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Research Article

Development And Characterization of Natural Gum-Based Sustained Release Matrix Tablets of Isoniazid

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ABSTRACT

The present study aimed to develop and optimize sustained release (SR) matrix tablets of Isoniazid using natural polymers to improve therapeutic efficacy and patient compliance by reducing dosing frequency. Matrix tablets were formulated by wet granulation employing Aloe gum, Mangifera indica gum, and xanthan gum, both individually (F1–F9) and in combinations (F10–F18) at varying concentrations. Precompression parameters indicated acceptable flow and compressibility of granules, while post-compression evaluation confirmed that all formulations complied with pharmacopeial limits for hardness, friability, weight variation, thickness, and drug content uniformity. In-vitro drug release studies revealed that polymer type and concentration significantly influenced the release profile. Among individual polymers, xanthan gum exhibited superior release-retarding properties, whereas Aloe gum showed faster hydration and initial drug release. Combination formulations demonstrated improved control over drug release due to synergistic interactions between polymers. The optimized formulation (F15), containing Aloe gum and xanthan gum (70:70), showed a controlled and extended drug release up to 24 hours. Kinetic analysis indicated that drug release followed the Korsmeyer–Peppas model with non-Fickian transport, suggesting a combined mechanism of diffusion and polymer relaxation. Swelling studies supported the formation of a robust gel matrix responsible for sustained release. Stability studies confirmed the robustness of the optimized formulation

INTRODUCTION

Oral drug delivery remains the most preferred route of drug administration owing to its convenience, patient compliance, ease of administration, and cost-effectiveness. Among the various oral dosage forms, tablets are widely accepted because of their stability, accurate dosing, ease of manufacturing, and suitability for large-scale production. However, conventional immediate-release formulations often require frequent administration to maintain therapeutic drug concentrations,

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resulting in fluctuations in plasma drug levels and reduced patient compliance. Such limitations have encouraged the development of modified-release dosage forms capable of providing prolonged therapeutic effects. (1,6)

Sustained-release (SR) drug delivery systems have been extensively investigated to overcome the drawbacks associated with conventional dosage forms. These systems are designed to release the drug at a predetermined rate for an extended period, thereby maintaining effective plasma drug concentrations, reducing dosing frequency, minimizing side effects, and improving patient adherence to therapy. Among the various approaches employed for sustained drug delivery, hydrophilic matrix tablets are widely used because of their simplicity, cost-effectiveness, ease of manufacturing, and ability to control drug release through swelling, diffusion, and matrix erosion mechanisms. (7,10)

Natural polymers have gained considerable attention as matrix-forming agents in sustained-release formulations due to their biodegradability, biocompatibility, non-toxicity, availability, and economic advantages over synthetic polymers. Plant-derived gums possess excellent swelling and gel-forming properties that contribute to controlled drug release. Aloe gum and *Mangifera indica* gum are natural polymers with significant potential for pharmaceutical applications owing to their hydrophilic nature and matrix-forming ability. The incorporation of such natural polymers in sustained-release systems offers an attractive alternative to synthetic release-retarding agents. (11,14)

Isoniazid is a first-line antitubercular agent widely used in the treatment and prophylaxis of tuberculosis caused by *Mycobacterium tuberculosis*. The drug exerts its antimicrobial activity by inhibiting the synthesis of mycolic acids, which are essential components of the mycobacterial cell wall. Following oral administration, isoniazid is rapidly absorbed from the gastrointestinal tract and attains peak plasma concentrations within 1–2 h. Due to its rapid absorption and relatively short biological half-life, repeated dosing is required to maintain therapeutic drug levels during prolonged tuberculosis therapy. Therefore, the development of a sustained-release formulation of isoniazid may provide prolonged drug release, reduce dosing frequency, and improve patient compliance. (15,21).

Numerous studies have demonstrated the effectiveness of natural and synthetic polymers in the development of sustained-release matrix tablets. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC), sodium alginate, xanthan gum, guar gum, chitosan, and various plant-derived gums have been extensively investigated owing to their excellent swelling, gel-forming, and release-retarding properties. Several researchers have reported that polymer concentration, viscosity, hydration behavior, and matrix integrity significantly influence drug release kinetics and overall formulation performance. Natural gums such as karaya gum, guar gum, locust bean gum, tamarind gum, and Mangifera indica gum have attracted considerable attention as economical and biocompatible alternatives to synthetic polymers for sustained drug delivery applications. Furthermore, combination polymer systems have been shown to provide superior control over drug release compared with single-polymer matrices due to synergistic effects on swelling, erosion, and diffusional pathways. Previous investigations involving antitubercular, antihypertensive, antidiabetic, and cardiovascular drugs have demonstrated that optimized matrix systems can successfully extend drug release up to 24 h while maintaining acceptable physicochemical characteristics and stability.

These findings emphasize the importance of polymer selection and optimization in the successful development of sustained-release oral dosage forms and provide a strong foundation for exploring novel natural gum combinations for isoniazid delivery.(22,31)

Despite the growing interest in natural polymer-based drug delivery systems, limited information is available regarding the comparative and synergistic utilization of Aloe gum, Mangifera indica gum, and xanthan gum for the sustained delivery of isoniazid. To the best of our knowledge, no systematic study has been reported evaluating these polymers individually as well as in combination to optimize matrix integrity, swelling behavior, and drug release characteristics of isoniazid sustained-release tablets. The present investigation was therefore designed to develop and characterize novel natural gum-based matrix tablets and to elucidate the influence of polymer composition on release kinetics and release-retarding efficiency. The study further explores the potential of Aloe gum and Mangifera indica gum as economical, biodegradable, and pharmaceutically acceptable matrix-forming agents for prolonged oral delivery of isoniazid. The findings are expected to provide a scientific basis for the utilization of indigenous natural gums in sustained-release formulations and contribute to the advancement of cost-effective oral drug delivery systems for long-term tuberculosis therapy.

MATERIALS AND METHODS

Materials

Isoniazid was obtained from Lupin Ltd., India. Microcrystalline cellulose (MCC), polyvinyl pyrrolidone K-30 (PVP K-30), magnesium stearate and talc were procured from S.D. Fine Chemicals Ltd., India. Xanthan gum was obtained from Tristar Formulations Pvt. Ltd., India. Aloe gum and *Mangifera indica* gum were isolated and purified in-house. All chemicals and reagents used in the study were of analytical grade.

Isolation of Natural Polymers

Isolation of Aloe Gum

Fresh mature leaves of *Aloe barbadensis Miller* were collected and washed thoroughly with distilled water. The outer rind was removed and the mucilaginous gel was separated. The gel was homogenized and filtered through muslin cloth to remove fibrous matter. The filtrate was treated with ethanol (95%) under continuous stirring to precipitate the mucilage. The precipitated material was separated, dried at 40–60°C, pulverized, passed through a suitable sieve and stored in airtight containers until further use.

Isolation of Mangifera indica Gum

Natural gum exudates were collected from the bark of *Mangifera indica* L. The collected gum was cleaned, dissolved in distilled water and filtered to remove insoluble impurities. The purified gum solution was dried at 40°C, pulverized and stored in airtight containers for further studies.

Drug–Excipient Compatibility Study

Compatibility studies between isoniazid and selected excipients were carried out using Fourier Transform Infrared (FTIR) spectroscopy. The spectra of pure drug and drug-polymer mixtures were recorded using the potassium bromide pellet technique and compared for any significant changes in characteristic peaks.

Preparation of Sustained Release Matrix Tablets

Sustained-release matrix tablets of isoniazid were prepared by the wet granulation technique. Isoniazid and the required quantity of polymer were

passed through sieve no. 40 and blended uniformly. The powder mixture was granulated using isopropyl alcohol containing PVP K-30 as binder. The wet mass was passed through sieve no. 18 and dried in a hot-air oven at 40°C. The dried granules were lubricated with magnesium stearate and talc and compressed using a rotary tablet compression machine fitted with 10-mm standard concave punches. The composition of single polymer-based sustained-release matrix tablets (F1–F9) is presented in Table 1.

Table 1. Composition of Single Polymer-Based Sustained Release Matrix Tablets of Isoniazid (F1–F9)

Ingredient (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Isoniazid	300	300	300	300	300	300	300	300	300	300	300	300
Aloe gum	100	120	140	-	-	-	-	-	-	50	60	70
Mangifera indica gum	-	-	-	100	120	140	-	-	-	50	60	70
Xanthan gum	-	-	-	-	-	-	100	120	140	-	-	-
Lactose	136	116	96	136	116	96	136	116	96	136	116	96
PVP K-30	7	7	7	7	7	7	7	7	7	7	7	7
Magnesium stearate	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Talc	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
Total weight (mg)	550	550	550	550	550	550	550	550	550	550	550	550

The composition of combination polymer-based sustained-release matrix tablets (F10–F18) is presented in Table 2.

Table 2. Composition of Combination Polymer-Based Sustained Release Matrix Tablets of Isoniazid (F10–F18)

Ingredient (mg/tablet)	F13	F14	F15	F16	F17	F18
Isoniazid	300	300	300	300	300	300
Aloe gum	50	60	70	-	-	-
Mangifera indica gum	-	-	-	50	60	70

Xanthan gum	50	60	70	50	60	70
Lactose	136	116	96	136	116	96
PVP K-30	7	7	7	7	7	7
Magnesium stearate	3.5	3.5	3.5	3.5	3.5	3.5
Talc	3.5	3.5	3.5	3.5	3.5	3.5
Total weight (mg)	**550**	**550**	**550**	**550**	**550**	**550**

Evaluation of Granules

The prepared granules were evaluated for pre-compression parameters including angle of repose, bulk density, tapped density, Carr's compressibility index and Hausner ratio using standard procedures. These parameters were determined to assess the flow and compression characteristics of the granules.

Evaluation of Matrix Tablets

The compressed tablets were evaluated for physical characteristics including hardness, thickness, friability, weight variation and drug content according to Indian Pharmacopoeial specifications. Drug content was determined spectrophotometrically at 263 nm using phosphate buffer (pH 6.8) as dissolution medium.

In Vitro Drug Release Study

The dissolution study was performed using USP Type II (paddle) dissolution apparatus containing 900 mL phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C and stirred at 50 rpm. Samples were withdrawn at predetermined time intervals, suitably diluted and analyzed spectrophotometrically at 263 nm. The cumulative percentage drug release was calculated and plotted against time.

Swelling Study

The swelling behavior of the matrix tablets was evaluated using 2% agar gel plates maintained at 37 ± 1°C. Tablets were weighed before and after swelling at predetermined time intervals and the swelling index was calculated.

Drug Release Kinetics

The dissolution data were fitted to Zero-order, First-order, Higuchi and Korsmeyer–Peppas kinetic models to determine the mechanism of drug release. The model showing the highest correlation coefficient (R^2) was considered as the best-fit model.

Stability Study

The optimized formulation was subjected to accelerated stability testing at 40 ± 2°C and 75 ± 5% RH for one month. After the storage period, tablets were evaluated for physical appearance, hardness, friability, drug content, swelling behavior and in vitro drug release characteristics.

RESULTS AND DISCUSSION

3.1 Characterization of Natural Gums

The isolated Aloe gum and *Mangifera indica* gum were evaluated for physicochemical properties. The total ash value of Aloe gum and *Mangifera indica* gum was found to be 19.20 ± 0.25% and

11.50 ± 0.45%, respectively. The alcohol-soluble extractive values were 8.50 ± 1.35% and 8.72 ± 1.35%, whereas the water-soluble extractive values were 12.50 ± 0.57% and 10.50 ± 0.20%, respectively. These results indicate the suitability of both natural polymers for pharmaceutical applications. The physicochemical characteristics of Aloe gum and Mangifera indica gum are presented in Table 3.

Table 3. Physicochemical Characteristics of Aloe Gum and Mangifera indica Gum

Parameter	Aloe Gum	Mangifera indica Gum
Total Ash (% w/w)	19.20 ± 0.25	11.50 ± 0.45
Alcohol Soluble Extractive Value (% w/w)	8.50 ± 1.35	8.72 ± 1.35
Water Soluble Extractive Value (% w/w)	12.50 ± 0.57	10.50 ± 0.20

The absence of significant changes in physicochemical properties and drug release profile after storage demonstrates the stability of the optimized formulation under accelerated conditions. This confirms the robustness of the developed matrix system.

3.2 Preformulation Studies

The melting point of isoniazid was found to be 172°C, confirming the identity and purity of the drug. The drug exhibited satisfactory flow characteristics with an angle of repose of 24.64°, compressibility index of 14.80%, and Hausner ratio of 1.18. As shown in Figure 1, the calibration curve exhibited excellent linearity with a correlation coefficient (R^2) of 0.9995, confirming the suitability of the analytical method for drug estimation. The calibration curve of isoniazid in phosphate buffer (pH 6.8) is shown in Figure 1.

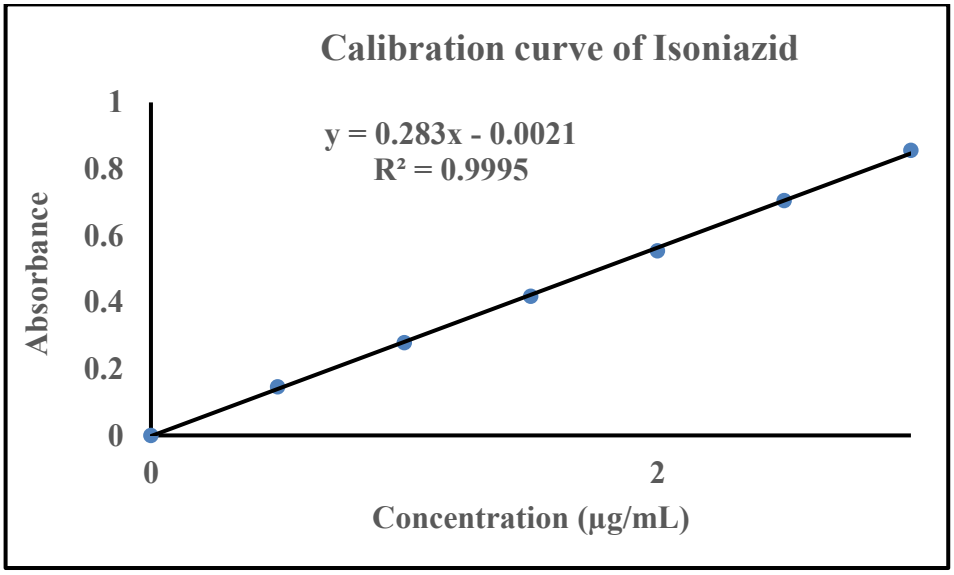

Figure 1. Standard Calibration Curve of Isoniazid in Phosphate Buffer (pH 6.8) at 263 nm

The preformulation results confirmed the identity, purity, and analytical suitability of isoniazid for formulation development. The excellent linearity obtained demonstrated the reliability of the UV

spectrophotometric method for subsequent drug analysis.

3.3 Drug–Excipient Compatibility Studies

FTIR spectroscopy was performed to investigate the compatibility of isoniazid with Aloe gum, *Mangifera indica* gum and xanthan gum. The characteristic peaks of isoniazid corresponding to N–H stretching, C=O stretching, C=N stretching and C–H stretching were retained in the optimized formulation. No significant peak shifting or disappearance was observed, indicating the absence of chemical interaction between the drug and excipients.

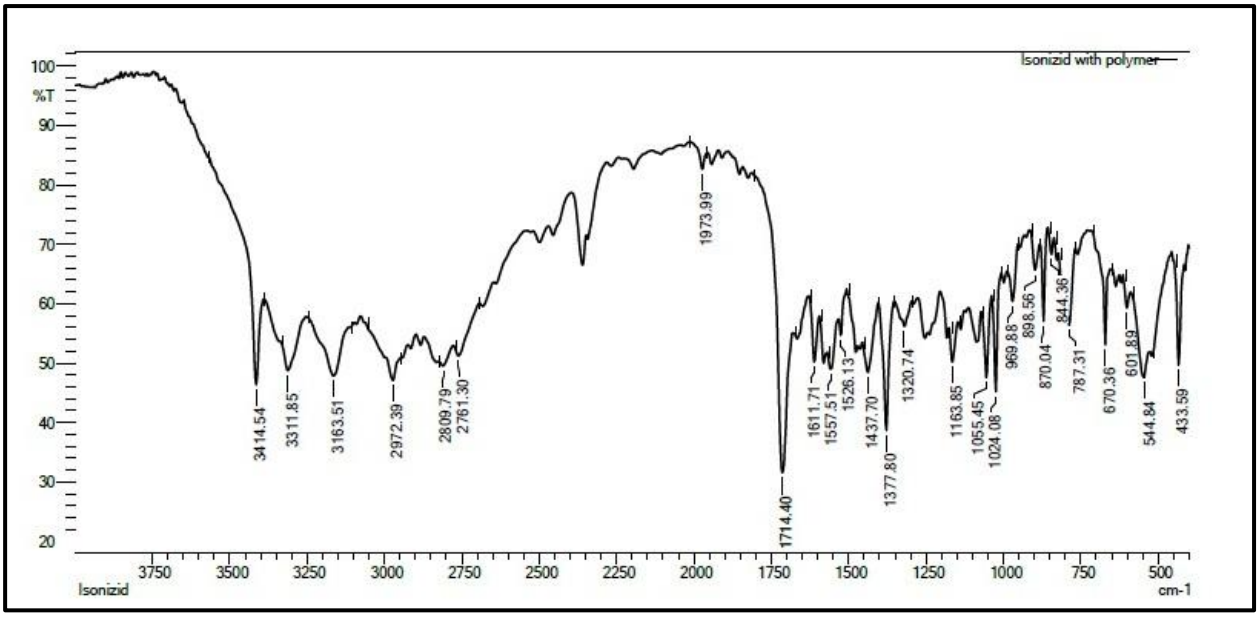

Figure 2. FTIR Spectrum of Pure Isoniazid

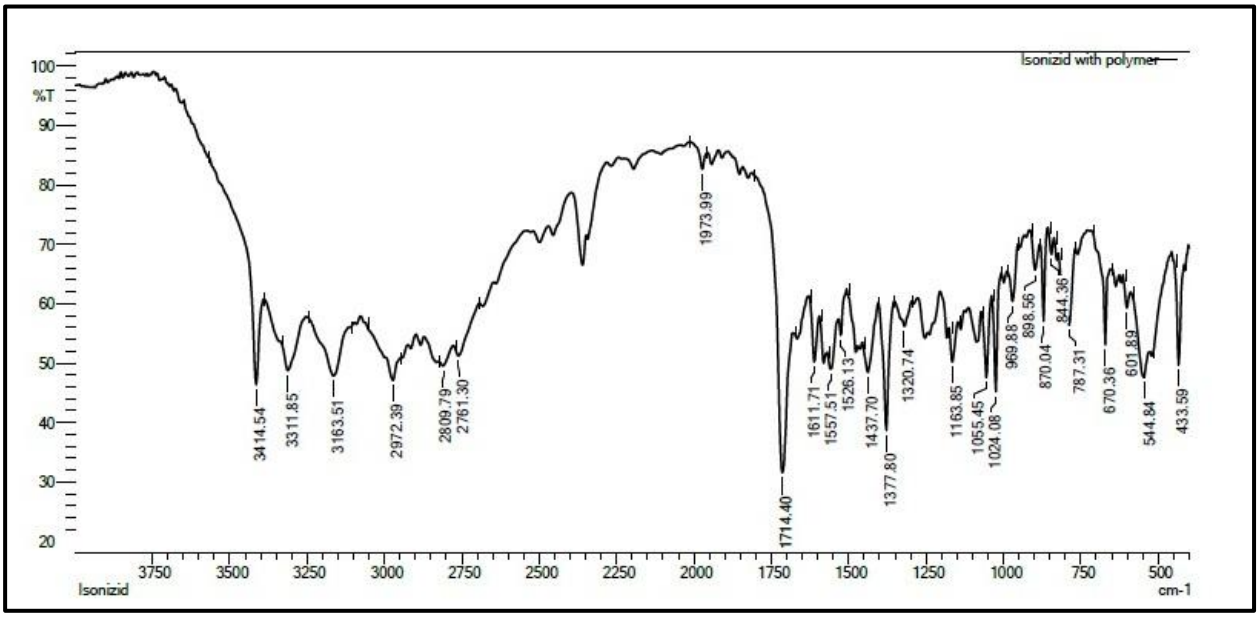

Figure 3. FTIR Spectrum of Optimized Formulation (F15)

As observed in Figures 2 and 3, the characteristic peaks of isoniazid were retained in the optimized formulation without significant changes, indicating compatibility between the drug and selected polymers.

FTIR analysis revealed the absence of significant interactions between isoniazid and the selected polymers. The retention of characteristic drug peaks indicates good compatibility and stability of the formulation components.

3.4 Evaluation of Granules

The prepared granules exhibited satisfactory flow properties. The angle of repose ranged from 21.32° to 28.37°, Carr's index ranged from 9.71% to 14.75%, and Hausner ratio ranged from 1.07 to 1.18, indicating good flowability and compressibility. The precompression parameters of all formulations are summarized in Table 4.

Table 4. Precompression Parameters of Isoniazid Matrix Tablets

Batch	Angle of Repose (°)	Bulk Density	Tapped Density	Carr's Index (%)	Hausner Ratio
F1	27°54′	0.2714	0.3974	12.63	1.18
F2	26°52′	0.2874	0.3464	14.74	1.09
F3	21°32′	0.2685	0.3249	9.71	1.08
F4	28°37′	0.2745	0.3360	10.12	1.07
F5	27°31′	0.2793	0.3372	14.75	1.12
F6	25°87′	0.2748	0.3350	13.89	1.16
F7	24°63′	0.2749	0.3369	13.97	1.14
F8	26°09′	0.2932	0.3675	10.47	1.14
F9	26°21′	0.2945	0.3374	11.31	1.12
F10	27°33′	0.2846	0.3235	12.29	1.09
F11	27°33′	0.2753	0.3492	12.45	1.17
F12	27°17′	0.2785	0.3345	12.78	1.16
F13	27°54′	0.2714	0.3975	12.64	1.18
F14	28°08′	0.2681	0.3374	13.74	1.11
F15	27°02′	0.2574	0.3312	13.17	1.13
F16	26°51′	0.2968	0.3607	14.71	1.12
F17	27°02′	0.2574	0.3312	13.17	1.13
F18	26°51′	0.2968	0.3607	14.71	1.12

The granules exhibited good flowability and compressibility, which may be attributed to the wet granulation process. These properties are essential for achieving uniform die filling and consistent tablet quality.

3.5 Evaluation of Matrix Tablets

All formulations complied with pharmacopeial requirements. Tablet hardness ranged from 5.1–6.5 kg/cm², friability remained below 1%, and drug content ranged from 98.3–99.9%. The increase in polymer concentration resulted in enhanced hardness and reduced friability due to improved matrix formation. The post-compression

parameters of all formulations are presented in Table 5.

Table 5. Post-compression Parameters of Sustained Release Matrix Tablets of Isoniazid

Formulation	Hardness (kg/cm²)	Thickness (mm)	Friability (%)	Weight Variation (mg)	Drug Content (%)
F1	5.1	4.08	0.74	548 ± 5	98.3
F2	5.5	4.15	0.69	551 ± 4	99.0
F3	5.9	4.22	0.63	550 ± 3	99.5
F4	5.2	4.10	0.72	549 ± 5	98.5
F5	5.6	4.16	0.67	551 ± 4	99.1
F6	6.0	4.25	0.61	552 ± 3	99.6
F7	5.4	4.12	0.70	550 ± 5	98.8
F8	5.8	4.20	0.65	551 ± 3	99.3
F9	6.3	4.30	0.58	552 ± 3	99.8
F10	5.3	4.10	0.71	549 ± 4	98.7
F11	5.7	4.18	0.66	551 ± 3	99.2
F12	6.1	4.26	0.60	552 ± 3	99.6
F13	5.5	4.14	0.69	550 ± 4	98.9
F14	6.0	4.22	0.63	551 ± 3	99.4
F15	6.4	4.32	0.57	552 ± 2	99.8
F16	5.6	4.15	0.68	550 ± 4	99.0
F17	6.1	4.24	0.62	551 ± 3	99.5
F18	6.5	4.35	0.55	552 ± 2	99.9

All formulations complied with pharmacopeial specifications for tablet quality. The increase in polymer concentration improved tablet hardness and reduced friability, indicating enhanced matrix integrity.

3.6 In Vitro Drug Release Study

The drug release profile was strongly influenced by polymer type and concentration. Formulations containing xanthan gum showed greater retardation of drug release than Aloe gum or *Mangifera indica* gum alone. Increasing polymer concentration from 100 mg to 140 mg resulted in a gradual decrease in release rate due to the formation of a thicker gel barrier. The comparative drug release profiles of single-polymer matrix tablets are shown in Figure 4.

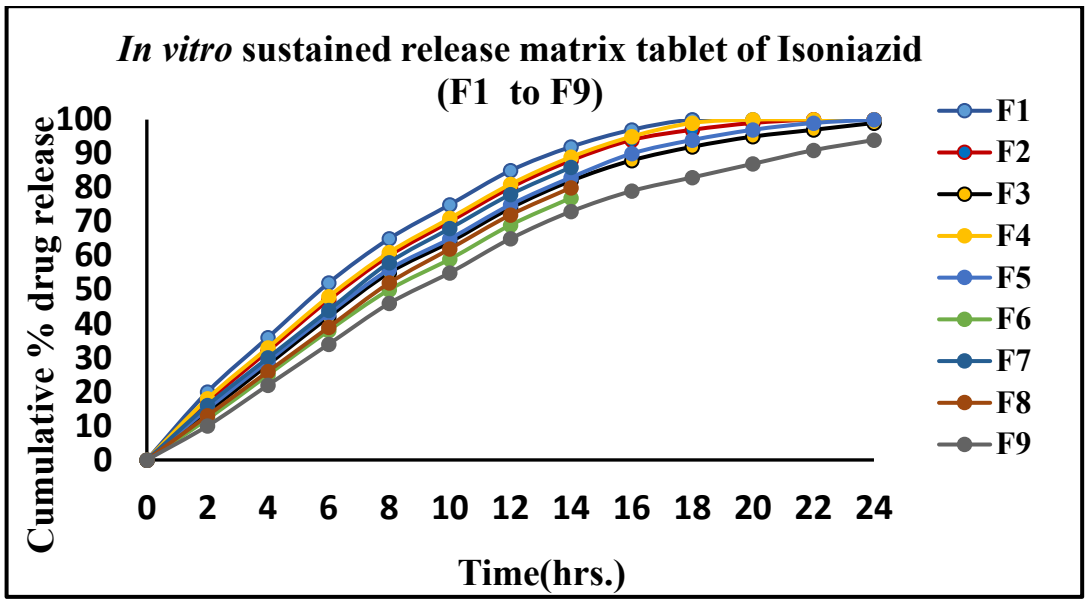

Figure 4. Comparative Drug Release Profiles of Single Polymer Matrix Tablets (F1–F9)

Combination polymer systems demonstrated superior sustained-release behavior compared with single-polymer formulations. Among all formulations, F15 containing Aloe gum and xanthan gum (70:70 mg) exhibited the most desirable release profile with controlled drug release extending up to 24 h.

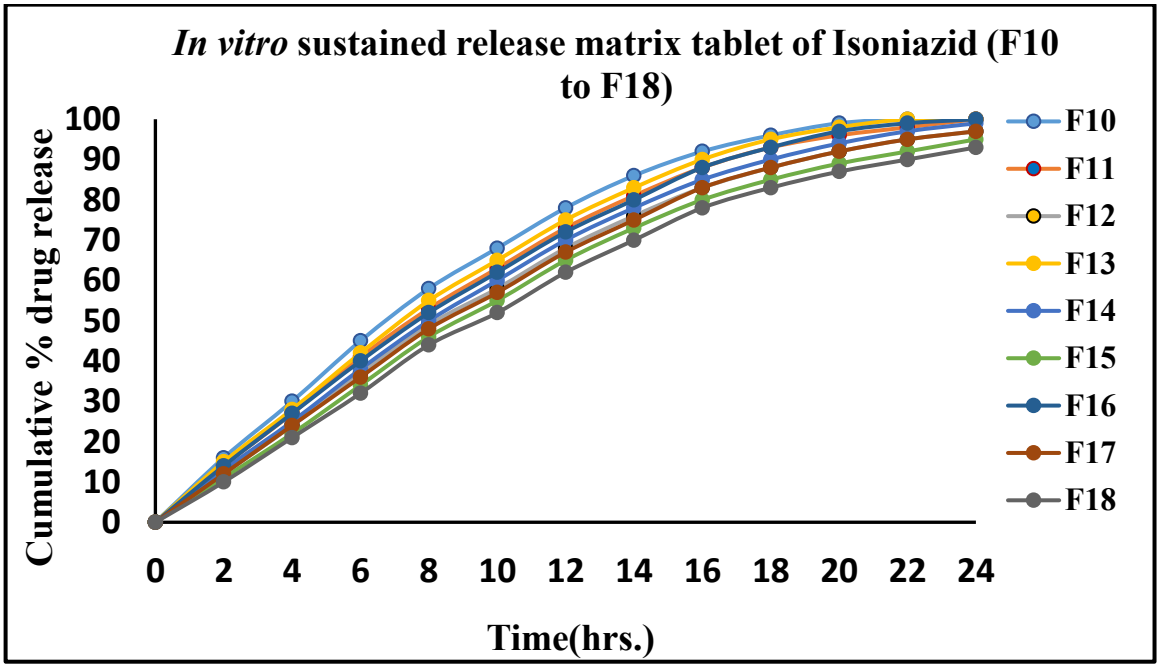

Figure 5. Comparative Drug Release Profiles of Combination Polymer Matrix Tablets (F10–F18)

Based on dissolution behavior and tablet characteristics, F15 was selected as the optimized formulation.

Combination polymer systems provided better control of drug release than individual polymers. The synergistic effect of Aloe gum and xanthan

gum contributed to sustained release over an extended period.

3.7 Swelling Study

The swelling index increased with time for all formulations, confirming progressive hydration and gel formation. Formulation F18 exhibited the highest swelling index, followed by F15. The swelling indices of the optimized formulations are presented in Table 6.

Table 6. Swelling Index of Optimized Formulations

Formulation	4 h	8 h
F15	182 ± 3	265 ± 5
F16	165 ± 4	238 ± 6
F17	178 ± 3	252 ± 5
F18	190 ± 4	275 ± 6

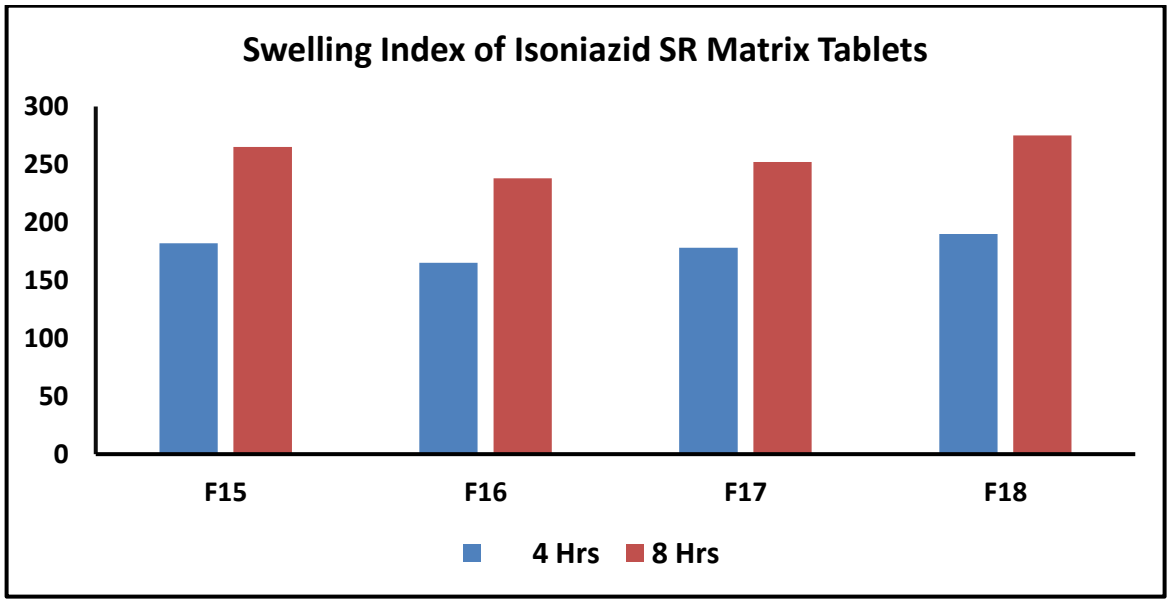

Figure 6. Swelling Index of Optimized Isoniazid Matrix Tablets

The higher swelling index observed in xanthan gum-containing formulations contributed to prolonged diffusional pathways and controlled drug release.

The increase in swelling index with time indicates progressive hydration and gel formation within the matrix. Greater swelling contributed to the formation of longer diffusional pathways, thereby sustaining drug release.

3.8 Drug Release Kinetics

The optimized formulation F15 was subjected to kinetic analysis. The release data showed excellent fitting to Zero-order and Korsmeyer–Peppas models. The drug release kinetic parameters of the optimized formulation are summarized in Table 7.

Table 7. Drug Release Kinetic Parameters of Optimized Formulation (F15)

Formulation	Zero Order (R^2)	First Order (R^2)	Higuchi (R^2)	Hixson-Crowell (R^2)	Korsmeyer-Peppas (R^2)
F15	0.9923	0.9614	0.9854	0.8570	0.9910

The diffusion exponent (n = 0.78) indicated a non-Fickian drug release mechanism involving both diffusion and polymer relaxation. Therefore, drug release from F15 was governed by swelling-controlled transport and matrix erosion.

The kinetic analysis suggests that drug release from the optimized formulation was governed by a combination of diffusion and polymer relaxation mechanisms. Such behavior is characteristic of hydrophilic matrix-based sustained-release systems.

3.9 Stability Study

The optimized formulation F15 was subjected to accelerated stability testing at 40 ± 2°C and 75 ± 5% RH for 30 days.

Table 8. Accelerated Stability Study of Optimized Formulation F15

Parameter	Initial	After 30 Days
Average Weight (mg)	552.0 ± 2.0	552.8 ± 1.8
Hardness (kg/cm²)	6.40 ± 0.49	6.40 ± 0.69
Thickness (mm)	4.32 ± 0.23	4.32 ± 0.23
Friability (%)	0.57 ± 0.2	0.58 ± 0.3
Drug Content (%)	99.80 ± 5.70	99.65 ± 4.2
Swelling Index (8 h)	265 ± 5	267 ± 5.6
Drug Release at 24 h (%)	95 ± 1.2	95 ± 0.9

As shown in Table 8, no significant changes were observed in tablet characteristics or drug release profile after storage, confirming the stability of the optimized formulation under accelerated conditions.

CONCLUSION

The present study successfully developed sustained-release matrix tablets of isoniazid using natural polymers, namely Aloe gum, *Mangifera indica* gum, and xanthan gum. FTIR studies confirmed the compatibility of isoniazid with the selected polymers, while all formulations exhibited satisfactory pre-compression and post-compression characteristics within acceptable pharmacopoeial limits. The in vitro dissolution studies demonstrated that both polymer type and concentration significantly influenced the drug release profile, with increasing polymer concentration resulting in enhanced release retardation.

Among all formulations, F15 containing Aloe gum and xanthan gum (70:70 mg) was identified as the optimized formulation based on its excellent physicochemical properties, satisfactory swelling behavior, and controlled drug release extending up to 24 h. Drug release kinetic analysis revealed a non-Fickian release mechanism involving both diffusion and polymer relaxation. Furthermore, the optimized formulation remained stable under accelerated storage conditions without significant changes in tablet characteristics or release behavior.

The findings of this study suggest that Aloe gum and xanthan gum can be effectively utilized as natural matrix-forming agents for the development of sustained-release oral delivery systems of isoniazid, offering a promising approach for improving patient compliance and therapeutic effectiveness in tuberculosis therapy.

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