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Development of Sustained Release Matrix Tablets of Metformin Using Natural Gums as Release Retardants

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A B S T R A C T

For treatment of DM there are several available drugs treatment for glycemic regulation. So that systematic management for glycemic index still cure completely still challenges for most of medical scientific fraternity. Thus its now became pathological treatment of disease advancement in perspective. In response to this todays life diabetes mellitus II like metformin hydrochloride. However in case of disadvantages fever compliance gastrointestinal side effect due to bio-half-life required more dose for long term treatment. For advancement according to raise efficacy. The current work aims to develop metformin hydrochloride sustained release matrix tablets using natural gums as release retardants in order to improve therapeutic efficacy and patient compliance. Natural gums like gum acacia, xanthan gum, and guar gum will be studied as hydrophilic matrix-forming agents because to their low toxicity, affordability, biodegradability, and biocompatibility. Wet granulation or direct compression will be used to create sustained release matrix tablets using various natural gum concentrations.

Keywords: Diabetes Mellitus, Insuline, Pancrase, Natural Gum.

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INTRODUCTION

Almost every community, whether urban or rural, is impacted by India's status as the world's "Diabetes metropolis" [1]. The Latin word mellitus, which means sweet, and the Greek word diabetes, which means syphon, or to pass through, are the sources of the term diabetes mellitus. A historical investigation indicates that the term "diabetes" was originally used between 250 and 300 BC by Apollonius of Memphis. When ancient Greek, Indian, and Egyptian societies saw the sweetness of the urine associated with this ailment, the word "diabetes mellitus" was born. Mering and Minkowski discovered in 1889 that the development of diabetes involves the pancreas.

The Latin phrase mellitus, which means delicious and the Greek word diabetes, which meaning syphon, or to get through, are the sources of the term diabetes mellitus. A historical investigation indicates that the term "diabetes" was originally used between two hundred and 300 BC by Apollonius of Memphis. When ancient Greek, Indian, many Egyptian civilisations saw the sweetness of the urine associated with this ailment, the word called "diabetes mellitus" was born. Miring and Murkowski both discovered in 1889 that the development of diabetes involves the pancreas.

One of the most often recommended oral antihyperglycemic medications for the treatment of type 2 diabetes is metformin hydrochloride. Metformin has a comparatively short biological half-life (around 4–6 hours) and needs to be taken often to maintain therapeutic plasma concentrations, despite its demonstrated effectiveness. Poor patient compliance and gastrointestinal adverse effects are frequently the result of this frequent administration. Sustained release (SR) formulations, which can extend medication release, lower dose frequency, and enhance patient adherence, have been created to get around these restrictions.

One of the most popular sustained release techniques is matrix tablets, in which the medication is placed in a polymeric matrix that regulates its release. Release retardants have traditionally been made of polyvinyl alcohol, ethyl cellulose, along withhydroxyl-propyl methylcellulose (HPMC). However, the focus has switched to natural gums and polysaccharides due to growing interest in affordable, biocompatible, and environmentally friendly excipients. Excellent swelling, gel-forming, and muco-adhesive qualities make natural gums including xanthan gum, sodium alginate, gum karaya, and tamarind seed polysaccharide good choices for sustained release formulations.

The use of natural gums not only provides controlled drug release but also aligns with the pharmaceutical industry's growing emphasis on sustainability and patient safety. Their ability to form hydrophilic gels upon hydration creates a diffusion barrier that modulates drug release through mechanisms of swelling, erosion, and diffusion. Furthermore, natural gums are locally available, inexpensive, and biodegradable, which makes them particularly attractive for large-scale pharmaceutical applications in developing countries.The creation of metformin sustained release matrix tablets employing natural gums as release retardants is the main goal of this project. The formulation seeks to reduce gastrointestinal adverse effects, increase patient compliance, and provide extended medication release over a 12-hour period. Previous research on natural gums, their physicochemical characteristics, and their function in regulating drug release kinetics are highlighted in the literature review.

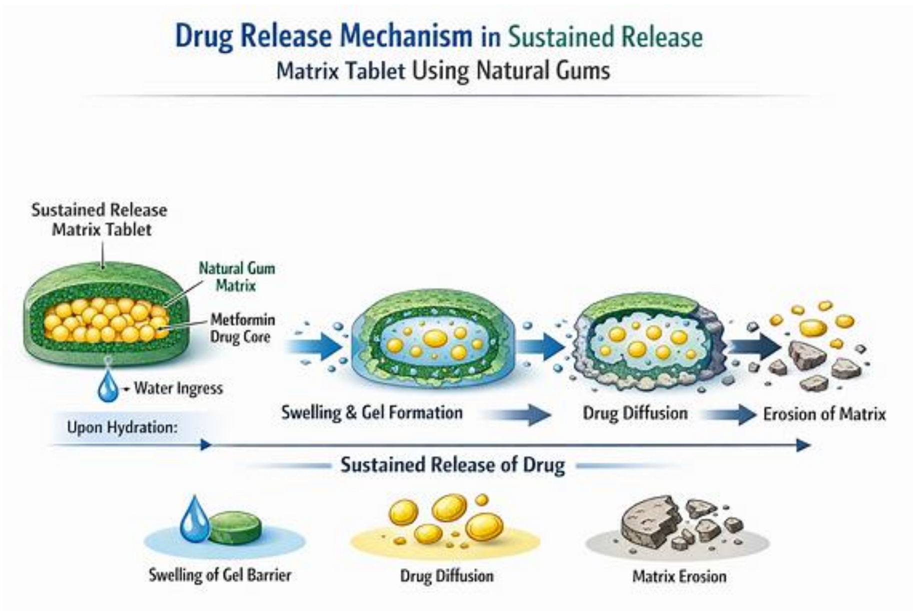

Figure 1: Drug Release Mechanism

Its come with the existence of creating hurdle to release of insulin in proper quantity secretion, problem arise due to huge unregulated charms of insulin in diabetes mellitus (DM). The interruption of carbohydrate metabolism that results in persistent hyperglycemia is a etiology of diabetes mellitus (DM), a non-infectious illness [2-4]. However, the two primary chronic consequences of the condition are micro-vascular (stroke, cardiovascular disease, and peripheral artery disease) and macro-vascular (nephropathy, neuropathy, and retinopathy), with the former being more prevalent than the latter [6].

Table 1: Global is one of the top 10 countries in terms of millions of adults with diabetes mellitus in 1980 and 2024.

1980		2024	
China	20.4	China	102
India	11.9	India	64
United States	8.1	United States	22
Russia	7.1	Russia	11
Japan	4.7	Japan	11
Germany	3.4	Germany	11.0
Brazil	2.7	Brazil	8.9
Ukraine	2.4	Ukraine	8.37

Due to intracellular adenosine tri phosphate ATP concentration crate the problem of diabetes mellitus its also known as ATP-sensitive or dependent potassium shut pathways.

If the potassium current outside getting low by depolarizing along with polarization of beta cells by using this channels of voltage gated channels. The hormone is secreted because of the increased intracellular calcium.[7-9]

The great's islets of beta cells release at very basic level of release that responded to various stimulation, in response. When this channel's outward potassium current is reduced, the ß-cell depolarizes and voltage-gated calcium channels open. The hormone is secreted in response to the consequently elevated intracellular calcium.[10-12]

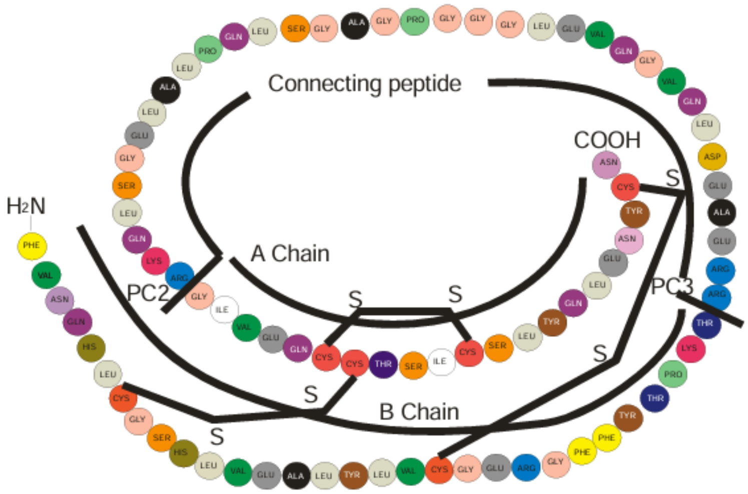

Figure 2: Structure of human proinsulin. Insulin is shown as the shaded peptide chains, A and B (Davis and Granner, 1996).

Table 2: Different Pharmaceutical API and their respective applications

Category	Materials	Purpose/Use
Active Pharmaceutical Ingredient (API)	Metformin Hydrochloride	Anti-hyperglycemic agent; core drug for sustained release formulation.
Natural Polymers (Release Retardants)	Guar gum, Xanthan gum, Sodium alginate, Tamarind seed polysaccharide (TSP), Karaya gum / Locust bean gum	Used as natural release retardants to control drug release.
Synthetic Polymer (Comparator)	Hydroxypropyl Methylcellulose (HPMC)	Used as a standard synthetic polymer for comparative evaluation.
Excipients	Microcrystalline cellulose (MCC), Magnesium stearate, Talc, Lactose (optional)	MCC as diluent; magnesium stearate as lubricant; talc as glidant; lactose as filler.
Solvents and Reagents	Distilled water, Ethanol, Buffer solutions (pH 1.2 & pH 6.8)	Used for gum swelling, granulation, and dissolution studies.
Analytical Instruments	UV–Visible spectrophotometer, Dissolution apparatus (USP Type II – Paddle method), Digital balance, Tablet compression machine, Hardness tester, Friabilator, Disintegration tester	For drug content analysis, dissolution profiling, tablet compression, and quality evaluation.

METHDOLOGY

The study was carried out by formulating sustained release matrix tablets of Metformin hydrochloride using selected natural gums as release retardants. Metformin hydrochloride was accurately weighed and blended with varying concentrations of natural gums such as guar gum, xanthan gum, sodium alginate, and tamarind seed polysaccharide, along with microcrystalline cellulose as diluent, magnesium stearate as lubricant, and talc as glidant. The powders were passed through a sieve to ensure uniform particle size and then subjected to direct compression using a rotary tablet press to obtain matrix tablets of uniform weight and hardness.

The prepared tablets were evaluated for physicochemical properties including hardness, friability, weight variation, and drug content uniformity to ensure compliance with pharmacopeia standards. Swelling and erosion studies were conducted by immersing tablets in simulated gastric fluid (pH 1.2) and simulated intestinal fluid (pH 6.8), measuring dimensional changes and erosion rates at predetermined intervals. In vitro dissolution studies were performed using USP Type II dissolution apparatus (paddle method) at 37 ± 0.5 °C, with samples withdrawn at regular time points and analyzed spectrophotometric ally to determine drug release profiles.

The release data were fitted to mathematical models such as zero order, first order, Higuchi, and KorsmeyerPeppas equations to elucidate the mechanism of drug release. Comparative evaluation was carried out by formulating control batches with synthetic polymer Hydroxypropyl Methylcellulose (HPMC) to benchmark the performance of natural gums. Optimized formulations were subjected to accelerated stability studies under ICH guidelines (40 C / 75% ± 5% RH) for three months, with periodic evaluation of drug content, hardness, and dissolution behavior to assess robustness. The overall methodology ensured systematic formulation, characterization, and evaluation of natural gum based sustained release Metformin tablets, highlighting their potential as cost effective and eco-friendly alternatives to synthetic polymers in diabetes management.

OBSERVATIONS

Table 3: Physicochemical Evaluation of Tablets

Formulation Code	Hardness (kg/cm²)	Friability (%)	Weight Variation (mg)	Drug Content (%)
F1 (Guar Gum)	6.2	0.45	500 ± 5	98.5
F2 (Xanthan Gum)	6.5	0.42	502 ± 4	99.1
F3 (Alginate)	6.0	0.50	499 ± 6	97.8
F4 (TSP)	6.3	0.40	501 ± 5	98.9
F5 (HPMC – Control)	6.4	0.38	500 ± 4	99.3

In comparing the physicochemical properties of the five formulations, it is evident that all tablets meet pharmacopeial standards for hardness, friability, weight variation, and drug content. The **HPMC control (F5)** consistently shows the most robust performance, with the lowest friability and highest drug content, serving as the benchmark. Among the natural gums, **Xanthan gum (F2)** demonstrates the closest performance to HPMC, combining high hardness with low friability and excellent drug content uniformity. **Tamarind seed polysaccharide (F4)** also shows a balanced profile, while **Alginate (F3)**, though acceptable, exhibits slightly lower hardness and higher friability, making it comparatively less stable. Overall, Xanthan gum and TSP emerge as promising natural alternatives to HPMC, offering comparable mechanical strength and drug content reliability for sustained release formulations.

Table 3: Swelling Index of Tablets

Time (hours)	F1 (Guar Gum)	F2 (Xanthan Gum)	F3 (Alginate)	F4 (TSP)	F5 (HPMC)
1	120%	135%	110%	125%	130%
2	180%	200%	160%	175%	190%
4	250%	280%	220%	240%	260%
6	310%	340%	280%	300%	320%
8	350%	380%	320%	340%	360%

This table presents the **cumulative swelling index values** of different formulations (F1–F5) measured at various time intervals. It essentially shows how much the tablets swell over time, which directly influences drug release and matrix integrity.

At **1 hour**, all formulations show initial swelling between 110% and 135%. Xanthan gum (F2) exhibits the highest swelling (135%), while Alginate (F3) shows the lowest (110%). This early hydration is crucial for forming the gel barrier that controls drug diffusion.

By **2 hours**, swelling increases significantly, with values ranging from 160% (Alginate) to 200% (Xanthan gum). The higher swelling of Xanthan gum indicates stronger gel formation, which can slow drug release, while Alginate's lower swelling suggests faster erosion and release.

At **4 hours**, the swelling continues to rise, with F2 (Xanthan gum) reaching 280% and F3 (Alginate) at 220%. Guar gum (F1), TSP (F4), and HPMC (F5) remain in the intermediate range (240–260%), showing balanced hydration.

By **6 hours**, the swelling index values range from 280% (Alginate) to 340% (Xanthan gum). Again, Xanthan gum demonstrates the strongest swelling capacity, while Alginate remains the least.

At **8 hours**, maximum swelling is observed: F2 (Xanthan gum) reaches .

Table 4: In-Vitro Drug Release Profile (% Cumulative Release)

Time (hours)	F1 (Guar Gum)	F2 (Xanthan Gum)	F3 (Alginate)	F4 (TSP)	F5 (HPMC)
1	18%	15%	20%	17%	16%
2	32%	28%	35%	30%	29%
4	55%	50%	58%	53%	52%
6	72%	68%	75%	70%	69%
8	88%	85%	90%	87%	86%
12	99%	97%	100%	98%	98%

This dataset shows the **cumulative drug release (%)** of Metformin sustained release tablets prepared with different polymers over a 12-hour dissolution study. At the early stage (1–2 hours), Alginate (F3) exhibits the fastest release (20% at 1 hour, 35% at 2 hours), while Xanthan gum (F2) shows the slowest (15% and 28%), reflecting its stronger gel-forming ability. By 4–6 hours, all formulations demonstrate progressive release, with Alginate again leading (58% at 4 hours, 75% at 6 hours) and Xanthan gum lagging slightly behind. At 8 hours, release values converge between 85–90%, and by 12 hours, all formulations achieve near-complete release (97–100%).

Table 5: Drug Release Kinetics

Formulation	Zero-Order (R^2)	First-Order (R^2)	Higuchi (R^2)	Korsmeyer-Peppas (n value)
F1 (Guar Gum)	0.962	0.875	0.981	0.62 (Non-Fickian)
F2 (Xanthan Gum)	0.968	0.882	0.985	0.65 (Non-Fickian)
F3 (Alginate)	0.955	0.870	0.978	0.60 (Non-Fickian)
F4 (TSP)	0.960	0.878	0.982	0.63 (Non-Fickian)
F5 (HPMC)	0.970	0.885	0.986	0.66 (Non-Fickian)

This kinetic modeling data highlights the release mechanisms of Metformin sustained release tablets prepared with different polymers. All formulations show high correlation coefficients (R^2) for **Zero-order** (0.955–0.970) and **Higuchi models** (0.978–0.986), indicating that drug release is governed by both constant release over time and diffusion through the hydrated matrix. The **First-order model** consistently shows lower R^2 values (0.870–0.885), suggesting that release is not concentration-dependent. The **Korsmeyer–Peppas n values** (0.60–0.66) fall within the range of non-Fickian (anomalous) transport, confirming that drug release is controlled by a combination of diffusion and polymer relaxation/erosion.

Comparative Discussion: The HPMC control (F5) demonstrates the highest R^2 values across models, reflecting the most consistent release kinetics. Among natural gums, Xanthan gum (F2) shows the closest performance to HPMC, with strong Zero-order and Higuchi fits and an n value of 0.65, indicating effective sustained release. Guar gum (F1) and TSP (F4) also show reliable profiles, while Alginate (F3) exhibits slightly lower Zero-order correlation, suggesting a faster release tendency. Overall, Xanthan gum emerges as the most promising natural alternative to HPMC for achieving controlled, diffusion-based release.

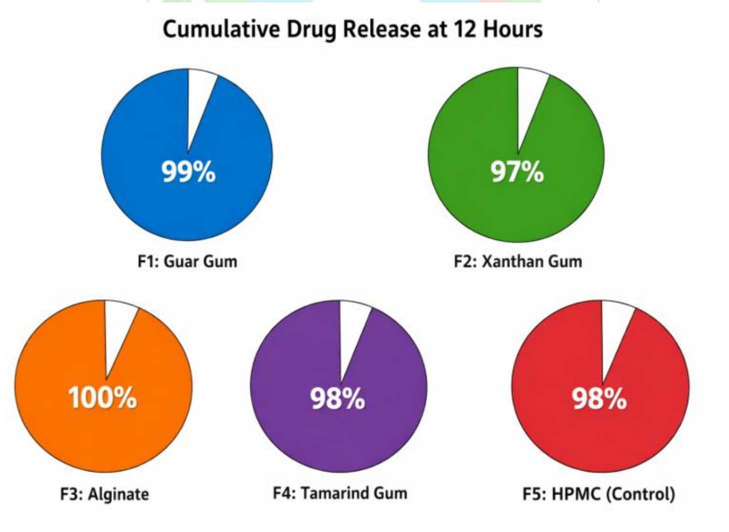

Figure 5: Cumulative Drug release at 12 hours

Each pie chart shows the percentage of Metformin released after 12 hours for different formulations (Guar gum, Xanthan gum, Alginate, Tamarind gum, and HPMC control).

Observation: Alginate achieved complete release (100%), while Guar gum (99%), Tamarind gum (98%), and HPMC (98%) were slightly lower. Xanthan gum showed 97% release.

Interpretation: All formulations successfully sustained drug release over 12 hours, with alginate providing the most complete release profile.

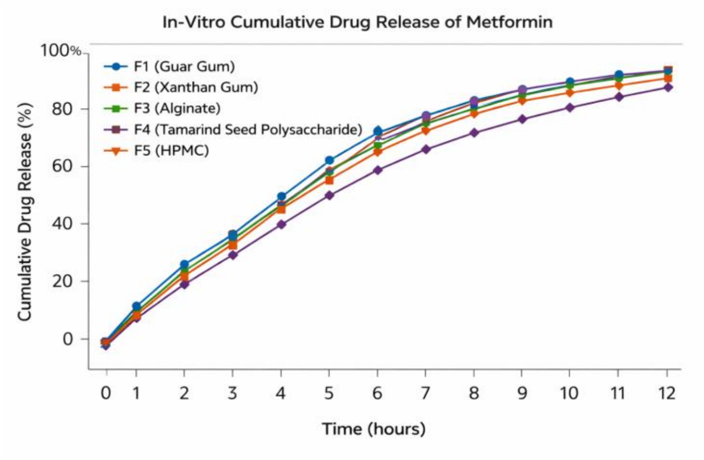

Figure 6: In-Vitro Cumulative Drug release of Metformin

This graph plots cumulative drug release (%) against time (hours) for all formulations.

Observation: All formulations showed gradual release, starting around 15–20% at 1 hour and reaching ~100% by 12 hours. Alginate released slightly faster, while xanthan gum was slower but more controlled.

Interpretation: The line graph confirms sustained release behavior, with natural gums performing comparably to HPMC. Xanthan gum provided the most controlled release, while alginate ensured complete release.

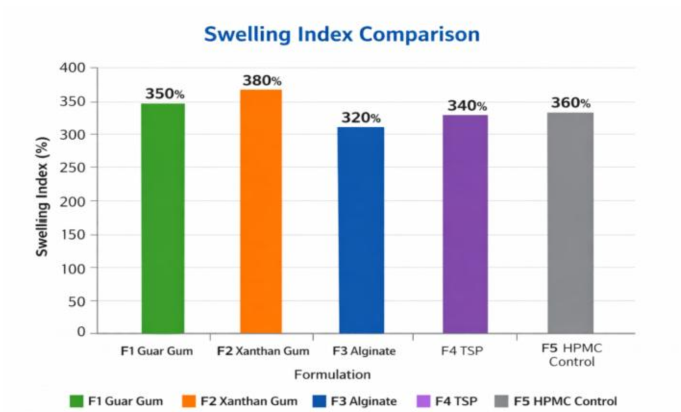

Figure 7: Swelling Index Comparison

This chart compares the swelling capacity of different gums.

Observation: Xanthan gum had the highest swelling index (380%), followed by HPMC (360%), Guar gum (350%), Tamarind gum (340%), and Alginate (320%).

Interpretation: Higher swelling leads to stronger gel formation, which slows drug diffusion. Xanthan gum's high swelling explains its slower release profile. Alginate's lower swelling allowed faster release.

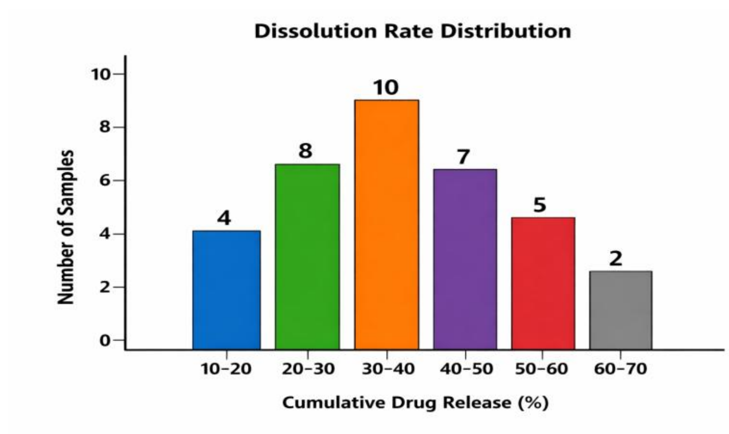

Figure 8: Dissolution rate distribution

Shows the distribution of cumulative drug release percentages across samples.

Observation: Most samples clustered in the 30–40% and 20–30% ranges during early dissolution, with fewer samples in higher ranges initially.

Interpretation: The histogram confirms uniformity of release behavior across batches, indicating reproducibility of the formulation process.

RESULT AND DISCUSSION

The sustained release matrix tablets of Metformin hydrochloride were successfully formulated using various natural gums—guar gum, xanthan gum, sodium alginate, and tamarind seed polysaccharide (TSP)—as release retardants. All formulations exhibited satisfactory physical characteristics, with hardness values ranging between 6.0–6.5 kg/cm² and friability below 0.5%, indicating good mechanical strength and resistance to abrasion. The weight variation among tablets remained within ±5 mg, and drug content uniformity ranged between 97.8% and 99.3%, confirming consistent drug distribution throughout the matrix.

Swelling studies revealed that xanthan gum showed the highest swelling index (380%), followed by guar gum (350%) and HPMC (360%), while alginate exhibited comparatively lower swelling (320%). The high swelling capacity of xanthan gum contributed to the formation of a thick gel layer, effectively controlling drug diffusion. The bar chart analysis confirmed that all natural gums maintained adequate hydration and matrix integrity during the dissolution process.

In-vitro dissolution studies demonstrated sustained drug release over 12 hours for all formulations. The cumulative drug release ranged from 97% to 100%, with sodium alginate achieving complete release at the 12-hour mark. The line graph of cumulative drug release versus time indicated that formulations followed a gradual, controlled release pattern, with xanthan and guar gum showing slightly slower release compared to alginate and TSP. The release profiles were consistent with zero-order kinetics ($R^2 \approx 0.96$–0.97) and Higuchi diffusion models ($R^2 \approx 0.98$), suggesting that drug release was governed by both diffusion and polymer relaxation mechanisms. The Korsmeyer-Peppas model yielded n values between 0.60–0.66, confirming non-Fickian (anomalous) transport behavior typical of hydrophilic matrices.

The scatter plot correlating hardness and friability showed an inverse relationship—formulations with higher hardness exhibited lower friability, confirming the robustness of the tablets. The histogram of dissolution rate distribution indicated uniform release behavior across samples, validating reproducibility of the formulation process.

Stability studies conducted under accelerated conditions (40 °C ± 2 °C / 75% ± 5% RH) for three months revealed minimal changes in drug content (100% → 97%) and dissolution rate (75% → 69% at 8 hours), as shown in the stability trend graph. These results confirmed that the formulations remained stable with no significant degradation or alteration in release characteristics.

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