African Journal of Pharmaceutical Research and Development
Available online at https://ajopred.com
Vol. 18 No.1; pp. 562-570 (2026)

Original Research Article

INFLUENCE OF SODIUM ALGINATE AND CARBOPOL ON THE RELEASE PROFILE OF ISONIAZID SUSTAINED RELEASE MATRIX TABLETS: A KINETIC AND MECHANISTIC EVALUATION

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ABSTRACT

Matrix systems remain one of the most popular oral controlled drug delivery technologies owing to their simplicity, cost-effectiveness, ease of manufacturing, and excellent reproducibility. This study sought to investigate the influence of polymer type and concentration on the release behavior of isoniazid from hydrophilic matrix tablets and to elucidate the underlying mechanisms of drug release using kinetic modeling. Sustained release isoniazid tablets were prepared by direct compression using sodium alginate (10 – 40 %w/w) and Carbopol 940 (5 – 20 %w/w) as the matrix-forming polymers. Powder blends were evaluated for some micromeritic properties and loss on drying, while the prepared tablets were assessed for physico-mechanical properties, swelling behavior, and *in vitro* drug release in 0.1N HCl (pH 1.2). All the formulations exhibited acceptable flow properties, had low moisture content and were within pharmacopoeial specifications for weight uniformity, hardness, friability, and drug content. Sodium alginate-based formulations demonstrated pronounced swelling and sustained drug release over 8 h (≈48 – 62 %), whereas the Carbopol formulations showed minimal swelling and rapid drug release (>80 % within 4 h). Kinetic modeling revealed that drug release from sodium alginate matrices followed the Higuchi model, indicating diffusion-controlled release, with Korsmeyer–Peppas analysis confirming non-Fickian (anomalous) transport. In contrast, Carbopol formulations exhibited Fickian diffusion with significant polymer erosion, resulting in poor sustained-release performance. Overall, sodium alginate proved to be a more effective matrix-forming polymer than Carbopol for sustained delivery of isoniazid due to its gel-forming and diffusion-modulating properties.

ARTICLE INFO

Received 15 February, 2026
Accepted 25 April, 2026
Published 30 April, 2026

KEYWORDS

Isoniazid, sustained release, sodium alginate, Carbopol, matrix tablets, release kinetics

INTRODUCTION

Oral drug delivery remains the most preferred route of drug administration due to its convenience, non-invasiveness, safety, and high patient compliance. However, conventional immediate-release dosage forms often lead to significant fluctuations in plasma drug concentrations, resulting in periods of sub-therapeutic effects or toxicity. Sustained-release (SR) drug delivery systems are designed to overcome these limitations by maintaining therapeutic drug levels for extended periods, reducing dosing frequency, minimizing side effects, and improving patient adherence [1,2]. Hydrophilic matrix systems are among the most widely used and effective approaches for achieving controlled drug release. These

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https://doi.org/10.59493/ajopred/2026.1.17 *ISSN: 0794-800X (print); 1596-2431 (online)*

systems rely on the swelling, gelation, and erosion properties of hydrophilic polymers to control drug release through diffusion, polymer relaxation, and matrix erosion [3]. Among the polymers commonly employed, sodium alginate, a natural anionic polysaccharide and Carbopol, synthetic cross-linked polyacrylic acid derivatives, (also known as carbomers) have gained significant attention due to their excellent biocompatibility, low cost-effectiveness, and versatile release-modifying properties [4,5].

Sodium alginate is known for its rapid hydration and ability to form a viscous gel barrier that modulates drug diffusion, thereby prolonging drug release. Sodium alginate hydrates rapidly in aqueous media to form a viscous gel layer that modulates drug diffusion, thereby prolonging drug release. In contrast, Carbopol exhibits high swelling capacity due to its cross-linked structure, though its behavior is often pH-dependent and influenced by erosion rates [6,7]. These complementary physicochemical characteristics make them suitable for matrix design. Despite their widespread application, there is paucity of information on the comparative evaluations of these two polymers within the same formulation to better understand their influence on drug release mechanisms.

Isoniazid (INH), is a first-line anti-tubercular agent, characterized by rapid absorption after oral administration and a relatively short biological half-life (0.5–1.6 h in fast acetylators and 2–5 h in slow acetylators), necessitating frequent dosing to maintain therapeutic plasma concentrations. These pharmacokinetic properties make it an ideal candidate for sustained-release formulation. The development of a sustained-release formulation of isoniazid therefore offers significant potential to improve therapeutic outcomes, minimize dosing frequency, and improve patient compliance, particularly in long-term tuberculosis therapy [8,9].

Although several studies have reported sustained-release matrix tablets of isoniazid, few have performed a mechanistic side-by-side comparison of different matrix-forming polymers using comprehensive kinetic modelling. Mathematical analysis with models such as zero-order, first-order, Higuchi, Hixson–Crowell, and Korsmeyer–Peppas provides valuable insights into the dominant release mechanisms [10,11].

Therefore, the aim of this study was to formulate sustained-release matrix tablets of isoniazid using sodium alginate and Carbopol (alone and in combination) as matrix-forming polymers, and to evaluate the influence of polymer type and concentration on drug release behavior and release kinetics to elucidate the underlying mechanisms governing drug release from the formulations using established mathematical models.

MATERIALS AND METHODS

Isoniazid was obtained from Gid Corporation (India). Sodium alginate (Kimica Corporation, Tokyo, Japan) and Carbopol-940 (Lubrizol Corporation, USA) were used as matrix-forming polymers. Magnesium stearate (Skant Healthcare, India) and talc (Beechamores, Mumbai, India) served as lubricant and glidant, respectively, while microcrystalline cellulose, Avicel PH 102 (FMC International, Ireland) was used as diluent. All other reagents were of analytical grade and used as received.

Preparation of Matrix Tablets

Eight batches of sustained release isoniazid granules and tablets (F1- F8) of were prepared by the direct compression method according to the composition presented in Table 1. All powders except magnesium stearate were passed through a 0.2 mm stainless steel sieve, while magnesium stearate was passed through a 0.5 mm sieve.

The drug, polymers, and excipients were mixed by geometric dilution to ensure uniform distribution. Magnesium stearate was then added and mixed for an additional 5 min. The final blend was compressed into tablets of average weight 600 mg using the F3-single-punch tablet press (Manesty machines, UK). Compression pressure was maintained constant for all the batches.

Table 1: Formula for preparing isonazid sustained release matrix tablets

Ingredients	Isoniazid (mg)	Sodium alginate (%)	Carbopol (%)	Magnesium stearate (mg)	Talc (mg)	Avicel PH 102 (mg)
Quantity	3000	10 - 40	5 – 20	600	600	q.s to 600

Evaluation of Powder blends

Powder blends of the prepared batches were evaluated for some micromeritic properties including bulk and tapped densities, Carr's compressibility index, Hausner's ratio, angle of repose, flow rate, and loss on drying using standard methods [12,13]. All measurements were done in triplicates and recorded as ± SD.

Evaluation of Isoniazid Tablets

The prepared tablets were subjected to some pharmacopoeia and non-pharmacopoeia tests such weight uniformity, hardness and friability, assay and dissolution profile studies using standard methods [14]. All measurements were done in triplicates and recorded as mean ± SD.

Mechanical properties of Isoniazid Tablets

Tablet hardness was determined using the Monsanto hardness tester on ten randomly selected tablets per batch, and the mean value was calculated.

The friability of the tablets was determined using the Erweka double chamber Friabilator. Five tablets were randomly selected from each batch, dusted and weighed (W_O) and subjected to abrasive shock in the friabilator at 25 rpm for 4 min. The tablets were removed from the chambers, dedusted and re-weighed (W). The percentage weight loss (friability) was calculated and values below 2% were considered acceptable for directly compressed tablets [14].

The swelling behavior of tablets was evaluated in 0.1 N HCl, pH 1.2, by measuring the weight gained by the tablets at predetermined intervals. Result was expressed as percentage swelling index [3].

***In vitro* Isoniazid Release**

Dissolution studies were carried out in 900 mL of 0.1N HCl, pH 1.2 maintained at 37 ± 0.5 ^oC using a magnetic stirrer at 50 rpm. Samples (10 mL) were withdrawn at predetermined time intervals (1 - 8 h) and replaced with fresh medium maintained at the same temperature. Sink conditions were maintained throughout the study. The isoniazid content per batch was determined spectrophotometrically (Barloworld, Essex CMB 31BWL, U.K) at 263 nm, and the cumulative drug release from the matrix tablet was calculated.

Drug Release Kinetics

Drug release data were fitted to various kinetic models including zero order, first order, Higuchi, and Korsmeyer-Peppas models to determine the mechanisms of drug release from the formulated matrix tablets. The model with the highest correlation coefficient (R^2) value was considered the best fit [10,11].

Statistical Analysis

All experiments were performed in triplicates unless otherwise stated, and the results are expressed as mean ± SD. Statistical analysis was performed using Design-Expert® Software (Stat-Ease Inc., USA). Differences between formulations were analyzed using one-way analysis of variance (ANOVA), and significance level was determined at $p < 0.05$.

RESULT

Micromeritic properties of the powder blend

The micromeritic properties of the powder blend are presented in Table 2. Powder blends exhibited bulk density ranged of 0.51 to 0.67 g/mL, and tapped density of 0.63 to 0.89 g/mL. The Carbopol based formulations (F5–F8), indicating relatively better flow. Hausner ratios for all batches were within acceptable limits (1.24 - 1.33), indicating generally good flow characteristics, supporting suitability for direct compression.

Mechanical properties of Isoniazid Tablets evaluated

All the formulated batches complied with pharmacopoeial specifications for weight uniformity, hardness, friability, and drug content (Table 3). Weights variation was within the acceptable limits for tablets ≥ 250 mg. Hardness ranged from 7.54 – 9.08 kgf, indicating adequate mechanical strength, while friability (0.68 - 1.51 %) was within the acceptable limit (< 2%) for direct compression tablets. Drug content (97 – 102 %) confirmed uniform drug distribution.

Table 2: Some micromeritic properties of isoniazid granules.

	B.D ± SD (g/ml)	T.D ± SD (g/ml)	C.I (%)	H.R	A.R ± SD (°)	F.R ± SD (g/s)	% LOD
F1	0.53±0.37	0.70±0.49	24.29	1.32	6.38±25.72	1.43±1.01	1.35
F2	0.59±0.42	0.77±0.54	23.38	1.31	33.69±23.82	1.33±0.94	1.20
F3	0.62±0.47	0.83±0.59	25.30	1.33	33.69±23.82	1.11±0.78	0.89
F4	0.67±0.36	0.89±0.63	24.72	1.33	34.79±24.60	2.00±1.41	1.13
F5	0.51±0.38	0.63±0.45	19.05	1.24	29.74±21.03	1.53±1.08	1.24
F6	0.54±0.39	0.69±0.49	21.74	1.28	27.74±19.62	1.67±1.18	0.96
F7	0.56±0.40	0.72±0.51	22.22	1.29	30.71±21.72	1.82±1.29	1.06
F8	0.57±0.40	0.72±0.51	20.83	1.26	30.28±21.41	2.50±3.13	1.21

Key: F1- F4: sodium alginate (10 – 40 %), F5 – F8: carbopol (5 – 20 %)

Table 3: Some mechanical properties of prepared isoniazid tablets

Batch	#Weight uniformity ± SD (mg)	#Tablet thickness (mm)	Friability (%)	*Hardness ± SD (kgf)	Drug content (%)
F1	598 ± 0.68	0.5 ± 0.12	0.85	8.42 ± 2.33	97.01
F2	601 ± 0.83	0.5 ± 0.12	1.02	7.54 ± 2.13	97.75
F3	600 ± 0.78	0.5 ± 0.12	1.39	9.08 ± 2.48	102.10
F4	599 ± 0.72	0.4 ± 0.09	0.68	7.60 ± 2.14	98.50
F5	599 ± 0.72	0.5 ± 0.12	1.49	8.07 ± 2.25	101.40
F6	600 ± 0.78	0.5 ± 0.12	1.08	9.01 ± 2.46	97.20
F7	599 ± 0.72	0.5 ± 0.12	1.19	7.89 ± 2.21	99.60
F8	602 ± 0.88	0.4 ± 0.09	1.51	7.60 ± 2.14	98.40

Key: F1- F4: sodium alginate (10 – 40 %), F5 – F8: carbopol (5 – 20 %), #mean of twenty tablets *mean of five tablets

Swelling behavior

Sodium alginate formulations (F1 – F4), showed a progressive increase in swelling index over time, with higher polymer concentrations showing greater water uptake (Figure 1). In contrast, Carbopol-based formulations (F5 – F8) exhibited negligible swelling and rapid disintegration upon contact with the dissolution medium, indicating limited gel formation capacity.

Calibration curve

The calibration curve of isoniazid in 0.1N HCl (Figure 2) showed acceptable linearity (R^2=0.961) with a slope of 0.731, confirming suitability for quantitative analysis.

***In vitro* drug release and kinetic studies**

The dissolution profiles of all the isoniazid formulations are presented in Figure 3A-B. Sodium alginate based formulations (F1 – F4) exhibited sustained drug release (≈ 48 – 62 %) over 8 h, whereas Carbopol-based formulations (F5–F8) showed rapid drug release (> 80 % within 4 h and ≈ 99 – 105 % at 8 h). Increasing polymer concentration decreased the rate of isoniazid release in the alginate systems. The sodium alginate batches were more closely aligned to USP sustained release limits compared to the Carbopol-based formulations.

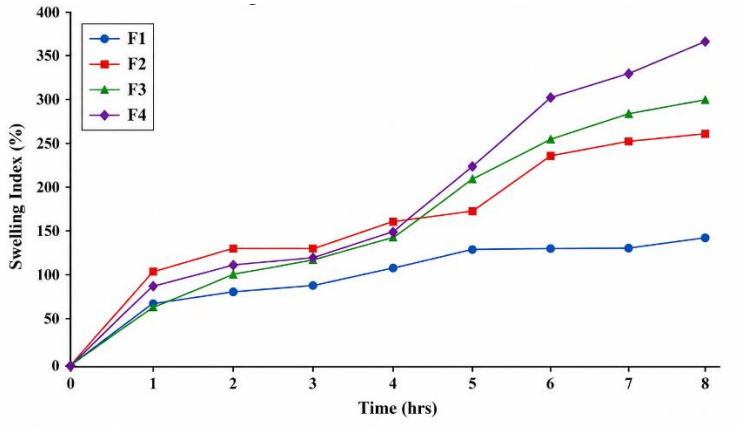

Figure 1: Swelling index of isoniazid tablets (F1-F4) over 8 h

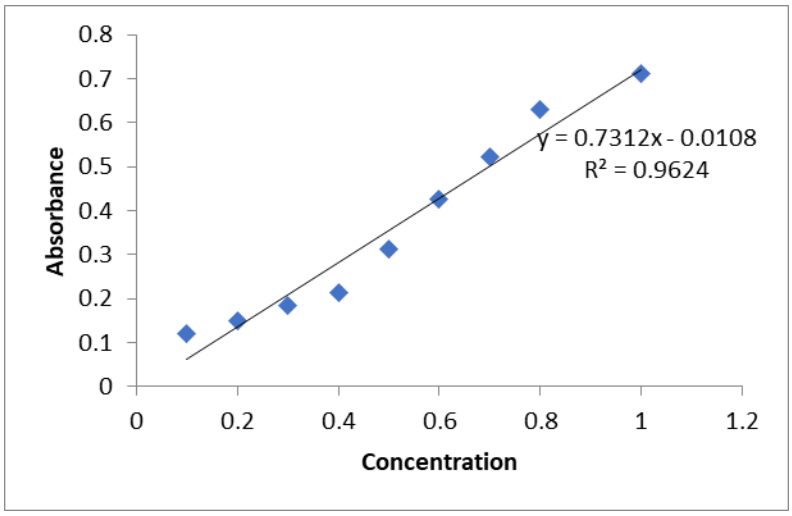

Figure 2: Beer's calibration curve for isoniazid

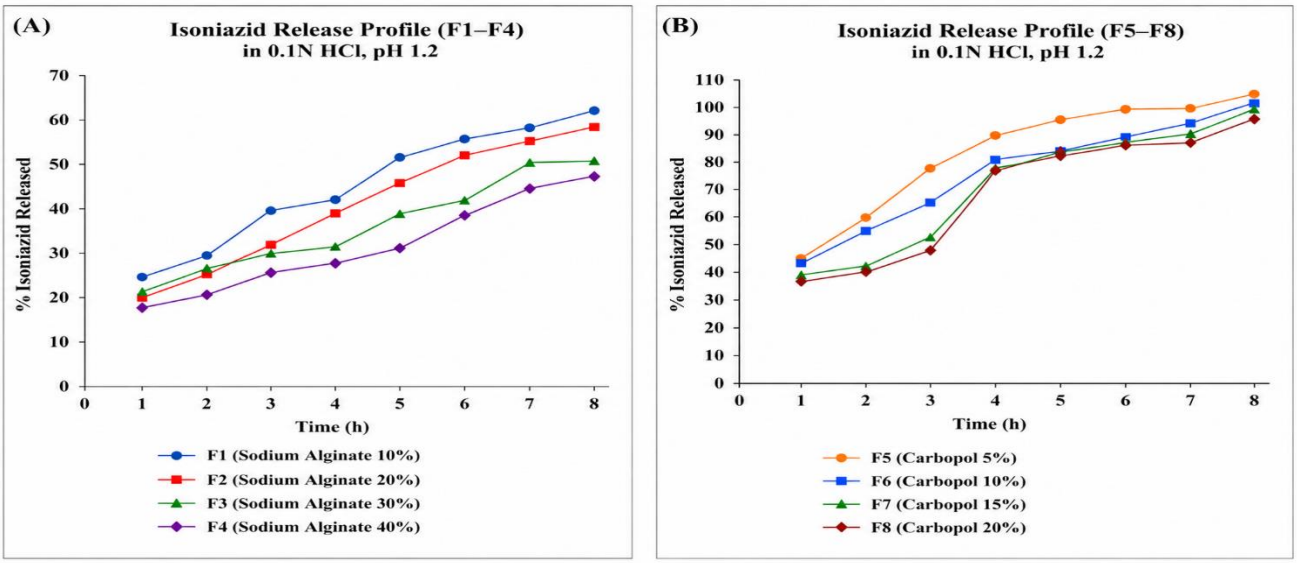

Figure 3A-B: *In vitro* release profile of isoniazid from sodium alginate and carbopol-based matrix formulations

Kinetic studies

The kinetic studies (Table 4, Figure 4A-D) revealed that the sodium alginate formulations (F1 – F4) exhibited higher correlation with Higuchi and first order models (R^2 ≈ 0.94–0.98), indicating diffusion-controlled release. Korsmeyer–Peppas analysis for alginate matrices showed non-Fickian transport (0.45 < n < 0.89) for most batches, confirming a combination of diffusion and polymer relaxation mechanisms. The Carbopol-based formulations (F5 – F8) on the other hand, showed weaker model fitting and predominantly Fickian or erosion-dominated release, consistent with their rapid drug release and minimal swelling behavior.

Table 4: Kinetic modeling parameters of isoniazid release from matrix tablets

Batch	Zero-order (R^2)	First-order (R^2)	Higuchi (R^2)	Peppas (n)	Mechanism
F1	0.964	0.981	0.979	0.48	Non-Fickian
F2	0.945	0.966	0.964	0.56	Non-Fickian
F3	0.969	0.955	0.937	0.41	Fickian
F4	0.978	0.963	0.936	0.49	Non-Fickian
F5	0.875	0.906	0.945	-	Erosion-controlled
F6	0.964	0.625	0.989	-	Diffusion (but rapid release)
F7	0.921	0.601	0.937	0.26	Fickian
F8	0.905	0.750	0.923	0.26	Fickian

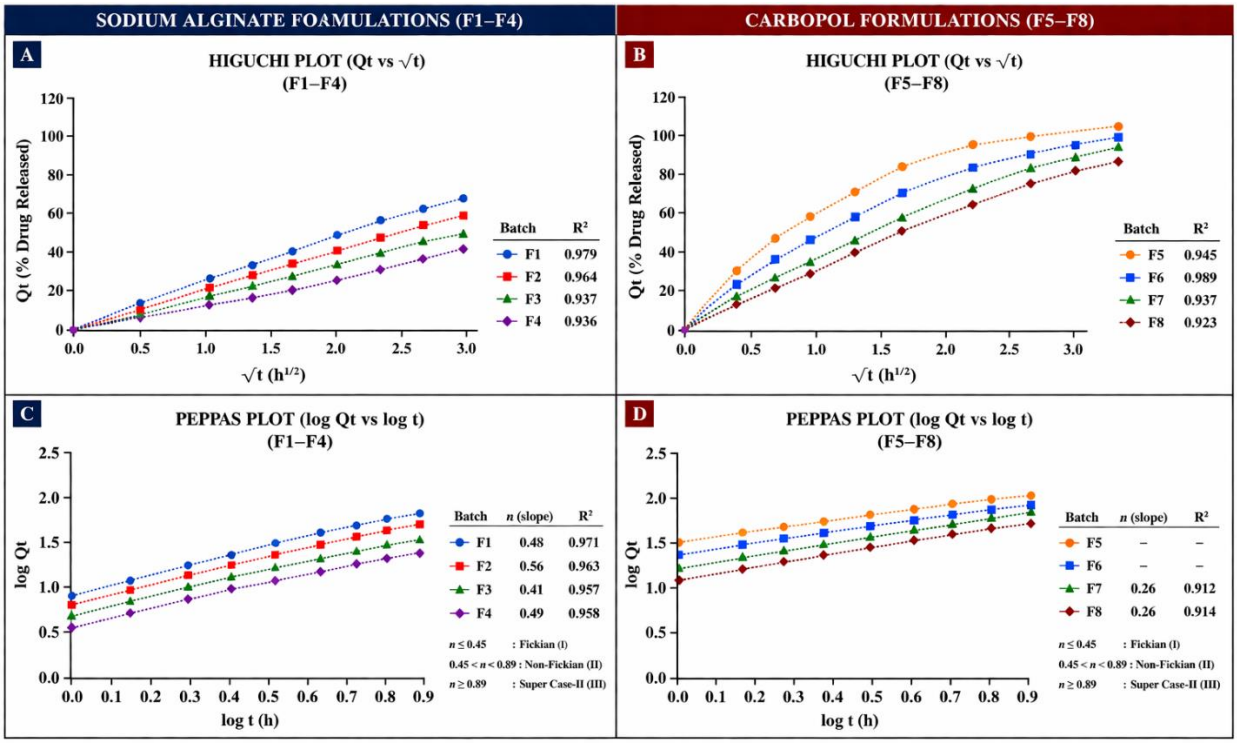

Figure 4: Kinetic modeling of Isoniazid release from matrix tablets in 0.1 NHCl pH 1.2 over 8h.
(A) Higuchi plot (F1-F4), (B) Higuchi plot (F5-F8), (C) Korsemeyer-Peppas plot (F1-F4), and (D) Korsemeyer-Peppas plot (F5-F8).

DISCUSSION

The micromeritic properties indicated that all powder blends were suitable for direct compression, with Carbopol-based formulations exhibiting relatively better flow characteristics. This improvement can be attributed to differences in interparticulate cohesion and the morphology of the polymers, consistent with established principles of powder rheology in pharmaceutical processing [15].

All tablet formulations met pharmacopoeial requirements for mechanical strength, demonstrating adequate

hardness and friability to withstand handling and packaging. The observed high hardness values likely resulted from effective particle packing and the inherent binding properties of the matrix-forming polymers and excipients used [16].

The swelling studies highlighted distinct behaviours between the two polymers. Sodium alginate formulations exhibited significant ($p < 0.05$), time-dependent swelling with the formation of a thick, viscous gel layer. In contrast, Carbopol-based formulations showed minimal swelling followed by rapid erosion and disintegration. These observations align with the known ability of alginate to create a robust hydrated gel barrier that impedes water penetration and drug diffusion, while Carbopol's highly cross-linked structure leads to rapid hydration that is often pH-dependent and prone to erosion under the experimental conditions [17,18].

In vitro dissolution studies further confirmed these differences. Sodium alginate matrices achieved sustained isoniazid release over 8 hours, with release rate decreasing as polymer concentration increased due to the formation of a thicker gel barrier that restricts drug diffusion. Conversely, Carbopol-based formulations released more than 80% of the drug within 4 h, indicating insufficient matrix integrity for prolonged release [18].

The kinetic modeling results confirm that sodium alginate based matrices provide a more controlled and predictable release profile compared to the Carbopol systems. Kinetic modeling revealed that sodium alginate formulations best fitted the Higuchi model, indicating diffusion-controlled release through the hydrated polymer network [19]. Korsmeyer–Peppas analysis further demonstrated that most of the alginate formulations exhibited non-Fickian (anomalous) transport ($0.45 < n < 0.89$), suggesting that both diffusion and polymer relaxation contributed to drug release. Similar findings have been reported for swellable polymer matrices where drug release is governed by a combination of diffusion and matrix swelling [20].

In contrast, Carbopol formulations showed a poorer correlation with diffusion-based models and exhibited low release exponent ($n < 0.45$), indicating predominantly Fickian diffusion coupled with significant matrix erosion. The rapid drug release observed in these formulations supports this mechanism and suggests that Carbopol, under the conditions employed, was unable to maintain a stable gel barrier required for sustained release [8].

Overall, the results demonstrate the critical influence of polymer type and concentration on the performance of hydrophilic matrix systems. Sodium alginate proved superior for sustained release of isoniazid owing to its excellent gel-forming and swelling characteristics, which enabled controlled drug diffusion. These findings are consistent with established theories of drug release from swellable hydrophilic matrices, where polymer hydration, gel strength, and erosion collectively govern release kinetics [19,22], and underscores the importance of careful polymer selection when designing sustained-release formulations for drugs with short half-lives such as isoniazid.

CONCLUSION

This study demonstrated that polymer type and concentration significantly influenced the release behaviour of isoniazid from hydrophilic matrix tablets. Sodium alginate-based formulations exhibited sustained and controlled drug release over 8 h, while Carbopol systems showed rapid drug release with limited control, limiting its suitability as a single matrix former for isoniazid sustained-release systems. Kinetic modeling revealed that drug release from sodium alginate matrices predominantly followed the Higuchi model, with Korsmeyer–Peppas analysis indicating non-Fickian (anomalous) transport, suggesting a combined mechanism of diffusion and polymer relaxation. In contrast, Carbopol formulations exhibited Fickian diffusion with a strong contribution from polymer erosion, resulting in burst release and poor sustained-release performance. These findings highlight the critical role of polymer selection and concentration in the design of hydrophilic matrix systems. Sodium alginate has proven to be a promising, biocompatible, and cost-effective rate-controlling polymer for isoniazid, a drug with a short half-life that requires frequent dosing in conventional regimens. By enabling reduced dosing frequency, such formulations could significantly improve patient adherence and therapeutic outcomes in long-term tuberculosis management, particularly in resource-limited settings. Overall, this study contributes valuable mechanistic insights into polymer behaviour in matrix systems and supports the continued development of patient-friendly sustained release anti-tubercular formulations.

However, further studies involving optimization of alginate-Carbopol combinations, evaluation of the influence of additional excipients on gel robustness, *in vivo* pharmacokinetic and bioavailability studies to confirm the clinical translation of these promising in vitro results, are recommended to validate and extend these findings.

ACKNOWLEDGMENT
The authors thank the Department of Pharmaceutical Technology and Industrial Pharmacy, University of Nigeria, Nsukka, Enugu State, Nigeria for providing the facility and permission to carry out this study.

AUTHORS' CONTRIBUTION
O.N.C.U did the conceptualization, methodology, investigation, and data curation. J.I.O contributed to analysis tools or data and editing of the manuscript. I.O did some aspects of the experiment, and writing initial original draft of the manuscript. E.C.O analyzed and interpreted data. S.I.O designed and supervised the work, contributed reagents, materials, manuscript reviews and editing.

CONFLICT OF INTEREST
The authors have no conflict of interest to declare.

FUNDING
There was no external funding for this research

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