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# Formulation, development, and evaluation of orally disintegrating tablets of Atenolol

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## Abstract

Orally disintegrating tablets (ODTs) have emerged as a patient-friendly dosage form designed to improve compliance, especially in pediatric, geriatric, and dysphagic patients. Atenolol, a $\beta_1$-selective adrenergic blocker widely prescribed for hypertension, requires long-term administration and is therefore an ideal candidate for ODT formulation. The present study aimed to develop and optimize Atenolol ODTs using the direct compression method. Nine formulations (F1–F9) were prepared employing different superdisintegrants—crospovidone, croscarmellose sodium, and sodium starch glycolate—at varying concentrations. Preformulation studies confirmed drug purity, solubility, and compatibility with excipients. Prepared blends were evaluated for pre-compression parameters, while compressed tablets were assessed for post-compression characteristics, special ODT tests, in-vitro disintegration, dissolution behavior, and stability. All formulations complied with pharmacopeial limits. Among them, formulation F2 containing crospovidone exhibited the shortest disintegration time (~16 s) and maximum drug release (~99.8% within 30 min). Statistical analysis using one-way ANOVA demonstrated significant differences among formulations ($p < 0.05$). Accelerated stability studies confirmed formulation stability. The study concludes that Atenolol can be successfully formulated as an ODT with rapid disintegration, fast drug release, and acceptable mechanical strength, offering a promising alternative to conventional tablets.

**Keywords:** Atenolol, Orally disintegrating tablets, Superdisintegrants, Direct compression, Dissolution, Stability.

## 1. Introduction

Oral drug delivery systems remain the most widely accepted and preferred route of drug administration due to their convenience, safety, cost-effectiveness, and high patient compliance [1]**.** Conventional solid oral dosage forms such as tablets and capsules account for a major share of pharmaceutical products because of their accurate dosing, stability, ease of manufacture, and patient acceptability [2-3]**.** However, these conventional dosage forms present significant challenges for certain patient populations, particularly pediatric, geriatric, bedridden, and dysphagic patients**,** who often experience difficulty in swallowing solid medications [4]**.** Such difficulties can lead to poor compliance, improper dosing, and reduced therapeutic outcomes [5].

To overcome these limitations, orally disintegrating tablets (ODTs) have emerged as an advanced and patient-centric dosage form [6]. ODTs are designed to disintegrate rapidly in the oral cavity within seconds, without the need for water, releasing the drug for immediate swallowing or absorption [7]. This dosage form offers distinct advantages such as ease of administration, rapid onset of action, improved compliance, and enhanced patient convenience, making it particularly suitable for chronic therapies and emergency situations [8].

The performance of ODTs largely depends on formulation variables, especially the type and concentration of superdisintegrants, which facilitate rapid tablet breakup through mechanisms such as wicking, swelling, and deformation recovery [9]. Selection of appropriate excipients and optimization of formulation parameters are therefore critical to achieve a balance between mechanical strength and rapid disintegration [10]**.**

Atenolol is a $\beta_1$-selective adrenergic receptor blocker widely prescribed in the management of hypertension, angina pectoris, and other cardiovascular disorders [11]. It is generally administered as conventional

tablets, which require water for swallowing and may be inconvenient for patients with swallowing difficulties, particularly during long-term therapy **[12]**. Although Atenolol exhibits good aqueous solubility and acceptable stability, its conventional dosage forms do not adequately address issues related to patient compliance and ease of administration [13].

Considering these factors, formulation of Atenolol as an orally disintegrating tablet represents a promising strategy to enhance patient acceptability, ensure rapid drug release, and maintain therapeutic efficacy [14]. The present study focuses on the development, formulation, optimization, and evaluation of Atenolol ODTs using the direct compression technique and different superdisintegrants, with the objective of developing a stable, effective, and patient-friendly oral dosage form.

This research is expected to contribute to the advancement of ODT technology and provide a practical alternative to conventional Atenolol tablets, particularly for patients requiring long-term antihypertensive therapy.

## 2. Materials and methods

### 2.1 Materials

Atenolol was obtained as a pharmaceutical-grade drug. Crospovidone, croscarmellose sodium, sodium starch glycolate, mannitol, microcrystalline cellulose, magnesium stearate, talc, sweetener, and flavor were used as excipients. All chemicals and reagents used were of analytical grade.

### 2.2 Preformulation Studies

Preformulation studies are a vital phase in formulation development, providing essential information about the physicochemical properties of the drug substance that influence formulation design, processing, stability, and performance of the final dosage form. In the present study, preformulation investigations were carried out on Atenolol to confirm its suitability for development as an orally disintegrating tablet (ODT) and to ensure reproducibility and quality of the formulation.

The preformulation studies included organoleptic evaluation, solubility analysis, melting point determination, UV–Visible spectrophotometric analysis, and drug–excipient compatibility studies.

#### 2.2.1 Organoleptic Properties

The organoleptic characteristics of Atenolol were evaluated by visual inspection to assess its physical appearance and sensory attributes.

**Table 1: Organoleptic Properties of Atenolol**

| Parameter | Observation |
|---|---|
| Appearance | White to off-white crystalline powder |
| Odor | Odorless |
| Taste | Slightly bitter |
| Texture | Fine and free-flowing |

**Discussion:**

The slightly bitter taste of Atenolol justified the incorporation of **sweeteners and flavors** in the ODT formulation to enhance palatability and patient acceptance.

2.2.2 Solubility Analysis

Solubility studies were conducted by adding excess drug to different solvents, followed by shaking and visual observation.

**Table 2: Solubility Profile of Atenolol**

| Solvent | Solubility |
|---|---|
| Distilled water | Freely soluble |
| 0.1 N HCl | Freely soluble |
| Phosphate buffer (pH 6.8) | Soluble |
| Ethanol | Slightly soluble |
| Chloroform | Practically insoluble |

**Discussion:**

Good aqueous solubility of Atenolol supports **rapid dissolution** after tablet disintegration, making it a suitable candidate for ODT formulation.

#### 2.2.3 Melting Point Determination

The melting point of Atenolol was determined using the capillary method.

**Observed melting point: 152–154 °C**

**Discussion:** The observed melting point was found to be in close agreement with reported literature values, confirming the **purity and crystalline nature** of the drug.

#### 2.2.4 UV–Visible Spectrophotometric Analysis

Atenolol was analyzed using a UV–Visible spectrophotometer to determine its maximum absorbance (λmax) and to develop an analytical method for further studies.

- **Solvent:** Distilled water / 0.1 N HCl
- **λmax: ≈ 224 nm**
- The calibration curve showed good linearity over the concentration range studied, obeying **Beer–Lambert's law**.

**Table 3: Linearity Data of Atenolol**

| Concentration (µg/mL) | Absorbance |
|---|---|
| 5 | 0.112 |
| 10 | 0.224 |
| 15 | 0.337 |
| 20 | 0.446 |
| 25 | 0.559 |

**Discussion:**

The linear calibration curve confirmed the suitability of the method for **quantitative estimation of Atenolol** during dissolution and drug content studies.

#### 2.2.5 Drug–Excipient Compatibility Studies

Drug–excipient compatibility was assessed using Fourier Transform Infrared (FTIR) spectroscopy by comparing spectra of pure Atenolol with those of physical mixtures containing selected excipients.

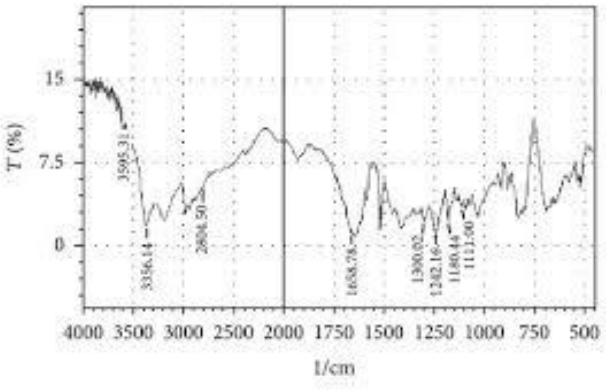


**Figure 1:** IR Sprectrum of Atenolol

**Key observations:**

- Characteristic peaks of Atenolol (O–H, N–H, C=O, aromatic C–H) were retained.
- No significant peak shift, disappearance, or formation of new peaks was observed.

The FTIR results indicated no chemical interaction between Atenolol and the selected excipients, confirming their compatibility and suitability for formulation using the direct compression method**.**

Preformulation investigations confirmed that Atenolol possesses favorable physicochemical properties, good aqueous solubility, acceptable purity, and compatibility with selected excipients. These findings provided a strong scientific basis for proceeding with the formulation and development of Atenolol orally disintegrating tablets.

**2.3 Formulation of Atenolol ODTs**

Atenolol ODTs were prepared by the direct compression method. Nine formulations (F1–F9) were developed by varying the type and concentration of superdisintegrants. All ingredients were accurately weighed, sieved, blended uniformly, lubricated, and compressed into tablets of uniform weight.

**Table 4: Formulation Composition of Atenolol ODTs (F1–F9)**

| Ingredient (mg/tablet) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Atenolol | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Crospovidone | 3 | 5 | 7 | – | – | – | – | – | – |
| Croscarmellose sodium | – | – | – | 3 | 5 | 7 | – | – | – |
| Sodium starch glycolate | – | – | – | – | – | – | 3 | 5 | 7 |
| Mannitol | 60 | 58 | 56 | 60 | 58 | 56 | 60 | 58 | 56 |
| MCC | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| Sweetener | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Flavor | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Magnesium stearate | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Talc | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Total weight (mg)** | **150** | **150** | **150** | **150** | **150** | **150** | **150** | **150** | **150** |

**2.4 Evaluation of Powder Blend (Pre-Compression Parameters)**

Powder blends were evaluated for angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio to assess flow properties and suitability for direct compression.

**2.5 Evaluation of Tablets (Post-Compression Parameters)**

Compressed tablets were evaluated for weight variation, thickness, hardness, friability, and drug content uniformity as per pharmacopeial guidelines.

**2.6 Special Evaluation Tests for ODTs**

ODTs were further evaluated for wetting time, in-vitro disintegration time, and water absorption ratio to assess performance under simulated oral conditions.

**2.7 In-Vitro Dissolution Studies**

Dissolution studies were performed using USP Type II (paddle) apparatus in 0.1 N HCl at 37 ± 0.5 °C. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically. Dissolution data were subjected to kinetic modeling (zero-order, first-order, Higuchi, and Korsmeyer–Peppas models).

**2.8 Stability Studies**

Accelerated stability studies of the optimized formulation were conducted as per ICH guidelines at 40 ± 2 °C and 75 ± 5% RH for three months. Tablets were evaluated for physical appearance, hardness, friability, drug content, disintegration time, and dissolution profile.

**2.9 Statistical Analysis**

Results were expressed as mean ± SD. One-way ANOVA was applied to evaluate statistical significance among formulations, with $p < 0.05$ considered significant.

## 3. Results and Discussion

The results obtained from the preformulation, formulation, and evaluation studies of Atenolol orally disintegrating tablets (ODTs) are presented and discussed in this chapter. The discussion focuses on the

influence of formulation variables—particularly the **type and concentration of superdisintegrants**-on tablet characteristics, disintegration behavior, and drug release performance. All experimental values are expressed as **mean ± SD**, and results are interpreted in accordance with pharmacopeial requirements.

### 3.1 Preformulation Study Results

Preformulation studies confirmed that Atenolol possessed suitable physicochemical characteristics for formulation as an ODT. The drug appeared as a white, crystalline, odorless powder with a slightly bitter taste. Solubility studies showed that Atenolol was freely soluble in aqueous media, supporting rapid dissolution after tablet disintegration. The melting point (152–154 °C) matched reported literature values, indicating purity.

UV–Visible spectrophotometric analysis showed a λmax at ~224 nm, and the calibration curve exhibited good linearity, confirming suitability for quantitative analysis during dissolution and drug content studies. FTIR compatibility studies demonstrated that all characteristic functional group peaks of Atenolol were retained in the drug–excipient mixtures, indicating absence of chemical interaction and confirming compatibility with selected excipients.

### 3.2 Pre-Compression Evaluation Results

The powder blends of all formulations (F1–F9) were evaluated for flow and compressibility parameters. Angle of repose values were below 32°, indicating good flow properties. Bulk and tapped density values were consistent, while Carr's index (<20%) and Hausner's ratio (<1.25) confirmed acceptable compressibility and flowability, making the blends suitable for direct compression.

Formulations containing crospovidone (F1–F3) showed comparatively better flow behavior, which may be attributed to the granular nature and lower cohesiveness of the excipient.

### 3.3 Post-Compression Evaluation Results

All compressed Atenolol ODTs complied with pharmacopeial limits for weight variation, thickness, hardness, friability, and drug content uniformity. Tablet hardness ranged between 2–4 kg/cm², which is ideal for ODTs, ensuring adequate mechanical strength without compromising disintegration. Friability values were below 1%, indicating sufficient resistance to abrasion during handling and packaging.

Drug content uniformity for all formulations ranged between 96–100%, confirming uniform drug distribution and consistency of the direct compression process.

### 3.4 Special Evaluation Tests for ODTs

Special tests such as wetting time, water absorption ratio, and in-vitro disintegration time were carried out to assess ODT performance. All formulations exhibited rapid wetting and highwater absorption capacity, which are essential for fast disintegration.

Formulation F2 showed the shortest wetting time and minimum disintegration time (~16 s). This rapid disintegration can be attributed to the wicking action of crospovidone, which facilitates quick penetration of saliva into the tablet matrix without forming a viscous gel. In contrast, sodium starch glycolate-based formulations showed slightly longer disintegration times, possibly due to gel formation at higher concentrations.

### 3.5 In-Vitro Dissolution Studies

Dissolution studies revealed that all formulations released more than **85% of Atenolol within 30 minutes**, fulfilling the criteria for immediate-release dosage forms. A clear correlation was observed between **disintegration time and dissolution rate**.

Formulation **F2** exhibited the fastest and most complete drug release (**~99.8% within 30 minutes**), which is consistent with its rapid disintegration. Crospovidone-based formulations showed superior early-stage dissolution compared to those containing croscarmellose sodium or sodium starch glycolate.

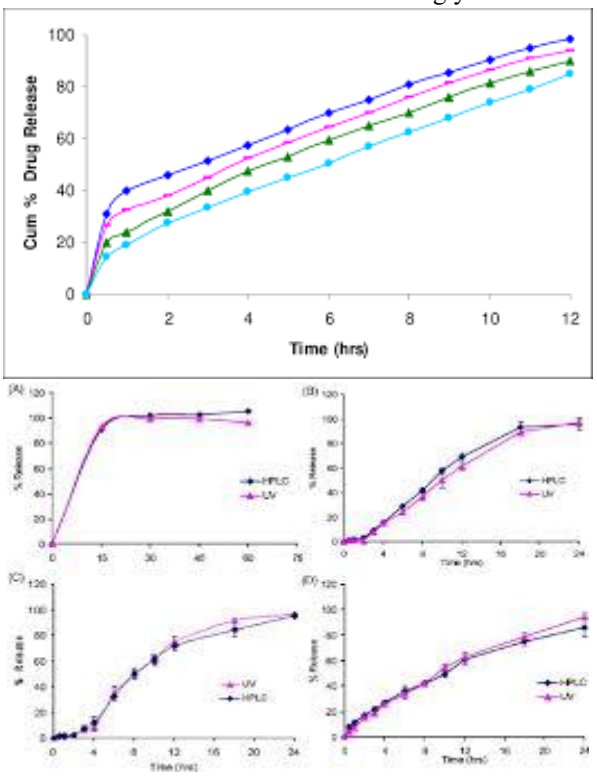


**Figure 2: *In vitro* Dissolution of Atenolol Tablets**

### 3.6 Optimization and Statistical Analysis

One-way ANOVA demonstrated that the differences observed in disintegration time and dissolution behavior among formulations were statistically significant (**$p < 0.05$**), confirming the strong influence of superdisintegrant type and concentration. Based on overall performance, formulation F2 was identified as the optimized batch.

### 3.7 Stability Study Results

Accelerated stability studies conducted as per ICH guidelines showed no significant changes in physical appearance, hardness, friability, drug content, disintegration time, or dissolution profile of the optimized formulation. These results indicate that the formulation was physically and chemically stable during the study period.

## Overall Discussion

The results clearly demonstrate that Atenolol can be effectively formulated as an orally disintegrating tablet using the direct compression technique. Among the tested superdisintegrants, crospovidone proved to be the most efficient in achieving rapid disintegration and fast drug release. The optimized formulation (F2) showed an excellent balance between mechanical strength, rapid disintegration, and dissolution performance, making it a promising patient-friendly alternative to conventional Atenolol tablets.

## 4. Conclusion

The present study successfully demonstrated the formulation and optimization of Atenolol orally disintegrating tablets using the direct compression technique. Among the tested formulations, crospovidone-based formulation F2 showed the best overall performance in terms of rapid disintegration, fast and complete drug release, acceptable mechanical strength, and stability. Atenolol ODTs developed in this study offer a patient-friendly and effective alternative to conventional tablets, with potential for improved compliance in long-term antihypertensive therapy.

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