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Research Article

Comparative Evaluation of Gum Ghatti-Based Sustained Release Formulation with A Marketed Diclofenac Sodium Product

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ABSTRACT

Sustained-release formulations are designed to prolong therapeutic effects, enhance patient compliance, and minimize side effects. Natural polymers such as Gum Ghatti (GG) offer a promising alternative to synthetic excipients due to their biocompatibility, cost-effectiveness, and gelling properties. This study aims to compare the performance of a Gum Ghatti-based sustained-release formulation of Diclofenac Sodium (GGF) with a marketed formulation (MF) in terms of physical parameters, drug release behavior, compatibility, and stability. A matrix tablet was formulated using 25% w/w Gum Ghatti and evaluated alongside a marketed sustained-release product. Comparative analysis included hardness, friability, weight variation, drug content, swelling behavior, in vitro drug release, and release kinetics. Drug-excipient compatibility was assessed using TLC and DSC, and stability testing was conducted under accelerated conditions (40°C ± 2°C / 75% RH ± 5%) for 60 days. GGF showed comparable drug content (98.25%) and acceptable hardness (5.64 ± 0.12 kg/cm²) with MF. The drug release profile of GGF was similar to MF over 12 hours, with cumulative release values of 64.89% and 63.10%, respectively. Both formulations followed non-Fickian (anomalous) release kinetics. No significant drug-excipient interactions were observed. Stability studies confirmed the physical and chemical integrity of GGF. The Gum Ghatti-based formulation demonstrated pharmaceutical equivalence to the marketed product, indicating its potential as a natural, effective, and stable excipient for sustained-release drug delivery systems.

Keywords: Gum Ghatti, Diclofenac Sodium, Sustained Release, Matrix Tablet, Compatibility, Stability, Drug Release Kinetics

1. Introduction

The advancement of pharmaceutical technology has led to an increasing demand forsustained-release (SR) drug delivery systems, which offer significant benefits over conventional immediate-release formulations. These systems are designed to maintain consistent plasma drug concentrations, reduce dosing frequency, minimize fluctuations in drug levels, and ultimately improve patient adherence and therapeutic outcomes [1]. Sustained-release formulations are especially beneficial for drugs with short biological half-lives or those requiring chronic administration.

Diclofenac Sodium is a widely prescribed non-steroidal anti-inflammatory drug (NSAID) used in the treatment of pain, inflammation, and musculoskeletal disorders. Despite its efficacy, Diclofenac Sodium has a relatively short half-life (1–2 hours) and poses a risk of gastrointestinal side effects with repeated dosing [2]. Therefore, transforming it into a sustained-release dosage form is advantageous for achieving prolonged therapeutic action while reducing adverse effects and the need for frequent administration.

In sustained-release tablets, matrix technology is one of the most commonly employed approaches. It involves the use of polymers that form a gel layer upon contact with gastrointestinal fluids, regulating the rate of drug release through diffusion and/or erosion mechanisms [3]. While several synthetic and semi-synthetic polymers have been used traditionally, there is growing interest in the use of natural polymers due to their biodegradability, availability, cost-effectiveness, and safety profile.

Gum Ghatti (GG) is a natural gum derived from *Anogeissus latifolia*, known for its emulsifying and gel-forming capabilities. Its potential as a matrix-forming polymer for sustained drug delivery is under-explored [4]. In this context, the present study focuses on the formulation of a Gum Ghatti-based matrix tablet of Diclofenac Sodium (GGF) and compares its performance with a marketed sustained-release formulation (MF).

The comparative evaluation includes critical pharmaceutical parameters such as tablet integrity, in vitro drug release, release kinetics, stability, and drug-excipient compatibility. The objective is to determine whether GGF can match the performance of MF and serve as a viable alternative using a natural, low-cost excipient [5].

2. Materials and Methods

2.1 Materials

Diclofenac Sodium and all excipients used, including **Gum Ghatti (GG)**, **Microcrystalline Cellulose (MCC)**, **Magnesium Stearate**, and **Talc**, were of pharmaceutical grade and procured from approved vendors. The **marketed formulation (MF)** of sustained-release Diclofenac Sodium was purchased from a licensed pharmacy for comparison. All solvents and reagents used were of analytical grade.

2.2 Formulation of Selected GGF (25% GG)

A matrix tablet of Diclofenac Sodium was prepared using 25% w/w Gum Ghatti, which had shown optimal sustained release performance in previous trials. The formulation also contained MCC as filler, Talc as glidant, and Magnesium Stearate as lubricant. The tablets were prepared by direct compression using a rotary tablet press [6, 7].

Table 1: Composition of the optimized formulation (GGF):

Ingredient	Quantity (% w/w)
Diclofenac Sodium	50.00
Gum Ghatti	25.00
Microcrystalline Cellulose	20.50
Magnesium Stearate	1.50
Talc	3.00
Total	**100.00**

Tablets weighing 600 mg each were compressed using 13 mm flat-faced punches.

2.3 Evaluation of GGF and MF

Both the GGF and the **marketed formulation (MF)** were evaluated for the following quality control parameters:

- **Hardness**: Measured using a Monsanto hardness tester and expressed in kg/cm².
- **Friability**: Determined using a Roche Friabilator at 25 rpm for 4 minutes. A loss of ≤1% was considered acceptable.
- **Weight Variation**: Twenty tablets from each batch were weighed individually. The average weight and standard deviation were calculated.
- **Drug Content Uniformity**: Ten tablets were crushed and a powder equivalent to 100 mg Diclofenac Sodium was dissolved, filtered, and analyzed spectrophotometrically at 276 nm using pH 6.8 phosphate buffer as the solvent [8-10].

2.4 In Vitro Dissolution Profile

The **dissolution behavior** of both GGF and MF was studied using a **USP Type I (basket) apparatus**:

- **Medium**: 0.1N HCl for 2 hours followed by phosphate buffer (pH 6.8) for 10 hours.
- **Conditions**: 900 ml medium, maintained at 37 ± 0.5°C, with a rotation speed of 50 rpm.
- **Sampling**: 10 ml aliquots were withdrawn at predetermined intervals and replaced with fresh medium.
- **Analysis**: Absorbance of the filtered samples was measured at 276 nm to determine cumulative drug release.

2.5 Accelerated Stability Study

To evaluate the **stability of the GGF formulation**, an accelerated stability study was conducted:

- **Conditions**: 40°C ± 2°C / 75% RH ± 5%
- **Duration**: 60 days
- **Parameters Evaluated**: Appearance, hardness, friability, drug content, and dissolution profile were assessed at 0, 30, and 60 days to determine any significant changes [8-10].

2.6 Thin Layer Chromatography (TLC)

TLC was performed to assess drug-excipient compatibility:

- **Samples**: Pure drug, Gum Ghatti, physical mixture, and tablet powder.
- **Solvent System**: Methanol: Toluene: Acetone (9:1:0.5)
- **Procedure**: Samples were spotted on silica gel plates and developed in the solvent chamber. After drying, the Rf values were calculated and compared for consistency [11].

2.7 Differential Scanning Calorimetry (DSC)

DSC analysis was used to evaluate the **thermal compatibility** between Diclofenac Sodium and Gum Ghatti:

- **Samples**: Pure drug, GG, physical mixture, and final formulation.
- **Procedure**: Samples (5–10 mg) were scanned in sealed aluminum pans at a rate of 10°C/min from 40°C to 300°C under nitrogen atmosphere.
- **Interpretation**: The presence of any additional peaks or shift in melting points was evaluated to detect possible interactions [12].

3. Results and Discussions

3.1 Tablet Evaluation of GGF vs MF

The GGF formulation and the marketed formulation (MF) were evaluated for key quality attributes. The results are summarized in Table 2.

Table 2: Evaluation Parameters of GGF and MF

Parameter	GGF	MF
Hardness (kg/cm²)	5.64 ± 0.12	8.96 ± 0.13
Friability (%)	0.3036	0.00
Thickness (mm)	3.97 ± 0.03	3.91 ± 0.01
Weight Variation (%)	Within permissible limits	Within permissible limits
Drug Content (%)	98.25 ± 0.89	99.68 ± 1.11

GGF exhibited slightly lower hardness and friability compared to MF but remained within acceptable pharmacopeial limits. Both formulations showed consistent weight and drug content uniformity.

3.2 In Vitro Drug Release Profile

The drug release profiles of GGF and MF over a 12-hour period were compared and illustrated in Figure 1.

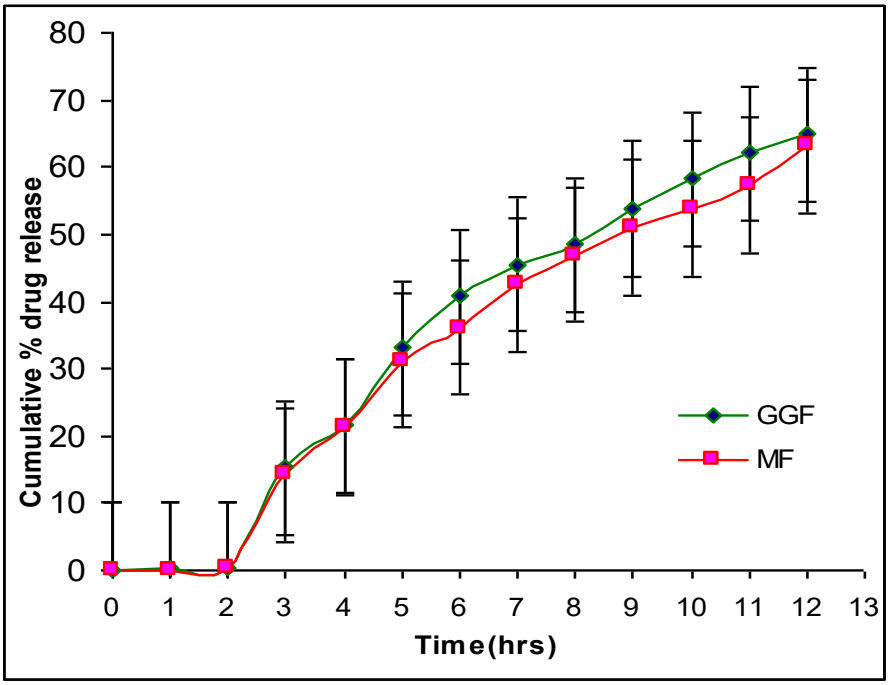


Figure 1: In Vitro Drug Release Profile of GGF vs MF

GGF: 64.89% ± 0.45 at 12 hours | MF: 63.10% ± 1.58 at 12 hours

GGF showed a release profile very similar to that of MF, with both maintaining sustained drug release over the 12-hour period. This similarity supports the potential equivalence of the test and reference formulations.

3.3 Drug Release Kinetics

The cumulative drug release data for both GGF and MF were fitted to various mathematical models. The kinetic parameters are summarized in Table 3.

Table 3: Release Kinetic Parameters of GGF and MF

Model	GGF	MF
Zero-order (r^2)	0.9643	0.9685
Higuchi (r^2)	0.9017	0.9026
Korsmeyer–Peppas (n)	0.8734	0.7016

Both formulations followed **anomalous (non-Fickian) diffusion**, indicating a combined mechanism of diffusion and erosion. Zero-order kinetics were predominant in both cases, suggesting constant drug release over time.

3.4 Drug-Excipient Compatibility (TLC Analysis)

TLC was performed to detect any potential interactions between Diclofenac Sodium and excipients in the GGF formulation. The Rf values obtained for the pure drug, physical mixture, and final formulation were consistent and identical, indicating no interaction or degradation.

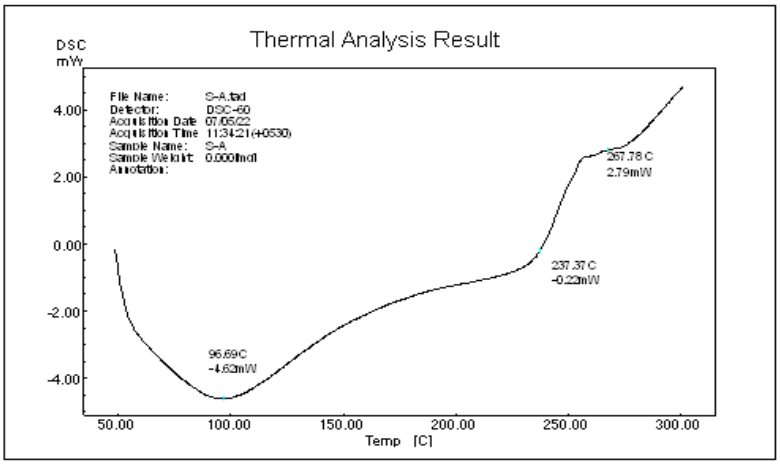
Table 4: TLC Rf Values

Sample	Rf Value
Pure Drug	0.53
Physical Mixture	0.53
Tablet Powder (GGF)	0.53

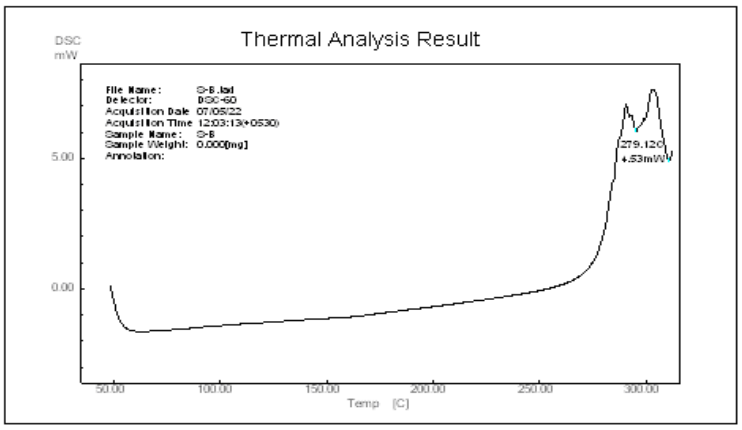
Figure 2: TLC Plates for Drug, Mixture, and Formulation
Visual evidence confirmed uniform and unchanged spot migration.

3.5 Differential Scanning Calorimetry (DSC)

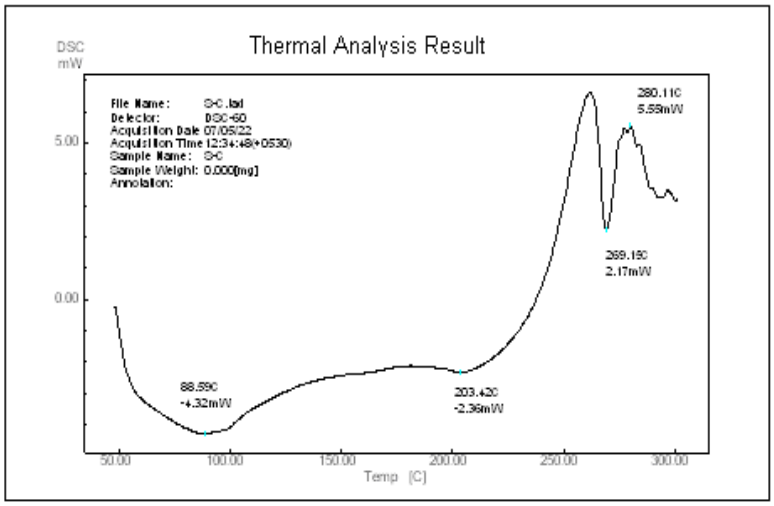
DSC thermograms of the pure drug, Gum Ghatti, their physical mixture, and the final formulation were analyzed to assess thermal compatibility.



S-A → Gum Ghatti Powder



S-B → Drug (Diclofenac Sodium)



S-C → Tablets (Powder)

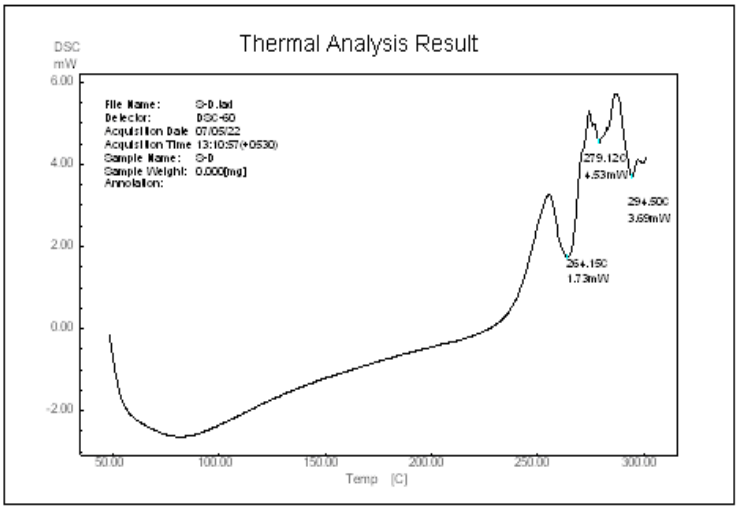


Figure 3: DSC Thermograms of Drug, GG, Physical Mixture, and GGF

No new peaks or significant shifts in melting point were observed in the physical mixture or final formulation, confirming thermal compatibility and the absence of interactions.

3.6 Accelerated Stability Study

GGF tablets were stored under accelerated conditions (40°C ± 2°C / 75% RH ± 5%) for 60 days. Physical characteristics, drug content, and release profile were reassessed at 30 and 60 days.

Table 5: Stability Data for GGF

Parameter	Day 0	Day 30	Day 60
Hardness (kg/cm²)	5.64	5.61	5.58
Friability (%)	0.3036	0.3154	0.3281
Drug Content (%)	98.25	97.91	97.36
Dissolution (%)	64.89	64.12	63.55

Minimal changes were observed, all within acceptable limits, indicating good physical and chemical stability of the GGF formulation over the study period.

4. Conclusion

The present study successfully demonstrates the feasibility of using Gum Ghatti (GG)as a natural polymer for sustained-release matrix tablets of Diclofenac Sodium, and its comparability with a marketed formulation (MF). The optimized GG-based formulation (GGF), containing 25% w/w GG, exhibited desirable tablet characteristics including acceptable hardness, friability, uniform weight, and consistent drug content.

The in vitro drug release profile of GGF closely matched that of the marketed product, with both formulations maintaining controlled release over a 12-hour period. Drug release kineticsindicated a non-Fickian (anomalous) mechanism governed by a combination of diffusion and erosion processes. Additionally, TLC and DSC studies confirmed the absence of any significant drug–excipient interactions, indicating good compatibility and formulation integrity.

The accelerated stability study further demonstrated that GGF retained its physical and chemical characteristics over 60 days under stress conditions, validating its shelf-stability.

Overall, Gum Ghatti proves to be a promising, cost-effective, and biocompatible natural polymer that can serve as an efficient matrix-forming agent in sustained-release drug delivery. Its successful comparison with a commercially available product highlights its potential for industrial applicati**on** in the development of natural polymer-based pharmaceutical formulations**.**

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