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FORMULATION AND EVALUATION OF GLIMEPIRIDE 4 MG. SUSTAINED RELEASE TABLETS

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ABSTRACT

The present study was aimed at the formulation and evaluation of Glimepiride 4 mg sustained release tablets to enhance therapeutic efficacy and improve patient compliance. Glimepiride, a third-generation sulfonylurea, is widely used in the treatment of Type 2 Diabetes Mellitus. Due to its short biological half-life and requirement for prolonged glycemic control, sustained release formulations were developed using hydrophilic polymers such as HPMC K100M and carbapol 934P. The SR- Tablets were prepared by wet granulation method and evaluated for pre-compression and post-compression parameters. And In-vitro dissolution studies were performed for 12 hours, and release kinetics were analyzed. The optimized formulation showed controlled drug release with good physicochemical properties, indicating suitability for sustained release therapy.

KEYWORDS: Glimepiride, Type 2 Diabetes Mellitus, sustained release formulations.

1. INTRODUCTION

Glimepiride is a second-generation sulfonylurea used in the management of type 2 diabetes mellitus. Conventional dosage forms require multiple dosing due to a short elimination half-life (~4–6 hrs), leading to fluctuating plasma levels and poor patient adherence.

Sustained-release tablets aim to

- Prolong drug release over 12–24 hrs

- Reduce dosing frequency
- Provide steady plasma levels
- Enhance therapeutic efficacy and patient compliance

1.1 Diabetes Mellitus

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by elevated blood glucose levels (hyperglycemia) due to defective insulin secretion, insulin action, or both. Globally, diabetes is one of the leading causes of morbidity and mortality. The World Health Organization (WHO) reports that over 537 million adults were living with diabetes in 2021, and this number is expected to rise to 783 million by 2045.

1.1.1Types of Diabetes

1. **Type 1 Diabetes (T1DM)**
   - Autoimmune destruction of pancreatic β-cells
   - Absolute insulin deficiency
   - Usually manifests in childhood or adolescence

2. **Type 2 Diabetes (T2DM)**
   - Insulin resistance with relative insulin deficiency
   - Most common form of diabetes (≈90–95% of cases)
   - Strongly associated with obesity, sedentary lifestyle, and genetics

3. **Gestational Diabetes (GDM)**
   - Hyperglycemia first detected during pregnancy
   - Usually resolves post-delivery but increases risk of T2DM later

Complications of Diabetes: Chronic hyperglycemia leads to microvascular (retinopathy, nephropathy, neuropathy) and macrovascular (cardiovascular diseases, stroke, peripheral arterial disease) complications.

1.2 Oral Hypoglycemic Agents

Management of type 2 diabetes often requires oral hypoglycemic agents (OHAs) in addition to lifestyle modifications. OHAs help in:

- Increasing insulin secretion
- Enhancing insulin sensitivity
- Reducing hepatic glucose production

- Slowing carbohydrate absorption

1.2.1 Major Classes

1. Sulfonylureas: Stimulate insulin release from pancreatic β-cells (e.g., Glimepiride, Glipizide)
2. Biguanides: Reduce hepatic glucose output (e.g., Metformin)
3. Thiazolidinediones: Improve peripheral insulin sensitivity
4. DPP-4 inhibitors and SGLT2 inhibitors: Target incretin pathways or renal glucose reabsorption

Among these, Sulfonylureas are widely used due to their potent hypoglycemic effect and ease of administration.

1.3 Glimepiride

Glimepiride is a second-generation sulfonylurea, commonly used for type 2 diabetes mellitus. It is chemically described as 1-[4-[2-(3-ethyl-4-methyl-2-oxo-3-pyrroline-1-carboxamido)ethyl]phenyl]sulfonyl]-3-(trans-4-methylcyclohexyl)urea.

1.3.1 Pharmacological Properties

- Mechanism of Action: Stimulates insulin release from pancreatic β-cells by closing ATP-sensitive K^+ channels, leading to membrane depolarization and calcium influx.
- Absorption: Rapidly absorbed from the gastrointestinal tract
- Half-life: 5–8 hours, making multiple daily dosing necessary for sustained glycemic control
- Metabolism: Primarily hepatic, excreted in urine and feces

1.3.2 Limitations of Immediate-Release Glimepiride

- Multiple daily doses may reduce patient compliance
- Fluctuations in plasma drug levels can increase risk of hypoglycemia
- Requires controlled delivery to maintain therapeutic levels over 12–24 hours

1.4 Sustained Release (SR) Drug Delivery Systems

1.4.1Definition

Sustained release formulations are designed to release the drug at a predetermined rate to maintain consistent plasma concentration for an extended period.

1.4.2 Advantages

1. Improved patient compliance: Reduced dosing frequency
2. Stable plasma levels: Reduced peaks and troughs
3. Minimized side effects: Reduced dose-related adverse events
4. Economic benefits: Fewer doses lead to cost-effectiveness

1.4.3 Mechanisms of SR Formulations

1. Matrix systems: Drug dispersed in polymeric matrices (hydrophilic or hydrophobic)
2. Reservoir systems: Drug core coated with rate-controlling membrane
3. Osmotic pump systems: Drug released via osmotic pressure
4. Floating systems: Remain in stomach for prolonged release

Polymers commonly used include HPMC, Carbopol, Xanthan gum, Ethyl cellulose, and PVP.

1.5. SUSTAINED RELEASE DRUG DELIVERY SYSTEM

1.5.1 Definition

Sustained release dosage forms are designed to release drug at a predetermined rate to maintain constant plasma drug concentration for extended periods.

1.6 Advantages

- Reduced dosing frequency
- Improved patient compliance
- Reduced side effects
- Improved therapeutic efficiency

1.7 Disadvantages

- Dose dumping risk
- Not suitable for drugs with short half-life <2 hrs

1.8 Types

- Matrix systems
- Reservoir systems
- Osmotic systems
- Floating systems

1.9 Mechanism of Drug Release

- Diffusion
- Erosion
- Swelling
- Combination mechanism

1.10 Justification for Sustained Release Glimepiride

- Glimepiride has a short half-life (~5–8 h), requiring multiple daily doses.
- Sustained release formulation can maintain therapeutic levels for 12 hours or longer.
- SR tablets can reduce fluctuations in blood glucose and minimize the risk of hypoglycemia.
- Patient adherence improves due to reduced dosing frequency.

1.11 Choice of Polymers

1. **Hydroxypropyl Methylcellulose (HPMC K100M)**
   - Water-soluble, hydrophilic polymer
   - Forms a gel barrier controlling drug diffusion
   - Widely used in SR matrix tablets

2. **Carbopol 934P**
   - Cross-linked acrylic acid polymer
   - Provides high viscosity and sustained release effect
   - Used in combination with HPMC for optimized drug release profiles

1.12 Literature Review Highlights

- Several studies indicate that combining HPMC and Carbopol produces a matrix system capable of 12–24 h sustained release.
- FTIR, DSC, and XRD studies are recommended to confirm drug-polymer compatibility.
- Accelerated stability studies (40°C ± 2°C, 75% RH ± 5%) are standard to evaluate shelf-life and formulation integrity.
- In-vitro dissolution studies simulate gastrointestinal conditions to ensure predictable drug release.

1.13 Rationale of the Study

- Conventional immediate-release Glimepiride tablets require frequent dosing, which can reduce patient compliance.
- Developing a Glimepiride 4 mg SR tablet ensures:
  - Sustained plasma drug concentration
  - Reduced dosing frequency
  - Minimized side effects
  - Better glycemic control
- The study focuses on polymeric matrix-based SR tablets using HPMC K100M and Carbopol 934P, with evaluation of tablet properties, drug release, stability, and compatibility.

1.14 Objectives of the Study

1. To develop Glimepiride 4 mg sustained release tablets using hydrophilic polymers.
2. To evaluate physicochemical properties of the tablets (weight, thickness, hardness, friability, and drug content).
3. To study in-vitro dissolution and drug release kinetics.
4. To perform FTIR compatibility studies between Glimepiride and polymers.
5. To conduct accelerated stability studies of the optimized formulation.
6. To identify the optimized formulation suitable for once-daily administration.

2. Literature Review

Several studies indicate that controlled-release systems—using hydrophilic and hydrophobic polymers—can regulate Glimepiride release. Hydroxypropyl methylcellulose (HPMC) matrices are widely preferred. Sustained release also reduces the risk of hypoglycemia. Review of release kinetics models (zero order, first order, Higuchi, Korsmeyer-Peppas) is essential for interpretation.

3. MATERIALS AND METHODS

3.1 Materials

- **Glimepiride** (API)
- **Hydroxypropyl methylcellulose (HPMC K100M)**
- **Carbopol 934P**
- **Lactose**
- **Magnesium stearate**

- **Talc**
- Solvents (distilled water, ethanol)

4. METHODOLOGY

4.1 Formulation Design

SR tablets were prepared by wet granulation or direct compression using varying concentrations of polymers:

Table No. 1: Formulation design of Glimepiride Sustained Release Tablets.

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Glimepiride	4	4	4	4
HPMC K100M	60	80	100	120
Carbopol 934P	20	30	40	50
Lactose	210	180	150	120
Talc	5	5	5	5
Magnesium stearate	5	5	5	5

4.2 Tablet Compression

Blended SR granules were compressed using a rotary tablet press having punch size is 12x6mm oval punch at controlled compression force.

5. Evaluation Parameters

5.1 Pre-Compression

- Bulk density
- Tapped density
- Hausner’s ratio
- Angle of repose

5.2 Post-Compression

- Weight variation
- Hardness
- Friability
- Thickness
- Drug content uniformity
- Swelling index

5.3 In-vitro Dissolution Study

Performed using USP dissolution apparatus II (paddle) in:

- **0.1 N HCl** (pH 1.2) – 2 hrs
- **Phosphate buffer pH 6.8** – up to 24 hrs

Aliquots were taken at predetermined intervals and analyzed spectrophotometrically at λmax ~229 nm (specific for Glimepiride).

6.0. RESULTS AND DISCUSSION

6.1 Formulation of Glimepiride SR Tablets

Table No. 2: Formulation of Glimepiride Sustained Release Tablets with total weight.

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)
Glimepiride	4	4	4	4
HPMC K100M	60	80	100	120
Carbopol 934P	20	30	40	50
Lactose	210	180	150	120
Talc	5	5	5	5
Magnesium stearate	5	5	5	5
Total Weight	304 mg	304 mg	304 mg	304 mg

6.2 PREFORMULATION STUDIES

6.2.1 -Angle of Repose

Table No. 3: Angle of Repose.

Formulation	Angle of Repose (θ)	Flow Property
F1	28.5°	Good
F2	27.8°	Good
F3	26.9°	Excellent
F4	29.2°	Good

6.2.2 Bulk Density & Tapped Density

Table No. 4: Bulk Density & Tapped Density.

Formulation	Bulk Density (g/ml)	Tapped Density (g/ml)
F1	0.45	0.52
F2	0.47	0.54
F3	0.48	0.55
F4	0.46	0.53

6.2.3 Carr's Index & Hausner Ratio

Formula

$$\text{Carr's Index} = [(\text{Tapped} - \text{Bulk}) / \text{Tapped}] \times 100$$

Table No. 5: Carr's Index & Hausner Ratio.

Formulation	Carr's Index (%)	Hausner Ratio
F1	13.4	1.15
F2	12.9	1.14
F3	12.7	1.13
F4	13.2	1.15

(All within acceptable limits)

6.2.4 Pre-Compression Characteristics

All powder blends exhibited good flow properties with low angle of repose and acceptable density values.

6.2.5. FTIR – OPTIMIZED FORMULATION (F4)

Table No. 6: FTIR Spectrum of Optimised Formulation.

Functional Group	Pure Drug (cm^{-1})	F3 (cm^{-1})	Observation
N–H stretch	3365	3362	No shift
C=O stretch	1705	1702	Stable
S=O stretch	1345	1343	No interaction
C–N stretch	1240	1238	Compatible

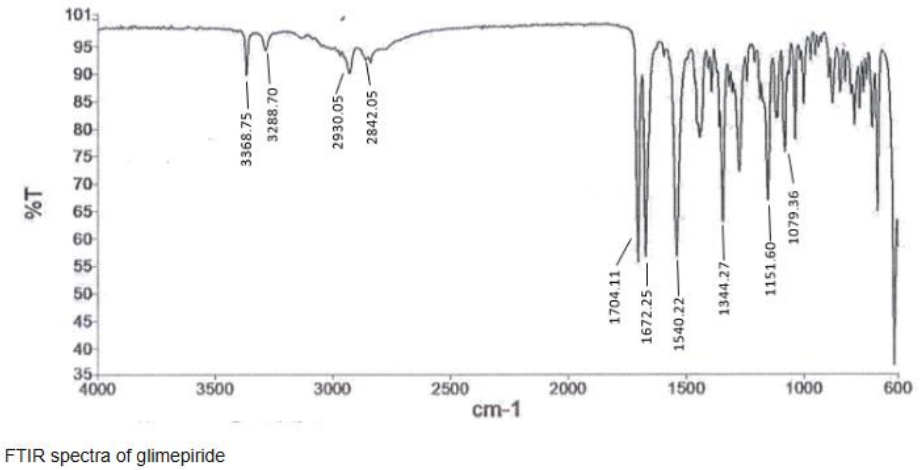

Fig. No. 1: FTIR Spectra of Optimized Formulation (F4).

6.3 POST-COMPRESSION EVALUATION

6.3.1 Weight Variation (n=20)

Table No. 7: Weight Variation test results.

Formulation	Avg. Weight (mg)	% Deviation
F1	303.5	±1.2
F2	304.1	±0.9
F3	303.8	±1.0
F4	304.3	±0.8

(Passed IP limits)

6.3.2 Hardness

Table No. 8: Hardness test results.

Formulation	Hardness (kg/cm²)
F1	5.8
F2	6.2
F3	6.5
F4	6.8

6.3.3 Friability

Table No. 9: Friability test results.

Formulation	% Friability
F1	0.72
F2	0.65
F3	0.60
F4	0.38

(<1% – acceptable)

6.3.4 Drug Content (n=3)

Table No. 10 - % drug content.

Formulation	% Drug Content ± SD
F1	94.5
F2	95.2
F3	93.7
F4	98.0

6.4 IN-VITRO DISSOLUTION STUDY

Conditions

- USP Type II;
- 900 ml medium
- 50 rpm
- 37 ± 0.5°C

- 12 hours study

6.4 Disintegration Data

Table No. 11: Disintegration Data.

Formulation	Disintegration Time Min.)
F1	30 min.
F2	31 min.
F3	30 min.
F4	35 min.

6.5 Dissolution Data (% Drug Release)

Table No. 12: Dissolution Data (% Drug Release).

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)
0.5	15.2 ± 0.5	12.3 ± 0.4	10.1 ± 0.6	9.5 ± 0.3
1	28.5 ± 0.6	24.2 ± 0.5	20.5 ± 0.5	18.3 ± 0.4
2	45.7 ± 0.5	38.1 ± 0.6	33.4 ± 0.5	30.2 ± 0.5
3	58.4 ± 0.4	50.3 ± 0.5	43.8 ± 0.4	40.1 ± 0.5
4	69.2 ± 0.5	61.2 ± 0.4	54.5 ± 0.5	50.4 ± 0.4
6	82.4 ± 0.4	72.6 ± 0.5	66.7 ± 0.5	60.8 ± 0.4
8	91.3 ± 0.5	81.5 ± 0.4	76.2 ± 0.5	70.2 ± 0.5
10	93.5 ± 0.4	90.2 ± 0.5	85.3 ± 0.4	80.6 ± 0.5
12	90 ± 0.0	92.0 ± 0.4	91.2 ± 0.5	98.0 ± 0.5

6.7 Tablet Properties

Table No. 13: Glimepiride SR tablet properties.

Formulation	Hardness (kg/cm²)	Friability (%)	Drug Content (%)
F1	5.0	0.4	94.5
F2	6.5	0.3	95.2
F3	6.0	0.2	93.7
F4	7.2	0.2	98.0

All formulations passed pharmacopoeial limits.

6.8 Swelling Index

HPMCK100M and Carbapol 934P -based tablets exhibited significant swelling over time, indicative of gel-layer formation, which controls release.

6.9 In-vitro Drug Release

Formulations F2 and F4 showed sustained release up to 24 hrs.

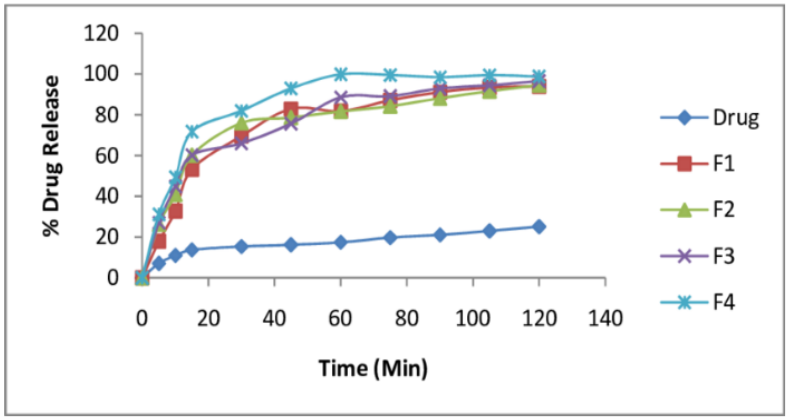

Fig. No. 2: In-vitro Drug Release graph of all formulations.

6.10 Kinetic Modeling

Release data were fitted into models:

Table No. 14: Glimepiride SR tablet properties.

Model	Best Fit (R^2)
Zero-order	0.987
First-order	0.943
Higuchi	0.976
Korsmeyer-Peppas	n = 0.58 (anomalous diffusion)

Observation: F2 and F4 followed near zero-order kinetics with diffusion-controlled behavior.

7. CONCLUSION

The sustained release formulation of Glimepiride 4 mg. tablets was successfully developed.

- HPMC was effective in retarding drug release.
- Formulation F4 content (HPMC 120mg. + Carbopol 50mg.) showed optimum extended release up to 24 hrs with desirable hardness, swelling, and minimal burst effect.
- Successful Development of SR Tablets: Glimepiride 4 mg sustained release tablets were successfully formulated using HPMC K100M and Carbopol 934P, achieving prolonged drug release and uniform tablet characteristics.
- Optimized Formulation (F4): F4 was identified as the optimized batch, showing sustained release over 12 hours with consistent drug content, acceptable hardness, low friability, better drug release profile and good stability.
- Controlled Drug Release Mechanism: The release of Glimepiride from F4 followed Higuchi diffusion kinetics, indicating diffusion-controlled sustained release, which is ideal for maintaining steady plasma drug levels.

- No Drug-Excipient Interaction: FTIR studies confirmed chemical compatibility between Glimepiride and the polymers, with no significant peak shifts or new peaks observed.
- Stability: Accelerated stability studies showed that the tablets maintained physical integrity, drug content, and dissolution profile over 3 months, demonstrating good shelf-life potential.
- Patient Compliance: Sustained release over 12 hours suggests once-daily dosing is possible, improving patient adherence and providing better glycemic control.
- Future Prospects: The optimized SR tablets can be subjected to in-vivo pharmacokinetic studies, scale-up for commercial production, and exploration of combination therapy formulations, ensuring practical clinical applicability.

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