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Design, development, and formulation of Glipizide fast-dissolving tablets

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Abstract

Fast-dissolving tablets (FDTs) are designed to disintegrate rapidly in the oral cavity, offering improved patient compliance and faster onset of action compared to conventional oral solid dosage forms. The present study was undertaken to design, develop, and evaluate fast-dissolving tablets of Glipizide, a second-generation sulfonylurea used in the management of Type-2 Diabetes Mellitus. Glipizide fast-dissolving tablets were formulated by the direct compression method using different superdisintegrants, namely crospovidone, croscarmellose sodium, and sodium starch glycolate, at varying concentrations. Preformulation studies were conducted to assess the physicochemical properties of the drug, and drug–excipient compatibility was evaluated using FTIR spectroscopy. The prepared formulations were evaluated for pre-compression parameters, post-compression characteristics, wetting time, disintegration time, drug content, and in-vitro dissolution behavior. Among the ten formulations developed, formulation F10 containing a combination of crospovidone and croscarmellose sodium exhibited the shortest disintegration time, rapid wetting, and nearly complete drug release within a short duration. Accelerated stability studies carried out as per ICH guidelines confirmed the physical and chemical stability of the optimized formulation. The study concludes that Glipizide fast-dissolving tablets prepared by direct compression represent a promising, patient-friendly alternative to conventional tablets, with potential benefits in terms of rapid onset of action and improved therapeutic compliance.

Keywords: Glipizide, Fast-dissolving tablets, Superdisintegrants, Direct compression, In-vitro dissolution.

1. Introduction

Oral drug delivery is the most widely used and preferred route of administration due to its simplicity, safety, cost-effectiveness, and high patient acceptance [1-2]. Conventional oral solid dosage forms such as tablets and capsules dominate the pharmaceutical market because of their accurate dosing, stability, ease of manufacture, and convenience in handling [3].

However, these dosage forms present significant challenges in certain patient populations, particularly geriatric, pediatric, dysphagic, and bedridden patients, who often experience difficulty in swallowing solid tablets [4]. Such difficulties may lead to poor patient compliance and reduced therapeutic efficacy [5].

To overcome these limitations, fast-dissolving tablets (FDTs)-also known as orally disintegrating or mouth-dissolving tablets—have been developed [6]. These tablets are designed to disintegrate rapidly in the oral cavity within seconds, without the need for water, forming a solution or suspension that can be easily swallowed [7]. The rapid disintegration and dissolution of FDTs result in a faster onset of action, improved patient convenience, and enhanced compliance [8].

FDTs are particularly advantageous in the management of chronic diseases where long-term medication adherence is essential [9].

Glipizide is a second-generation sulfonylurea antidiabetic agent widely prescribed for the treatment of Type-2 Diabetes Mellitus [10]. It acts by stimulating insulin secretion from pancreatic β-cells and is commonly administered in low doses [11].

Although effective, conventional Glipizide tablets may exhibit delayed onset of action and patient compliance issues, particularly among elderly diabetic patients who often require long-term therapy [12].

Considering the low dose requirement, short half-life, and need for rapid glycemic control, Glipizide is a suitable candidate for formulation as a fast-dissolving tablet [13]. The development of Glipizide FDTs is expected to enhance dissolution rate, provide faster onset of action, and improve patient compliance [14]. Therefore, the present study focuses on the design, development, and evaluation of fast-dissolving tablets of Glipizide using suitable superdisintegrants and the direct compression technique.

This research aims to contribute to the advancement of patient-centric oral drug delivery systems, offering a convenient and effective alternative to conventional Glipizide tablets.

2. Materials and methods

2.1 Materials

The materials used in the present study for the formulation of **Glipizide fast-dissolving tablets** were of **pharmaceutical grade** and were used as received without further purification.

Glipizide was obtained as a gift sample from a reputed pharmaceutical manufacturer (Cadila Pharmaceuticals) and was used as the active pharmaceutical ingredient (API). The drug was selected based on its **therapeutic relevance in Type-2 Diabetes Mellitus, low dose requirement, and suitability for fast-dissolving tablet formulation**.

All chemicals and reagents used for analytical studies were of **analytical reagent (AR) grade**, and distilled water was used throughout the study.

2.2 Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical and analytical characteristics of Glipizide, which are essential for the rational design and development of fast-dissolving tablets. These studies help in understanding the drug's identity, purity, solubility behavior, and analytical profile, thereby guiding formulation and evaluation strategies.

2.2.1 Organoleptic Properties

The organoleptic properties of Glipizide were assessed to obtain preliminary information about its physical appearance.

Method:

A small quantity of Glipizide was examined visually under daylight to determine color and appearance, while odor was assessed carefully.

2.2.2 Melting Point Determination

The melting point of Glipizide was determined to assess the purity and crystalline nature of the drug.

Method:

The melting point was determined using the capillary tube method. A small amount of drug was filled into a capillary tube and placed in a melting point apparatus. The temperature range at which the drug melted was recorded and compared with reported literature values.

2.2.3 Solubility Studies

Solubility studies were performed to understand the solubility profile of Glipizide in various solvents, which directly influences dissolution and bioavailability.

Method:

An excess amount of Glipizide was added separately to different solvents and shaken for 24 hours at room temperature. The solubility of the drug was observed visually.

Solvents used:

- Distilled water
- 0.1 N HCl
- Phosphate buffer pH 6.8
- Methanol
- Ethanol

2.2.4 UV–Visible Spectroscopic Analysis

UV–Visible spectrophotometric analysis was carried out for drug identification and quantitative estimation during formulation evaluation and dissolution studies.

Method:

A standard stock solution of Glipizide was prepared in a suitable solvent. The solution was scanned in a UV–Visible spectrophotometer over a wavelength range of 200–400 nm to determine the wavelength of maximum absorbance (λmax). This λmax was used for further analytical studies such as drug content estimation and in-vitro dissolution analysis.

Table 1: Summary of Preformulation Studies of Glipizide

Parameter	Observation
Color	White to off-white
Appearance	Crystalline powder
Odor	Odorless
Melting point	205–210°C
Solubility in water	Practically insoluble
λmax	~276 nm

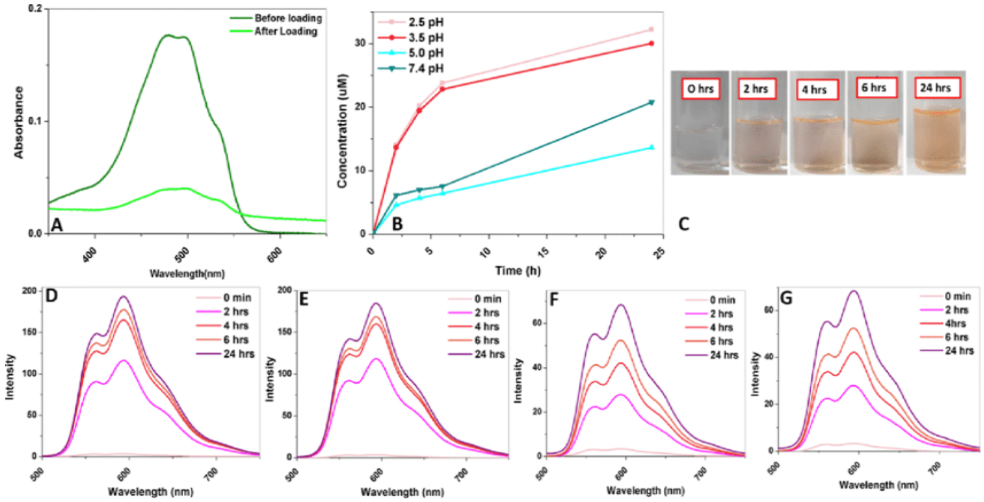

Figure 1: UV–Visible Absorption Spectrum of Glipizide

2.3 Drug–Excipient Compatibility Studies

Drug–excipient compatibility studies were performed to evaluate possible **chemical interactions** between **Glipizide** and the selected excipients used in the formulation of fast-dissolving tablets. Compatibility assessment is essential to ensure **stability, efficacy, and safety** of the final dosage form. In the present study, compatibility was investigated using **Fourier Transform Infrared (FTIR) spectroscopy**, a widely accepted technique for detecting interactions at the molecular level.

Table 2: Characteristic FTIR Peaks of Glipizide

Functional Group	Characteristic Peak (cm^{-1})	Inference
N–H stretching	3300–3500	Sulfonylurea moiety
C=O stretching	1650–1700	Carbonyl group
S=O stretching	1150–1350	Sulfonyl group
C–N stretching	1020–1250	Urea linkage
C–H stretching	2850–2950	Aliphatic groups

The FTIR spectrum of pure Glipizide showed all characteristic peaks corresponding to its functional groups. Comparison of spectra of Glipizide with those of physical mixtures containing various excipients revealed **no significant shifts, disappearance, or formation of new peaks**. Minor variations in peak intensity were attributed to physical mixing rather than chemical interaction.

The FTIR compatibility study confirmed that **Glipizide is compatible with all selected superdisintegrants and excipients** used in the formulation. The absence of chemical interactions supports their suitability for further formulation development and evaluation of fast-dissolving tablets.

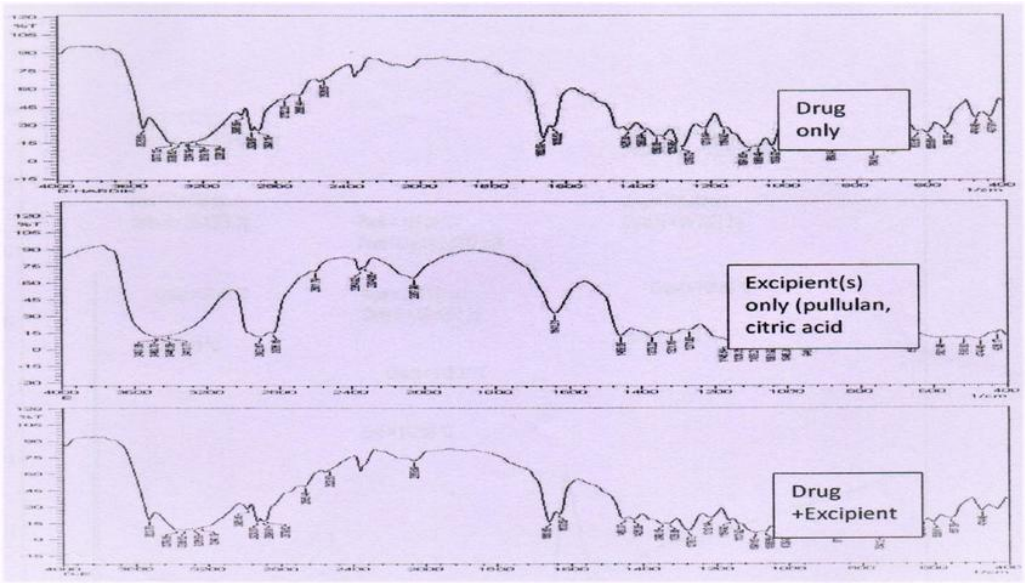

Figure 2: IR Spectrum of Glipizide

2.4 Formulation of Fast-Dissolving Tablets

Fast-dissolving tablets (FDTs) of Glipizide were prepared by the direct compression method, which was selected due to its simplicity, cost-effectiveness, fewer processing steps, and suitability for moisture- and heat-sensitive drugs. The formulation strategy involved the use of different superdisintegrants either alone or in combination to achieve rapid tablet disintegration and enhanced drug dissolution.

2.4.1 Formulation Design

A total of ten formulations (F1–F10) were designed to study the effect of type and concentration of superdisintegrants on tablet performance. Crospovidone, croscarmellose sodium, and sodium starch glycolate were used at varying concentrations, while one formulation contained a combination of superdisintegrants to evaluate synergistic effects.

All formulations were prepared to a constant tablet weight, with Glipizide content kept uniform across batches. Mannitol and microcrystalline cellulose were used as diluent and directly compressible binder, respectively, while magnesium stearate and talc were added as lubricant and glidant.

Table 3: Formulation Composition of Glipizide Fast-Dissolving Tablets (F1–F10)

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Glipizide	5	5	5	5	5	5	5	5	5	5
Crospovidone	4.5	7.5	10.5	–	–	–	–	–	–	7.5
Croscarmellose sodium	–	–	–	4.5	7.5	10.5	–	–	–	7.5
Sodium starch glycolate	–	–	–	–	–	–	4.5	7.5	10.5	–
Mannitol	100.5	97.5	94.5	100.5	97.5	94.5	100.5	97.5	94.5	90
Microcrystalline cellulose (MCC)	30	30	30	30	30	30	30	30	30	30
Aspartame	3	3	3	3	3	3	3	3	3	3
Flavor	2	2	2	2	2	2	2	2	2	2
Talc	3	3	3	3	3	3	3	3	3	3
Magnesium stearate	2	2	2	2	2	2	2	2	2	2
Total weight (mg)	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**	**150**

2.5 Evaluation of Powder Blend

Powder blends were evaluated for:

- Angle of repose
- Bulk density
- Tapped density
- Carr's index
- Hausner's ratio

2.6 Post-Compression Evaluation

Prepared tablets were evaluated for:

- Weight variation
- Thickness
- Hardness
- Friability
- Drug content uniformity
- Wetting time
- Disintegration time

2.7 In-Vitro Dissolution Studies

Dissolution studies were carried out using USP Apparatus II (paddle method) in phosphate buffer pH 6.8 at 37 ± 0.5°C. Samples were analyzed using UV spectrophotometry.

2.8 Stability Studies

Stability studies were carried out to evaluate the physical and chemical stability of the optimized Glipizide fast-dissolving tablet formulation under accelerated storage conditions. Stability testing is essential to ensure that the formulation maintains its quality, safety, and performance throughout its intended shelf life. The study was conducted in accordance with ICH guidelines for accelerated stability testing.

Table 4: Stability Study Conditions and Evaluation Parameters

Parameter	Condition / Acceptance Criteria
Storage condition	40 ± 2°C / 75 ± 5% RH
Duration	3 months
Appearance	No visible change
Hardness	No significant variation
Friability	≤ 1%
Drug content	90–110%
Disintegration time	≤ 60 seconds
Dissolution profile	Comparable to initial

3. Results and Discussion

The present study was undertaken to **design, develop, and evaluate fast-dissolving tablets of Glipizide** using different superdisintegrants by the direct compression method. The results obtained from **preformulation studies, drug–excipient compatibility studies, pre-compression evaluation, post-compression evaluation, in-vitro dissolution studies, optimization, and stability studies** are discussed in detail in this chapter.

The discussion emphasizes the **effect of formulation variables**, particularly the **type and concentration of superdisintegrants**, on critical quality attributes such as **flow properties, tablet integrity, wetting time, disintegration time, and drug release behavior**. The outcomes are interpreted in light of **pharmacopeial standards and previously reported literature**.

3.1 Preformulation Study Results

Preformulation studies confirmed the identity, purity, and suitability of Glipizide for fast-dissolving tablet formulation. The drug exhibited a melting point within the reported range, indicating purity, and showed poor aqueous solubility, justifying the need for formulation strategies to enhance dissolution. The characteristic UV absorption maximum enabled reliable quantitative estimation throughout the study.

3.2 Drug–Excipient Compatibility Results

FTIR spectra of pure Glipizide and its physical mixtures with selected excipients showed **no significant shifts, disappearance, or formation of new peaks**, indicating the absence of chemical interaction. This confirmed that all selected excipients were **compatible with Glipizide** and suitable for formulation development.

3.3 Pre-Compression Evaluation Results

Pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio indicated that all powder blends possessed acceptable flow and compressibility, making them suitable for direct compression. Formulations containing crospovidone and the combined superdisintegrant system exhibited better flow characteristics compared to sodium starch glycolate–based formulations.

3.4 Post-Compression Evaluation Results

All formulations complied with pharmacopeial limits for weight variation, hardness, friability, and drug content uniformity. Wetting time and disintegration time varied significantly with the type of superdisintegrant used. Tablets containing crospovidone showed faster wetting and disintegration due to efficient wicking action, while sodium starch glycolate formulations showed relatively slower disintegration, possibly due to gel formation.

3.5 In-Vitro Dissolution Results

In-vitro dissolution studies revealed that the **rate and extent of drug release** were strongly influenced by the superdisintegrant system. Crospovidone-based formulations showed faster drug release compared to croscarmellose sodium and sodium starch glycolate. The formulation containing a **combination of crospovidone and croscarmellose sodium (F10)** exhibited **nearly complete drug release within a short duration**, indicating a synergistic effect.

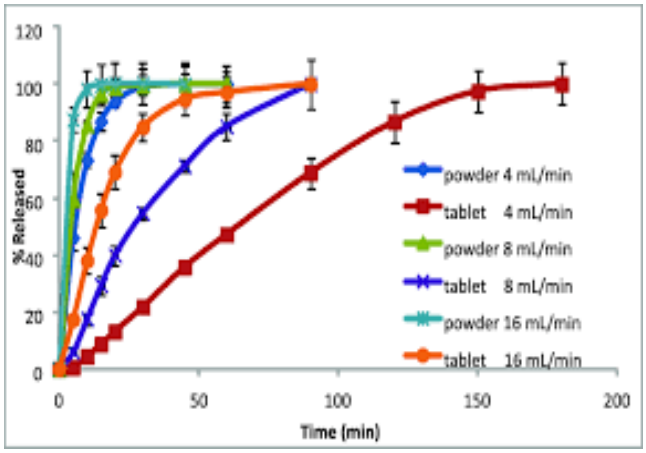

Figure 3: *In Vitro* Dissolution Studies of Glipizide

3.6 Optimization and Stability Study Results

Based on overall performance, **formulation F10** was selected as the optimized formulation. Accelerated stability studies conducted as per ICH guidelines showed **no significant changes in physical appearance, drug content, disintegration time, or dissolution profile**, confirming the stability of the optimized formulation.

The results of the present investigation clearly demonstrate that **fast-dissolving tablets of Glipizide can be successfully formulated by the direct compression method**. The combined use of crospovidone and croscarmellose sodium proved to be the most effective approach in achieving **rapid disintegration, enhanced dissolution, and acceptable mechanical strength**. The findings of this study are in good agreement with reported literature and highlight the potential of Glipizide fast-dissolving tablets as a **patient-friendly alternative to conventional dosage forms**.

4. Conclusion

The present study successfully demonstrated the formulation of Glipizide fast-dissolving tablets using the direct compression method. Among the tested formulations, F10 containing a combination of crospovidone and croscarmellose sodium was identified as the optimized formulation based on rapid disintegration, maximum drug release, and stability. Glipizide fast-dissolving tablets offer a patient-friendly and effective alternative to conventional tablets, particularly for geriatric and dysphagic patients.

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