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Formulation and Evaluation of Extended-Release Glipizide Capsules Using Ethyl Cellulose and HPMC K100M for Once-Daily Oral Delivery

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Abstract:

Background: Glipizide is a second-generation sulfonylurea used in the management of type 2 diabetes mellitus, but its short elimination half-life and poor aqueous solubility make it a suitable candidate for extended-release oral drug delivery. Hydrophilic-hydrophobic matrix systems based on hydroxypropyl methylcellulose (HPMC) and ethyl cellulose (EC) are widely used to modulate drug release through combined diffusion, swelling, and matrix relaxation mechanisms.

Objective: The study aimed to develop and evaluate extended-release matrix capsules of glipizide using different EC: HPMC K100M ratios and to identify an optimized formulation capable of sustained release over 24 hours.

Materials and Methods: Six formulation batches (F1-F6) containing 10 mg glipizide and a constant total polymer load of 200 mg per capsule were prepared by wet granulation while varying the EC: HPMC ratio from 90:10 to 40:60. Granules were evaluated for bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose, and filled capsules were assessed for weight variation, content uniformity, disintegration time, and in vitro drug release in phosphate buffer pH 7.4 for 24 hours. Dissolution data were fitted to zero-order, first-order, Higuchi, and Korsmeyer-Peppas models, and the optimized batch was subjected to accelerated and long-term stability studies for 3 months.

Results: All formulation blends showed acceptable flow and filling properties, and all capsule batches complied with pharmacopeial limits for fill weight, drug content, and shell disintegration. Drug release increased progressively as the proportion of HPMC increased and the proportion of EC decreased, confirming the central role of polymer balance in release modulation. Batch F3 (EC:HPMC 70:30) showed the most desirable release pattern, with 9.8% release at 1 hour, 15.3% at 2 hours, approximately 60% at 12 hours, and 89.2% at 24 hours. Korsmeyer-Peppas provided the best fit for all formulations, and the release exponent for F3 ($n = 0.71$) indicated anomalous non-Fickian transport. Stability studies showed no meaningful loss of

drug content or extended-release performance over 3 months under either accelerated or long-term conditions.

Conclusion: EC-HPMC K100M matrix capsules can be optimized to provide once-daily extended release of glipizide with good manufacturability, predictable kinetics, and acceptable short-term stability. Formulation F3 emerged as the optimized batch and represents a promising oral ER system for improved long-term management of type 2 diabetes mellitus.

Keywords: Glipizide; extended-release capsules; ethyl cellulose; HPMC K100M; matrix system; wet granulation; sustained release; type 2 diabetes mellitus.

Introduction

Type 2 diabetes mellitus is a chronic metabolic disease characterized by persistent hyperglycaemia resulting from insulin resistance, impaired insulin secretion, or both, and it continues to impose a major global and long-term therapeutic burden. Effective treatment requires maintenance of consistent glycaemic control over prolonged periods, and formulation strategies that reduce dosing frequency may improve adherence in chronic therapy.

Glipizide is a second-generation sulfonylurea that lowers blood glucose primarily by stimulating pancreatic beta-cell insulin release. It remains clinically relevant in type 2 diabetes because of its efficacy, affordability, and continued use in low- and middle-income settings, including India. However, glipizide is also associated with pharmacotechnical limitations relevant to formulation design: it is a BCS class II drug with poor aqueous solubility, high permeability, and a relatively short elimination half-life, which can contribute to fluctuating plasma concentrations with immediate-release dosage forms.

Extended-release oral systems are intended to sustain drug release over longer periods, reduce dosing frequency, minimize peak-trough fluctuations, and improve therapeutic consistency. For glipizide, a successful ER dosage form could help maintain more uniform exposure across the dosing interval while potentially reducing dosing inconvenience associated with repeated administration. Previous glipizide ER and SR systems have used hydrophilic, hydrophobic, floating, matrix, microsphere, and solid-dispersion approaches to prolong release and improve therapeutic performance.

Among available matrix-forming polymers, HPMC is one of the most widely used hydrophilic release-retarding materials in controlled oral dosage forms because it hydrates rapidly to form a viscous gel layer that modulates solvent penetration and drug diffusion. Ethyl cellulose is a non-ionic, hydrophobic, water-insoluble polymer that slows release by reducing matrix wettability and increasing the tortuosity of the diffusion path.

When combined in the same matrix system, EC and HPMC can provide a rational hydrophobic-hydrophilic balance in which EC supplies structural rigidity and release retardation while HPMC contributes channel formation, gelation, and diffusional control.

The present study was designed to formulate and evaluate extended-release glipizide capsules using different EC: HPMC K100M ratios while keeping the drug dose and total polymer load constant. The specific objective was to identify a formulation capable of providing sustained release over 24 hours with acceptable granule flow, capsule quality, predictable release kinetics, and short-term stability.

Materials and Methods Materials

Glipizide was used as the active pharmaceutical ingredient. Ethyl cellulose (Ethocel Standard 45 Premium) and HPMC K100M were used as the principal release-retarding polymers, lactose monohydrate served as a diluent, microcrystalline cellulose (MCC PH-101) as filler-binder, PVP K-30 as wet granulation binder, magnesium stearate as lubricant, and size 0 hard gelatin capsules as the final unit dosage shell.

In Vitro Buoyancy Studies: The in vitro buoyancy data for all six batches are summarised in Table 6. A clear inverse relationship between $NaHCO_3$ concentration and FLT was observed — increasing $NaHCO_3$ from 10% (F1) to 17.5% (F4) reduced FLT from 3.8 ± 0.3 min to 1.5 ± 0.1 min, reflecting accelerated CO_2 generation. Only batches F3 (FLT 1.9 ± 0.2 min) and F4 (FLT 1.5 ± 0.1 min) met the predefined FLT target of ≤ 2 minutes.

TFT values increased with HPMC K100M concentration, ranging from 13.2 h (F1) to ≥ 24.0 h (F6), with all batches exceeding the 12- hour minimum.

Table 1: Quantitative composition of extended-release glipizide capsule formulations F1-F6

Ingredient	F1	F2	F3	F4	F5	F6	Function
Glipizide (mg)	10	10	10	10	10	10	API
Ethyl Cellulose (mg)	180	160	140	120	100	80	Hydrophobic matrix polymer
HPMC K100M (mg)	20	40	60	80	100	120	Hydrophilic matrix polymer
EC:HPMC Ratio	90:10	80:20	70:30	60:40	50:50	40:60	Variable primary optimization factor
Total Polymer (mg)	200	200	200	200	200	200	Constant across all batches
Lactose Monohydrate (mg)	150	150	150	150	150	150	Filler / Diluent
MCC PH-101 (mg)	100	100	100	100	100	100	Binder / Filler
PVP K-30 (mg)	25	25	25	25	25	25	Granulation binder
Magnesium Stearate (mg)	5	5	5	5	5	5	Lubricant (1% w/w)
Total Fill Weight (mg)	490	490	490	490	490	490	Capsule Size 0 (fill capacity ~600 mg)
Glipizide (% w/w)	2.04	2.04	2.04	2.04	2.04	2.04	Dose per capsule: 10 mg

Preformulation studies: Preformulation evaluation included confirmation of drug identity, melting point determination, wavelength of maximum absorption, calibration curve preparation, solubility assessment in representative media, and compatibility studies by FTIR and DSC. The melting point of glipizide was determined by capillary method, and UV analysis was carried out in 0.1 N HCl and phosphate buffers as described in the thesis.

FTIR spectra were recorded for pure glipizide, individual excipients, and 1:1 physical mixtures of glipizide with each excipient, while

DSC thermograms were used to evaluate possible solid-state incompatibility.

Preparation of granules and capsule filling

Six ER capsule formulations were prepared by wet granulation. Glipizide, EC, HPMC K100M, lactose monohydrate, and MCC were accurately weighed, sieved, and dry blended. PVP K-30 was dissolved in isopropyl alcohol to prepare a 5% w/v binder solution, which was added gradually to form a coherent wet mass. The mass was passed through a 20-mesh sieve, dried at 50 ± 2 °C until loss on drying was not more than 2%, resized, lubricated with magnesium stearate for 3-5 minutes, and filled into size 0 hard gelatin capsules to a target fill weight of 490 mg.

Evaluation of granules

Granules were evaluated for bulk density, tapped density, Carr's index, Hausner ratio, and angle of repose using standard procedures described in the thesis. Measurements were performed in triplicate, and the data were used to assess flow, compressibility, and suitability for capsule filling.

Evaluation of filled capsules

Filled capsules were evaluated for weight variation, drug content uniformity, disintegration time, and dimensions. Twenty capsules from each batch were weighed individually, ten capsules were assayed for glipizide content, and six capsules were tested for shell disintegration time. Acceptance criteria were based on IP/USP-style limits described in the thesis.

In vitro dissolution study

In vitro dissolution studies were conducted using USP apparatus II (paddle method) in 900 mL phosphate buffer pH 7.4 at 37 ± 0.5 °C and 50 rpm. Samples were withdrawn at 1, 2, 4, 6, 8, 10, 12, 16, 20, and 24 hours, replaced with fresh medium, and analyzed by UV spectrophotometry at 276 nm. Cumulative percentage drug release was calculated after correction for sample replacement.

Drug Release Kinetic Analysis

Dissolution data for each batch were fitted to zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. The model with the highest regression coefficient was considered to provide the best mathematical description of release behavior. The Peppas release exponent n was used to interpret whether release was predominantly diffusion-controlled, anomalous non-Fickian, or closer to Case II transport.

Stability Studies

The optimized formulation was subjected to accelerated stability testing at 40 ± 2°C/75 ± 5% RH for 3 months. Samples were withdrawn at predefined intervals and evaluated for appearance, capsule integrity, drug content, and dissolution behavior. Release profile similarity over storage was assessed to determine preservation of extended-release performance.

Result Preformulation Study

Confirmation of Drug Identity by FTIR

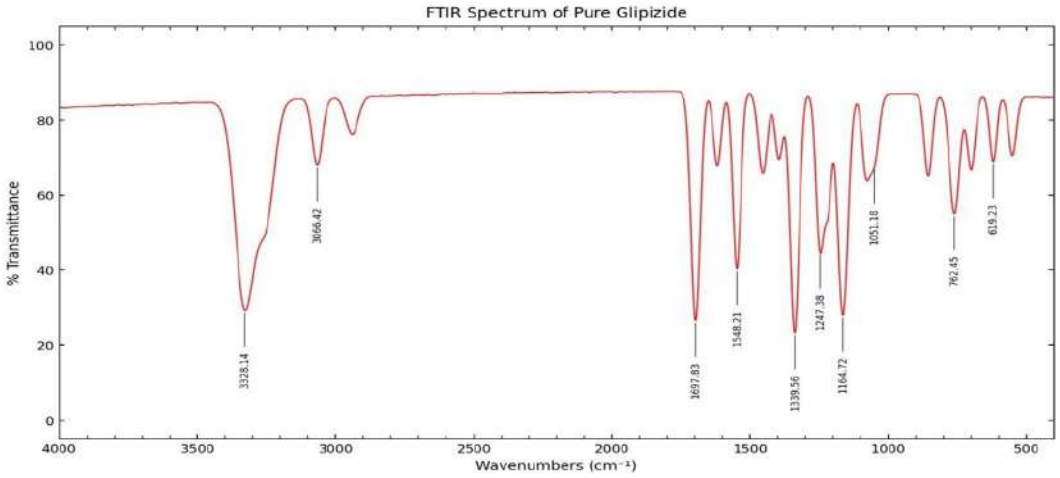

Fig 1: FTIR Spectra of Glipizide

Interpretation: FTIR spectrum of pure glipizide displayed distinct bands for all major functional groups, confirming its chemical identity and structural integrity. The broad band at 3338 cm^{-1} (N–H stretching), peaks at 3066 cm^{-1} (aromatic C–H), 1697 cm^{-1} (C=O), 1548 cm^{-1} (N–H bending), and the 1339–1164 cm^{-1} region (S=O and C–N/C–O stretching), along with bands at 1051, 762, and 619 cm^{-1} (C–S and aromatic C–H bending), together indicate that glipizide remained chemically intact without structural alteration.

Calibration Curve of Glipizide in 0.1 N HCl (pH 1.2)

The calibration curve was constructed over a concentration range of 0.0–25.0 µg/mL in phosphate buffer pH 7.4.

The absorbance values at each concentration level, measured in triplicate, are presented in Table 2 along with the regression statistics.

Excellent linearity was observed over the entire concentration range, with a regression coefficient (R^2) of 0.9998 demonstrating compliance with Beer–Lambert law.

The regression equation (y = 0.0410x + 0.0008) showed a near-zero intercept, confirming the absence of systematic measurement error.

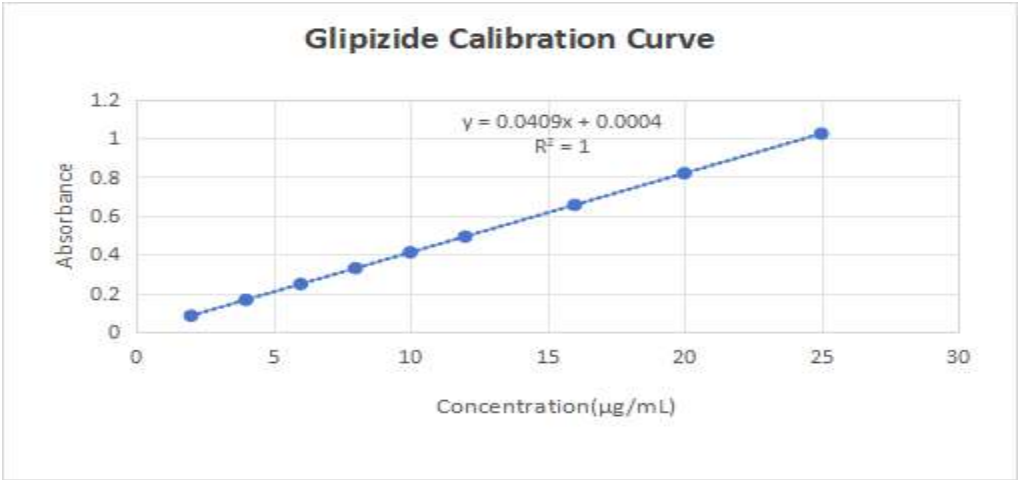

Fig 2: Calibration Curve of Glipizide in 0.1 N HCl (pH 1.2)

Table 2 Calibration Data for Glipizide in 0.1 N HCl

S.No.	Concentration(µg/mL)	Absorbance(mean, n=3)
1.	0.0	0.000 ± 0.000
2.	2.0	0.082 ± 0.002
3.	4.0	0.164 ± 0.003
4.	6.0	0.246 ± 0.003
5.	8.0	0.328 ± 0.004
6.	10.0	0.410 ± 0.004
7.	12.0	0.491 ± 0.005
8.	16.0	0.655 ± 0.006
9.	20.0	0.819 ± 0.007
10.	25.0	1.023 ± 0.008

Drug & Excipient Compatibility by FTIR

Drug-excipient compatibility was evaluated by FTIR of pure glipizide, individual excipients, and 1:1 (w/w) drug–excipient physical mixtures. All mixtures retained the characteristic glipizide peaks without meaningful shifts, loss of bands, or new peaks, indicating no detectable chemical interaction and confirming that the selected excipients are compatible for use in the extended-release matrix capsules.

Compatibility: Glipizide + Ethyl Cellulose (1:1Physical Mixture)

Interpretation

The FTIR spectrum of the 1:1 physical mixture of Glipizide and Ethyl Cellulose was examined against the spectrum of pure Glipizide. All major Glipizide absorption bands, including those attributed to N–H stretching, carbonyl (C=O) stretching, and sulfonyl (S=O) vibrations, were present in the mixture at nearly the same wavenumbers, with only minor, non-significant shifts.

No new peaks appeared, and none of the characteristic drug peaks disappeared in the presence of the polymer.

These observations indicate that Glipizide does not undergo detectable chemical interaction with Ethyl Cellulose in the solid state and therefore can be considered compatible with this excipient for formulation of the extended release matrix.

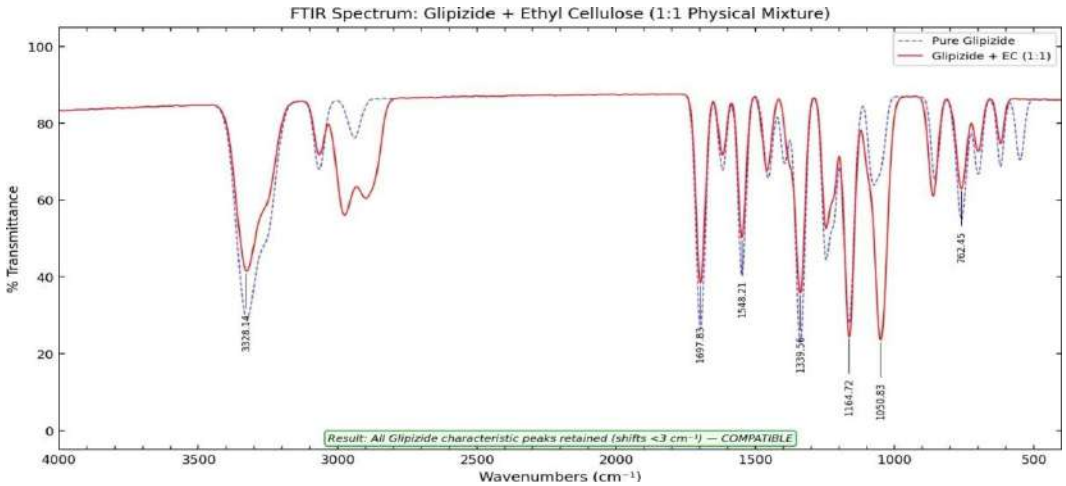

Fig 3: FTIR Overlay: Pure Glipizide vs Glipizide + Ethyl Cellulose (1:1Physical Mixture)

Compatibility: Glipizide + HPMC K100M (1:1PhysicalMixture)

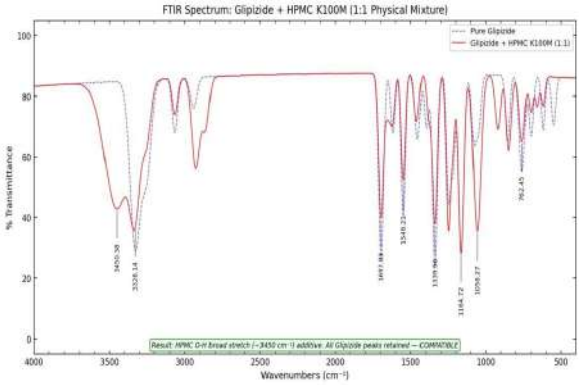

Fig 4: FTIR Overlay: Pure Glipizide vs. Glipizide + HPMC K100M (1:1PhysicalMixture)

Interpretation

The FTIR spectrum of the 1:1 physical mixture of Glipizide and HPMC K100M was compared with that of pure Glipizide.

All characteristic Glipizide peaks, including those due to N–H stretching, carbonyl (C=O) stretching, and sulfonyl (S=O) vibrations, were retained in the mixture at nearly the same wave numbers, with only minor shifts of negligible magnitude. An additional broad band in the higher wave number region corresponded to O–H stretching of HPMC, as expected for this hydrophilic polymer.

No new absorption bands or disappearance of key drug peaks was observed, indicating that Glipizide remains chemically stable in the presence of HPMC K100M and that no significant drug–polymer interaction occurs in the solid state.

Compatibility: Glipizide + Lactose Monohydrate (1:1)

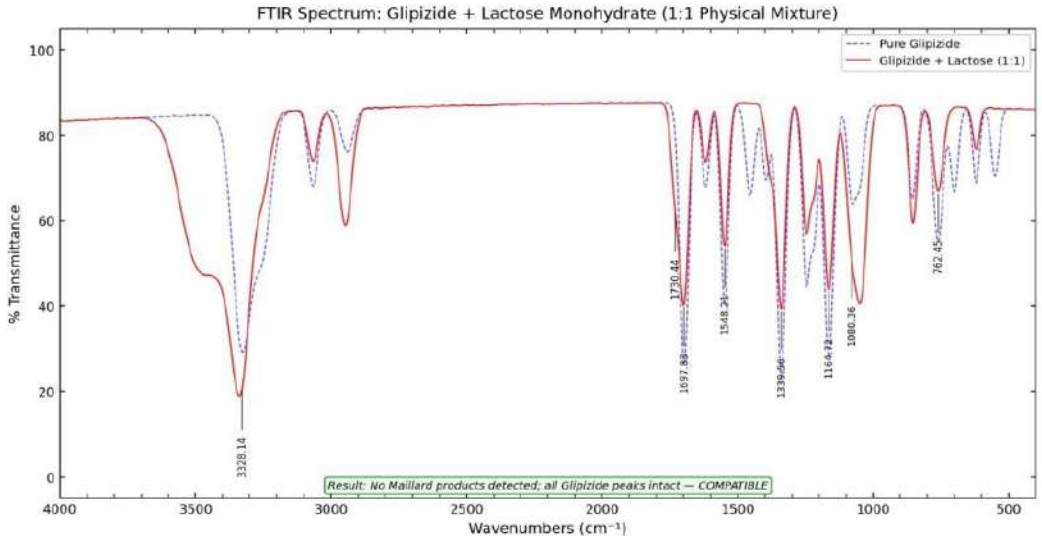

Fig 5: FTIR Overlay: Pure Glipizide vs. Glipizide + Lactose Monohydrate (1:1Physical Mixture)

Interpretation

The FTIR spectrum of the 1:1 physical mixture of Glipizide and Lactose Monohydrate retained the key Glipizide absorption bands, including the N–H stretching band in the region around 3300–3400 cm^{-1}, the strong C=O stretching band of the urea carbonyl near 1690–1700 cm^{-1}, and the S=O stretching peaks of the sulfonyl group in the range of about 1340–1160 cm^{-1}. Characteristic lactose bands, such as broad O–H stretching around 3400 cm^{-1} and C–O–C/C–O stretching vibrations between 1150–1000 cm^{-1}, were also evident without noticeable distortion. The coexistence of these N–H, C=O, S=O, O–H, and C–O–C stretching bands at their expected positions supports the absence of significant interaction between Glipizide and Lactose in the solid mixture

Compatibility: Glipizide + MCCPH-101 (1:1)

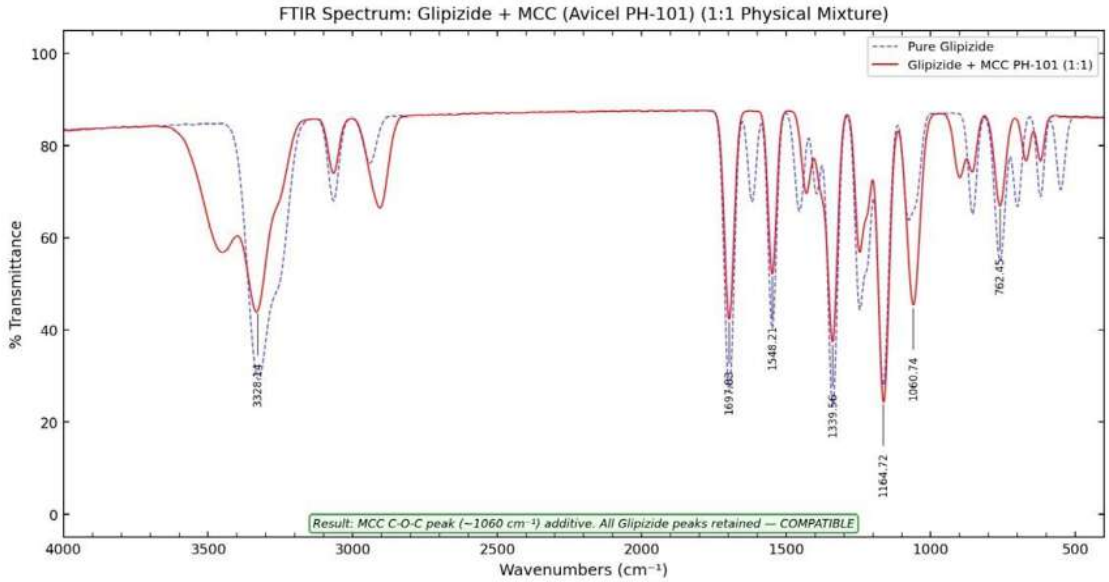

Fig 6: FTIR Overlay: Pure Glipizide vs. Glipizide + MCCPH-101(1:1Physical Mixture)

Interpretation

The FTIR spectrum of the 1:1 physical mixture of Glipizide and Microcrystalline Cellulose (Avicel PH-101) was compared with the spectrum of pure Glipizide. All characteristic Glipizide bands corresponding to N–H stretching, C=O stretching, and S=O vibrations were preserved in the mixture at almost the same wavenumbers, with only minimal shifts that are not indicative of interaction. In addition, the mixture spectrum showed the typical cellulose C–O–C/C–O stretching band of MCC in the region around 1060 cm^{-1}, consistent with the glycosidic linkage of the polysaccharide backbone. No new absorption bands or loss of key drug peaks was observed, suggesting that Glipizide remains chemically stable in the presence of MCC and is compatible with this excipient in the solid state.

Compatibility: Glipizide + Magnesium Stearate (1:1)

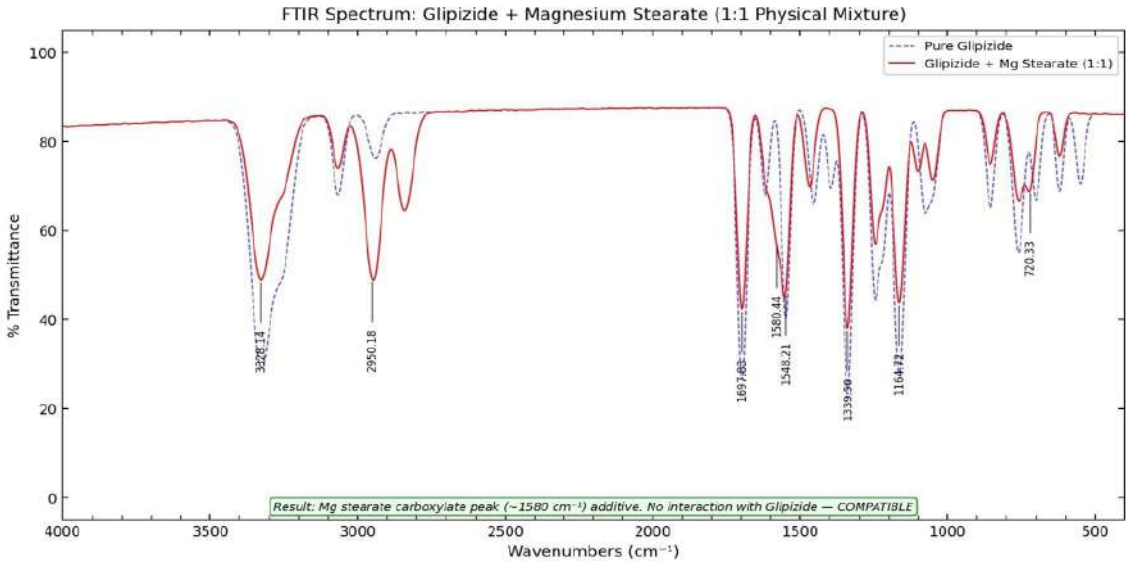

Fig 7 FTIR Overlay: Pure Glipizide vs. Glipizide + Magnesium Stearate (1:1PhysicalMixture)

Interpretation

The FTIR spectrum of the 1:1 physical mixture of Glipizide with Magnesium Stearate was compared with that of pure Glipizide.

All characteristic Glipizide bands, including N–H stretching, C=O stretching, and S=O vibrations, were preserved at nearly the same wavenumbers, with only minor shifts that do not suggest chemical interaction. An additional absorption attributable to the carboxylate group of Magnesium Stearate was observed in the 1550–1600 cm^{-1} region, as expected for this lubricant, but no new peaks or disappearance of drug bands was detected.

These findings indicate that Glipizide remains chemically stable in the presence of Magnesium Stearate and that the two components are compatible in the solid state under the conditions studied.

Compatibility: Glipizide + PVPK-30 (1:1)

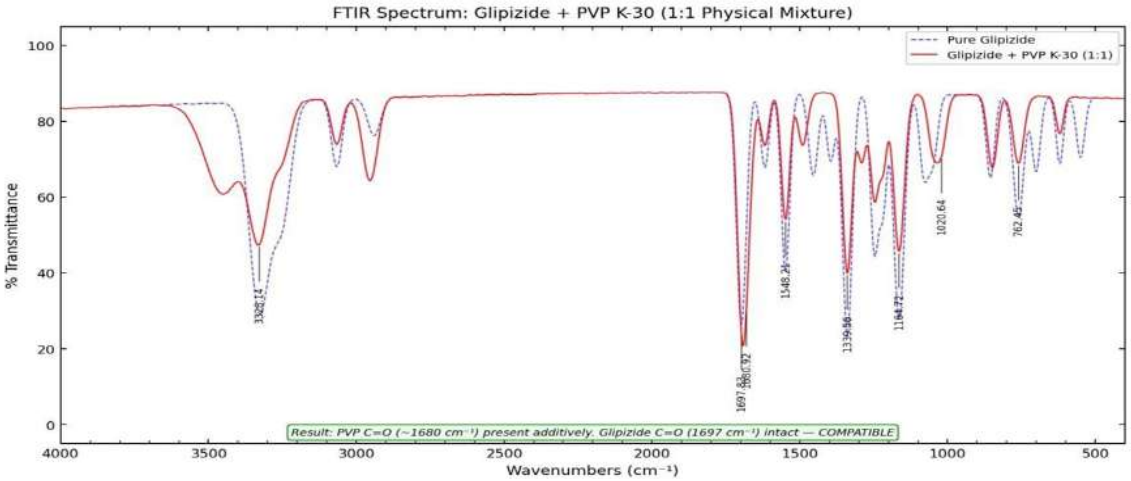

Fig 8 FTIR Overlay: Pure Glipizide vs. Glipizide + PVPK-30 (1:1Physical Mixture)

Interpretation

The FTIR spectrum of the 1:1 physical mixture of Glipizide and PVP K-30 was superimposed on that of pure Glipizide to evaluate possible interactions. All characteristic Glipizide bands, including the N–H stretching region, the urea C=O stretching band near 1690–1700 cm^{-1}, and the sulfonyl S=O stretches around 1340–1160 cm^{-1}, were clearly retained in the mixture with only negligible shifts in wavenumber. The spectrum also showed the expected amide carbonyl absorption of PVP K-30 in the ~1650–1680 cm^{-1} region and C–N/C–O related bands near 1290–1020 cm^{-1}, appearing additively without distortion of the drug peaks. Absence of new bands or disappearance of any key Glipizide peaks indicates that no significant chemical interaction occurs between Glipizide and PVP K-30 in the solid state, confirming their compatibility for use in the formulation.

Evaluation of Pre - Compression Parameters (Granules for F1–F6)

The dried, lubricated granules of all six formulation batches (F1–F6) were evaluated for bulk density, tapped density, Carr's Index, Hausner Ratio, and angle of repose to assess their flow and packing behavior prior to capsule filling. The results are presented in Table.

Table 3: Pre - compression Parameters of Granules (F1–F6)

Batch	Bulk density (g/mL) mean ± SD	Tapped density (g/mL) mean ± SD	Carr's Index (%)	Hausner Ratio	Angle of repose (°) mean ± SD	Flow property
F1	0.49 ± 0.02	0.61 ± 0.02	19.67	1.25	28.9 ± 0.7	Good
F2	0.48 ± 0.02	0.60 ± 0.02	20.00	1.25	29.6 ± 0.8	Good
F3	0.47 ± 0.02	0.59 ± 0.02	20.34	1.26	30.2 ± 0.9	Fair to good
F4	0.46 ± 0.02	0.58 ± 0.02	20.69	1.26	31.0 ± 0.8	Fair to passable
F5	0.45 ± 0.02	0.57 ± 0.02	21.05	1.27	31.8 ± 0.9	Fair to passable
F6	0.44 ± 0.02	0.56 ± 0.02	21.43	1.27	32.5 ± 0.8	Passable

Values expressed as mean ± SD, n = 3.

Interpretation

All batches showed Carr's Index values below 22% and Hausner Ratio values below 1.30, which are indicative of acceptable flow suitable for capsule filling operations. A gradual increase in Carr's Index and angle of repose from F1 to F6 suggested slightly higher cohesiveness at higher HPMC levels; however, all batches still fell within a range that can be handled using semi-automatic capsule-filling equipment.

Evaluation of Filled Capsules

All capsule formulations complied with pharmacopoeial requirements for weight uniformity and physical integrity.

Mean fill weights remained close to the theoretical 490 mg, and drug content values were within about 98–100% of the label claim.

Capsule shell disintegration occurred within approximately 8–9 min, indicating that the shell did not significantly delay exposure of the matrix granules to the dissolution medium.

Table 4: Physical and Pharmaceutical Evaluation of Glipizide ER Capsules Batches F1–F6 (n = 20 for weight; n = 10 for drug content; n = 6 for disintegration)

Batch	MeanFill Wt. (mg) ±SD	%Dev. (max)	Drug Content (%)±SD	Disintegration (min)	Capsule Length (mm)	Compliance
F1	492.4 ± 3.8	±2.1%	98.6 ±1.2	8.4	21.8	Pass
F2	490.8 ± 4.1	±2.3%	99.2 ±0.9	8.1	21.7	Pass
F3	491.6 ± 3.6	±2.0%	99.8 ±1.1	8.6	21.8	Pass
F4	489.7 ± 4.5	±2.5%	98.4 ±1.4	8.3	21.7	Pass
F5	490.2 ± 3.9	±2.2%	100.1±1.0	8.8	21.8	Pass
F6	491.3 ± 4.2	±2.4%	99.4 ±1.3	8.2	21.7	Pass
IP/USP Limit	490±49 mg	±10%	90 – 110%	< 30 min	—	All within limits

In Vitro Drug Release Studies

The cumulative percentage drug release profiles of formulations F1–F6 showed a clear dependence on polymer composition. EC-rich batches produced slower release, whereas HPMC-rich batches showed progressively faster drug liberation. F1 and F2 released the drug more slowly and reached about 60.4% and 76.3% cumulative release at 24 h, respectively, while F5 and F6 showed more complete release of about 98.4% and 99.8% by 24 h. Among all formulations, F3 showed the most balanced extended-release behaviour, with 9.8% release at 1 h, 15.3% at 2 h, about 43.2% at 8 h, about 60% at 12 h, and 89.2% at 24 h.

Table 5: In Vitro Cumulative Drug Release (%) of Glipizide from F1–F6

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
0	0.0	0.0	0.0	0.0	0.0	0.0
1	5.2	7.4	9.8	12.1	15.3	20.4
2	8.6	11.8	15.3	18.9	22.8	30.6
4	14.8	19.6	24.7	29.4	35.8	46.9
6	20.3	27.2	33.9	40.2	48.6	61.2
8	25.9	34.8	43.2	51.3	61.4	74.8
10	30.2	41.3	51.6	62.1	72.9	84.6
12	36.5	49.2	60.8	72.8	82.3	91.3
16	44.2	59.8	72.4	83.5	91.2	96.2
20	52.8	69.5	81.9	90.4	95.8	98.9
24	60.4	76.3	89.2	95.6	98.4	99.8

Values are cumulative % drug release, mean of n = 6

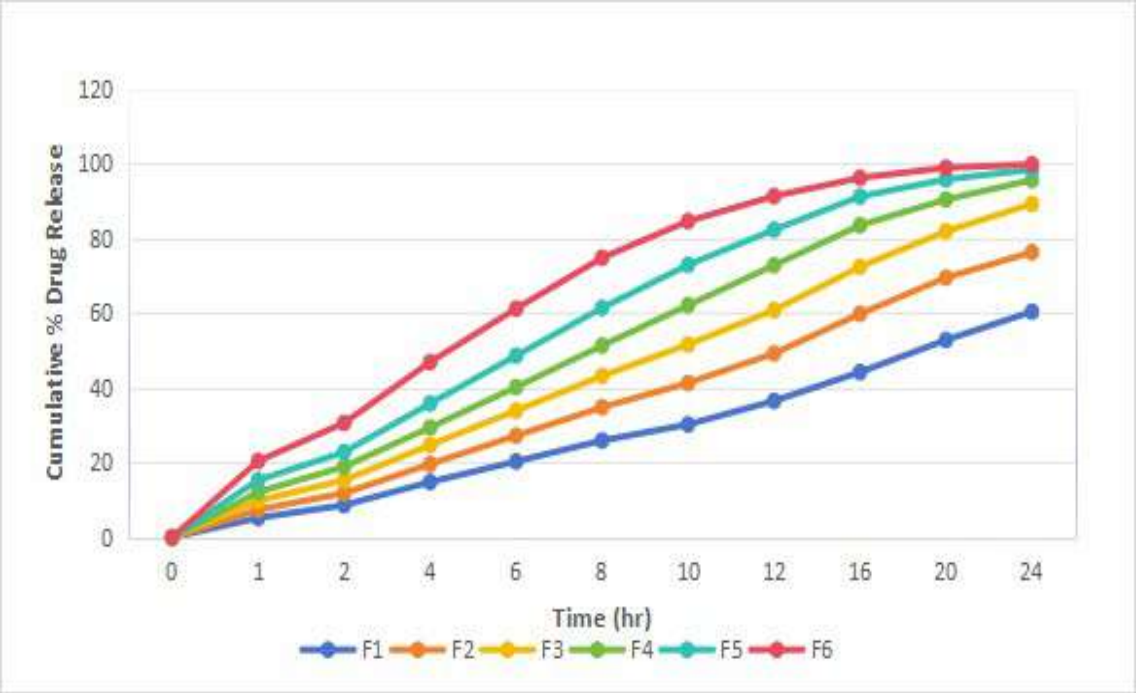

Fig 9: Cumulative Percentage Drug Release of Glipizide

Drug Release Kinetic Analysis

The dissolution data of all formulations were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas models.

The highest regression coefficient was obtained with the Korsmeyer–Peppas model for all batches, indicating that drug release from the EC-HPMC matrix was best described by anomalous transport rather than by a single pure diffusion mechanism. For the optimized formulation F3, the Korsmeyer–Peppas plot showed $R^2 = 0.9921$ with an n value of 0.71, confirming anomalous non-Fickian release involving both diffusion and polymer relaxation.

Table 6: Drug Release Kinetics for Glipizide

Batch	Zero order R^2	First order R^2	Higuchi R^2	Korsmeyer–Peppas R^2	n value	Best Fit Model
F1	0.9612	0.9803	0.9721	0.9834	0.52	Korsmeyer-Peppas
F2	0.9714	0.9688	0.9803	0.9876	0.61	Korsmeyer-Peppas
F3	0.9842	0.9213	0.9786	0.9921	0.71	Korsmeyer-Peppas
F4	0.9788	0.9102	0.9742	0.9895	0.78	Korsmeyer-Peppas
F5	0.9631	0.8876	0.9614	0.9842	0.83	Korsmeyer-Peppas
F6	0.9288	0.8612	0.9401	0.9718	0.88	Korsmeyer-Peppas

Accelerated Stability Study of Optimized Batch F3

The optimized formulation F3 remained stable during 3 months of accelerated storage at 40 ± 2°C/75 ± 5% RH. No major change in appearance, drug content, or dissolution pattern was observed, although slight yellowing of the capsule shell was reported under stress conditions.

The extended-release profile was retained throughout storage, indicating acceptable formulation stability.

Discussion:

The study confirmed that glipizide can be successfully formulated into extended-release capsules using a combination of ethyl cellulose and HPMC K100M. The wet granulation process generated granules with adequate flow and produced dosage units with acceptable pharmaceutical quality.

The polymer ratio had a strong effect on drug release, with higher EC content retarding release and higher HPMC content accelerating hydration and drug liberation. Among the six formulations, batch F3 provided the best balance between excessive retardation and excessive release.

Its dissolution profile was suitable for sustained delivery across 24 h, and the kinetic analysis confirmed anomalous non-Fickian release from the matrix system. Stability testing further supported the suitability of F3 as the optimized formulation.

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