ISSN 2582-6441 [Online]
RESEARCH JOURNAL OF PHARMACY AND LIFE SCIENCES
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An International Peer Reviewed Journal
RJPLS

**Research Article**

# Neem Gum as a Sustainable Natural Binder for Zidovudine Sustained Release Tablets: A Comparative Evaluation with Synthetic Polymer PVP-K30

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**ARTICLE INFO**
Date of submission: 23-09-2025
Date of Revision: 19-10-2025
Date of acceptance: 12-11-2025
**Key Words:**
Natural binder, Sustained release, Zidovudine, Neem gum, PVP K30, Drug release kinetics

**ABSTRACT**
This research explores the formulation and evaluation of Zidovudine sustained release (SR) tablets using neem (*Azadirachta indica*) gum and compares its performance with a commonly used synthetic binder, polyvinylpyrrolidone (PVP K30). Zidovudine, an antiretroviral drug with a short half-life, requires frequent dosing, which may be reduced with sustained release systems. Neem gum, a natural biopolymer, was investigated as an eco-friendly and cost-effective binder alternative. Tablets were prepared using wet granulation with varying concentrations (2%, 4%, 6%, and 8% w/w) of both neem gum (Formulations F1–F4) and PVP K30 (Formulations F5–F8). All batches were evaluated for pre-compression and post-compression parameters, in vitro drug release, and release kinetics. Both binders produced pharmaceutically acceptable tablets; however, the formulation with 6% neem gum (F3) showed comparable sustained release over 12 hours to its PVP counterpart (F7). Drug release from neem gum followed Higuchi and Korsmeyer-Peppas models, indicating a diffusion-controlled mechanism. This study concludes that neem gum can effectively replace synthetic binders like PVP K30 in SR formulations, offering environmental and economic advantages.



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## INTRODUCTION

Human Immunodeficiency Virus (HIV) infection remains a persistent global health challenge despite substantial advances in antiretroviral therapy (ART). Effective ART demands sustained therapeutic plasma concentrations to prevent viral replication, resistance development, and progression to Acquired Immunodeficiency Syndrome (AIDS) [1, 2]. Zidovudine (AZT), a cornerstone nucleoside reverse transcriptase inhibitor, has been widely used for decades in combination regimens due to its proven efficacy, predictable safety profile, and ability to suppress HIV replication. However, its rapid elimination (short half-life) necessitates frequent dosing, which can lead to fluctuating blood levels, increased side effects, and decreased patient compliance—particularly in chronic HIV management [3].

The development of sustained release (SR) oral dosage forms aims to deliver drugs at a controlled rate over extended periods, offering multiple therapeutic benefits, including improved pharmacokinetic profiles, reduced dosing frequency, enhanced patient adherence, and minimized adverse events [4,5]. SR dosage forms strategically modulate drug release via mechanisms such as diffusion, swelling, and erosion of polymeric matrices, thereby achieving more stable plasma concentrations over 8–24 hours.[2]

The choice of polymeric excipients profoundly influences SR tablet performance. Synthetic binders and matrix formers such as Polyvinylpyrrolidone (PVP), Hydroxypropyl Methylcellulose (HPMC), and Eudragit derivatives have long been established in sustained release tablets due to their reproducible physical properties and robust control over release kinetics [6]. However, increasing regulatory emphasis on biocompatibility, environmental sustainability, and green manufacturing has triggered a shift toward natural and plant-derived polymers [7, 8].

Natural gums and mucilages are renewable, biodegradable, and often non-toxic, offering functional properties—such as swelling capacity, gel formation, and viscosity enhancement—ideal for controlled delivery systems. Excipients like guar gum, xanthan gum, pectin, and locust bean gum have demonstrated efficacy in modulating drug release profiles in sustained release formulations.[4] Contemporary research underscores that natural polymers can serve as effective matrix formers, binders, and release modifiers while fulfilling eco-friendly and cost-effective requirements absent in many synthetic counterparts [11].

Despite this growing trend, data comparing novel natural polymers with conventional synthetic binders for specific drug candidates remain relatively scarce. Among

potential candidates, neem gum- a plant derived polysaccharide from *Azadirachta indica,* exhibits promising physicochemical properties (e.g., high swelling index, hydrophilicity, and film-forming ability) that could favour sustained drug release. While widely recognized for its antimicrobial and therapeutic bioactivities, scientific evaluation of neem gum as a pharmaceutical binder and matrix former is limited, presenting a significant research opportunity to establish its systematic utility in SR formulations.

This study addresses this gap by exploring neem gum as a functional binder/matrix for sustained release Zidovudine tablets and comparing its performance with the widely accepted synthetic binder PVP K30. Understanding the interplay between binder type, binder concentration, granule characteristics, mechanical integrity, and drug release kinetics is essential for robust SR design and formulation optimization. The study further aims to elucidate mechanistic aspects of drug release modulation via natural versus synthetic excipients, supported by physicochemical evaluations, dissolution profiling, and kinetic analysis.

By integrating neem gum into Zidovudine matrix tablets, this work contributes to the emerging body of knowledge on sustainable excipient development, aligns with green pharmaceutical manufacturing trends, and reinforces the clinical relevance of tailored SR drug delivery systems for chronic disease management [11, 13].

## MATERIALS AND METHODS

Zidovudine (AZT) was procured from a certified pharmaceutical supplier (specify source). Neem gum was collected from authenticated *Azadirachta indica* trees. All analytical reagents, including ethanol, distilled water, and solvents, were of analytical grade and used without further purification unless otherwise stated.

## EXTRACTION AND PREPARATION OF NEEM GUM

Neem gum was obtained from the natural exudates of *Azadirachta indica* trees and processed using a previously reported purification protocol [12, 13], involving aqueous extraction and ethanol precipitation with slight modifications, designed to remove extraneous matter, reduce microbial load, and ensure suitability for pharmaceutical application. Following step by step procedure was followed for obtaining purified Neem gum for further use.

### Step-by-Step Procedure

i. **Collection and Pre-Processing:** Fresh neem gum exudates were collected early in the morning from the bark of *Azadirachta indica* and transferred to sterile containers to minimize contamination and maintain biochemical integrity. Visible debris

and foreign materials were manually removed before further processing.

ii. **Cleaning and Drying:** The crude gum was washed with distilled water to eliminate dust and inorganic impurities and then dried in a hot air oven at 40–45 °C for 24 hours to reduce moisture content below 10%, preventing degradation of polysaccharide components.

iii. **Particle Size Reduction:** The dried gum pieces were coarsely ground using a stainless-steel grinder operated at low speed to avoid heat generation, thereby increasing surface area for efficient extraction.

iv. **Aqueous Extraction:** The powdered gum was dispersed in distilled water in a 1:10 (w/v) ratio and stirred for 6 hours at room temperature using a magnetic stirrer. The dispersion was then allowed to hydrate overnight to ensure complete solubilization of gum polysaccharides.

v. **Filtration and Clarification:** The hydrated mixture was filtered through multiple layers of muslin cloth to remove insoluble materials and then centrifuged at 3000 rpm for 10 minutes to obtain a clear polymer solution.

vi. **Precipitation and Washing:** The clarified filtrate was slowly added to excess cold absolute ethanol (**3:1 v/v**) under continuous stirring to precipitate the gum polymer. The precipitate was collected and repeatedly washed with ethanol to remove pigments and low-molecular-weight impurities.

vii. **Final Drying:** The purified gum precipitate was dried in a hot air oven at 40 °C until constant weight was obtained to preserve the functional properties of the polymer.

viii. **Size Standardization:** The dried material was passed through a #60 mesh sieve to obtain uniform particle size suitable for pharmaceutical formulation processes such as granulation and tablet preparation.

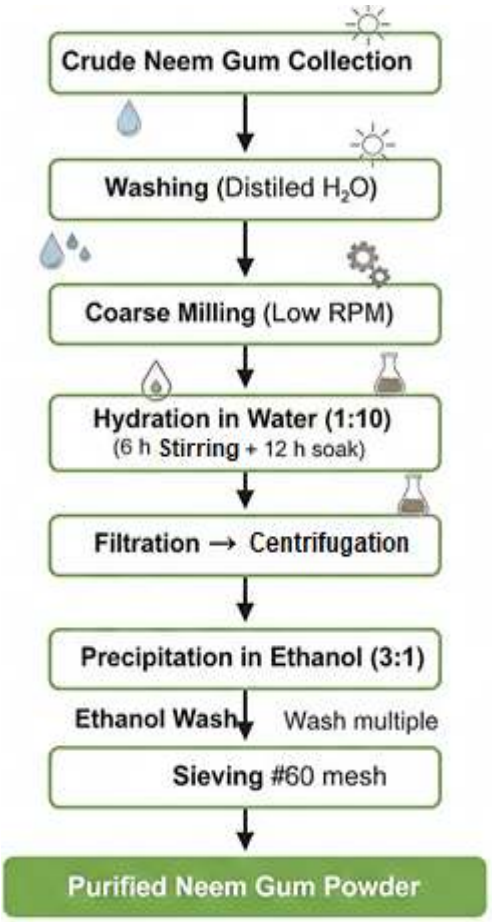



**Figure 1: Scheme for obtaining purified neem gum**

**Preliminary Characterization of Neem Gum [16, 17].**

Preliminary characterization of neem gum was performed to evaluate its suitability as a pharmaceutical binder and matrix former. Organoleptic properties were assessed visually, while the pH of a 1% solution was measured for compatibility with drug stability. Moisture content (USP- Loss on Drying) was determined to measure drying efficiency, and the swelling index (USP) for its hydrophilicity. Viscosity, measured using a Brookfield viscometer, to assess binder strength. Total ash content (USP) was estimated for presence of inorganic impurities, and water solubility was determined gravimetrically. FT-IR analysis was performed for confirmation of functional groups, and thermogravimetric analysis (TGA) was assessed for thermal stability.

**Table 1: Pharmaceutical Characteristics studied for Neem Gum**

| Test | Purpose | Method/Standard |
|---|---|---|
| **Organoleptic Properties** | Preliminary quality check | Visual and tactile assessment |
| **pH of 1% Solution** | Evaluate effect on drug stability | pH meter |
| **Moisture Content (LOD)** | Assess drying efficiency | Loss on Drying, USP |
| **Swelling Index** | Indicator of hydrophilicity | USP Methods |
| **Viscosity Measurement** | Binder strength predictor | Brookfield viscometer |
| **Total Ash** | Inorganic contamination level | USP Ash Test |
| **Water Solubility** | Functional performance predictor | Gravimetric |
| **FT-IR Spectroscopy** | Functional group integrity | FT-IR analysis |
| **Thermogravimetric Analysis (TGA)** | Thermal stability | TGA |

**Calibration Curve of Zidovudine (pH 6.8 Buffer)**

A stock solution of Zidovudine (100 µg/mL) was prepared in phosphate buffer (pH 6.8). From this, serial dilutions were made to obtain concentrations of 2, 4, 6, 8, 10, and 12 µg/mL**.** The absorbance of each solution was measured at 266 nm using a UV–Visible spectrophotometer, with phosphate buffer as blank.

**FORMULATION OF ZIDOVUDINE SUSTAINED RELEASE TABLETS**

Sustained release (SR) tablets of Zidovudine were prepared by the wet granulation method using neem gum (F1–F4) as a natural binder and PVP K30 (F5–F8) as a synthetic binder. Zidovudine and microcrystalline cellulose were passed through a #60 mesh sieve and blended uniformly. The binder solution was

prepared in purified water and added gradually to the powder blend to form a cohesive wet mass. The wet mass was passed through a #16 mesh sieve to obtain granules and dried in a hot air oven at 40–45 °C. Dried granules were resized through a #20 mesh sieve, lubricated with talc and magnesium stearate, and finally compressed using a multi-station rotary die press (Karnavati Minipress) tablet compression machine to obtain tablets of 400 mg weight [15,18].

**Table 2: Formulation Composition of Zidovudine Sustained Release Tablets**

| Ingredients (in mg) | F1 (2%) | F2 (4%) | F3 (6%) | F4 (8%) | F5 (2%) | F6 (4%) | F7 (6%) | F8 (8%) |
|---|---|---|---|---|---|---|---|---|
| Zidovudine | 300 | 300 | 300 | 300 | 300 | 300 | 300 | 300 |
| Neem Gum | 8 | 16 | 24 | 32 | – | – | – | – |
| PVP K30 | – | – | – | – | 8 | 16 | 24 | 32 |
| MCC | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Lactose q.s. | q.s. | q.s. | q.s. | q.s. | q.s. | q.s. | q.s. | q.s. |
| Talc | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Stearate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Total Weight** | 400 | 400 | 400 | 400 | 400 | 400 | 400 | 400 |

## EVALUATION OF ZIDOVUDINE SUSTAINED RELEASE TABLETS

### Pre-Compression Parameters

Evaluation of pre-compression parameters was performed to assess the flow and compressibility characteristics of the prepared granules prior to tablet compression. Key parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were determined for all formulations [19].

### Post-Compression Parameters

Post-compression evaluation was carried out to ensure the quality, uniformity, and mechanical integrity of the prepared tablets. Parameters such as weight variation, hardness, thickness, friability, and drug content were assessed for all formulations [14, 15].

### *In Vitro* Dissolution Study of Zidovudine Sustained Release Tablets

Dissolution testing was performed using a USP Type II Dissolution Apparatus (Paddle) with 900 mL phosphate buffer (pH 6.8) at 37 ± 0.5°C and 50 rpm [20]. One tablet was placed in each vessel, and 5 mL samples were withdrawn at 1, 2, 4, 6, 8, 10, and 12 hours, replacing with fresh medium

to maintain sink conditions. Samples were filtered, diluted if necessary, and analyzed by UV spectrophotometry at 266 nm.

## RESULTS AND DISCUSSION

### Physicochemical Characterization of Neem Gum

The purified neem gum was subjected to comprehensive physicochemical evaluation to establish its suitability as a pharmaceutical excipient for sustained release matrix systems.

### Organoleptic and Basic Properties

The gum appeared as an off-white, odourless powder with a slightly mucilaginous taste, indicating polysaccharide-rich composition typical of plant-derived hydrophilic polymers.

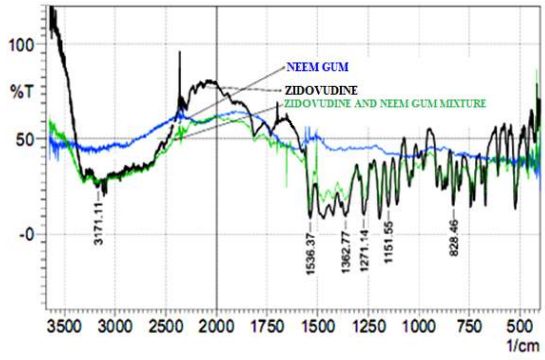
**Table 3. Physicochemical Properties of Purified Neem Gum**

| Parameter | Result | Significance |
|---|---|---|
| Appearance | Off-white powder | Indicates adequate purification |
| pH (1% w/v) | 6.4 ± 0.2 | Near-neutral; compatible with most APIs |
| Moisture Content | 7.1 ± 0.4% | Within acceptable pharmacopeial limits |
| Swelling Index | 185 ± 6% | Suggests strong hydration capacity |
| Viscosity (1% solution) | 312 ± 8 cps | Predictive of binder strength |
| Total Ash | 2.3 ± 0.3% | Low inorganic contamination |
| Solubility | Dispersible in water | Favourable for matrix formation |

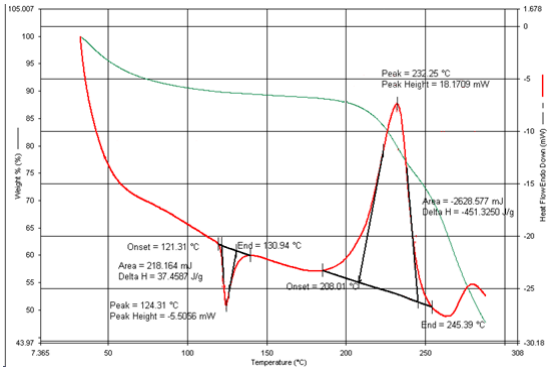
The high swelling index confirms the gum's ability to form a hydrated gel barrier, a fundamental requirement for diffusion-controlled drug release. Near-neutral pH reduces the risk of drug degradation and gastrointestinal irritation. Moisture content below 10% supports polymer stability and prevents microbial growth [16]. Collectively, these findings suggest that neem gum possesses the physicochemical attributes necessary to function as both a binder and release-retarding polymer.

**Structural and Thermal Analysis:** FT-IR analysis of neem gum revealed characteristic polysaccharide peaks, including a broad band at ~3400 $cm^{-1}$ (O–H stretching), a peak near ~2920 $cm^{-1}$ (C–H stretching), a strong band at ~1600 $cm^{-1}$ (bound water/carboxyl groups), and a region between 1000–1200 $cm^{-1}$ corresponding to C–O–C glycosidic linkages, confirming its polymeric carbohydrate structure responsible for hydration and gel formation. Thermogravimetric analysis (TGA) showed a two-stage weight loss pattern, with initial moisture evaporation occurring between 50–120°C followed by polymer

decomposition above 250°C, indicating adequate thermal stability for conventional processing methods such as wet granulation and compression. SEM analysis revealed irregular, porous particles, which facilitate water penetration and promote controlled swelling and drug release behaviour.




**(A)**




**(B)**

**Figure 2. Characterization of Neem Gum and its compatibility study with Zidovudine (A) FTIR peaks and (B) DSC thermogram)**

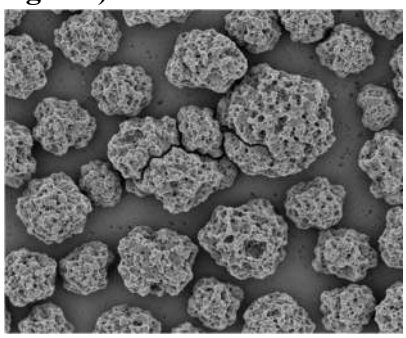


**Figure 3. Scanning Electron Micrograph of purified Neem Gum**

**Calibration Curve of Zidovudine**

The overlay UV spectra of Zidovudine (Figure 2) in phosphate buffer (pH 6.8) exhibited a common absorption maximum at 266 nm for all concentrations, with increasing absorbance proportional to concentration. The calibration curve showed good linearity in the range of 2–10 µg/mL with a regression equation: $y = 0.050x + 0.002$ and $R^2 = 0.999$. The absence of spectral shift in the overlay spectra confirms the stability of the drug and adherence to Beer–Lambert law [21].

**Table 4: Observed Data for Calibration Curve of Zidovudine in Phosphate Buffer (pH 6.8)**

| Concentration (µg/mL) | Absorbance at 266 nm |
|---|---|
| 2 | 0.102 |
| 4 | 0.198 |
| 6 | 0.301 |
| 8 | 0.402 |
| 10 | 0.505 |

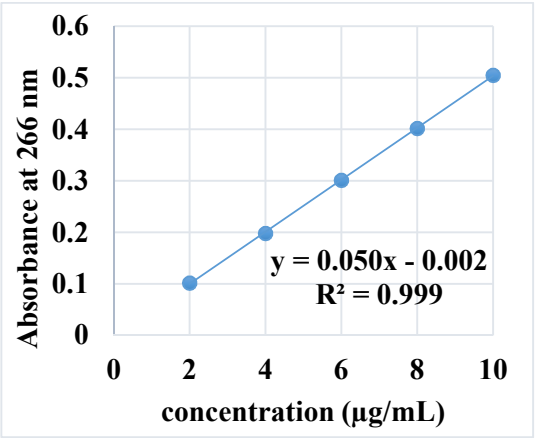



**Figure 4: Calibration Curve of Zidovudine in Phosphate Buffer (pH 6.8)**

**Pre-Compression Evaluation;** Granule flow properties directly influence tablet uniformity and manufacturing reproducibility.

**Table 5: Pre-Compression Parameters**

| Formulation | Angle of Repose (ø) | Carr's Index (%) | Hausner Ratio |
|---|---|---|---|
| F1 | 27.4 ± 0.6 | 13.2 | 1.15 |
| F2 | 26.8 ± 0.4 | 12.7 | 1.14 |
| F3 | 25.9 ± 0.5 | 11.8 | 1.13 |
| F4 | 28.1 ± 0.7 | 14.1 | 1.16 |
| F5 | 26.5 ± 0.6 | 12.5 | 1.14 |
| F6 | 27.2 ± 0.5 | 13.4 | 1.15 |
| F7 | 25.6 ± 0.4 | 11.6 | 1.12 |
| F8 | 28.4 ± 0.8 | 14.6 | 1.17 |

The results indicated that all batches exhibited good to excellent flow properties, with angle of repose values below 30° and Carr's index values less than 15%, confirming adequate flowability and compressibility. These findings suggest that the granules were suitable for uniform die filling and consistent tablet production without flow-related issues.

**Post-Compression Evaluation**

All tablets complied with pharmacopeial limits for mechanical strength and friability (<1%). Increasing binder concentration improved hardness due to enhanced intergranular cohesion.

Neem gum demonstrated binding efficiency comparable to PVP K30, reinforcing its potential as a natural substitute. Drug content was found to be within 97.2–101.3%, confirming uniform drug distribution. Overall, the tablets demonstrated satisfactory post-compression characteristics suitable for sustained release formulation (Table 6).

**Table 6: Post-Compression Characteristics**

| Formulation | Hardness (kg/cm²) | Friability (%) | Drug Content (%) |
|---|---|---|---|
| F1 | 5.1 ± 0.2 | 0.88 | 98.4 |
| F2 | 5.3 ± 0.3 | 0.81 | 99.1 |
| F3 | 5.5 ± 0.2 | 0.72 | 99.8 |
| F4 | 5.7 ± 0.4 | 0.69 | 98.9 |
| F5 | 5.2 ± 0.2 | 0.85 | 98.6 |
| F6 | 5.4 ± 0.3 | 0.79 | 99.3 |
| F7 | 5.6 ± 0.2 | 0.70 | 99.5 |
| F8 | 5.8 ± 0.3 | 0.68 | 98.7 |

**In-Vitro Drug Release Study**

Cumulative drug release was calculated and plotted. Lower binder concentrations showed faster release, higher concentrations retarded release, while 6% binder formulations (F3, F7) exhibited optimal sustained release up to 12 hours.

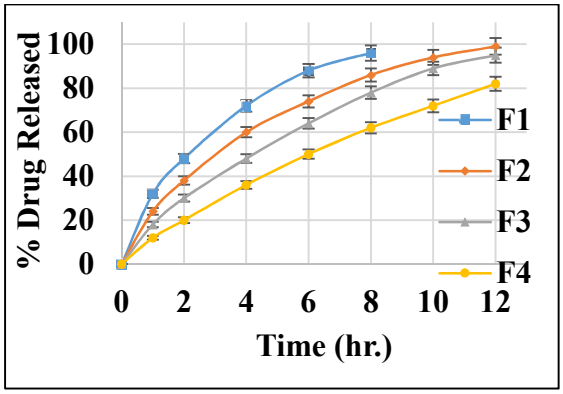



**Figure 5: Dissolution profiles demonstrating comparable sustained release behaviour between different concentration (%) of neem gum (F1 to F4) matrices.**

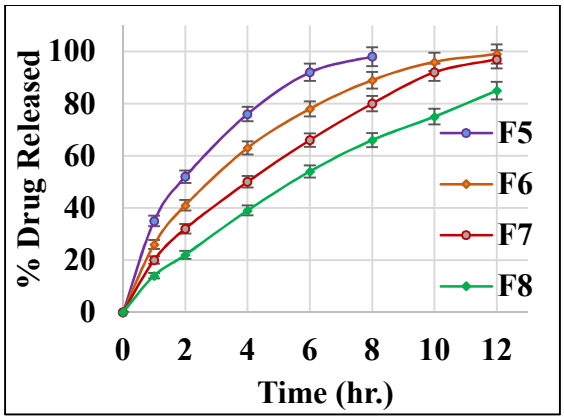



**Figure 6: Dissolution profiles demonstrating comparable sustained release behaviour between different concentration (%) of PVP K30 (F5 to F8) matrices.**

**Release Behaviour Interpretation:**

Lower binder concentrations resulted in rapid drug release due to the formation of weaker matrices, whereas higher concentrations (8%) caused excessive retardation owing to dense gel formation. An optimal balance was observed at 6% binder concentration, which provided adequate matrix integrity while maintaining a suitable diffusion path for controlled drug release. Additionally, neem gum formulations exhibited slightly slower initial drug release, indicating stronger gel barrier formation, a beneficial property for minimizing the risk of dose dumping (Figure 5 and 6).

**Drug Release Kinetics**

**Table 7: Release Model Fitting**

| Model | F3 (Neem Gum) | F7 (PVP K30) |
|---|---|---|
| Zero Order ($R^2$) | 0.918 | 0.924 |
| First Order ($R^2$) | 0.903 | 0.909 |
| Higuchi ($R^2$) | **0.9 87** | **0.989** |
| Peppas (n) | 0.65 | 0.62 |

The highest correlation with the Higuchi model confirms diffusion-controlled release. Peppas exponent ($0.5 < n < 0.89$) indicates anomalous transport, where both diffusion and polymer relaxation govern release (Table 7). This behaviour is typical

of hydrophilic matrices that swell upon hydration [23, 24].

## CONCLUSION

This study successfully establishes neem gum as a functional, sustainable, and pharmaceutically robust natural binder for sustained release Zidovudine tablets. The polymer demonstrated excellent swelling behaviour, favourable mechanical strength, and controlled drug release kinetics comparable to the synthetic binder PVP K30 [25, 26].

The optimized formulation achieved diffusion-governed release over 12 hours, highlighting neem gum's ability to form an effective hydrophilic matrix capable of modulating drug transport while preserving tablet integrity.

Beyond formulation performance, the adoption of neem gum aligns with the broader shift toward environmentally responsible pharmaceutical manufacturing. Its biodegradability, renewability, and cost advantages position it as a promising candidate for next-generation excipient design. Collectively, these findings support the growing paradigm that natural polymers can transition from supportive roles to primary functional excipients in controlled drug delivery systems. Neem gum therefore represents a compelling alternative to synthetic binders, with significant implications for sustainable pharmaceutics and patient-centric dosage form development. Further in vivo evaluation and long-term stability studies are warranted to translate these findings into clinically viable sustained release products.

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