



CODEN [USA]: IAJPBB

ISSN : 2349-7750

**INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES**

SJIF Impact Factor: 7.187

<https://doi.org/10.5281/zenodo.20632393>Available online at: <http://www.iajps.com>

Research Article

**FORMULATION DEVELOPMENT AND EVALUATION OF
FAST DISSOLVING ORAL THIN FILM OF ANTIDIABETIC
DRUG GLIMEPIRIDE FOR ORAL DRUG DELIVERY****Mamta D. Chavan***, Dr. Ravi Uttamrao Kurhade, Mr. Nishinandan Manikrao Shinde
MDA School of Pharmacy, Kolpa, Latur, Maharashtra 413531**Abstract:**

The present study focuses on the formulation and evaluation of mouth dissolving oral films of Glimepiride with the aim of enhancing its dissolution rate, bioavailability, and patient compliance. Glimepiride, a BCS Class II drug, exhibits poor aqueous solubility, which limits its therapeutic effectiveness when administered through conventional dosage forms. Preformulation studies, including organoleptic evaluation, solubility analysis, melting point determination, and FTIR spectroscopy, confirmed the purity, identity, and compatibility of the drug with selected excipients such as HPMC, PVA, and PEG 400. Mouth dissolving films were prepared using the solvent casting method by varying the concentrations of polymers and plasticizer. A total of nine formulations (F1–F9) were developed and evaluated for physicochemical and performance parameters including weight variation, folding endurance, disintegration time, surface pH, drug content, and in vitro drug release. All formulations exhibited satisfactory characteristics with good uniformity and mechanical strength. Among the prepared batches, formulation F7 was identified as the optimized formulation, demonstrating excellent properties such as rapid disintegration (24 ± 1.80 sec), high folding endurance (232 ± 6), near-neutral surface pH (6.91 ± 0.04), uniform drug content ($99.82 \pm 0.60\%$), and complete drug release (100% within 10 minutes). Stability studies conducted under accelerated conditions revealed that the optimized formulation remained stable over a period of three months, with no significant changes in its physicochemical properties or drug release profile. In conclusion, the developed mouth dissolving oral film of Glimepiride represents a promising drug delivery system for improving dissolution rate, bioavailability, and patient compliance, particularly in geriatric and pediatric populations.

KEYWORDS: Glimepiride, Mouth dissolving film, Solvent casting method, Fast dissolving oral film, BCS Class II drug, In vitro dissolution, Drug release, Polymer (HPMC, PVA), PEG 400, Stability study etc.

Corresponding author:**Mamta D. Chavan,**

M.Pharm Scholar,

MDA School of Pharmacy, Kolpa,

Latur, Maharashtra 413531

Email: chavanmamta99@gmail.com

QR CODE

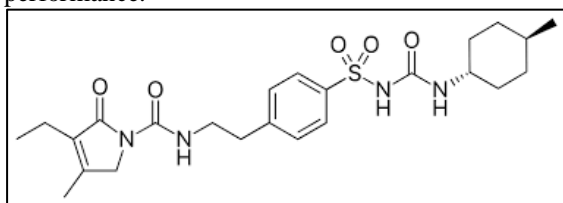


Please cite this article in press Mamta D. Chavan et al., Formulation Development And Evaluation Of Fast Dissolving Oral Thin Film Of Antidiabetic Drug Glimepiride For Oral Drug Delivery..., Indo Am. J. P. Sci, 2026; 13(06).

INTRODUCTION:

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It is one of the most prevalent non-communicable diseases worldwide and is associated with serious complications such as cardiovascular diseases, nephropathy, neuropathy, and retinopathy.¹ The increasing global prevalence of type 2 diabetes mellitus has created a significant demand for effective therapeutic strategies that can improve glycemic control while enhancing patient adherence to treatment regimens.²

Glimepiride is a third-generation sulfonylurea antidiabetic agent widely used in the management of type 2 diabetes mellitus.³ It acts by stimulating insulin release from pancreatic β -cells, thereby reducing blood glucose levels. Despite its effectiveness, Glimepiride exhibits poor aqueous solubility and undergoes first-pass metabolism, which may limit its dissolution rate and oral bioavailability. These limitations necessitate the development of novel drug delivery systems capable of improving drug release and therapeutic performance.⁴



Fast dissolving oral thin films (FDOFs) have emerged as an innovative and patient-friendly drug delivery platform.⁵ These films are thin, flexible polymeric strips that rapidly disintegrate and dissolve when placed on the tongue, releasing the drug for absorption. Oral thin films offer several advantages, including ease of administration without water, rapid onset of action, improved patient compliance, accurate dosing, and enhanced convenience for pediatric, geriatric, and dysphagic patients. Additionally, the large surface area and rapid hydration of the film matrix can improve the dissolution rate of poorly water-soluble drugs.⁶

The formulation of Glimepiride as a fast dissolving oral thin film represents a promising approach to overcome challenges associated with conventional oral dosage forms. The incorporation⁷ of hydrophilic polymers and suitable excipients can facilitate rapid film disintegration, enhance drug release, and potentially improve bioavailability. Furthermore, oral thin films provide an attractive alternative to tablets and capsules by offering improved portability, convenience, and patient acceptance.⁸

Therefore, the present study was undertaken to formulate, develop, and evaluate fast dissolving oral thin films of Glimepiride using suitable film-

forming polymers and excipients. The prepared films were evaluated for their physicochemical properties, mechanical strength, disintegration behavior, drug content, in vitro drug release, and stability to identify an optimized formulation capable of providing rapid and efficient drug delivery for the management of type 2 diabetes mellitus.

MATERIALS AND METHODS:**MATERIALS:**

Glimepiride was obtained as a gift sample from Sun Pharmaceutical Industries Ltd., India. Hydroxypropyl methylcellulose (HPMC E5/E15), used as the film-forming polymer, was procured from Colorcon Asia Pvt. Ltd., Goa, India. Polyvinyl alcohol (PVA) was purchased from Loba Chemie Pvt. Ltd., Mumbai, India. Polyethylene glycol (PEG 400) and glycerol, employed as plasticizers, were obtained from Merck Life Science Pvt. Ltd., India. Sodium starch glycolate and croscopovidone, used as superdisintegrants, were supplied by Signet Chemical Corporation Pvt. Ltd., Mumbai, India. Citric acid and aspartame were procured from S.D. Fine Chemicals Ltd., Mumbai, India. A suitable flavoring agent was purchased from a local supplier in India. Methanol of analytical grade was obtained from Merck Life Science Pvt. Ltd., India, while distilled water was prepared in-house and used throughout the study. All chemicals and reagents used were of analytical reagent grade and utilized without further purification.

METHODOLOGY:**Selection of Drug and Excipients**

Glimepiride was selected as the model antidiabetic drug for the development of fast dissolving oral thin films owing to its poor aqueous solubility, extensive first-pass metabolism, and requirement for rapid therapeutic action in the management of type 2 diabetes mellitus. The formulation was designed to enhance drug dissolution, improve oral bioavailability, and increase patient compliance. HPMC E5/E15 and PVA were employed as film-forming polymers, while PEG 400 and glycerol were used as plasticizers. Sodium starch glycolate and croscopovidone served as superdisintegrants to facilitate rapid film disintegration. Citric acid was incorporated as a saliva-stimulating agent, whereas aspartame and flavoring agents were added to improve palatability.

Procurement of Materials

Glimepiride was obtained as a gift sample from Sun Pharmaceutical Industries Ltd., India. HPMC E5/E15, PVA, PEG 400, glycerol, sodium starch glycolate, croscopovidone, citric acid, aspartame, and flavoring agents were procured from reputed pharmaceutical suppliers. All chemicals and

reagents used were of analytical or pharmaceutical grade and were utilized without further purification. The materials were stored under suitable conditions until further use.⁹⁻¹⁰

Preformulation Studies

Preformulation studies were conducted to evaluate the physicochemical characteristics of Glimepiride and to ensure its suitability for oral thin film formulation. The studies included drug identification, physical characterization, solubility analysis, melting point determination, UV spectrophotometric analysis, and Fourier Transform Infrared (FTIR) spectroscopy.¹¹⁻¹³

Drug Identification and Characterization

The identity and purity of Glimepiride were confirmed by evaluating its physical appearance, melting point, UV absorption spectrum, and FTIR spectrum. The obtained results were compared with reported literature values to verify the authenticity of the drug sample.¹⁴⁻¹⁶

Solubility Study

The solubility of Glimepiride was investigated in distilled water, methanol, ethanol, and phosphate buffer (pH 6.8). Excess drug was added to each solvent, shaken for 24 h, filtered, and analyzed spectrophotometrically. The study revealed that Glimepiride exhibited poor aqueous solubility and better solubility in organic solvents.¹⁷⁻²⁰

Melting Point Determination

The melting point of Glimepiride was determined by the capillary tube method using a digital melting point apparatus. The melting range obtained was compared with reported values to assess the purity and identity of the drug.²¹

UV Spectrophotometric Analysis

A standard solution of Glimepiride was prepared in methanol and suitably diluted with phosphate buffer (pH 6.8). The solution was scanned over the wavelength range of 200–400 nm using a UV-Visible spectrophotometer to determine the maximum absorption wavelength (λ_{max}), which was subsequently used for quantitative analysis.²²

FTIR Spectroscopic Study

FTIR spectroscopy was performed using the KBr pellet technique to identify the characteristic functional groups of Glimepiride and confirm its chemical integrity. The spectrum was recorded in the range of 4000–400 cm^{-1} and compared with standard reference spectra for drug authentication.²³

Analytical Method Development and Validation

A UV-Visible spectrophotometric method was developed for the quantitative estimation of Glimepiride due to its simplicity, accuracy, and

cost-effectiveness. The method was validated to ensure its suitability for routine analysis during formulation development and evaluation studies.²⁴⁻²⁷

UV Spectral Analysis

A standard solution of Glimepiride was prepared in methanol and suitably diluted with phosphate buffer (pH 6.8). The solution was scanned over the wavelength range of 200–400 nm using a UV-Visible spectrophotometer. The maximum absorbance (λ_{max}) was observed at 228 nm, which was selected for all subsequent analytical measurements.²⁸⁻³⁰

Preparation of Calibration Curve

A calibration curve of Glimepiride was prepared by dissolving an accurately weighed quantity of the drug in methanol to obtain a standard stock solution. Appropriate dilutions were made with phosphate buffer (pH 6.8) to obtain concentrations ranging from 5–30 $\mu g/mL$. The absorbance of each solution was measured at 228 nm, and a graph of concentration versus absorbance was plotted. The method exhibited good linearity within the selected concentration range in accordance with Beer-Lambert's law.³¹⁻³²

Formulation Development of Fast Dissolving Oral Thin Films

Fast dissolving oral thin films of Glimepiride were prepared by the solvent casting method. The formulation was designed by varying the concentrations of film-forming polymers and plasticizers to achieve films with desirable mechanical properties, flexibility, and rapid disintegration. HPMC E5/E15 and PVA were used as film-forming polymers, PEG 400 as a plasticizer, sodium starch glycolate as a superdisintegrant, citric acid as a saliva-stimulating agent, and aspartame with flavoring agents as taste-masking agents. A series of formulations (F1–F9) were prepared while maintaining a constant drug concentration and optimizing the polymer and plasticizer levels.³³⁻³⁵

Preparation of Fast Dissolving Oral Thin Films

The required quantity of polymer was dissolved in distilled water with continuous stirring to obtain a clear and homogeneous solution. Glimepiride was dissolved separately in a suitable solvent and incorporated into the polymeric solution. Plasticizer, superdisintegrant, citric acid, sweetener, and flavoring agent were then added with continuous stirring to obtain a uniform casting solution. The resulting solution was poured onto a suitable casting surface and dried at room temperature. After complete drying, the films were carefully removed, cut into uniform dimensions containing the required dose of Glimepiride, and stored in airtight containers for further

evaluation.³⁶⁻³⁸

Table 1: Composition of Mouth Dissolving Films of Glimepiride

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F8	F8	F9
Glimepiride	2	2	2	2	2	2	2	2	2
HPMC E5	100	120	140	100	120	140	80	100	120
PVA	50	50	50	80	80	80	90	90	90
PEG 400	15	20	25	15	20	25	15	20	25
Sodium starch glycolate	10	10	10	12	12	12	15	15	15
Citric acid	5	5	5	5	5	5	5	5	5
Aspartame	8	8	8	8	8	8	8	8	8
Flavor (q.s.)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Distilled water (mL)	10	10	10	10	10	10	10	10	10

Preparation of Fast Dissolving Oral Thin Films

Fast dissolving oral thin films of Glimepiride were prepared by the solvent casting method. The required quantities of HPMC and PVA were dissolved in distilled water under continuous magnetic stirring to obtain a clear polymeric solution. Glimepiride was separately dissolved in methanol and gradually incorporated into the polymer solution with continuous stirring. Subsequently, PEG 400, sodium starch glycolate, citric acid, aspartame, and flavoring agent were added and mixed thoroughly to obtain a homogeneous casting solution. The prepared solution was poured into a leveled glass Petri dish and allowed to dry at room temperature or in a hot air oven at 40–45°C for 24 h. The dried films were carefully peeled off, cut into uniform strips of the desired dimensions, wrapped in aluminum foil, and stored in a desiccator until further evaluation.³⁹⁻⁴²

Evaluation of Fast Dissolving Oral Thin Films

The prepared oral thin films were evaluated for physicochemical and performance characteristics, including weight variation, folding endurance, disintegration time, surface pH, drug content, and in vitro drug release. Weight variation was determined by weighing individual film strips and calculating the mean weight. Folding endurance was assessed by repeatedly folding the film at the

same position until breakage occurred. Disintegration time was measured by placing the film in simulated saliva fluid (phosphate buffer pH 6.8) and recording the time required for complete disintegration. Surface pH was determined by moistening the film with distilled water and measuring the pH using a digital pH meter. Drug content was analyzed by dissolving a film strip in a suitable solvent, followed by UV spectrophotometric estimation at 228 nm. In vitro dissolution studies were carried out using USP dissolution apparatus II (paddle method) containing 900 mL phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples were withdrawn at predetermined intervals, analyzed spectrophotometrically at 228 nm, and the cumulative percentage drug release was calculated.⁴³⁻⁴⁷

RESULTS AND DISCUSSION:

Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical properties of Glimepiride prior to formulation development. The parameters assessed included organoleptic characteristics, solubility profile, and melting point determination. The results confirmed the identity, purity, and suitability of the drug for the development of fast dissolving oral thin films.

Table 2: Preformulation Studies of Glimepiride

Parameter	Observation/Result	Interpretation
Appearance	White to off-white crystalline powder	Complies with official standards
Odor	Odorless	Indicates absence of impurities
Solubility in Water	Practically insoluble	Poor aqueous solubility
Solubility in Phosphate Buffer (pH 6.8)	Slightly soluble	Limited dissolution in aqueous media
Solubility in Methanol	Freely soluble	Suitable solvent for analytical studies
Solubility in Ethanol	Slightly soluble	Moderate solubility
Melting Point	206–208°C	Comparable with standard value (207–209°C)
Nature of Drug	Crystalline	Indicates purity and stability

Organoleptic Properties

The organoleptic evaluation revealed that Glimepiride was a white to off-white, odorless crystalline powder. These observations were in agreement with pharmacopoeial specifications, confirming the identity and purity of the drug sample. The absence of any discoloration or characteristic odor suggested that the drug was free from visible contamination and degradation.

Solubility Studies

The solubility study demonstrated that Glimepiride was practically insoluble in distilled water and only slightly soluble in phosphate buffer (pH 6.8), whereas it was freely soluble in methanol. This behavior confirms the hydrophobic nature of the drug and supports its classification as a BCS Class II compound. The poor aqueous solubility is a major factor limiting its dissolution and oral bioavailability. Therefore, the development of fast dissolving oral thin films was considered a suitable strategy to improve the dissolution rate and enhance therapeutic performance.

Melting Point Determination

The melting point of Glimepiride was found to be between 206–208°C, which closely matched the reported standard value of 207–209°C. The narrow melting range indicated the crystalline nature and

high purity of the drug. The observed value confirmed the authenticity of the received drug sample and its suitability for formulation development.

The preformulation studies established that Glimepiride possesses the required physicochemical characteristics for the development of fast dissolving oral thin films. The drug was confirmed to be pure, crystalline, and hydrophobic in nature. Its poor aqueous solubility justified the selection of oral thin film technology as an approach to enhance dissolution, improve bioavailability, and achieve rapid onset of antidiabetic action.

UV Spectral Analysis and Calibration Curve of Glimepiride

The UV absorption spectrum of Glimepiride was recorded in the wavelength range of 200–400 nm. The drug exhibited a maximum absorbance (λ_{max}) at 228 nm, which was selected for further quantitative analysis. The calibration curve was prepared in the concentration range of 5–30 $\mu\text{g/mL}$ and showed good linearity with a regression equation of $y = 0.0407x + 0.0227$ and a correlation coefficient ($R^2 = 0.9995$), indicating excellent compliance with Beer-Lambert's law.

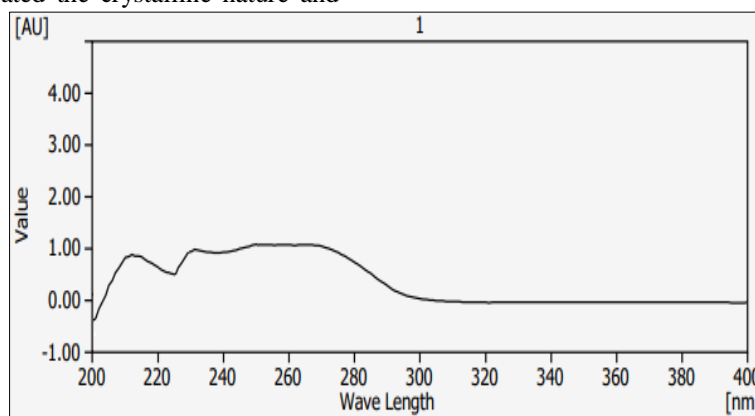


Figure 1: λ_{max} of drug Glimepiride (Maximum wavelength)

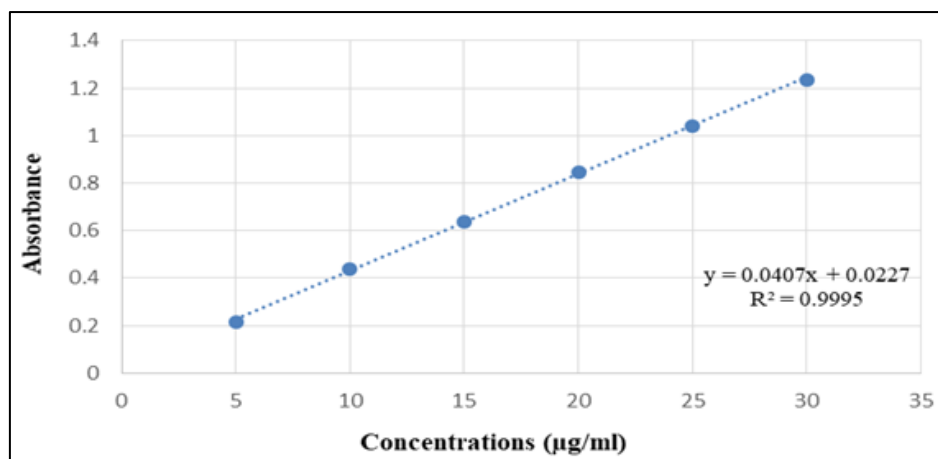


Figure 2: Calibration curve for Glimepiride

FTIR Compatibility Study

FTIR spectroscopy was performed to investigate the compatibility of Glimepiride with the selected excipients used in the oral thin film formulation. The characteristic peaks of Glimepiride were retained in the spectra of the drug-excipient mixtures without any significant shift or disappearance. These findings confirmed the absence of chemical interaction between the drug and excipients, indicating good compatibility and suitability of the selected formulation components.

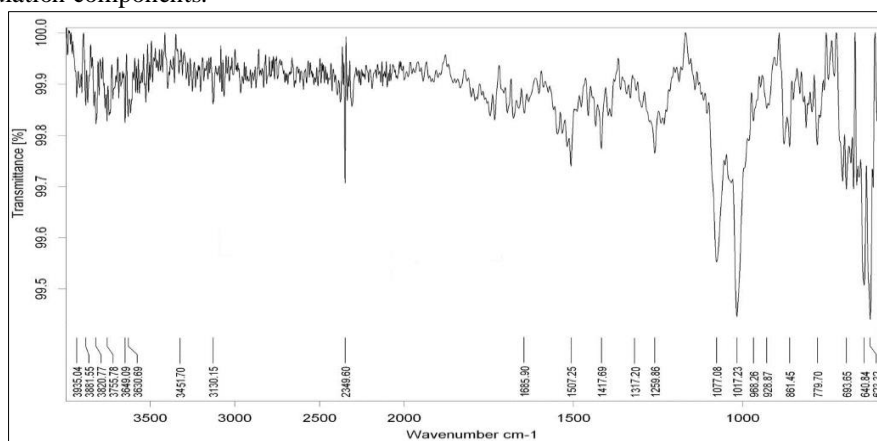


Figure 3: FTIR Spectrum of Glimepiride

Formulation Development of Fast Dissolving Oral Films

Fast dissolving oral films of Glimepiride were successfully prepared by the solvent casting method. Nine formulations (F1–F9) were developed by varying the concentrations of HPMC E5, PVA, and PEG 400 while maintaining a constant drug concentration. All formulations produced smooth, transparent, and flexible films with satisfactory appearance. Films containing balanced concentrations of HPMC and PVA exhibited superior film-forming properties, flexibility, and mechanical strength. Lower polymer concentrations resulted in comparatively fragile films, whereas higher polymer levels produced stronger films with slightly prolonged disintegration time.

Table 3: Composition of Fast Dissolving Oral Films of Glimepiride

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Glimepiride	2	2	2	2	2	2	2	2	2
HPMC E5	100	120	140	100	120	140	80	100	120
PVA	50	50	50	80	80	80	90	90	90
PEG 400	15	20	25	15	20	25	15	20	25
Sodium Starch Glycolate	10	10	10	12	12	12	15	15	15
Citric Acid	5	5	5	5	5	5	5	5	5
Aspartame	8	8	8	8	8	8	8	8	8
Flavor	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Distilled Water (mL)	10	10	10	10	10	10	10	10	10

Evaluation of Film Formation

All formulations successfully formed uniform films without visible air bubbles, cracks, or drug crystallization. The films were smooth, transparent, and easy to peel from the casting surface. Increasing polymer concentration improved film strength and integrity, while PEG 400 effectively enhanced flexibility and minimized brittleness. The absence of phase separation confirmed uniform drug distribution throughout the film matrix. Among the formulations, F4–F6 demonstrated an optimum balance between mechanical strength and expected disintegration behavior.

Weight Variation

Weight variation studies were performed to assess formulation uniformity and reproducibility. The average film weight increased progressively from F1 to F9 due to the increasing polymer concentration. All formulations exhibited low standard deviation values (± 1.0 mg), indicating uniform distribution of drug and excipients and good control over the solvent casting process. The successful preparation of all formulations confirmed the suitability of the solvent casting method for developing Glimepiride oral thin films. Polymer concentration significantly influenced film characteristics, with higher levels producing stronger and heavier films. The uniform weight distribution and low standard deviation values demonstrated excellent reproducibility of the manufacturing process. Based on visual appearance, flexibility, and expected performance, formulations F4–F6 were considered the most promising formulations for further evaluation.

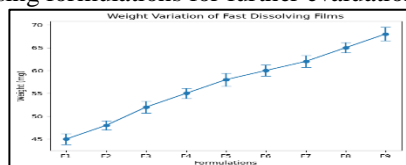


Figure 4: Weight Variation of Fast Dissolving Films

Evaluation of Fast Dissolving Oral Films Folding Endurance

The folding endurance values ranged from 118 ± 4 to 268 ± 6 , indicating good flexibility and mechanical strength of all formulations. Folding endurance increased with increasing polymer concentration. Formulations F7–F9 exhibited superior flexibility, with F7 providing an optimum balance between strength and rapid disintegration.

Disintegration Time

The disintegration time ranged from 24 ± 1.80 to 52 ± 4.55 seconds. A decrease in disintegration time was observed from F1 to F7 due to the optimized polymer ratio and superdisintegrant concentration. Formulation F7 showed the fastest disintegration (24 ± 1.80 sec), while a slight increase was observed in F8 and F9 because of higher polymer content.

Surface pH and Drug Content

The surface pH of all formulations was within the physiological range (6.18–7.10), indicating suitability for oral administration without mucosal irritation. Drug content ranged from 94.35% to 99.82%, confirming uniform drug distribution throughout the films. Formulation F7 exhibited the highest drug content ($99.82 \pm 0.60\%$) and near-neutral pH (6.91 ± 0.04).

Among all formulations, F7 was identified as the optimized formulation due to its excellent folding endurance (232 ± 6), shortest disintegration time (24 ± 1.80 sec), near-neutral surface pH (6.91 ± 0.04), and highest drug content ($99.82 \pm 0.60\%$). These results indicate that F7 possessed the best balance of mechanical strength, rapid disintegration, and drug uniformity for fast dissolving oral film delivery of Glimepiride.

Table 4: Evaluation Data of Fast Dissolving Oral Films

Formulation	Folding Endurance (Mean \pm SD)	Disintegration Time (sec) Mean \pm SD	Surface pH Mean \pm SD	Drug Content (%) Mean \pm SD
F1	118 ± 4	52 ± 4.55	6.18 ± 0.09	94.35 ± 1.25
F2	137 ± 5	46 ± 3.68	6.32 ± 0.08	95.48 ± 1.12
F3	158 ± 6	41 ± 3.20	6.47 ± 0.07	96.72 ± 1.05
F4	176 ± 5	36 ± 2.85	6.60 ± 0.06	97.40 ± 0.92
F5	198 ± 6	33 ± 2.40	6.73 ± 0.05	98.15 ± 0.85
F6	214 ± 5	30 ± 2.10	6.84 ± 0.05	99.05 ± 0.72
F7	232 ± 6	24 ± 1.80	6.91 ± 0.04	99.82 ± 0.60
F8	251 ± 5	27 ± 2.00	7.04 ± 0.06	98.75 ± 0.82
F9	268 ± 6	29 ± 2.20	7.10 ± 0.07	97.65 ± 0.95

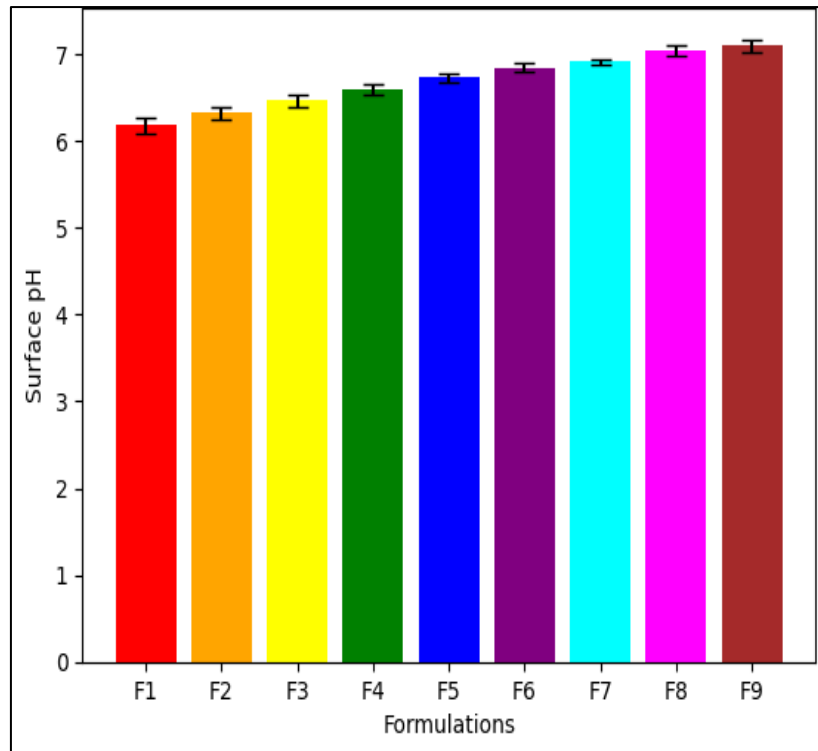


Figure 5: Surface pH of Fast Dissolving Films

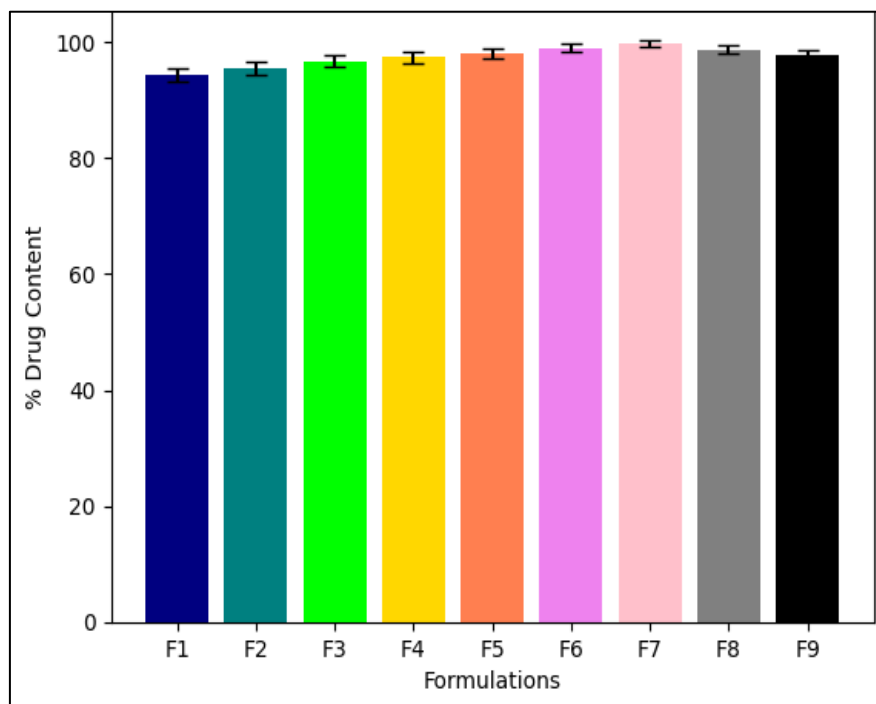


Figure 6: Drug Content of Fast Dissolving Films

In Vitro Dissolution Study

The *in vitro* dissolution study showed rapid and progressive drug release from all formulations. Formulation F7 exhibited the highest drug release profile, achieving 95% release within 5 min and 100% release within 10 min. The enhanced release was attributed to the optimized polymer concentration and superdisintegrant content. Therefore, F7 was selected as the optimized formulation.

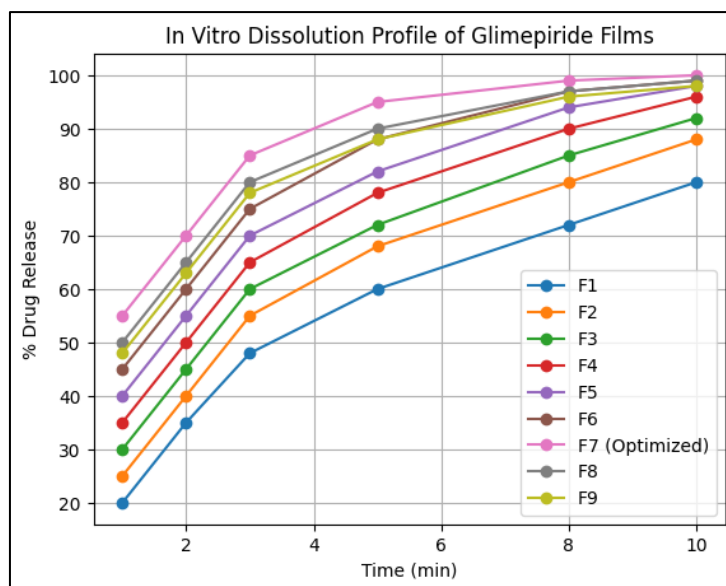


Figure 7: *In Vitro* Drug Release Profile of Fast Dissolving Films

Optimized Formulation (F7)

Based on evaluation parameters, formulation F7 was selected as the optimized batch due to its excellent mechanical strength, rapid disintegration, high drug content, and complete drug release.

Table 5: Evaluation Parameters of Optimized Formulation F7

Parameter	Result (Mean \pm SD)
Weight Variation (mg)	62.00 \pm 1.20
Folding Endurance	232 \pm 6
Disintegration Time (sec)	24 \pm 1.80
Surface pH	6.91 \pm 0.04
Drug Content (%)	99.82 \pm 0.60
Drug Release at 10 min (%)	100 \pm 1.20

The optimized formulation F7 showed excellent film characteristics with high flexibility, rapid disintegration, near-neutral surface pH, uniform drug content, and complete drug release within 10 min. These findings indicate its suitability as an effective fast dissolving oral film for Glimepiride delivery.

Stability Study of Optimized Formulation (F7)

The stability study conducted under accelerated conditions (40 \pm 2°C/75 \pm 5% RH) for 3 months revealed no significant changes in the physicochemical properties of the optimized formulation. The films remained smooth and transparent throughout the study period.

Table 6: Stability Study of Optimized Formulation F7

Time	Appearance	Disintegration Time (sec)	Drug Content (%)	Drug Release (%)
Initial	Smooth, transparent	24 \pm 1.80	99.82 \pm 0.60	100 \pm 1.20
1 Month	No change	25 \pm 1.75	99.10 \pm 0.65	99.20 \pm 1.10
2 Months	No change	26 \pm 1.70	98.45 \pm 0.70	98.60 \pm 1.15
3 Months	No change	27 \pm 1.85	97.80 \pm 0.75	97.90 \pm 1.20

The optimized formulation F7 remained stable throughout the study period with no significant changes in appearance, disintegration time, drug content, or drug release profile. The results confirmed the physical and chemical stability of the developed fast dissolving oral film under accelerated storage conditions.

CONCLUSION:

The present study successfully developed and evaluated fast dissolving oral thin films of Glimepiride using the solvent casting method. Preformulation studies confirmed the purity, compatibility, and suitability of the drug for oral thin film formulation. Nine formulations (F1–F9) were prepared and evaluated for various physicochemical and performance parameters. Among all formulations, F7 was identified as the optimized formulation, exhibiting excellent

mechanical strength, rapid disintegration (24 \pm 1.80 sec), near-neutral surface pH (6.91 \pm 0.04), high drug content (99.82 \pm 0.60%), and complete drug release (100%) within 10 minutes. Stability studies demonstrated that the optimized formulation remained stable under accelerated storage conditions for three months without significant changes in its properties. The findings suggest that the developed fast dissolving oral thin film of Glimepiride is a promising oral drug delivery system capable of providing rapid drug release, improved patient compliance, and enhanced

therapeutic efficacy in the management of type 2 diabetes mellitus.

CONFLICT OF INTREST:

The author declares that there is no conflict of interest.

REFERENCES:

- Irfan M, Rabel S, Bukhtar Q, Qadir MI, Jabeen F, Khan A. Oral fast dissolving films: a modern expansion in drug delivery system. *Saudi Pharm J*. 2016;24(5):537–546.
- Haque S, et al. Development and evaluation of fast dissolving films of metformin using chitosan. *Int J Pharm Pharm Sci*. 2015;7(4):234–239.
- Boateng JS, Stevens HNE, Eccleston GM, Auffret AD, Humphrey MJ, Matthews KH. Development and mechanical characterization of solvent-cast polymeric films. *Drug Dev Ind Pharm*. 2009;35(8):986–996.
- Jelvehgari M, et al. Preparation and evaluation of fast dissolving oral thin films of ergotamine tartrate and caffeine. *Adv Pharm Bull*. 2015;5(2).
- Kumar S, et al. Development of oral fast dissolving films of salbutamol sulphate. *Int J Pharm Sci Nanotechnol*. 2014;7(2):2450–2457.
- Gill B, et al. Enhancement of solubility and dissolution of glimepiride using solid dispersion technique with poloxamer 188. *J Pharm Sci Res*. 2014;6(9).
- Siddiqui N, Garg G, Sharma PK. Fast dissolving films: preparation, characterization and applications. *Drug Deliv*. 2011;18(7).
- Garsuch V, Breikreutz J. Comparative investigations on different polymers for preparation of fast dissolving oral films. *Drug Dev Ind Pharm*. 2010;36(3).
- Müller G, Wied S, Crecelius A, Köhnke R, Eckel J. Glimepiride: evidence for dual mechanisms of action. *Diabetes Res Clin Pract*. 1998;40(Suppl):S147–S153.
- Proks P, Reimann F, Green N, Gribble F, Ashcroft F. Sulfonylurea stimulation of insulin secretion. *Diabetes*. 2002;51(Suppl 3):S368–S376.
- Davis SN. The role of glimepiride in the effective management of Type 2 diabetes. *J Diabetes Complications*. 2004;18(6):367–376.
- Drug Bank. Glimepiride: pharmacological profile and properties. *DrugBank Database*. 2023.
- United States Pharmacopeia (USP 43–NF 38). Rockville, MD: United States Pharmacopeial Convention; 2020.
- Sweetman SC, editor. *Martindale: The Complete Drug Reference*. 38th ed. London: Pharmaceutical Press; 2014.
- Rowe RC, Sheskey PJ, Quinn ME, editors. *Handbook of Pharmaceutical Excipients*. 6th ed. London: Pharmaceutical Press; 2009.
- Nokhodchi A, Ford JL, Rubinstein MH. Studies on the interaction between HPMC and drugs. *Int J Pharm*. 1997;157(1):61–73.
- Siepmann J, Peppas NA. Modeling of drug release from delivery systems based on HPMC. *Adv Drug Deliv Rev*. 2012;64:163–174.
- Hassan CM, Peppas NA. Structure and applications of polyvinyl alcohol hydrogels. *Adv Polym Sci*. 2000;153:37–65.
- Boateng JS, Auffret AD, Matthews KH, Humphrey MJ, Stevens HN, Eccleston GM. Characterisation of freeze-dried wafers and films. *Eur J Pharm Biopharm*. 2010;76(2):268–276.
- Rowe RC, Sheskey PJ, Quinn ME. *Handbook of Pharmaceutical Excipients*. London: Pharmaceutical Press; 2009.
- Strickley RG. Solubilizing excipients in oral and injectable formulations. *Pharm Res*. 2004;21(2):201–230.
- Desai PM, Liew CV, Heng PW. Review of disintegrants and superdisintegrants. *Int J Pharm*. 2016;510(2):395–406.
- Mohanachandran PS, Sindhumol PG, Kiran TS. Superdisintegrants: an overview. *Int J Pharm Sci Rev Res*. 2011;6(1):105–109.
- Shangraw RF, Mitrejev A, Shah M. A new era of tablet disintegrants. *Pharm Technol*. 1980;4:49–57.
- Zhao N, Augsburger LL. Functionality comparison of crospovidone. *AAPS PharmSciTech*. 2005;6(4):E634–E640.
- Magnuson BA, Burdock GA, Doull J, et al. Aspartame: safety evaluation. *Crit Rev Toxicol*. 2007;37(8):629–727.
- Butchko HH, Stargel WW. Aspartame: scientific evaluation in food. *Regul Toxicol Pharmacol*. 2001;34(3):221–233.
- Socrates G. *Infrared and Raman Characteristic Group Frequencies*. 3rd ed. Wiley; 2001.
- Rowe RC, Sheskey PJ, Quinn ME. *Handbook of Pharmaceutical Excipients*. London: Pharmaceutical Press; 2009.
- Indian Pharmacopoeia Commission. *Indian Pharmacopoeia*. Vol. II. Ghaziabad: IPC; 2018.
- United States Pharmacopeial Convention. *United States Pharmacopeia 43–National Formulary 38*. Rockville, MD: USP; 2020.
- ICH. Q2(R1): Validation of Analytical Procedures: Text and Methodology. International Conference on Harmonisation; 2005.
- Banker GS, Rhodes CT. *Modern Pharmaceutics*. 4th ed. New York: Marcel Dekker; 2002.
- Aulton ME, Taylor K. *Aulton's*

- Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. London: Elsevier; 2018.
35. Lachman L, Lieberman HA, Kanig JL. *The Theory and Practice of Industrial Pharmacy*. 3rd ed. Mumbai: Varghese Publishing House; 2009.
 36. Allen LV. *Pharmaceutical Dosage Forms and Drug Delivery Systems*. 10th ed. Philadelphia: Lippincott Williams & Wilkins; 2014.
 37. Rasve V, Chakraborty AK, Jain SK, Vengurlekar S. Comparative evaluation of antidiabetic activity of ethanolic leaves extract of *Clematis triloba* and their SMEDDS formulation in streptozotocin-induced diabetic rats. *J Popul Ther Clin Pharmacol*. 2022;29(4):959-971. doi:10.53555/jptcp.v29i04.2360.
 38. Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: An innovative drug delivery system. *Int J ChemTech Res*. 2010;2(1):576-83.
 39. Bhyan B, Jangra S, Kaur M, Singh H. Orally fast dissolving films: Innovations in formulation and technology. *Int J Pharm Sci Rev Res*. 2011;9(2):50-7.
 40. Cilurzo F, Cupone IE, Minghetti P, Selmin F, Montanari L. Fast dissolving films made of maltodextrins. *Eur J Pharm Biopharm*. 2008;70(3):895-900.
 41. Preis M, Knop K, Breitzkreutz J. Mechanical strength test for orodispersible and buccal films. *Int J Pharm*. 2014;461(1-2):22-9.
 42. Garsuch V, Breitzkreutz J. Novel analytical method for the characterization of oral wafers. *Eur J Pharm Biopharm*. 2010;73(1):195-201.
 43. Guidance for Industry: Dissolution Testing of Immediate Release Solid Oral Dosage Forms. US FDA; 1997.
 44. Patel VF, Liu F, Brown MB. Advances in oral transmucosal drug delivery. *J Control Release*. 2011;153(2):106-16.
 45. Boateng JS, Auffret AD, Matthews KH, Humphrey MJ, Stevens HNE, Eccleston GM. Characterisation of freeze-dried wafers. *Eur J Pharm Biopharm*. 2010;76(2):296-303.
 46. Kulkarni AS, Deokule HA, Mane MS, Ghadge DM. Exploration of different polymers for use in the formulation of oral fast dissolving strips. *J Curr Pharm Res*. 2010;2(1):33-5.
 47. Siddiqui MN, Garg G, Sharma PK. A short review on "A novel approach in oral fast dissolving drug delivery system and their patents". *Adv Biol Res*. 2011;5(6):291-303.