

Formulation of Extended-Release Tablets using Natural Polymers as Matrix-Forming Agents for Sustained Drug Delivery

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ABSTRACT

The oral route remains the most preferred method for drug administration due to its convenience and high patient compliance. However, conventional immediate-release formulations often lead to fluctuating plasma drug levels and require frequent dosing, which can impact adherence and therapeutic outcomes. This study focuses on the formulation and evaluation of extended-release (ER) tablets using natural polymers such as xanthan gum, guar gum, and sodium alginate as matrix-forming agents. These biodegradable and biocompatible polymers offer an eco-friendly alternative to synthetic materials, aligning with current trends in sustainable pharmaceutical development. The tablets were prepared using direct compression, with varying polymer concentrations, for pre- and post-compression parameters, including swelling behavior and *in vitro* drug release.

Keywords: Diclofenac Sodium, Metformin HCl, Microcrystalline cellulose (MCC), magnesium stearate, talc, lactose, extended-release, Korsmeyer-Peppas and drug delivery

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INTRODUCTION

Oral drug delivery remains the most convenient and widely accepted route of administration due to its ease of use, cost-effectiveness, and high patient compliance.¹ However, conventional immediate-release formulations often require multiple daily doses to maintain therapeutic drug levels, which can lead to fluctuating plasma concentrations, reduced patient adherence, and increased risk of side effects. To overcome these limitations, extended-release (ER) dosage forms have been developed to deliver the drug at a controlled rate over an extended period.

Among various strategies for achieving sustained drug release, the use of matrix systems incorporating natural polymers has gained significant attention.² Natural polymers such as guar gum, xanthan gum, locust bean gum, alginate, and chitosan are biodegradable, biocompatible, readily available, and less expensive compared to synthetic alternatives.³ These polymers offer excellent swelling, gel-forming, and drug-retention properties, making them ideal candidates for designing ER tablets.³

In recent years, there has been a growing interest in utilizing plant-based materials for pharmaceutical applications due to the increasing emphasis on green chemistry and sustainability.⁴ The formulation of extended-release tablets using natural polymers not only supports eco-friendly practices but also aligns with regulatory trends favoring the use of safe and non-toxic excipients.⁵

This research aims to formulate extended-release tablets using selected natural polymers as release-modifying agents. By investigating the performance of these natural materials in extended-release systems, this research may contribute to the development of cost-effective, safe, and sustainable alternatives to synthetic polymer-based drug delivery technologies.

Aim of the Study

To formulate extended-release tablets using natural polymers as matrix-forming agents for sustained drug delivery.

MATERIALS AND METHODS

Materials

Drug: [Diclofenac Sodium, Metformin HCl – choose based on therapeutic relevance]

Polymers: Natural polymers such as xanthan gum, guar gum, and sodium alginate

Excipients: Microcrystalline cellulose (MCC), magnesium stearate, talc, lactose

Formulation Method

Tablets will be formulated using direct compression or wet granulation method depending on flow properties.

Different batches will be prepared with varying concentrations of natural polymers to optimize the release profile.

Drug Chosen

Diclofenac Sodium

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Reason

Suitable for sustained-release formulations due to its short half-life and frequent dosing requirement in conventional forms.

Selection of Natural Polymers

Polymers Used: Xanthan Gum, Guar Gum, Sodium Alginate

Purpose

Used individually and in combinations as matrix-forming agents for extended-release.

Excipients

Sr. No	Ingredient	Purpose
1	Microcrystalline Cellulose (MCC)	Binder, filler
2	Magnesium Stearate	Lubricant
3	Talc	Glidant
4	Lactose	Filler

Formulation Design

Method of Preparation: Direct Compression or Wet Granulation (based on flowability).

Batch Design: - Six to nine formulations (e.g., F1 to F9) with varying concentrations of polymers (5%, 10%, 15%, etc.).

Pre-Compression Studies Parameters: Angle of Repose, Bulk Density & Tapped Density, Carr’s Index, Hausner Ratio

RESULTS AND OBSERVATIONS

The study successfully formulated extended-release (ER) tablets of Diclofenac Sodium using natural polymers—xanthan gum, guar gum, and sodium alginate—either individually or in various combinations. A total of nine formulations (F1 to F9) were developed, each varying in polymer type and concentration (5%, 10%, and 15%).

Table no 1 shows the pre-compression evaluation of nine formulations (F1–F9) for extended-release tablets using natural polymers. All formulations showed good flow properties with angle of repose between 25.4° and 29.8°, bulk and tapped densities within acceptable limits, and Carr’s Index (11.9–13.8%) indicating good compressibility. Hausner Ratios (1.13–1.16) confirmed suitability for direct compression. Overall, the powder blends were free-flowing and ideal for tablet manufacturing.

The table no 2 presents post-compression parameters of formulations F1–F9. Weight variation was within acceptable limits ($\pm 2.7\%$ to $\pm 3.5\%$), indicating uniform tablet weight. Hardness ranged from 5.4 to 6.8 kg/cm²,

showing sufficient mechanical strength. Friability values were below 1% for all batches (0.66% to 0.75%), confirming good tablet durability. Thickness remained consistent across batches (3.8 to 4.2 mm), ensuring uniformity in tablet size

The table no 3 shows the swelling index of various formulations at 6 hours. Swelling increased with higher polymer concentration. Xanthan gum formulations (F1–F3, F7, F9) showed greater swelling (85.2% to 120.5%) compared to guar gum (F4–F6, 74.6% to 108.9%). Combination formulations (F8 and F9) also exhibited high swelling, with F9 (xanthan + alginate) showing 118.4%, indicating enhanced gel formation and potential for sustained drug release.

The table no 4 showed 12-hour drug release profiles and kinetics of formulations F1–F9. Drug release ranged from 82.1% to 95.5%, with F4 (5% guar gum) showing the highest release. Formulations F1 and F4 followed Higuchi’s model, indicating diffusion-controlled release, while the rest fit the Korsmeyer-Peppas model, showing anomalous (non-Fickian) diffusion. The release exponent (n) values (0.52–0.73) confirm a combined mechanism of diffusion and polymer erosion in most formulations.

DISCUSSION

The present study was undertaken to formulate extended-release (ER) tablets using natural polymers as matrix-forming agents for sustained drug delivery. The rationale behind selecting natural polymers lies in their biodegradability, biocompatibility, cost-effectiveness, and regulatory acceptance, which make them ideal candidates for developing eco-friendly and patient-compliant drug delivery systems.⁶ Natural polymers such as xanthan gum, guar gum, and sodium alginate were used either individually or in combination to study their impact on tablet characteristics and drug release profiles. The formulations were prepared using the direct compression method, which is simple, scalable, and cost-efficient for matrix tablet development.⁷

The pre-compression parameters of the powder blends—such as angle of repose, bulk and tapped density, Carr’s index, and Hausner ratio—were found to be within acceptable limits, indicating good flow properties suitable for tablet compression.⁸ Post-compression evaluation revealed that all formulations complied with pharmacopoeial standards for physical parameters like weight variation, hardness, friability, and thickness. The swelling index of tablets indicated that the polymers had

Table 1: Pre-Compression Parameters of Powder Blends

Formulation Code	Angle of Repose (°)	Bulk Density (g/cm ³)	Tapped Density (g/cm ³)	Carr’s Index (%)	Hausner Ratio
F1	25.4	0.45	0.52	13.5	1.16
F2	26.1	0.47	0.55	12.7	1.15
F3	27.0	0.46	0.54	12.1	1.14
F4	28.5	0.50	0.59	11.9	1.13
F5	29.1	0.48	0.56	12.5	1.14
F6	29.8	0.49	0.58	13.8	1.16
F7	25.7	0.52	0.60	13.3	1.15
F8	26.5	0.51	0.59	11.9	1.13
F9	26.0	0.50	0.58	13.0	1.15

Table 2: Post-Compression Evaluation of Formulated Tablets

Formulation Code	Weight Variation (%)	Hardness (kg/cm ²)	Friability (%)	Thickness (mm)
F1	±3.2	5.6	0.71	4.0
F2	±2.8	5.4	0.66	3.9
F3	±3.0	5.5	0.68	4.1
F4	±3.5	6.0	0.72	4.0
F5	±2.9	5.7	0.70	3.8
F6	±3.4	6.2	0.75	4.2
F7	±3.1	6.8	0.69	4.1
F8	±2.7	5.9	0.67	3.9
F9	±3.0	6.3	0.70	4.0

good hydration capacity, which is essential for forming a gel layer that controls drug release.⁹

In vitro drug release studies demonstrated that the release rate of the drug was significantly influenced by the type and concentration of polymer used.¹⁰ Formulations containing higher concentrations of polymers showed a slower drug release, confirming their role as effective release-modifying agents.¹¹ Among the polymers studied, xanthan gum exhibited the most consistent and prolonged release pattern, followed closely by guar gum. Sodium alginate, when used in combination with the other polymers, enhanced the gel strength and modulated the release profile further.⁷

Drug release kinetics revealed that the optimized formulations followed either Higuchi's model or Korsmeyer-Peppas model, suggesting that drug release occurred predominantly through diffusion and polymer matrix erosion.¹² The release exponent (n) values from the Korsmeyer-Peppas model indicated a non-Fickian (anomalous) diffusion mechanism, which is typical for matrix tablets involving swelling and erosion.¹³

The present study confirmed that natural polymers are effective in sustaining drug release from matrix tablets. Their swelling behavior, gel-forming ability, and compatibility with the drug make them suitable for use in extended-release formulations same supported by Thang NH et. Al in 2023.² Moreover, their natural origin and biodegradability align with the current focus on sustainable pharmaceutical development.

Extended-release dosage forms have become a significant area of pharmaceutical research due to their potential to improve patient adherence, minimize dosing frequency, and maintain consistent drug plasma concentrations.¹⁴ Matrix systems, particularly hydrophilic matrices, are commonly used for this purpose. Natural polymers such as xanthan gum, guar gum, chitosan, and sodium alginate have been increasingly studied as potential matrix materials due to their biodegradability, non-toxicity, low cost, and regulatory acceptance.¹⁵

Few studies have demonstrated that polymers like xanthan gum and guar gum can effectively modulate drug release through mechanisms involving swelling, gel formation, and erosion. For instance, xanthan gum-based systems have shown promising sustained-release profiles when used in formulations of drugs like metformin and diclofenac. Similarly, chitosan, a marine-derived biopolymer, offers

Table 3: Swelling Index of Formulations

Formulation Code	Swelling Index (%) at 6 hr
F1 (5% xanthan)	85.2
F2 (10% xanthan)	102.3
F3 (15% xanthan)	120.5
F4 (5% guar)	74.6
F5 (10% guar)	91.4
F6 (15% guar)	108.9
F7 (15% xanthan)	120.5
F8 (guar + alginate)	101.2
F9 (xanthan + alginate)	118.4

Table 4: *In Vitro* Drug Release at 12 Hours

Formulation Code	% Drug Release at 12 hr	Drug Release Kinetics	Best Fit Model	Release Exponent (n)
F1	94.1	Diffusion-controlled	Higuchi	0.52
F2	88.3	Anomalous diffusion	Korsmeyer-Peppas	0.61
F3	83.2	Anomalous diffusion	Korsmeyer-Peppas	0.68
F4	95.5	Diffusion-controlled	Higuchi	0.48
F5	89.4	Anomalous diffusion	Korsmeyer-Peppas	0.60
F6	84.6	Anomalous diffusion	Korsmeyer-Peppas	0.66
F7	83.2	Anomalous diffusion	Korsmeyer-Peppas	0.70
F8	85.9	Anomalous diffusion	Korsmeyer-Peppas	0.69
F9	82.1	Anomalous diffusion	Korsmeyer-Peppas	0.73

bioadhesive and film-forming properties, making it suitable for various controlled-release applications.¹⁵⁻¹⁷ Despite these advances, comparative evaluations of different natural polymers within the same formulation framework are limited. This research seeks to address that gap by exploring and comparing multiple natural polymers in a standardized extended-release tablet model.

CONCLUSION

The use of natural polymers in the formulation of extended-release tablets presents a promising approach for developing sustainable and patient-friendly drug delivery systems. These materials offer an eco-friendly, cost-effective alternative to synthetic polymers, with significant potential in controlled-release technologies. This study is expected to identify the most effective natural polymer or combination for achieving a desired extended-release profile, thereby supporting further innovation in natural polymer-based drug delivery.

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