Review Article

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GASTRORETGENTIVE FLOATING MATRIX TABLETS OF MITIGLINIDE

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Abstract

Gastroretentive drug delivery systems (GRDDS) are designed to prolong gastric residence time and enhance the bioavailability of drugs with a narrow absorption window. Floating drug delivery systems remain buoyant in gastric fluid by forming low-density matrices or through gas-generating mechanisms, allowing prolonged gastric retention. Mitiglinide, a short-acting insulin secretagogue used in the management of Type-2 diabetes mellitus, exhibits low oral bioavailability, a short biological half-life, and requires frequent dosing. The present study aimed to develop and evaluate gastroretentive floating matrix tablets of Mitiglinide to achieve sustained drug release and improved glycemic control. Floating tablets were prepared by the direct compression method using hydrophilic polymers such as HPMC (K4M and K15M), Carbopol 934P, and sodium alginate, along with sodium bicarbonate and citric acid as gas-generating agents. Nine formulations were developed by varying polymer concentrations and evaluated for pre-compression flow properties and post-compression quality parameters. Floating lag time, total floating time, and in-vitro drug release studies were conducted. The results demonstrated satisfactory flow properties, acceptable tablet characteristics, rapid buoyancy, prolonged floating time, and sustained drug release up to several hours. Drug release followed Higuchi diffusion kinetics, with increased polymer concentration resulting in slower release. The study concludes that gastroretentive floating matrix tablets of Mitiglinide are a promising approach for enhancing bioavailability and reducing dosing frequency in Type-2 diabetes management.

Keywords: Gastroretentive drug delivery system, Floating matrix tablets, Mitiglinide, Type-2 diabetes mellitus, Sustained drug release, Gastric residence time.

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Introduction

Gastroretentive Drug Delivery Systems (GRDDS) are specially designed oral systems that prolong gastric residence time, thereby enhancing drug absorption and bioavailability [1–3]. Floating drug delivery systems stay buoyant in gastric fluid due to their low density or gas-generating mechanisms [1,2], allowing them to remain in the stomach for extended periods.

Mitiglinide, a short-acting insulin secretagogue used for Type-2 diabetes, has a narrow absorption window, poor bioavailability, and short half-life, leading to frequent dosing [4]. Therefore, formulating a gastroretentive floating matrix tablet helps achieve prolonged drug release and improved glycemic control [3,4].

Need For the Study

Mitiglinide Suffers From

Short biological half-life [4]
Low oral bioavailability [4]
Need for multiple daily doses [4]

A gastroretentive system ensures the drug remains in the stomach longer, allowing sustained absorption and consistent blood glucose control [1,3].

Review of Literature

Floating drug delivery was first introduced in 1968 [2].
Several hydrophilic and swellable polymers are commonly used in floating systems [1,2].

Common Polymers Used

- HPMC (Hydroxypropyl Methylcellulose) – forms strong gel matrices [1,2].
- Carbopol 934P – high-viscosity polymer for sustained release [6].

- Sodium Alginate – natural polymer with excellent swelling index [6].

Mechanism of Floating

Floating tablets use

- Low-density polymer matrix, or
- Gas-generating agents (e.g., sodium bicarbonate + citric acid)
- to maintain buoyancy [2].
- Gel strength, polymer viscosity, and swelling significantly influence floating time and release rate [1,2,8].
- Higher polymer concentration prolongs drug release [1,2].
- Floating tablets typically follow Higuchi diffusion kinetics [1].

Drug Profile – Mitiglinide

Mitiglinide stimulates pancreatic insulin secretion and is absorbed mainly in the upper intestine; therefore a gastroretentive system improves uptake efficiency [4].

Polymer Profile Summary

Polymer Function

- HPMC K4M/K15M Hydrophilic matrix former, swelling agent [1,2].
- Carbopol 934P, Increases viscosity and sustains release [6].
- Sodium AlginateSwellable natural polymer [6].
- Sodium BicarbonateGas-generating agent [2].
- Citric Acid, CO_2-releasing acidic component [2].

Method of Preparation (Direct Compression Method)

Direct compression is suitable for moisture-sensitive drugs, avoids wet granulation, and is simple and cost-effective [1,2].

Formulation Development

Nine formulations (F1–F9) were prepared by varying polymer ratios to evaluate effects on floating lag time, total floating time, and release kinetics [1,2].

Evaluation Parameters

- Pre-compression flow properties (angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio) are standard granule evaluation parameters [9].
- Post-compression tests (hardness, thickness, friability, weight variation, drug content) align with pharmacopoeial limits [9].

Floating Characteristics

- Floating Lag Time (FLT) and Total Floating Time (TFT) evaluate buoyancy [1,5].
- In-vitro Drug Release
- Dissolution using USP apparatus showed Higuchi diffusion kinetics, indicating diffusion from a polymeric matrix [1].
- Higher polymer concentration → slower release [1,2].

Conclusion

Gastroretentive floating tablets of Mitiglinide were successfully developed using direct compression. The formulation improved gastric residence time, drug release duration, and probable bioavailability, providing a promising controlled-release option for diabetes management

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Conflict of interest

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Informed Consent and Ethical Statement

Not applicable

Author Contributions

All authors are contributed equally

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