forms. This limitation can result in poor adherence to therapy [2,3]. The development of orodispersible pheniramine maleate tablets provides several potential advantages:

- Rapid disintegration in the oral cavity.
- Administration without water.
- Improved convenience.
- Potentially improved patient acceptability.
- Rapid dispersion of the drug.
- Potentially faster dissolution compared with conventional tablets.
- Suitability for patients who have difficulty swallowing conventional tablets [2,4].

A reported pheniramine maleate formulation study was specifically designed to improve patient compliance and provide rapid disintegration and drug release [6].

4. Preformulation Studies

Preformulation studies are performed before formulation development to determine the physical and chemical characteristics of the drug and its suitability for incorporation into a dosage form.

Important preformulation parameters include:

- Solubility
- Melting point
- pH
- Bulk density
- Tapped density
- Angle of repose
- Carr's compressibility index
- Hausner's ratio
- Moisture content
- Drug-excipient compatibility

In the reported pheniramine maleate study, solubility was investigated in water, chloroform, ethanol and ether. The drug was reported to be freely soluble in water, chloroform and ethanol and very slightly soluble in ether. The reported pH was 5, bulk density was 0.55 g/mL, tapped density was 0.62 g/mL and melting point was 107–109°C [6].

Table 1. Reported preformulation characteristics of pheniramine maleate

Sr. No.	Parameter	Observation
1	Solubility	Freely soluble in water, chloroform and ethanol; very slightly soluble in ether
2	pH	5
3	Bulk density	0.55 g/mL
4	Tapped density	0.62 g/mL
5	Compressibility	1.12%
6	Loss on drying	0.4%
7	Melting point	107–109°C

5. Orodispersible Tablets

Orodispersible tablets are solid dosage forms intended to disintegrate rapidly in the oral cavity. They are particularly useful when rapid administration and ease of swallowing are desired [2,4]. The European Pharmacopoeia describes an orodispersible tablet as a tablet intended to be placed in the mouth where it disperses rapidly before being swallowed. Modern ODT development focuses on achieving a balance between rapid disintegration and adequate mechanical strength [4].

5.1 Advantages of ODTs

Important advantages include:

1. Ease of administration.
2. No requirement for water during administration.
3. Rapid disintegration.
4. Improved patient convenience.
5. Potential improvement in patient compliance.
6. Suitability for patients with swallowing difficulties.
7. Rapid drug dissolution after tablet disintegration [2,4].

5.2 Limitations of ODTs

Despite their advantages, ODTs may have certain limitations:

- Poor mechanical strength in some formulations.
- Sensitivity to moisture.
- Taste of the active pharmaceutical ingredient may become important.
- Specialized packaging may sometimes be necessary.
- Formulation optimization is required to achieve both strength and rapid disintegration [2,4].

6. Formulation Components of Pheniramine Maleate Tablets

The selection of excipients is an important factor in the development of pheniramine maleate tablets.

6.1 Diluent

Diluents provide bulk to the tablet formulation and may influence compressibility, mouthfeel, disintegration and dissolution. Microcrystalline cellulose and mannitol were used in the reported pheniramine maleate orodispersible tablet formulation [6].

6.2 Superdisintegrants

Superdisintegrants are among the most important excipients in ODT formulation. They promote rapid breakup of the tablet after contact with saliva or aqueous fluid.

The reported pheniramine maleate study investigated:

- Croscarmellose sodium
- Crospovidone
- Sodium starch glycolate
- Low-substituted hydroxypropyl cellulose
- Pregelatinized starch [6]

Superdisintegrants act through mechanisms such as swelling, wicking, deformation recovery and strain recovery. Their efficiency depends on the type, concentration, particle characteristics and interactions with other excipients [8,9].

6.3 Croscarmellose sodium

Croscarmellose sodium is a cross-linked cellulose derivative used as a superdisintegrant. Its rapid water uptake and swelling characteristics can promote tablet breakup and facilitate drug dissolution [8]. In the reported pheniramine maleate study, increasing the concentration of croscarmellose sodium improved drug release, and the formulation containing 10% croscarmellose sodium showed almost complete drug release within six minutes under the reported test conditions [6].

6.4 Crospovidone

Crospovidone is a cross-linked polymer of N-vinyl-2-pyrrolidone. It promotes rapid tablet disintegration predominantly through capillary action and wicking. The pheniramine maleate formulation study reported rapid wetting and disintegration for crospovidone-containing formulations [6]. A formulation containing 10% crospovidone achieved approximately complete drug release within six minutes in the reported dissolution study [6].

6.5 Sodium starch glycolate

Sodium starch glycolate is a modified starch superdisintegrant. It rapidly hydrates and swells upon contact with water, facilitating tablet disintegration [8,9].

6.6 Low-substituted hydroxypropyl cellulose

Low-substituted hydroxypropyl cellulose can act as a disintegrant and contributes to tablet structure. Its performance depends on concentration and formulation composition [8].

6.7 Pregelatinized starch

Pregelatinized starch has multifunctional properties and may contribute to binding, disintegration and compressibility depending on its concentration and formulation conditions [8].

6.8 Lubricants and glidants

Magnesium stearate and talc are commonly incorporated into tablet formulations to improve manufacturing characteristics. Magnesium stearate reduces friction between the tablet formulation and tooling, while talc can improve powder handling and reduce adhesion. The reported pheniramine maleate formulation contained magnesium stearate and talc and incorporated them during the final blending stage [6].

6.9 Sweeteners and flavouring agents

Taste is an important consideration in orally disintegrating formulations because the formulation remains in the mouth before swallowing. Sweeteners and flavours may therefore be incorporated to improve palatability. Aspartame and strawberry flavour were used in the reported pheniramine maleate ODT formulation [6].

7. Methods for Preparation Of Pheniramine Maleate Tablets

Several techniques may be used to manufacture orodispersible tablets.

7.1 Direct compression

Direct compression is a simple and economical technique in which powders are blended and directly compressed into tablets. It avoids granulation and drying steps and can be performed using conventional tablet compression equipment [4,10]. A reported pheniramine maleate study used direct compression. The drug and excipients were mixed and co-ground, followed by addition of talc and magnesium stearate. The final blend was compressed into 170-mg tablets using a single-punch machine [6].

Manufacturing sequence

Pheniramine maleate + diluent + superdisintegrant + other excipients

↓

Blending

↓

Addition of talc + magnesium stearate

↓

Final mixing

↓

Compression

↓

Orodispersible tablets

7.2 Effervescent method

The effervescent approach uses an acid-base combination that generates carbon dioxide when the tablet contacts saliva or water. The generated gas promotes rapid tablet disintegration. An experimental study specifically evaluated pheniramine maleate orodispersible tablets prepared using the effervescent method with the objective of improving patient compliance [11].

7.3 Other ODT manufacturing approaches

Other techniques used for ODT development include:

- Freeze drying/lyophilization.
- Sublimation.
- Spray drying.
- Molding.
- Mass extrusion.
- Cotton-candy process.
- Nanoparticle-based approaches.
- Co-processed excipient-based direct compression [2,4,10].

The selection of manufacturing technique depends on the drug dose, solubility, stability, required mechanical strength and desired disintegration time.

8. Evaluation of Pheniramine Maleate Tablets

8.1 Pre-compression evaluation

The powder blend should be evaluated for flow and compressibility before compression.

Angle of repose

Angle of repose provides an indication of powder flowability. Lower values generally indicate better flow.

Bulk density

Bulk density is the mass of powder divided by its untapped volume.

Tapped density

Tapped density is determined after mechanically tapping the powder to achieve a more compact arrangement.

Carr's compressibility index

Carr's index is calculated from bulk and tapped density and is used to estimate powder flow and compressibility.

Hausner's ratio

Hausner's ratio is the ratio of tapped density to bulk density and provides an additional indication of powder flow characteristics. The reported pheniramine maleate study evaluated bulk density, tapped density, angle of repose, porosity, Carr's index and Hausner's ratio for the formulation blends [6].

9. Post-Compression Evaluation

9.1 Weight variation

Weight variation is performed to assess uniformity of tablet mass. The reported pheniramine maleate formulations complied with the prescribed weight-variation requirements [6].

9.2 Hardness

Hardness indicates the mechanical strength of a tablet. An ODT should possess adequate strength to withstand handling while still disintegrating rapidly. The reported formulations showed hardness values within approximately 3.3–3.6 kg/cm² [6].

9.3 Friability

Friability evaluates the tendency of tablets to lose particles during handling and transportation. Excessive friability indicates inadequate mechanical strength. The reported pheniramine maleate formulations demonstrated friability within acceptable limits [6].

9.4 Thickness

Tablet thickness is useful for maintaining batch-to-batch dimensional uniformity. The reported

pheniramine maleate formulations had thickness values approximately between 2.46 and 2.56 mm [6].

9.5 Drug content

Drug-content testing is performed to confirm the uniform distribution of the active pharmaceutical ingredient. The reported pheniramine maleate formulations showed drug-content values between approximately 98.9% and 101.5% [6].

10. Wetting Time

Wetting time is an important parameter for ODTs because rapid wetting facilitates subsequent disintegration. In the reported study, a double-folded tissue paper was placed in a Petri dish containing 6 mL of water or buffer, and the tablet was placed on the moistened tissue. The time required for complete wetting was determined at approximately 37°C [6]. The reported wetting times for the formulations ranged approximately from 29.8 to 65.8 seconds. Crospovidone-containing formulations showed particularly rapid wetting compared with several other superdisintegrant-containing formulations [6].

11. In-Vitro Dispersion Time

Dispersion time measures the time required for a tablet to disperse in a specified aqueous medium. In the reported study, tablets were placed in 10 mL phosphate buffer of pH 6.8 maintained at approximately 37 ± 0.5°C, and the time required for complete dispersion was measured [6]. The selected formulations F6 and F7 showed dispersion times of 30.2 ± 0.83 and 26.8 ± 1.92 seconds, respectively [6].

12. In-Vitro Disintegration Time

Disintegration time is one of the most important quality attributes of an ODT. Rapid disintegration allows the drug to become available for dissolution and subsequent absorption. In the reported pheniramine maleate study, disintegration was evaluated using a disintegration apparatus at approximately 37 ± 2°C [6]. The formulation results demonstrated that increasing the concentration of appropriate superdisintegrants generally improved disintegration performance [6]. The selected formulations F6 and F7 showed disintegration times of approximately 25.6 and 20.0 seconds, respectively [6].

13. In-Vitro Dissolution Study

Dissolution testing is used to determine the rate and extent of drug release from the tablet. The reported pheniramine maleate study employed USP type II dissolution apparatus containing 900 mL of 0.1 M hydrochloric acid at 50 rpm and 37 ± 0.5°C. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically [6]. The study demonstrated that increasing the concentration of superdisintegrants increased the rate of drug release. Formulations containing 10% croscarmellose sodium and 10% crospovidone achieved approximately complete drug release at six minutes, whereas the marketed conventional tablet reached approximately complete release at 45 minutes under the reported conditions [6].

Table 2. Reported dissolution performance

Formulation	Drug release at 6 min
F6	Approximately 100%
F7	Approximately 100%
Marketed tablet	Approximately 96.69% at 30 min and 99.37% at 45 min

14. Effect of Superdisintegrants On Tablet Performance

Superdisintegrants have a major influence on the performance of pheniramine maleate ODTs. The reported formulation study demonstrated that increasing the concentration of superdisintegrants increased the cumulative drug release. Croscarmellose sodium and crospovidone produced particularly rapid dissolution [6]. Crospovidone-containing formulation F7 demonstrated a disintegration time of approximately 20 seconds and

dispersion time of approximately 26.8 seconds, while F6 containing croscarmellose sodium showed approximately 25.6 seconds disintegration and 30.2 seconds dispersion [6]. The selection of superdisintegrant should therefore consider not only concentration but also mechanism of action, compatibility, compression force, tablet hardness and the desired dissolution profile [8,9].

15. Comparison with Marketed Tablets

Comparison with a conventional marketed tablet can help establish the performance advantage of an ODT. The reported study compared selected formulations with a marketed pheniramine maleate tablet. F6 and F7 demonstrated substantially shorter disintegration, wetting and dispersion times than the marketed tablet [6].

Table 3. Comparison of selected formulations with marketed tablet

Parameter	F6	F7	Marketed tablet
Hardness (kg/cm²)	3.4	3.4	6.3
Friability (%)	0.65	0.88	0.31
Drug content (%)	100.25	99.94	99.98
Disintegration time (sec)	25.6	20.0	281
Wetting time (sec)	33.2	29.8	819.3
Dispersion time (sec)	30.2	26.8	650.6

16. Stability Studies

Stability studies are necessary to determine whether the physical characteristics and drug-release properties of the formulation remain acceptable during storage. The reported pheniramine maleate study subjected selected formulations F6 and F7 to stability conditions of 30°C/65% RH and 40°C/75% RH. Samples were evaluated at 10-day intervals for 30 days [6]. The reported results indicated no significant variation in the evaluated parameters during the 30-day stability period [6]. For example, at 30°C/65% RH, F6 showed only a small change in hardness from 3.4 to 3.6 kg/cm² and drug content from 100.1% to 99.66% over 30 days. F7 also showed relatively small changes in the corresponding parameters [6].

17. Recent Developments in Orodispersible Tablets

Modern ODT development has moved beyond conventional superdisintegrant-based formulations. Current approaches include the use of co-processed excipients, novel disintegration technologies, taste-masking approaches, lyophilization and quality-by-design-based optimization [4,10]. Direct compression remains attractive because it can utilize conventional tablet-manufacturing equipment and requires fewer processing steps than wet granulation [10]. The use of optimized combinations of superdisintegrants may provide improved disintegration without compromising tablet strength. Recent research has also investigated systematic formulation optimization and design-of-experiment approaches for achieving desirable critical quality attributes [10].

18. Advantages of Pheniramine Maleate Orodispersible Tablets

The major advantages of pheniramine maleate ODTs include:

1. Rapid disintegration.
2. Convenient oral administration.
3. Reduced dependence on water.
4. Improved acceptability for patients with swallowing difficulty.
5. Rapid dispersion.
6. Potentially faster dissolution.
7. Simple manufacturing by direct compression.
8. Possibility of improving patient compliance [2,4,6].

LIMITATIONS

Several formulation challenges should be considered:

19.1 Mechanical strength

ODTs must be sufficiently strong to withstand manufacturing and handling while still maintaining rapid disintegration.

19.2 Taste

Since the tablet remains in the oral cavity, taste masking can be important.

19.3 Moisture sensitivity

Some ODT formulations may be sensitive to moisture because of the hygroscopic nature of certain excipients.

19.4 Packaging

Some formulations may require protective packaging to maintain stability and mechanical integrity.

19.5 Formulation optimization

The concentration of superdisintegrant, compression force, diluent type and lubricant concentration must be optimized to achieve the desired balance between hardness, friability and disintegration [2,4].

FUTURE PERSPECTIVES

Future development of pheniramine maleate tablets may focus on systematic optimization of formulation variables using Quality by Design (QbD) principles. The use of design-of-experiment approaches may allow researchers to identify the influence of formulation and process variables on critical quality attributes. Novel co-processed excipients may improve flowability and compressibility while maintaining rapid disintegration. Taste-masking technologies can further improve patient acceptability. Advanced ODT technologies may also be explored for improving drug dissolution and achieving reproducible performance [4,10]. For pheniramine maleate specifically, further comparative studies between conventional tablets and optimized ODTs could evaluate disintegration, dissolution, patient acceptability and stability using standardized conditions.

CONCLUSION

Pheniramine maleate is a first-generation H1-antihistaminic drug that has been investigated in several oral dosage-form approaches. Conventional tablets provide a convenient and stable means of administration, but orodispersible tablets offer additional advantages for patients who have difficulty swallowing conventional solid dosage forms. The reviewed formulation studies demonstrate that pheniramine maleate can be successfully formulated into orodispersible tablets using direct compression and effervescent approaches. Selection of appropriate superdisintegrants is particularly important for achieving rapid tablet disintegration and drug release. Croscarmellose sodium and crospovidone demonstrated particularly favorable performance in the reported formulation study, with selected formulations showing rapid disintegration and approximately complete drug release within six minutes under the specified dissolution conditions [6].

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