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Tensile And Disintegration Efficacy Of Terminalia Avicennioides Gum In Extended-Release Aceclofenac Tablet.

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Abstract:
Background: *Conventional immediate-release aceclofenac formulations require frequent dosing due to the drug's short elimination half-life (2–4 hours), leading to potential plasma concentration fluctuations and reduced patient compliance. Extended-release (ER) matrix systems overcome these limitations by maintaining steady therapeutic levels over prolonged periods. Natural plant gums offer safe, biodegradable, and cost-effective alternatives to semi-synthetic polymers like hydroxypropyl methylcellulose (HPMC), but their performance as release-controlling matrix formers requires rigorous evaluation. This study evaluated the tensile and disintegration efficacy of Terminalia avicennioides gum resin as a sustained-release matrix polymer in aceclofenac 200 mg tablets in direct comparison to HPMC K100M.*
Materials and Methods: Purified T. *avicennioides gum resin was extracted, purified, and formulated into five matrix tablet batches (A1–A5) at varying polymer concentrations (20%, 30%, 40%, 50%, and 60% w/w) alongside constant amounts of calcium carbonate (6.8% w/w) and microcrystalline cellulose using an aqueous wet granulation method. A reference batch (A6) containing 28.8% w/w HPMC K100M was prepared under identical compaction parameters. Granules were evaluated for flow and density metrics (angle of repose, bulk/tapped density, Carr's index, Hausner ratio). Compressed tablets were subjected to pharmacopoeial post-compression quality control tests including friability, weight uniformity, crushing strength (hardness), and in vitro disintegration testing using standard USP apparatus.*
Results: *Granules containing T. avicennioides gum exhibited cohesive flow behavior, with angles of repose ranging from 43.49° (A4) to 65.90° (A5), while displaying high bulk densities (0.500–0.588 g/mL) and low Hausner ratios (1.11–1.19). All formulation batches complied with official USP limits for friability (0.329%–0.704%) and weight uniformity (CV < 5%). Tablet crushing strength demonstrated a clear polymer concentration-dependent increase, rising from 3.80 ± 0.48 kgf at 20% gum (A1) to 8.10 ± 0.66 kgf at 60% gum (A5), with Batch A5 successfully reaching the target extended-release hardness range (7–10 kp). The reference HPMC batch (A6) exhibited the highest hardness (10.50 ± 0.41 kgf). In vitro disintegration times progressively increased with higher gum loadings, extending from 30.0 ± 1.5 min (A1) to 65.0 ± 4.0 min (A5), compared to 75.0 ± 3.5 min for the HPMC control (A6).*
Conclusion*: Native Terminalia avicennioides gum resin possesses excellent binding properties and produces mechanically robust compacts with low friability. Although higher loadings (60% w/w) effectively retard disintegration and yield acceptable tablet tensile strength, the unmodified native gum hydratably erodes faster than HPMC K100M. Chemical modification of the gum is recommended to enhance matrix integrity and gel layer viscosity for full functional equivalence to synthetic polymer standards in extended-release formulations.*
Key Word: *Terminalia avicennioides gum; Aceclofenac; Extended-release matrix; Tensile efficacy; Disintegration efficacy; HPMC K100M*

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I. Introduction

Oral drug delivery remains the most preferred and widely utilized route of drug administration because of its convenience, non-invasiveness, high patient compliance, cost-effectiveness, and formulation flexibility. Despite these advantages, conventional immediate-release dosage forms often produce rapid fluctuations in plasma drug concentrations, necessitating frequent dosing, which may reduce patient adherence and increase the

risk of concentration-dependent adverse effects. To overcome these pharmacokinetic limitations, considerable attention has been directed toward the development of extended-release (ER) or sustained-release (SR) drug delivery systems, which are designed to maintain therapeutic drug concentrations for prolonged periods by regulating drug release through polymeric matrices (Aulton and Taylor, 2022; Alqahtani et al., 2021). These systems improve therapeutic outcomes by minimizing peak-to-trough plasma fluctuations, reducing dosing frequency, and enhancing patient compliance, particularly in the management of chronic diseases requiring long-term pharmacotherapy (Aulton and Taylor, 2022).

A broad spectrum of therapeutic agents used for the long-term management of chronic diseases or characterized by short biological half-lives have been successfully formulated into extended-release (ER) dosage forms to improve therapeutic efficacy and patient adherence. Extended-release formulations maintain more consistent plasma drug concentrations, reduce fluctuations associated with repeated dosing, and improve the safety profile of many drugs (Alqahtani et al., 2021; Aulton and Taylor, 2022). For example, aceclofenac, a non-steroidal anti-inflammatory drug (NSAID) with a relatively short elimination half-life of approximately 2–4 hours, has been formulated into extended-release matrix tablets to prolong analgesic and anti-inflammatory activity while reducing dosing frequency and minimizing gastrointestinal adverse effects (Halwai and Mishra, 2023). Similarly, metoprolol succinate is widely available as an extended-release formulation to provide sustained 24-hour blood pressure control and improve cardiovascular outcomes in hypertensive patients. In addition, extended-release formulations of metformin hydrochloride have been developed to reduce gastrointestinal intolerance, improve patient compliance, and maintain effective glycaemic control in individuals with type 2 diabetes mellitus (Fu et al., 2021).

Extended-release formulations offer several advantages over conventional immediate-release dosage forms. By releasing the drug gradually over an extended period, they help maintain more stable plasma drug concentrations, reduce the frequency of dosing, and improve patient adherence to treatment. They also reduce the occurrence of peak drug concentrations that may increase the risk of adverse effects, while maintaining drug levels within the therapeutic range for longer periods. These benefits are especially important in the management of chronic diseases where continuous drug therapy is required (Aulton and Taylor, 2022; Alqahtani et al., 2021). In addition, extended-release systems may improve overall treatment outcomes and patient quality of life by simplifying medication schedules and reducing fluctuations in drug response (Froelich et al., 2023).

Aceclofenac is a phenylacetic acid derivative belonging to the class of non-steroidal anti-inflammatory drugs (NSAIDs). It works mainly by inhibiting cyclooxygenase-2 (COX-2), thereby reducing the production of prostaglandins responsible for pain, inflammation, and fever. Clinically, aceclofenac is widely used in the treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis because of its effectiveness and relatively better gastrointestinal tolerability compared with some conventional NSAIDs (Netrapal and Azharuddin, 2025). However, its relatively short elimination half-life of about 2–4 hours requires repeated dosing to maintain therapeutic drug levels, making it a suitable candidate for extended-release formulations (Halwai and Mishra, 2023).

To overcome the limitations associated with conventional aceclofenac tablets, the drug has been formulated into extended-release matrix tablets. These formulations commonly use hydrophilic or hydrophobic polymers to control the rate of drug release. When the tablet comes into contact with gastrointestinal fluids, the polymer absorbs water and forms a gel layer around the tablet. This gel layer slows the penetration of fluid into the tablet and controls the gradual release of the drug over an extended period. As the tablet moves through the gastrointestinal tract, the gel layer slowly erodes, allowing aceclofenac to be released in a controlled manner. This controlled-release mechanism helps maintain therapeutic drug levels for a longer period, reduces dosing frequency, and improves patient compliance (Halwai and Mishra, 2023; Alqahtani et al., 2021; Aulton and Taylor, 2022).

In recent years, researchers have explored different polymer systems to improve the extended-release performance of aceclofenac tablets. Hydroxypropyl methylcellulose (HPMC), particularly the high-viscosity grade HPMC K100M, remains one of the most widely used polymers because it forms a stable gel layer that effectively controls drug release over an extended period. More recently, attention has shifted towards combining synthetic polymers with natural gums such as xanthan gum, guar gum, and gellan gum. These combinations improve the mechanical strength of the tablet and provide more controlled and predictable drug release. In addition, several studies have shown that some natural polymers can be used alone to produce effective extended-release tablets when properly processed, making them promising alternatives to synthetic materials (Froelich et al., 2023; Halwai and Mishra, 2023; Alqahtani et al., 2021).

Hydroxypropyl methylcellulose (HPMC), also known as hypromellose, is one of the most commonly used polymers in the formulation of extended-release oral tablets. High-viscosity grades such as HPMC K100M and HPMC K15M are widely used as matrix-forming agents because they rapidly hydrate in the presence of gastrointestinal fluids to form a strong gel barrier around the tablet. This gel barrier controls the penetration of

water into the tablet and slows the release of the drug over time. Besides its use as a matrix former, HPMC is also employed in gastro-retentive drug delivery systems to prolong gastric residence time and as a film-coating agent to protect tablets from moisture and improve product stability. These properties have made HPMC the reference polymer for many extended-release formulations (Aulton and Taylor, 2022; Almuqbil et al., 2024; Froelich et al., 2023).

The widespread use of HPMC in extended-release formulations is mainly due to its reliable performance and ease of formulation. During tablet compression, HPMC undergoes plastic deformation, producing tablets with good mechanical strength, low friability, and high resistance to breakage. When exposed to gastrointestinal fluids, it forms a consistent gel layer that controls water penetration and drug diffusion, resulting in a predictable and sustained drug release profile. In addition, the release rate can be easily adjusted by changing the concentration or viscosity grade of the polymer, making HPMC a flexible and dependable choice for the formulation of extended-release tablets (Aulton and Taylor, 2022; Almuqbil et al., 2024; Maderuelo et al., 2021).

Although synthetic and semi-synthetic polymers such as HPMC have been widely used in extended-release tablet formulations, there is increasing interest in the use of natural polymers as alternative excipients. This interest is driven by the need for materials that are biodegradable, biocompatible, environmentally friendly, and readily available. Natural gums are also attractive because they are generally less expensive, renewable, and can be obtained from local plant sources. In addition, many natural polymers possess excellent swelling and gel-forming properties, making them suitable for controlling drug release in extended-release matrix tablets. As a result, researchers are increasingly investigating plant-derived gums as potential substitutes or complements to synthetic polymers in pharmaceutical formulations (Froelich et al., 2023; Nep et al., 2020; Alqahtani et al., 2021).

In response to the growing demand for safe, affordable, and biodegradable pharmaceutical excipients, researchers have increasingly explored plant-derived polymers from indigenous species. One such plant is *Terminalia avicennioides* Guill. & Perr., a member of the family Combretaceae, which is widely distributed across the savannah regions of West Africa, including Nigeria, Niger, and Burkina Faso. Traditionally, different parts of the plant have been used in African herbal medicine for the treatment of inflammatory conditions, gastrointestinal disorders, wounds, and microbial infections. Recent studies have also reported that *T. avicennioides* contains bioactive compounds such as tannins, flavonoids, saponins, and glycosides, which contribute to its medicinal properties and support its potential use in pharmaceutical applications (Dingwoke et al., 2025; Azeez et al., 2015).

Beyond its traditional medicinal uses, *Terminalia avicennioides* has attracted interest in pharmaceutical research because of the physicochemical properties of its natural gum. Plant gums are widely recognized as useful pharmaceutical excipients due to their ability to swell in aqueous media, form viscous gels, and act as binders or controlled-release matrix formers. The gum obtained from *T. avicennioides* is therefore being investigated as a potential natural polymer for the formulation of extended-release tablets. In addition to being biodegradable and biocompatible, it is locally available and may provide a cost-effective alternative to conventional synthetic polymers, particularly in developing countries (Nep et al., 2020; Froelich et al., 2023; Dingwoke et al., 2025).

Natural gums have been widely investigated as matrix-forming agents in extended-release tablet formulations because of their ability to absorb water, swell, and form a gel layer around the tablet after administration. This gel layer acts as a barrier that slows the penetration of the dissolution medium into the tablet and controls the release of the drug over time. The rate of drug release depends on factors such as the concentration of the polymer, its viscosity, degree of swelling, and erosion of the matrix. Because of these properties, natural gums have shown considerable potential as alternatives to synthetic polymers in controlled drug delivery systems (Nep et al., 2020; Froelich et al., 2023; Bakre and Odeku, 2020).

Although many natural gums have been studied for use in controlled drug delivery systems, there is still limited information on the application of *Terminalia avicennioides* gum as a matrix-forming polymer in extended-release tablets. Most previous studies on this plant have focused on its phytochemical composition and medicinal properties, while relatively few have investigated its pharmaceutical excipient potential. In particular, there is limited information on its ability to control drug release, produce tablets with acceptable mechanical properties, and serve as an alternative to established polymers such as HPMC. Therefore, further studies are needed to evaluate its suitability as a natural matrix-forming agent for extended-release drug delivery (Nep et al., 2020; Froelich et al., 2023; Nnamani and Muazu, 2026).

Despite the widespread use of synthetic polymers such as hydroxypropyl methylcellulose (HPMC) in extended-release tablet formulations, there is growing interest in identifying natural alternatives that are safe, biodegradable, readily available, and cost-effective. Natural plant gums have shown promising pharmaceutical properties, but many remain underutilized and insufficiently studied. Although *Terminalia avicennioides* has been widely investigated for its medicinal and phytochemical properties, there is limited information on the

ability of its purified gum resin to function as a matrix-forming polymer in extended-release tablet formulations. This knowledge gap limits its potential application as a locally sourced pharmaceutical excipient. Therefore, there is a need to evaluate the performance of *Terminalia avicennioides* gum resin as a sustained-release matrix former using aceclofenac as a model drug and compare its performance with a conventional polymer such as HPMC (Nep et al., 2020; Froelich et al., 2023; Nnamani and Muazu, 2026).

The search for safe, effective, and affordable natural polymers has become an important area of pharmaceutical research due to the increasing demand for sustainable and environmentally friendly excipients. If *Terminalia avicennioides* gum is found to possess suitable matrix-forming properties, it could serve as a locally available alternative to synthetic polymers used in extended-release tablet formulations. This may help reduce the dependence on imported pharmaceutical excipients and encourage the utilization of indigenous plant resources in drug formulation. Furthermore, the findings of this study will contribute to the existing knowledge on natural polymers and provide useful information for future research on the development of extended-release drug delivery systems using plant-derived excipients (Froelich et al., 2023; Nep et al., 2020).

Consequently, this work explicitly intends to evaluate and compare the extended-release tablet properties of HPMC matrices with those formulated using *Terminalia avicennioides* gum. By evaluating these two polymeric configurations under identical compaction parameters, this study directly measures how a plant-derived polysaccharide network competes with a semi-synthetic cellulose ether in controlling the release of a hydrophobic, brief half-life model drug like aceclofenac.

The core of this comparison centers on balancing two critical, opposing structural behaviors:

Tensile Efficacy: The study evaluates the mechanical consolidation, plastic deformation, and post-compression crushing strength of the tablets to ensure that *T. avicennioides* matrices can match the exceptional mechanical integrity and low friability typical of commercial HPMC compacts.

Disintegration Efficacy: The investigation monitors how effectively the natural gum regulates water penetration and matrix erosion over a 12-to-24-hour cycle. This provides a strict benchmark against the uniform, non-rupturing gel boundaries produced by HPMC, ensuring the natural polymer can prevent premature matrix structural failure or accidental dose dumping.

II. Material And Methods

Aceclofenac API (purity ≥ 99.5%; Sigma-Aldrich, Germany) was used as the model drug throughout this study. *T. avicennioides* gum resin exudate was collected from authenticated trees at the botanical garden of the Department of Pharmacognosy, Dora Akunyili College of Pharmacy, Igbinedion University, Okada, Edo State, Nigeria (Herbarium voucher number IUO/16/127), Hydroxypropyl Methylcellulose, (HPMC K100M; Colorcon, UK) was used as the reference extended-release matrix polymer in Batch A6. Lactose monohydrate BP/USP (Meggle, Germany), microcrystalline cellulose BP/USP (Avicel® PH 101; FMC BioPolymer, USA), calcium carbonate BP/USP (Merck, Germany), and magnesium stearate BP/USP (Peter Greven, Netherlands) were used as excipients. Absolute ethanol (99.9% purity; BDH Chemicals, UK), distilled water (freshly prepared in-house), 0.1N hydrochloric acid (analytical grade; Merck, Germany), and phosphate buffer pH 6.8 (prepared from potassium dihydrogen phosphate and sodium hydroxide, analytical grade; Sigma-Aldrich, Germany) were used as solvents and dissolution media. All chemicals and reagents were of analytical or pharmaceutical grade unless otherwise stated.

III. Methodology:

Collection, Authentication, and Extraction of *T. avicennioides* Gum Resin

Fresh gum resin exudate of *Terminalia avicennioides* Guill. and Perr. (family Combretaceae) was collected from authenticated trees at the botanical garden of the Department of Pharmacognosy, Dora Akunyili College of Pharmacy, Igbinedion University, Okada, Edo State, Nigeria. Botanical authentication was performed by a certified taxonomist, and a voucher herbarium specimen (IUO/16/127) was deposited in the departmental herbarium for future reference.

The raw gum resin exudate was collected by making shallow incisions in the stem bark of authenticated *T. avicennioides* trees and allowing the exudate to harden naturally on exposure to air. The hardened exudate was harvested, cleaned of bark debris and foreign matter, and subjected to the following aqueous extraction and purification procedure: (i) the raw exudate was dissolved in distilled water (1:5 w/v) with continuous stirring at 60°C for 2 hours; (ii) the solution was filtered through a double layer of muslin cloth to remove insoluble debris; (iii) the filtrate was precipitated by addition of three volumes of absolute ethanol (99.9% v/v) with continuous stirring; (iv) the precipitate was collected by vacuum filtration through Whatman No. 1 filter paper, washed twice with absolute ethanol to remove lipophilic impurities, and air-dried at ambient temperature for 24 hours; (v) the dried precipitate was further oven-dried at 45°C for 4 hours; and (vi) the dried product was milled in a laboratory hammer mill and passed through a 250 µm stainless steel sieve to yield a purified *T. avicennioides* gum resin powder. The percentage yield was calculated and the purified powder was

stored in airtight amber glass containers at ambient temperature, protected from light and moisture, pending characterisation and formulation.

Physicochemical Characterisation of *T. avicennioides* Gum Resin

The purified *T. avicennioides* gum resin powder was characterised for the following physicochemical parameters prior to formulation:

Organoleptic Evaluation: Colour, odour, and texture were assessed by direct sensory examination in accordance with the British Pharmacopoeia (2023).

Tablet Formulation Design

Six batches of extended-release aceclofenac 200 mg matrix tablets (A1–A6) were formulated as described in Table 1. Batches A1–A5 contained *T. avicennioides* gum resin as the sole release-controlling matrix polymer at 20, 30, 40, 50, and 60% w/w of the total tablet weight, respectively. Batch A6 contained hydroxypropyl methylcellulose (HPMC K100M) as the reference extended-release matrix polymer, prepared by an identical wet granulation process and compressed under identical conditions. Calcium carbonate was incorporated at a fixed concentration of 40 mg per tablet (2 g per batch of 50 tablets, equivalent to 6.8% w/w of the total tablet weight) across all batches. At this loading, calcium carbonate serves a dual functional role: as a pH-modifying excipient that buffers the microenvironmental pH of the tablet matrix against the acidic gastric environment (pH 1.2), thereby protecting aceclofenac from acid-catalysed hydrolysis during the gastric phase of dissolution; and as an inert inorganic diluent contributing to the tablet bulk weight and compressibility. Because its concentration was maintained constant across all six batches, any contribution to drug release kinetics would be uniform and would not confound the concentration-response relationship attributed solely to the *T. avicennioides* gum resin primary matrix former. Microcrystalline cellulose served as a compression aid, lactose monohydrate as a pore-forming diluent, and magnesium stearate as the extragranular lubricant. All non-matrix excipient components were maintained constant across batches to isolate the independent effect of gum resin concentration on formulation performance.

Table 1: Formulation of Extended-Release Aceclofenac 200 mg Matrix Tablets (Batches A1–A6) by Wet Granulation

Ingredient (g/batch for 50 tablets)	A1 (20% w/w)	A2 (30% w/w)	A3 (40% w/w)	A4 (50% w/w)	A5 (60% w/w)	A6 (Reference)
Aceclofenac (API)	10	10	10	10	10	10
T. avicennioides gum resin	5.9	8.85	11.8	14.75	17.7	—
Hydroxypropyl methylcellulose (HPMC K100M)	—	—	—	—	—	8.5
Lactose monohydrate	10.6	7.65	4.7	1.75	—	6.5
Microcrystalline cellulose	2	2	2	2	2	2
Calcium carbonate	2	2	2	2	2	2
Magnesium stearate	0.5	0.5	0.5	0.5	0.5	0.5
Total batch weight (g)	**29.5**	**29.5**	**29.5**	**29.5**	**29.5**	**29.5**

— = Calcium carbonate, MCC, lactose monohydrate are intragranular; magnesium stearate is the extragranular lubricant blended into dried granules immediately before compression.

Ingredient (mg/tablet)	A1 (20% w/w)	A2 (30% w/w)	A3 (40% w/w)	A4 (50% w/w)	A5 (60% w/w)	A6 (Reference)
Aceclofenac (API)	200	200	200	200	200	200
T. avicennioides gum resin	118	177	236	295	354	—
Hydroxypropyl methylcellulose (HPMC K100M)	—	—	—	—	—	170
Lactose monohydrate	212	153	94	35	—	130
Microcrystalline cellulose	40	40	40	40	40	40
Calcium carbonate	40	40	40	40	40	40
Magnesium stearate	10	10	10	10	10	10
Total tablet weight (mg)	**590**	**590**	**590**	**590**	**590**	**590**

Table 2: Per-Tablet Composition of Extended-Release Aceclofenac 200 mg Matrix Tablets (Batches A1–A6) Derived from Batch Formula (Table 1)

(batch quantities ÷ 50 tablets). — = Calcium carbonate and MCC serve as diluents and functional pH modifier/compression aid respectively; magnesium stearate is an extragranular lubricant. Total tablet weight = 590 mg.

Wet Granulation Procedure

All six batches (A1–A6) were prepared by aqueous wet granulation following the validated methodology of Nnamani and Muazu (2026), adapted for the *T. avicennioides* gum resin primary matrix system. The procedure comprised the sequential stages described below.

Preparation of Granulating Solution

For Batches A1–A5, the requisite quantity of purified *T. avicennioides* gum resin powder — corresponding to 20, 30, 40, 50, or 60% w/w of the final tablet weight respectively — was dissolved in the minimum volume of distilled water required to produce a viscous but pourable granulating solution. The solution was prepared freshly on the day of use and allowed to hydrate completely for 30 minutes with continuous stirring at ambient temperature prior to use. For Batch A6, HPMC K100M was dispersed in cold water (approximately 15°C) with continuous stirring and allowed to hydrate overnight at 4°C, forming a clear, viscous granulating solution at a concentration equivalent to the target 28.8% w/w hydroxypropyl methylcellulose content of the final tablet.

Dry Blending

Aceclofenac API (200 mg per tablet equivalent) was accurately weighed and passed through a 250 µm stainless steel sieve to break up any agglomerates. The intragranular fractions of lactose monohydrate, microcrystalline cellulose, and calcium carbonate (per the batch formula in Table 1) were similarly sieved and combined with aceclofenac. The powder blend was dry-mixed in a planetary mixer (Kenwood Chef, UK) at low speed for 5 minutes to achieve a homogeneous premix, confirmed by visual uniformity of the blend.

Wet Massing and Granulation

The granulating solution — *T. avicennioides* gum resin solution for Batches A1–A5 and HPMC solution for Batch A6 — was added to the dry premix in small, measured increments with continuous mixing in the planetary mixer at medium speed. Wet massing was continued for 5–10 minutes until a coherent, non-sticky granular mass of uniform consistency was achieved; the end point was assessed by the hand-squeeze test, where the mass held its shape without crumbling or adhering excessively to the glove. The wet mass was manually extruded through a stainless steel sieve (mesh size 1.0 mm) mounted on a granulating tray to produce uniform rod-shaped granular structures.

Drying and Milling

The wet granules were spread in a single layer on clean stainless steel drying trays and dried in a hot-air oven at 50°C for 2–3 hours until the residual moisture content of the dried granules was within the target range of 1–3% w/w, determined by loss on drying at 105°C for 1 hour on a representative sample. Drying at 50°C was specifically selected to avoid thermal degradation of the polysaccharide and tannin fractions of the gum resin, which exhibit onset of thermal degradation above 150°C as determined by TGA. Dried granules were milled in a laboratory hammer mill (Erweka AR400, Germany) and passed through a 500 µm stainless steel sieve to obtain granules of uniform particle size distribution suitable for tableting.

Blending of Extragranular Excipients

The milled, sized granules were transferred to a clean polythene bag. Magnesium stearate (1.25% w/w of total tablet weight), pre-sieved through a 250 µm sieve, was added to the granule blend and mixed by manual tumbling for 5 minutes to achieve a uniformly lubricated granule blend. The lubricated blend was used for tablet compression within 30 minutes to minimise lubricant over-mixing, which can reduce tablet hardness.

Tablet Compression

Lubricated granule blends for all six batches were compressed into biconvex tablets using a single-punch tablet press (Manesty B3B, UK) fitted with 11.28 mm round punches and dies. Compression force was adjusted to produce tablets with a target hardness of 7–10 kp. Tablets were produced in batches of not less than 200 per formulation and stored in airtight amber glass containers at ambient temperature (25 ± 2°C) for 24 hours prior to evaluation to allow for elastic recovery of the compressed matrix.

Evaluation of Granules and Tablets

Pre-Compression Granule Characterisation

Angle of Repose

The angle of repose of granules from each batch (A1–A6) was determined by the fixed-funnel method. Twenty grams of granules were allowed to flow freely through a funnel clamped at a fixed height of 5.0 cm

above a flat horizontal surface. The height (h) and radius (r) of the granule heap formed were measured, and the angle of repose (θ) was calculated as:

$\theta = \tan^{-1}(h/r)$ … Equation 1

Determinations were performed in triplicate and mean values with standard deviations were recorded. Angles below 30° indicate excellent flow; 30–40° indicate good flow; above 40° indicate poor flow (Aulton and Taylor, 2022).

Bulk Density and Tapped Density

Twenty grams of granules from each batch were carefully poured into a 100 mL graduated glass cylinder. The initial bulk volume (V_0) was recorded. The cylinder was subjected to 100 mechanical taps on a Copley tap density tester (Copley Scientific, UK), and the final tapped volume (V_t) was recorded. Bulk density (BD) and tapped density (TD) were calculated as:

$BD = W / V_0$ … Equation 2

$TD = W / V_t$ … Equation 3

where W is the weight of granules (g). All determinations were performed in triplicate (USP, 2023).

Carr's Compressibility Index and Hausner Ratio

Carr's Compressibility Index (CI) and Hausner Ratio (HR) were calculated from the bulk and tapped density values as:

$CI\ (\%) = [(TD - BD) / TD] \times 100$ … Equation 4

$HR = TD / BD$ … Equation 5

CI values below 15% and HR below 1.25 indicate good-to-excellent powder flow. CI above 25% and HR above 1.34 indicate poor flow (Aulton and Taylor, 2022).

Post-Compression Tablet Evaluation

Organoleptic Evaluation

Tablets from all batches (A1–A6) were evaluated visually for colour uniformity, surface smoothness, and absence of cracks, chips, or lamination, and by tactile examination for surface texture. Tablets were also assessed for odour. The characteristic mild earthy-resinous odour of *T. avicennioides* gum resin was expected at low intensity in Batches A1–A5, with intensity increasing proportionally with gum resin concentration; Batch A6 (HPMC K100M reference) was expected to be white to off-white and odourless (British Pharmacopoeia, 2023).

Weight Uniformity

Twenty tablets from each batch were individually weighed on an analytical balance (Mettler AE240, Switzerland) accurate to 0.1 mg. The mean tablet weight and standard deviation were calculated. Acceptance criteria required that not more than two tablets deviate from the mean weight by more than 5%, and that no individual tablet deviate by more than 10% from the mean (British Pharmacopoeia, 2023).

Hardness (Crushing Strength)

The crushing strength of ten tablets per batch was determined using a motorised tablet hardness tester (Erweka TBH 28, Germany). Mean hardness values with standard deviations were reported in kilopond (kp). A target hardness range of 7–10 kp was specified for all batches to ensure adequate mechanical integrity for extended-release matrix tablets without compromising the dissolution performance of the matrix.

Friability

Ten pre-weighed tablets from each batch (total weight approximately 6.5 g) were placed in a Roche friabilator (Erweka TA3R, Germany) and rotated at 25 rpm for 4 minutes (100 revolutions). Tablets were removed, dedusted, and reweighed. Friability was calculated as:

$Friability\ (\%) = [(W_0 - Wf) / W_0] \times 100$ … Equation 6

where W_0 and Wf are the initial and final tablet weights respectively. A friability value of ≤1.0% is considered acceptable (USP, 2023). Determinations were performed in triplicate.

In Vitro Disintegration Testing

The disintegration time of the compressed extended-release matrix tablets was evaluated in triplicate using a standard USP disintegration tester (Apparatus A) maintained at a physiological temperature of 37 degrees Celsius. One tablet was placed into each of the six glass tubes of the basket-rack assembly, and purified water was utilized as the immersion fluid. The apparatus was operated at a constant frequency of 30 cycles per minute. The disintegration endpoint was visually monitored and recorded at the exact moment no solid core or palpable mass remained on the screen mesh of the apparatus.

IV. Results

The micromeritic evaluation of all 6 batches (A1-A6) of granules are presented in Table 3.

Table 3: Micromeritic Properties of Formulated Granules (Batches A1–A6)

BATCH ID.	Angle of Repose (°)	Bulk Density (g/mL)	Tapped Density (g/mL)	Compressibility Index (%)	Hausner's Ratio
Batch A1	47.66	0.500	0.571	12.50	1.14
Batch A2	48.99	0.541	0.645	16.22	1.19
Batch A3	52.13	0.571	0.645	11.43	1.13
Batch A4	43.49	0.588	0.656	10.29	1.11
Batch A5	65.90	0.526	0.625	15.79	1.19
Batch A6 (Control)	37.83	0.417	0.526	20.83	1.26

Post compression evaluation

Table 4: Post compression properties of the tablets (Batches A1-A6)

Batch ID	Friability, %F (%)	Disintegration time (Minutes) (n=3)	Mean Weight (mg)	SD	CV (%)	Mean Hardness (kgf/kp)	SD	CV (%)
A1	0.340	30.0 ± 1.5	584.50	±14.61	2.50	3.80	±0.48	12.63
A2	0.704	37.0 ± 2.1	586.00	±14.49	2.47	5.30	±0.48	9.06
A3	0.336	50.0 ± 2.8	587.50	±11.64	1.98	5.50	±0.41	7.45
A4	0.329	57.0 ± 3.2	589.00	±9.66	1.64	6.50	±0.53	8.15
A5	0.685	65.0 ± 4.0	604.00	±26.23	4.34	8.10	±0.66	8.15
A6 (Control)	0.315	75.0 ± 3.5	613.00	±30.57	4.99	10.50	±0.41	3.90

Friability

The percentage friability of granules/tablets from all 6 batches (A1–A6) was determined and is presented in **Table 4.** All batches complied with the USP acceptance limit of ≤1.0%.

Weight uniformity

Individual tablet weights (n = 20 per batch) and statistical uniformity profiles for all 6 batches (A1–A6) are presented in **Table 4**. The USP weight variation limit permits a maximum deviation of ±5% from the calculated mean.

Hardness (Crushing Strength)

Post-compression tablet hardness (crushing strength), determined for 10 tablets per batch (A1–A6), is presented in **Table 4.** A target hardness range of 7–10 kp was specified for all batches.

Disintegration

In vitro disintegration time profiles for all 6 batches (A1–A6) are presented in **Table 4.** Only Batch A1 met the USP conventional disintegration limit of ≤30 minutes, at the upper boundary; all other batches exceeded this limit, reflecting a sustained/extended disintegration trend consistent with the extended-release matrix design.

V. Discussion

Granule Properties (Pre-Compression)

The flow of the granules is really important because it affects how evenly the powder fills the machine die before pressing. The results for all our granule batches (A1 to A5) and the HPMC control (A6) are in **Table 3.**

We used the angle of repose to check how well the granules flow. Usually, an angle under 30 degrees is excellent, 30 to 40 degrees is good, and anything above 40 degrees is poor (Aulton and Taylor, 2022). For our gum batches, the angles were quite high, ranging from 43.49 degrees (Batch A4) to 65.90 degrees (Batch A5). These high numbers show that the *Terminalia avicennioides* granules do not flow very well and are quite sticky. This is a normal thing with natural plant gums because they easily absorb moisture and have rough, irregular shapes (Nep et al., 2020).

Interestingly, the flow did not just get worse as we added more gum. Batch A4 (which has 50% gum) actually flowed the best out of the gum batches, with an angle of repose of 43.49 degrees. Even though this is still considered poor flow, its Compressibility Index was 10.29% and its Hausner's Ratio was 1.11. This means it can pack together really well once it is tapped (Aulton and Taylor, 2022). It seems the amount of water/binder we used in this specific batch was just right to make the granules a bit more even.

At 60% gum (Batch A5), the flow got very bad, with an angle of 65.90 degrees. This happened because using too much of this thick gum makes the wet mass too sticky. It takes a long time to dry and ends up milling into rough, uneven chunks that do not slide easily (Olayemi et al., 2020).

Our gum granules also had higher bulk and tapped densities than the HPMC control (A6). HPMC is very light and fluffy, but our natural gum granules are heavier (Almuqbil et al., 2024). Having heavier granules is actually good because they pack tightly in the machine and help prevent the tablets from cracking under pressure (Muazu et al., 2021).

Evaluation of the Compressed Tablets

Tablet Friability

Friability testing shows if the tablets will chip or break when handled or packed. All our batches easily passed the official limit of less than 1.0% weight loss, and none of the tablets cracked or split (USP, 2023).

The weight loss was very low, between 0.315% and 0.704%. This proves that the purified *Terminalia avicennioides* gum works great as a binder. Under pressure, the gum particles deform and lock together tightly (Kunle et al., 2020). Batch A4 had a very low friability of 0.329%, which matches how well its granules packed together.

Weight Uniformity

This test checks if the tableting machine is filling the die consistently so that every tablet weighs about the same. For tablets over 324 mg, the individual weights should not vary by more than 5% from the average (British Pharmacopoeia, 2023).

All our batches passed this test, but the results directly matched how well the granules flowed. Batch A4 had the best granule flow and gave us the most uniform tablets. Its average weight was 589.00 mg with a very small standard deviation of 9.66 mg (and a CV of only 1.64%). This shows that granules that pack well give much more consistent tablet weights (Patel et al., 2021).

On the other hand, Batch A5 (CV of 4.34%) and the control Batch A6 (CV of 4.99%) had the highest weight variations. For Batch A5, this was because the sticky granules (angle of 65.90 degrees) did not flow smoothly into the machine. For Batch A6, the variation came from the high compressibility resistance of pure HPMC, which is normal when compressing it without extra flow-aids (Almuqbil et al., 2024).

Hardness (Crushing Strength)

Hardness shows how much force it takes to break the tablet. We saw a clear pattern: the more gum we added, the harder the tablets got. The average hardness went from 3.80 kgf (Batch A1) up to 8.10 kgf (Batch A5).

We set a target hardness of 7.0 to 10.0 kgf for these tablets. Batches A1 (3.80 kgf), A2 (5.30 kgf), A3 (5.50 kgf), and A4 (6.50 kgf) all failed to meet this lower limit. This means that at lower concentrations, the gum does not bind the particles strongly enough. Only the 60% batch (A5) made it into our target range with 8.10 kgf.

The HPMC control (Batch A6) was the hardest at 10.50 kgf. This is because commercial synthetic cellulose derivatives are known to form extremely strong hydrogen bonds when compressed (Maderuelo et al., 2021).

Hydration and Disintegration Behavior

The disintegration times observed for all formulation batches (A1–A5) and the HPMC-bound control batch (A6) are compiled in Table 4, with values expressed as the Mean and Standard Deviation (SD) of triplicate determinations (n = 3).

While immediate-release solid dosage forms are pharmacopoeially required to break down rapidly to facilitate swift drug dissolution (typically within 15 minutes for uncoated tablets), there is no official disintegration time limit specified in the United States Pharmacopeia (USP) or British Pharmacopoeia (BP) for extended-release formulations. Because these matrix systems are engineered to remain structurally intact to control drug diffusion over a period of 8 to 24 hours, the disintegration apparatus was utilized here not as a pass/fail compliance test, but as a preliminary mechanical stress test to evaluate the hydration and physical erosion kinetics of the polymer networks.

A distinct, concentration-dependent relationship was observed between the percentage of *Terminalia avicennioides* gum in the matrix and the overall disintegration time, which progressed from 30.0 SD 1.5 minutes at a 20% w/w polymer load (Batch A1) to 65.0 SD 4.0 minutes at a 60% w/w polymer load (Batch A5).

The tight standard deviations across these triplicate runs (ranging from 1.5 to 4.0 minutes are highly significant. They provide mathematical proof of a homogenous distribution of the natural polymer throughout the compressed matrix cores during the wet granulation stage. Substantial variation in intra-batch disintegration

times would typically indicate poor powder mixing or localized binding anomalies, but the narrow variance established here confirms consistent processing and structural uniformity.

The progressive retardation of tablet disintegration as the polymer load increases can be described by the classic mechanisms of hydrophilic matrix behavior (Bakre and Odeku, 2020). Upon immersion in the aqueous fluid, the surface-localized *Terminalia avicennioides* gum particles undergo rapid hydration and relaxation of their polysaccharide chains, quickly forming a viscous, contiguous gel layer (Bakre and Odeku, 2020). This gel layer acts as a physical barrier that restricts the rate of further water medium penetration into the dry tablet core. As the concentration of the gum climbs from 20% to 60%, a thicker, more cohesive gel framework is generated, which significantly extends the path length for water diffusion and reduces the rate of surface erosion (Maderuelo et al., 2021).

However, a critical comparison reveals that the control batch (Batch A6), prepared with 28.8% w/w HPMC K100M, achieved a disintegration time of 75.0 SD 3.5 minutes. This means that even at its highest concentration of 60% (Batch A5), the native *Terminalia avicennioides* gum matrix breaks down faster than a low-concentration commercial hypromellose matrix.

This difference highlights the unique hydration kinetics and structural gel strengths of the two polymers. HPMC K100M undergoes rapid polymer chain entanglement, forming a highly resilient, visco-elastic gel barrier that strongly resists mechanical erosion and water influx (Almuqbil et al., 2024). In contrast, the native, un-modified *Terminalia avicennioides* gum forms a more porous, hydrogel structure that is more susceptible to bulk fluid erosion and surface detachment (Nep et al., 2020).

These findings clearly indicate that while native *Terminalia avicennioides* gum exhibits excellent potential as a sustainable, bio-derived matrix binder, its raw form possesses an inherently high rate of hydration-coupled erosion. This directly supports the necessity of executing chemical modifications—such as carboxymethylation or cross-linking—to lower the gum's hydration rate, enhance its net gel layer viscosity, and allow it to better match the sustained-release performance of commercial standards like HPMC K100M (Nep et al., 2020).

VI. Conclusion

This study evaluated the tensile and disintegration efficacy of extended-release aceclofenac 200 mg matrix tablets formulated with purified *Terminalia avicennioides* gum resin at 20–60% w/w (Batches A1–A5), benchmarked against a reference batch containing 28.8% w/w HPMC K100M (Batch A6).

On tensile performance, mechanical consolidation improved consistently with increasing gum concentration: crushing strength rose from 3.80 kgf at 20% gum (Batch A1) to 8.10 kgf at 60% gum (Batch A5), with only Batch A5 falling within the 7–10 kp target hardness range. All batches, including the HPMC reference, met the USP friability limit of ≤1.0%, confirming that native *T. avicennioides* gum binds granules effectively under compression even at lower loadings.

On disintegration efficacy, the gum matrices showed a clear concentration-dependent extension of disintegration time, from 30.0 minutes at 20% w/w to 65.0 minutes at 60% w/w. Even at its highest loading, however, the gum matrix disintegrated faster than the HPMC K100M reference (75.0 minutes), indicating that native, unmodified *T. avicennioides* gum forms a more porous, erosion-prone gel layer than HPMC's hydrogen-bonded gel network.

Overall, native *T. avicennioides* gum resin shows clear potential as a locally sourced, biodegradable matrix-forming excipient, particularly for its binding and mechanical properties at higher loadings. However, its raw form does not yet match the water-uptake and erosion resistance of HPMC K100M at the concentrations tested, supporting the case for chemical modification of the gum before it can be considered a like-for-like substitute for HPMC in extended-release tablet design.

VII. Recommendation

Press Batch A4 harder: Batch A4 (50% gum) had the most consistent weight and very low friability, but its hardness was 6.50 kgf, which is just under our 7.0 kgf target. We should try increasing the compression force on the machine for this batch to see if we can make it hard enough without losing its good properties.

Add flow-aids (glidants): Since all our gum granules had poor flow (especially Batch A5 at 65.90 degrees), we should add things like talc or Aerosil to the mix before tableting. This will help the granules slide into the machine much better.

Try mixing the gum with HPMC: Since the HPMC control (Batch A6) was the hardest and lasted the longest, mixing our natural gum with a little bit of HPMC might give us a stronger, more stable gel layer.

Run dissolution tests: Now that we know the gum forms a good gel barrier, the next step is to run 12-hour dissolution tests. We should fit the release data to mathematical models (like Higuchi or Korsmeyer-Peppas) to see exactly how the drug is being released.

Do stability and safety tests: Natural plant gums can absorb moisture and go bad over time. We need to run stability tests under different temperatures and humidities (ICH guidelines) and run some basic safety tests to make sure the gum is clean and safe to swallow.

Test the gum with highly soluble drugs: Aceclofenac is a poorly soluble drug, so the gum had an easier time slowing down its release. Future work should test this *Terminalia avicennioides* gum with highly water-soluble drugs (like Metformin) to see if the gel layer is strong enough to stop a highly soluble drug from washing out too quickly.

Optimize the drying time and temperature: Since Batch A5 became very sticky and rough during wet massing, we should study how different drying temperatures affect the granules. Finding the exact right moisture content will help improve the final granule flow and stop them from clumping up.

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