

Valorization of *Musa paradisiaca* Pseudo Stem Biomass-Based Matrix Co-Excipient in Extended-Release Diclofenac Sodium Tablets

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ABSTRACT

Background: The valorization of agricultural biomass into pharmaceutical excipients offers a sustainable approach to developing functional materials while reducing biomass waste. *Musa paradisiaca* pseudo stem is a cellulose-rich agricultural residue with potential application as a pharmaceutical matrix material. Incorporation of a hydrophobic excipient such as carnauba wax may further modify its drug-release properties.

Objective: This study investigated the preparation, physicochemical characteristics, and in-vitro drug-release behaviour of extended-release diclofenac sodium tablets formulated with co-processed *Musa paradisiaca* pseudostem cellulose-carnauba wax as a matrix co-excipient.

Methods: Modified *Musa paradisiaca* pseudo stem cellulose (MMPP cellulose) was extracted with a yield of 48.04% and co-processed with varying concentrations of carnauba wax to produce formulation batches A-G. The resulting materials were evaluated using Fourier-transform infrared spectroscopy (FTIR), micromeritic and compaction assessments, while the formulated tablets were evaluated for relevant post-compression properties and in-vitro dissolution behaviour over 12 h using USP apparatus II in an acidic dissolution medium. Drug-release data were further analysed using appropriate mathematical kinetic models.

Results: FTIR spectra of MMPP cellulose, diclofenac sodium, and their physical mixtures showed retention of the characteristic absorption bands of the individual components, with no major spectral changes indicative of a detectable chemical interaction. The powder/granule formulations exhibited acceptable flow characteristics, with bulk density of 0.30–0.36 g/mL, Hausner ratios of 1.25–1.33, and angles of repose of 22.7–27.9°. The compressed tablets exhibited acceptable weight uniformity (0.351–0.378 g), crushing strength (6.68–7.84 kgf), and friability (0.14–0.52%). Increasing the proportion of carnauba wax was associated with a progressive increase in disintegration time from 2.37 min in Batch A to 3.37 min in Batch G and produced a measurable modification of diclofenac sodium release over the 12-h dissolution period.

Conclusion: The findings demonstrate that co-processing MMPP cellulose with carnauba wax can produce a cellulose–wax excipient system capable of modifying the release behaviour of diclofenac sodium tablets. The results support the potential of *Musa paradisiaca* pseudostem cellulose as a biomass-derived pharmaceutical matrix material and provide evidence for the utility of carnauba wax in modulating its drug-release characteristics. Further structural and mechanistic studies would be required to establish the precise microstructural basis of the observed release behaviour.

INTRODUCTION

The paradigm of pharmaceutical excipient engineering is evolving from single-function materials toward multifunctional, co-processed platforms. This progression is largely propelled by the widespread implementation of direct compression technology, which demands excipient particles capable of concurrently optimizing powder

flowability, compressibility, compactibility, and API compatibility. Because single-component excipients rarely possess these diverse attributes in tandem, physical co-processing at the sub-particle level utilizing methods such as spray drying, solvent-assisted thermal fusion, or melt granulation offers a non-chemical route to create complementary and synergistic bulk material behavior¹⁻⁴.

Simultaneously, the pharmaceutical sector is addressing material sustainability by shifting from traditional forestry-derived cellulose to agricultural waste streams. Post-harvest *Musa paradisiaca* (plantain) pseudostem represents an underutilized lignocellulosic biomass with high cellulose yield. Extraction and solid-state characterization of pseudostem-derived microcrystalline cellulose confirm its viability as a compressible core matrix, provided critical material attributes such as degree of crystallinity, moisture content, particle morphology, and degree of polymerization are thoroughly evaluated and standardized⁵.

To modulate drug release from the hydrophilic, fibrous cellulose framework, carnauba wax a natural hydrophobic lipid extracted from *Copernicia prunifera* functions as a complementary co-processing agent. When engineered alongside cellulosic fibers, carnauba wax coats the sub-particle surfaces, lowering surface roughness and improving bulk powder micromeritics. Within a compacted tablet matrix, the lipophilic wax creates a tortuous barrier that limits aqueous medium ingress, decreases drug dissolution rate, and increases diffusional resistance through pore networks^{1,6}.

Combining *Musa paradisiaca* pseudostem cellulose with carnauba wax leverages two distinct functional mechanisms within a single binary co-excipient system: the cellulosic fraction supplies the mechanical strength and compactibility required for tablet formation, while the lipid phase confers hydrophobic release-retarding properties. This approach aligns with contemporary multifunctional design principles by engineering agricultural biomass to match or complement the performance of established semi-synthetic polymers while introducing key sustainability benefits²⁻⁴.

Diclofenac sodium is a well-suited model active pharmaceutical ingredient (API) to validate this sustained-release co-excipient system⁷. As a nonsteroidal anti-inflammatory drug (NSAID) characterized by a short biological half-life (1–2 hours), poor powder compressibility, pH-dependent solubility, and gastrointestinal irritation risks upon frequent administration, it necessitates extended-release matrix delivery^{8,7}. Hydrophobic lipid matrices containing carnauba wax have consistently demonstrated superior release-retardation capabilities compared to conventional hydrophilic carriers for this class of drug^{1,6}.

Accordingly, this study investigates the **valorization of *Musa paradisiaca* pseudostem biomass as a matrix co-excipient in combination with carnauba wax for the formulation of extended-release diclofenac sodium tablets**. The study evaluates the physicochemical characteristics, micromeritic properties, compressional

behaviour, solid-state characteristics, tablet quality attributes, and in-vitro dissolution performance of the developed formulations. Particular attention was given to establishing the relationship between the biomass-derived cellulose-carnauba wax composition and the resulting drug-release profile. The study consequently seeks to demonstrate that an underutilized agricultural biomass can be transformed into a multifunctional pharmaceutical excipient and potentially provide a sustainable alternative or complement to conventional excipient systems used in extended-release tablet manufacture.

MATERIALS

Fresh *Musa paradisiaca* pseudostems and carnauba wax 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. Diclofenac sodium (Cato Pharmaceutical, China) was used as the model drug for tablet formulation.), 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.

METHODS

Collection, Authentication, and Extraction and modification of *Musa paradisiaca* pseudo stem cellulose

Fresh *Musa paradisiaca* pseudo stem was collected as harvest waste from a farm in Ovia North East local government area, Okada, Edo state, Nigeria. Botanical authentication was performed by a certified taxonomist, and a voucher herbarium specimen (IUO/16/129) was deposited in the departmental herbarium for future reference.

Cellulose was extracted from *Musa paradisiaca* pseudo stem using a modified procedure adapted from Prithivirajan et al. (2020). The washed pseudo stems were cut into 2-3 cm pieces, dried, pulverized and treated with 5.0% v/v nitric acid at a 1:10 solid-to-liquor ratio for 24 h at room temperature, followed by boiling in 2.0 M hydrochloric acid for 15 min. The fibres were washed with distilled water and maintained in distilled water for 7 days, after which they were washed and treated with 1.0% w/w sodium hydroxide by boiling for 15 min. The material was washed,

neutralized with 0.2% v/v acetic acid, and subjected to oxidative bleaching with 0.3% w/v hydrogen peroxide containing 0.1% w/v sodium hydroxide and 0.15% w/v sodium silicate at 90–95 °C for 30 min using a 1:20 solid-to-liquor ratio. The bleached cellulose was thoroughly washed, filtered, dried to constant weight, pulverized, and passed through a 0.22-mm sieve. The resulting modified *Musa paradisiaca* pseudostem cellulose (MMPP cellulose) was weighed, packaged, and stored in a dry container pending further characterization and formulation studies.

Tablet Formulation Design

The diclofenac sodium extended-release tablets were designed as a hydrophilic–hydrophobic matrix system comprising diclofenac sodium, *Musa paradisiaca* pseudostem-derived cellulose (MMPP cellulose), carnauba wax, corn starch, talc, and magnesium stearate. As presented in Table 1, each formulation contained 10 g of diclofenac sodium, equivalent to 100 mg per tablet, while the total matrix-co-excipient quantity was maintained at 25 g across batches A–G. The experimental variable was the progressive replacement of MMPP cellulose (25.00–20.00 g) with carnauba wax (0–5.00 g), thereby permitting assessment of the effect of increasing hydrophobic wax content on matrix performance and drug release. MMPP cellulose served as the principal hydrophilic matrix-forming and structural component, providing a cellulose-rich framework for tablet formation, whereas carnauba wax functioned as the hydrophobic release-modifying

component by increasing resistance to aqueous penetration and drug diffusion. Batch A, containing 25 g MMPP cellulose and no carnauba wax, was therefore designated the wax-free control formulation against which the effects of increasing carnauba wax concentration in B–G could be evaluated.

The supporting excipients were deliberately maintained at constant concentrations throughout the formulation series to minimize formulation-variable confounding. Corn starch (0.89 g) functioned principally as a binder during wet granulation, promoting interparticle adhesion and formation of coherent granules; talc (0.36 g) served as a glidant and anti-adherent to facilitate granule handling and reduce adhesion during compression; while magnesium stearate (0.36 g) functioned as a lubricant to reduce die-wall friction and facilitate tablet ejection. Maintaining these excipients at constant levels was particularly important because variations in binder, glidant or lubricant concentration could independently influence granule flow, compactibility, tablet mechanical strength and dissolution behaviour. Thus, the formulation design primarily isolated the MMPP cellulose–carnauba wax ratio as the experimental factor, providing a rational basis for relating matrix composition to tablet quality and diclofenac release. The observed progressive increase in disintegration time and retardation of drug release from Batch A toward Batch G further supports the functional contribution of increasing carnauba wax within the cellulose-based matrix.

Table 1: Formula for 100 Tablets of 100 mg Diclofenac Sodium Tablets

	Components	Weight (g)						
	Batches	A	B	C	D	E	F	G
Co-processed excipient	<i>M.Paradisica</i>	25	24.75	24.5	24.25	24	22.5	20
	Carnauba Wax	0	0.25	0.5	0.75	1	2.5	5
API	Diclofenac sodium	10	10	10	10	10	10	10
Binder	Starch (corn starch)	0.89	0.89	0.89	0.89	0.89	0.89	0.89
Glidant	Talc	0.36	0.36	0.36	0.36	0.36	0.36	0.36
Lubricant	Magnesium Stearate	0.36	0.36	0.36	0.36	0.36	0.36	0.36
TOTAL		36.61	36.61	36.61	36.61	36.61	36.61	36.61

NB: Each 36.61g tablet contains 100 mg diclofenac sodium.

Cellulose yield

The dry weight of the chopped *Musa paradisiaca* pseudostem and weight of the MMPP cellulose was used to calculate MMPP cellulose yield. The recorded weight of chopped *Musa paradisiaca* pseudostem was estimated to contain 96% water, as reported by many studies including Gupal *et al.* ⁶.

Determination of Drug–Excipient Compatibility Studies

FTIR, x-ray diffraction (XRD) compatibility studies were carried out on the powder blend. The FTIR analysis of MMPP cellulose, diclofenac sodium, and their physical mixtures was carried out using a Shimadzu FTIR-8400S spectrophotometer. Each sample (2 mg) was blended with 198 mg of dry KBr, pulverized, and dried at 110 °C for 2 h. The dried mixture was compressed into a 13-mm KBr pellet at 8 tons for 3 min. Spectra were recorded at room temperature over 4000–650 cm⁻¹ at a resolution of 4 cm⁻¹. Similar analysis was performed on 1:1 physical mixtures of diclofenac sodium with MMPP cellulose and carnauba wax. The spectra obtained were compared with those of the individual components to identify characteristic functional groups and assess potential drug-excipient compatibility based on changes in the position, intensity, appearance, or disappearance of characteristic absorption bands. Powder X-ray diffraction (PXRD) analysis was conducted to evaluate the solid-state characteristics of diclofenac sodium and the formulated matrix systems. Approximately 2 mg of each powdered sample was uniformly packed into the sample holder and analysed using Cu K α radiation under the instrument's preset conditions. Diffraction patterns were recorded as intensity against 2 θ , and the major reflections were compared in terms of peak position and relative intensity. Changes in the diffraction profiles following incorporation of carnauba wax and *Musa paradisiaca* pseudostem were used to assess alterations in the crystalline organization of diclofenac sodium.

Co-processing

Carnauba wax and *Musa paradisiaca* cellulose were co-processed using a solvent-assisted thermal fusion technique inspired by the thermo kinetic compounding principles described by Thompson et al. Predetermined quantities of Musa cellulose and carnauba wax were accurately weighed and blended. Thereafter, 15 mL of 20% ethanol was gradually added to the mixture, which was heated on a water bath with continuous stirring to facilitate the softening and uniform distribution of the carnauba wax over the cellulose particles. The resulting wet mass was spread in a thin layer and air dried at room temperature for 24 hours to ensure complete evaporation of the solvent. The dried co-processed material was milled for 5 min in a Kenwood Multi-mill tube mill (Kenwood Corporation, Hachiji, Tokyo, Japan) and passed through a 250 μ m stainless sieve.

TABLET FORMULATION AND PREPARATION

Granulation:

Diclofenac sodium tablets were prepared by wet granulation following the general principles described by Aulton and Taylor (2018), with slight modifications. Accurately weighed quantities of diclofenac sodium, co-processed *Musa paradisiaca* pseudostem cellulose-carnauba wax excipient, and other intragranular excipients in table1 were accurately weighed using an analytical balance and thoroughly blended in a stainless-steel mixing bowl to obtain a homogeneous powder mixture. An aqueous starch binder solution was gradually incorporated with continuous mixing using a laboratory spatula until a cohesive wet mass of suitable consistency was obtained. The wet mass was passed through a 500 μ m stainless-steel sieve to produce moist granules and dried in a hot air oven at a temperature of 50° for 35 min. The dried granules were subsequently passed through a 250- μ m sieve to break up agglomerates to obtain granules with uniform size distribution. The resized granules were then blended with the required extragranular excipients, including the lubricant, before compression into tablets. The resulting formulations were coded A-G and stored in well-closed containers prior to evaluation and compression.

Micromeritic evaluation of granule blend

Angle of repose

The angle of repose of granules from each batch (A-G) 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:

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

Carr's compressibility index and Hausner's ratio

10g of granules from each batch was poured through a dry funnel into a clean dry 50 ml measuring cylinder. The cylinder was gently tapped three times, and the steady volume of the granules was recorded as bulk volume. The bulk density of the cellulose was calculated by dividing the sample weight (10g) by the recorded bulk volume and recorded. The cylinder was then gently tapped from a height of 3 cm on a table surface 200 times. The volume occupied by the cellulose after the 200 taps was recorded as tapped volume. The ratio of the mass (10 g) of the cellulose to the tapped volume was calculated and recorded as the tapped density of the cellulose. Carr's compressibility index and Hausner's ratios of the cellulose were calculated from the bulk and tapped densities using equations 2 and 3. 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 flow¹².

$$\text{Carr's index \%} = \frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} \times 100$$

Equation 2

$$\text{Hausner's ratio} = \frac{\text{tapped density}}{\text{bulk density}} \quad \text{Equation 3}$$

Compression of Diclofenac Granule Prepared by Wet Granulation Technology

Lubricated granule blends for all seven 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 and stored in airtight amber glass containers at ambient temperature for 24 hours prior to evaluation to allow for elastic recovery of the compressed matrix.

Post-compression evaluation of diclofenac sodium tablets

Organoleptic Evaluation

Tablets from all batches (A-G) 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.

¹³.

Weight variation:

Twenty tablets from each batch were randomly selected and each of the tablets was weighed using the electronic balance (Mettler, Switzerland), and recorded. All 20 tablets in the individual batch were weighed, and the average weight of the 20 tablets was calculated. The variation of each tablet weight from this average weight and the 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 mean¹³.

Tablet Crushing strength: Using a Monsanto tablet hardness tester (Monsanto Chemical Company, Liverpool, England), the hardness of ten individual tablets per batch was measured by diametric crushing. The crushing strengths were recorded and used to calculate the mean and standard deviation.

Percentage friability: Tablet friability apparatus (Monita, India Corps Limited, India) was used to determine the friability of twenty selected tablets per batch. The twenty

tablets were weighed and placed in the friabilator and operated at 25 rpm for 4 min. The tablets were brought out, dedusted and weighed. The percentage loss of weight was calculated and recorded as tablet friability.

$$\text{Friability (\%)} = [(W_o - W_f) / W_o] \times 100$$

Equation 4

where W_o and W_f are the initial and final tablet weights respectively. A friability value of $\leq 1.0\%$ is considered acceptable¹⁴.

In Vitro Disintegration Testing: The disintegration time of the compressed tablets were evaluated 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 distilled 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.

Dissolution Test

The in vitro dissolution analyses of the various batches of the diclofenac tablets were carried out using the BP paddle method. A dissolution apparatus containing 900 ml of 0.1 M HCl solution maintained at $37 \pm 0.5^\circ\text{C}$ with a revolution speed of 50 rpm was used. Samples (5 ml) were withdrawn from the dissolution fluid at specific time intervals over a period of 12h and replaced with an equal volume maintained at same temperature ($37 \pm 0.5^\circ\text{C}$). The withdrawn samples were filtered and diluted appropriately with 0.1 M HCl solution.

The resulting solutions were subjected to spectrophotometric analysis at max of 276 nm. The amount and the percentage of drug released at each time interval was calculated using the equation from the standard calibration plot obtained from pure diclofenac powder.

Results

Cellulose Yield

The extraction and modification process yielded of 48.04% cellulose demonstrating that *Musa paradisiaca* pseudostem is a viable renewable source of pharmaceutical-grade cellulose. The yield obtained is comparable to previous reports identifying banana pseudostem as a cellulose-rich agricultural residue suitable for pharmaceutical and biomaterial applications^{9,10}. The relatively high recovery further supports the utilization of agricultural waste as a sustainable raw material for excipient production, thereby

contributing to circular bioeconomy initiatives.

FT-IR cellulose analysis

The FT-IR spectra for MMPP cellulose, carnauba wax, diclofenac sodium, and 1:1 dispersion of diclofenac sodium and MMPP cellulose, 1:1 dispersion of diclofenac sodium and carnauba wax scanned at 4000 - 650 cm^{-1} are presented in Figures 1, 2, 3, 4 and 5 respectively.

The carnauba wax spectrum (figure 2) shows prominent absorptions associated with its long-chain lipid/wax structure. Strong bands are evident around 2918 and 2851 cm^{-1} , together with absorptions in the fingerprint region, including bands around 1464, 1423, 1315, 1051 and approximately 1028 cm^{-1} . The strong absorptions near 2918 and 2851 cm^{-1} are consistent with the presence of aliphatic hydrocarbon chains, while the fingerprint-region bands reflect additional functional groups within the complex wax matrix.

The MMPP cellulose spectrum (figure 3) exhibits a broad absorption in the ~3200–3600 cm^{-1} region, with prominent bands around 3585, 3325 and 3213 cm^{-1} , consistent with hydroxyl-containing cellulose and associated hydrogen-bonded structures. A band near 1640 cm^{-1} is also evident, while strong fingerprint-region absorptions occur around 1379 and approximately 1028–1050 cm^{-1} . These absorptions are characteristic of the polysaccharide framework and are consistent with the presence of hydroxyl-rich cellulose and C–O-containing structural features.

The spectrum of the 1:1 MMPP cellulose-diclofenac sodium physical mixture retains absorption features attributable to both components. The broad hydroxyl-region absorption remains evident, while characteristic fingerprint-region bands associated with diclofenac sodium and cellulose are also retained. Importantly, there is no obvious emergence of a new dominant absorption band or pronounced displacement of the major characteristic bands relative to the individual components. (figure 4).

The FT-IR spectrum of the diclofenac sodium–carnauba wax physical mixture retains characteristic absorptions attributable to both the drug and wax components. The major bands associated with the aliphatic portion of carnauba wax remain visible, while several characteristic diclofenac sodium fingerprint-region absorptions are also retained. No major new absorption band or substantial displacement of the principal characteristic peaks is apparent in comparison with the spectra of the individual components (figure 5).

The XRD patterns demonstrated clear differences between diclofenac sodium and the formulated systems, indicating

modification of their solid-state diffraction profiles following incorporation of the matrix-forming excipients. Diclofenac sodium exhibited distinct reflections at 13.70°, 19.02°, 20.52°, 21.32°, 22.02° and 26.32° 2 θ , with the highest observed intensity at 21.32°. The diclofenac–carnauba wax formulation displayed a substantially altered profile, characterized by a prominent reflection at 16.04° 2 θ (551 counts) and additional reflections within the 14.50–26.28° range. The diclofenac–*Musa paradisiaca* pseudostem formulation showed reflections at approximately 13.30°, 14.64°, 18.86°, 21.24–22.50° and 25.80° 2 θ , generally with lower relative intensities than the carnauba-containing system. The persistence of diffraction features in the 20–26° region suggests that incorporation of either matrix did not completely eliminate the ordered crystalline component of diclofenac sodium. The differences in peak intensity, position and overall profile indicate changes in the relative solid-state organization of the formulations. However, because PXRD patterns of the individual excipients were not obtained, the observed reflections cannot be definitively attributed to specific formulation components or interpreted as evidence of new crystalline phases. Overall, the findings demonstrate that carnauba wax and *M. paradisiaca* pseudostem modified the PXRD profile of diclofenac sodium, with the Musa-based system exhibiting a comparatively less intense diffraction pattern.

Micromeretic properties Of The Granules

BatchA:

Batch A had a bulk density of 0.31 g/mL, tapped density of 0.41 g/mL, Hausner ratio of 1.33, Carr's index of **24.4%**, and angle of repose of **22.7°**. The relatively high Hausner ratio and Carr's index indicate fair/passable rather than excellent flow, despite the relatively low angle of repose.

BatchB:

Batch B exhibited a bulk density of 0.30 g/mL and tapped density of 0.40 g/mL, with a Hausner ratio of 1.33 and Carr's index of 25.0%. These values indicate a comparatively higher degree of compressibility and interparticle cohesion than Batch C.

BatchC:

Batch C demonstrated the most favourable packing-related values, with a bulk density of 0.36 g/mL, tapped density of 0.45 g/mL, Hausner ratio of 1.25, and Carr's index of only 9%. This indicates substantially better powder-flow characteristics than the other batches based on Carr's index.

BatchD:

Batch D recorded a Hausner ratio of 1.29 and Carr's index of 22.5%, indicating fair flow characteristics.

BatchE:

Batch E showed values similar to Batch D, with a Hausner ratio of 1.29 and Carr's index of 22.5%, indicating acceptable/fair flow.

BatchF:

Batch F recorded a Hausner ratio of 1.30 and Carr's index of 25%, indicating relatively greater interparticle cohesion and poorer packing behaviour than C–E.

BatchG:

Batch G exhibited a Hausner ratio of 1.30, Carr's index of 23.1%, and the highest flow rate of 4.6 g/s. Thus, although its Carr's index suggests only fair flow, its measured flow rate was the highest among the formulations.

Tablet properties

The compressed tablets demonstrated crushing strengths ranging from 6.68 to 7.84 kgf, indicating adequate mechanical resistance across the formulations. Batch A exhibited the highest crushing strength (7.84 ± 0.31 kgf), while Batch F showed the lowest (6.68 ± 0.69 kgf). The values did not show a strictly progressive decrease with increasing carnauba wax concentration, indicating that other formulation and processing variables may also have contributed to tablet mechanical strength.

Friability

Friability ranged from 0.14–0.52%, with all formulations remaining below the commonly accepted 1% criterion. Batch A showed the lowest friability (0.14%), whereas

Batch G showed the highest (0.52%). Thus, all batches possessed adequate resistance to abrasion and mechanical attrition under the test conditions.

Weight uniformity

Mean tablet weights ranged from approximately 0.351 to 0.378 g. The relatively narrow distribution indicates reasonably consistent tablet manufacture. Batch D had the lowest mean weight (0.351 ± 0.017 g), while Batch A had the highest (0.378 ± 0.011 g).

Disintegration

Disintegration time increased from 2.40 min in Batch A to 3.40 min in Batch G. The progressive increase is consistent with increasing incorporation of the hydrophobic carnauba wax fraction. Increasing hydrophobicity can reduce water penetration into the tablet matrix and thereby prolong the time required for matrix disruption. However, the increase is relatively modest, suggesting that the cellulose component continued to facilitate hydration and matrix breakup.

Dissolution studies

The dissolution figure demonstrates that all formulations released diclofenac sodium progressively over the 12-h test period, but the profiles differed according to formulation composition. Batch A, containing 25 g MMPP cellulose and no carnauba wax, exhibited the most rapid drug release and approached complete release within approximately the first 10 h according to the plotted profile. With incorporation of carnauba wax in B–G, the release profile became progressively more retarded. The greatest retardation was observed in Batch G, containing 20 g MMPP cellulose and 5 g carnauba wax, with the manuscript reporting approximately 88% release at 12 h.

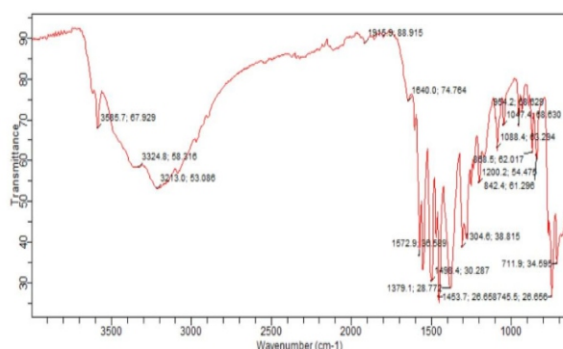


Figure 1: FTIR of diclofenac sodium

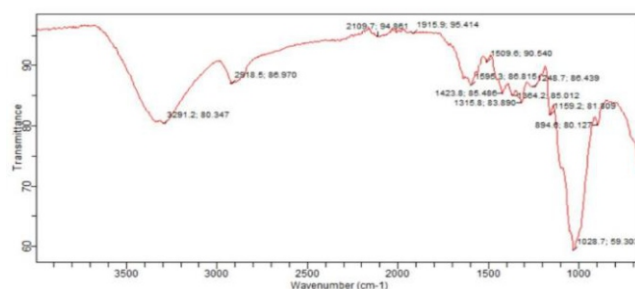


Figure 3: FTIR of modified *Musa paradisiaca* pseudostem

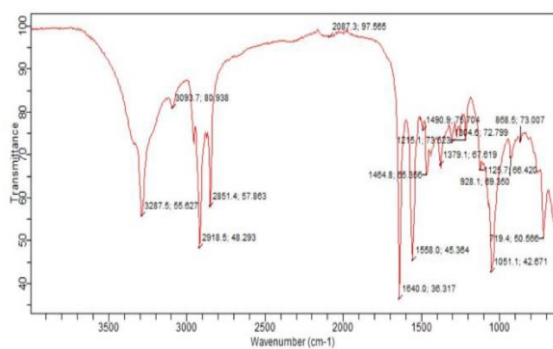


Figure 2: FTIR of Carnauba wax

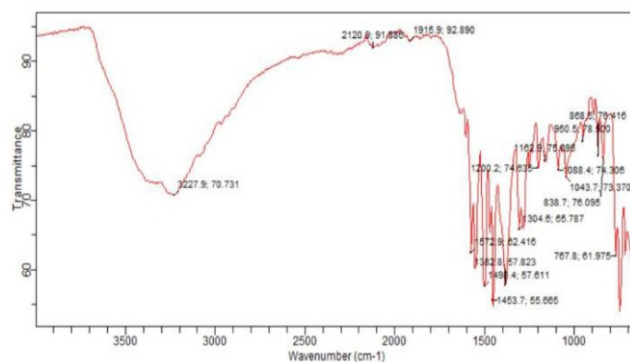


Figure 4: FTIR of modified *Musa paradisiaca* pseudostem & diclofenac sodium

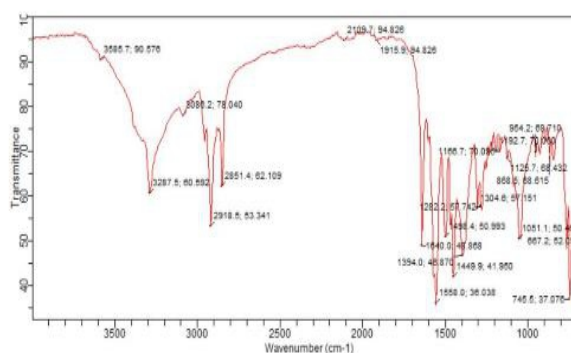


Figure 5: FTIR of Carnauba wax and diclofenac sodium

Table 2: Micromeritics properties of the various batches of diclofenac blends

Parameters	Bulk Volume ml	Tapped Volume ml	Bulk density g/ml	Tapped density g/ml	Hausner ratio	Carr's index	Angle of repose
A	32	24	0.31	0.41	1.33	24.4	22.7
B	33.8	25	0.30	0.4	1.33	25	26.5
C	28	22	0.36	0.45	1.25	9	25.5
D	32.1	25	0.31	0.4	1.29	22.5	27.9
E	32.2	24.4	0.31	0.40	1.29	22.5	27.9
F	32.3	25	0.30	0.4	1.3	25	24.7
G	33	25.8	0.30	0.39	1.3	23.1	27.6

General information

Analysis date	2026-06-06 13:27:27	Measurement start time	2026-06-06 12:55:01
Analyst	Default	Operator	Default
Sample name	027 API DICLOFENAC 1g	Comment	
Measured data name	C:\WallPaper\06-06-2026\027 API DICLOFENAC 1g_202606...	Memo	

Multiple Profile

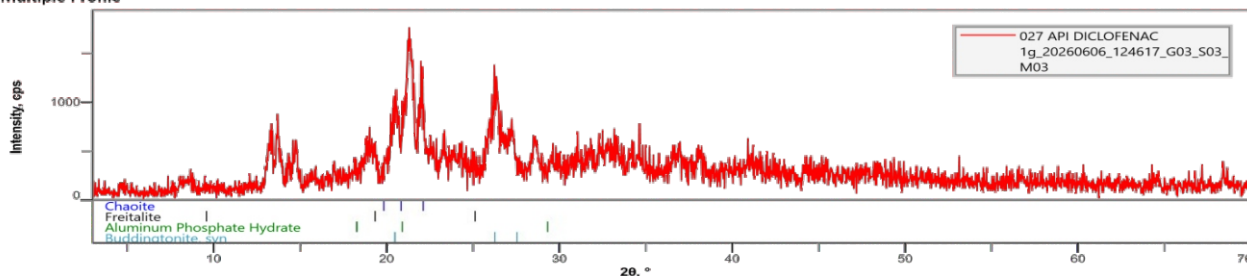


Figure 6: XRD diclofenac sodium

General information

Analysis date	2026-06-06 13:31:23	Measurement start time	2026-06-06 13:22:51
Analyst	Default	Operator	Default
Sample name	028 1g CANUBA WAX+1g DICLOFENAC	Comment	
Measured data name	C:\WallPaper\06-06-2026\028 1g CANUBA WAX+1g DICLO...	Memo	

Multiple Profile

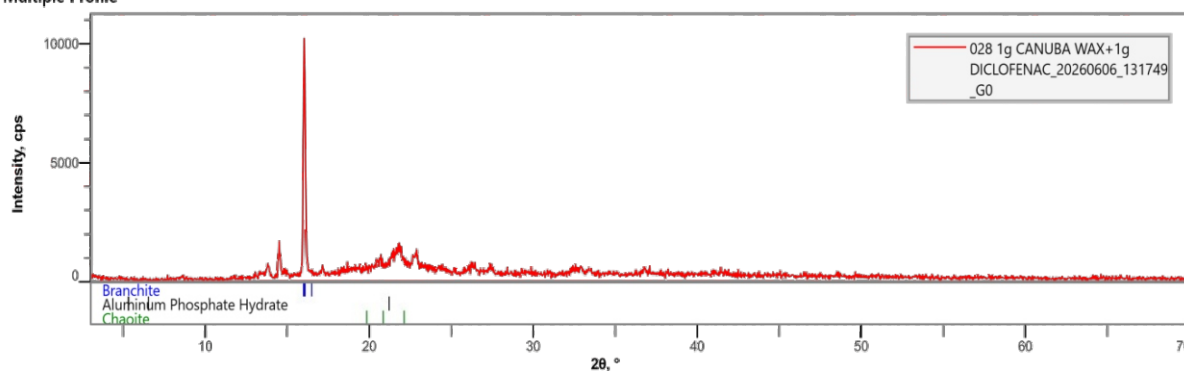


Figure7: XRD for diclofenac and canuba wax

General information

Analysis date	2026-06-06 13:35:05	Measurement start time	2026-06-06 12:58:48
Analyst	Default	Operator	Default
Sample name	029 MUS P.+1g DICLOFENAC	Comment	
Measured data name	C:\WallPaper\06-06-2026\029 MUS P.+1g DICLOFENAC_20...	Memo	

Multiple Profile

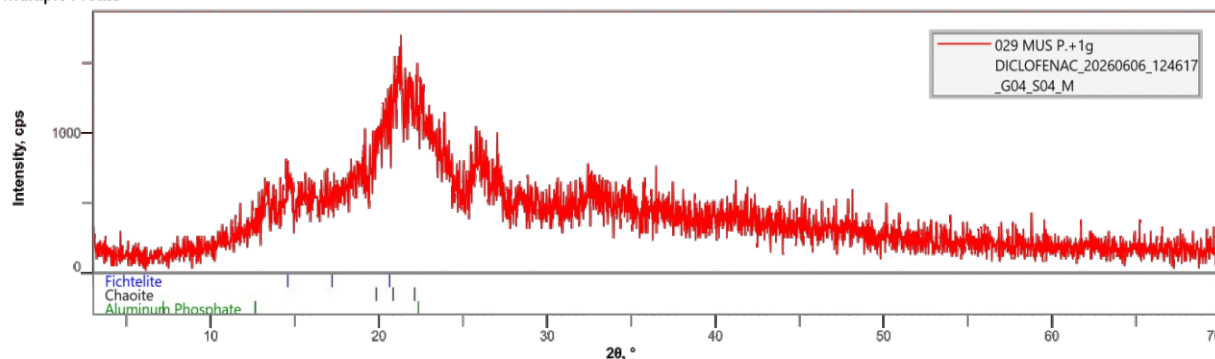


Figure8: XRD for diclofenac sodium & Modified *Musa paradisiaca pseudostem*

Table 3: Tablet properties

Parameters	Crushing strength (Kgf)	Percentage friability	Weight uniformity (g)	Disintegration time (min)
A	7.84 ± 0.31	0.14	0.378 ± 0.011	2.37 ± 0.06
B	7.64 ± 0.42	0.26	0.370 ± 0.031	2.49 ± 0.03
C	7.28 ± 0.46	0.25	0.376 ± 0.013	2.50 ± 0.09
D	7.68 ± 0.30	0.26	0.351 ± 0.017	3.05 ± 0.09
E	7.40 ± 0.54	0.23	0.369 ± 0.015	3.12 ± 0.01
F	6.68 ± 0.69	0.26	0.371 ± 0.012	3.23 ± 0.03
G	7.60 ± 0.47	0.52	0.372 ± 0.010	3.37 ± 0.03

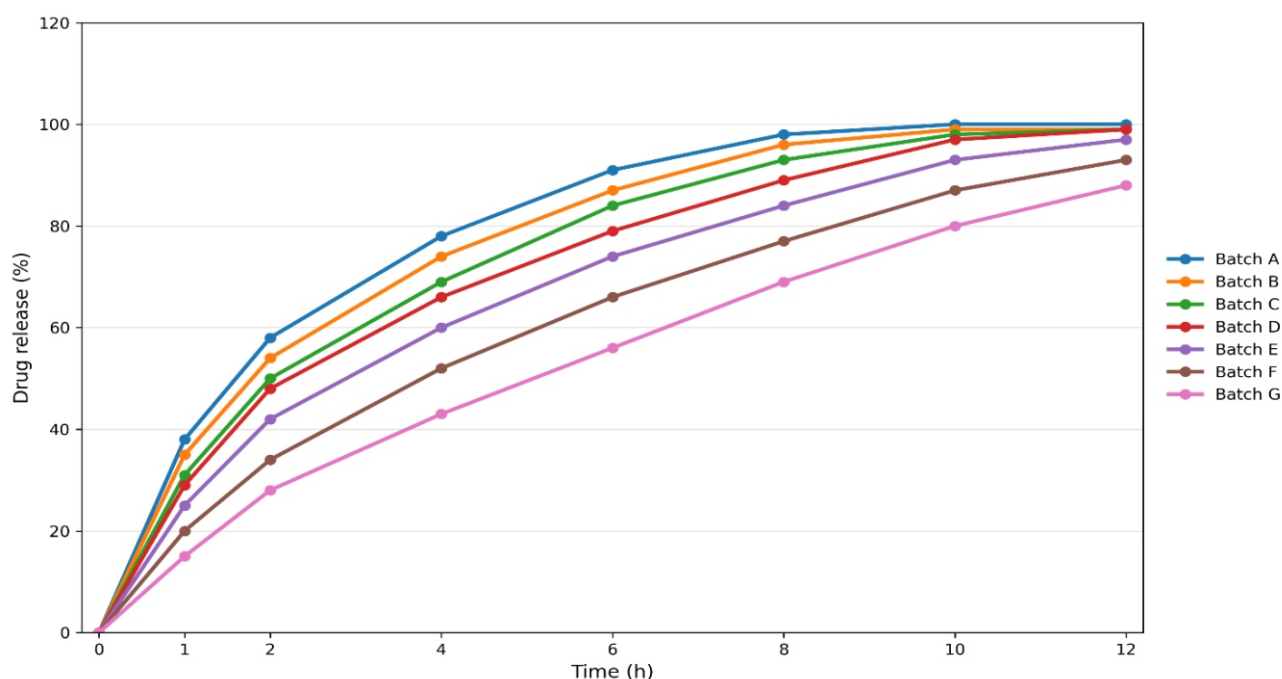


Figure 9: Dissolution profiles of diclofenac sodium extended-release tablets formulated with *Musa paradisiaca*-carnauba wax co-excipient.

DISCUSSION

The extraction and modification of *Musa paradisiaca* pseudostem produced MMPP cellulose at an overall yield of 48.04%, indicating substantial recovery of a cellulose-rich fraction from the agricultural biomass. This yield is comparable with previous reports demonstrating the feasibility of banana/plantain pseudostem as a cellulose source, although differences in plant variety and extraction conditions make direct numerical comparisons difficult. The FT-IR spectra showed retention of the characteristic absorption bands of MMPP cellulose, diclofenac sodium

and carnauba wax in their respective physical mixtures, without major new bands or pronounced peak shifts. This finding is consistent with previous work on modified *Musa paradisiaca* pseudostem cellulose–diclofenac systems and suggests the absence of major detectable drug–excipient interactions under the conditions investigated. However, FT-IR alone cannot exclude weak or non-covalent interactions.^{5,15}

The granules exhibited variable but generally workable micromeritic properties, with bulk density of 0.30–0.36

g/mL, Hausner ratios of 1.25-1.33, Carr's indices of 9-25%, and angles of repose of 22.7-27.9°. These findings are broadly comparable with previous investigations of modified *Musa paradisiaca* cellulose, although the present formulations did not demonstrate uniformly excellent flow. The compressed tablets exhibited crushing strengths of 6.68-7.84 kgf and friability of 0.14-0.52%, indicating adequate mechanical integrity and resistance to abrasion. Disintegration time increased progressively from 2.40 min in Batch A to 3.40 min in Batch G, corresponding with increasing carnauba wax content. This behaviour is consistent with the hydrophobic nature of carnauba wax and its potential to reduce aqueous penetration into the tablet matrix. Previous diclofenac matrix studies have similarly demonstrated that increasing carnauba-wax concentration can retard drug release and modify matrix behaviour.¹⁶⁻¹⁸

The dissolution profiles demonstrated a clear formulation-dependent release pattern, with Batch A, containing MMPP cellulose without carnauba wax, exhibiting the most rapid release, while progressive incorporation of carnauba wax increasingly retarded diclofenac sodium release; Batch G achieved approximately 88% release at 12 h. This behaviour agrees with earlier studies showing that carnauba wax functions as an effective hydrophobic matrix former for sustained-release diclofenac formulations.^{16-18,7} The principal contribution of the present study is therefore the integration of two complementary materials plantain pseudostem-derived cellulose as a biomass-based hydrophilic matrix component and carnauba wax as a natural hydrophobic release-modifying component into a single co-processed excipient system. Unlike previous studies that primarily investigated *Musa* cellulose as an excipient or carnauba wax as an independent matrix former, the present work demonstrates the feasibility of combining these functions to produce a tunable extended-release diclofenac sodium matrix. This provides a potentially sustainable route for converting agricultural biomass into a functional pharmaceutical excipient while simultaneously modifying drug-release behaviour.¹⁻⁶

CONCLUSION

This study successfully demonstrated the feasibility of valorizing *Musa paradisiaca* pseudo stem biomass into a functional pharmaceutical matrix co-excipient for the development of extended-release diclofenac sodium tablets. The extraction and modification process yielded 48.04% MMPP cellulose, supporting the potential of plantain pseudo stem as a renewable cellulose source. The physicochemical and solid-state investigations further demonstrated that the MMPP cellulose was compatible

with diclofenac sodium under the conditions investigated, with FTIR spectra of the drug-excipient mixtures retaining the characteristic absorption bands of the individual components and showing no major spectral changes suggestive of a detectable chemical interaction. PXRD analysis demonstrated modification of the drug diffraction profiles following incorporation of the matrix-forming materials, although the persistence of crystalline reflections indicated that the drug was not completely rendered amorphous.

The formulation strategy was deliberately designed to allow the effect of the MMPP cellulose–carnauba wax composition to be evaluated without introducing unnecessary variation in the other formulation variables. Accordingly, diclofenac sodium, starch binder, talc and magnesium stearate were maintained at constant quantities across batches A-G, while the co-processed matrix composition was progressively changed from 25 g MMPP cellulose with no carnauba wax in Batch A to 20 g MMPP cellulose with 5 g carnauba wax in Batch G. Talc and magnesium stearate were each maintained at 0.36 g per 100 tablets. This constant-excipient approach is scientifically appropriate because talc primarily functions as a glidant/anti-adherent, whereas magnesium stearate functions principally as a lubricant; allowing their concentrations to vary between batches could independently alter powder flow, die filling, ejection behaviour, interparticle bonding and tablet mechanical properties, thereby confounding interpretation of the effect attributable to carnauba wax. Thus, the equal and constant quantities should be regarded as controlled formulation variables, rather than as independently optimized variables, unless separate preliminary optimization experiments are available.

Batch A was appropriately designated as the control formulation because it contained the same principal formulation components and processing conditions as the experimental batches but contained no carnauba wax. It therefore provided the reference condition against which the incremental effects of incorporating carnauba wax could be evaluated. Specifically, Batch A contained 25 g MMPP cellulose and 0 g carnauba wax, whereas the subsequent formulations progressively replaced a portion of the cellulose component with carnauba wax while maintaining the quantities of diclofenac sodium, starch, talc and magnesium stearate essentially constant. Consequently, differences in tablet performance and drug-release behaviour between Batch A and B-G can be interpreted principally in relation to the increasing hydrophobic wax fraction, although other formulation and processing effects cannot be completely excluded.

The experimental findings support this formulation rationale. All batches produced tablets with acceptable mechanical integrity, with crushing strengths ranging from 6.68 to 7.84 kgf and friability values of 0.14-0.52%, all below the commonly applied 1% limit. Batch A exhibited the highest crushing strength (7.84 ± 0.31 kgf) and lowest friability (0.14%), demonstrating that the MMPP cellulose matrix alone was capable of producing mechanically robust compacts under the selected processing conditions. The granules also demonstrated workable micromeritic characteristics, although flow was not uniformly excellent across all formulations. Notably, Batch C showed the most favourable packing-related properties, with a Hausner ratio of 1.25 and Carr's index of 9%, indicating that incorporation of a relatively low proportion of carnauba wax did not compromise the basic manufacturability of the system.

Most importantly, the dissolution study demonstrated a clear formulation-dependent modification of diclofenac sodium release. Batch A, containing MMPP cellulose without carnauba wax, exhibited the most rapid release, whereas progressive incorporation of carnauba wax into B-G increasingly retarded drug release. Batch G, containing 20 g MMPP cellulose and 5 g carnauba wax, produced the greatest release retardation, with approximately 88% diclofenac sodium released at 12 h. This progressive change provides practical evidence that the hydrophobic wax component contributed substantially to modulation of drug release within the cellulose-based matrix. The observed behaviour is consistent with the proposed complementary functionality of the two matrix components, whereby the cellulose fraction provides a hydrophilic, structurally supportive matrix while carnauba wax increases hydrophobicity and resistance to aqueous penetration and drug diffusion.

Overall, the study establishes that co-processing MMPP cellulose with carnauba wax provides a rational means of transforming an underutilized agricultural biomass into a multifunctional pharmaceutical excipient capable of modifying the release of diclofenac sodium. The use of Batch A as the wax-free control and the maintenance of talc, magnesium stearate, binder and drug quantities across the formulation series strengthened the experimental comparison by reducing avoidable formulation-variable confounding. Nevertheless, because the present study did not include a formal design-of-experiments or factorial optimization specifically evaluating talc and magnesium stearate concentrations, their fixed quantities should be described as controlled formulation levels selected for manufacturing consistency, rather than statistically optimized concentrations. Future work should employ

systematic formulation optimization, including variation of matrix concentration, carnauba wax level, lubricant concentration and processing variables, together with model-dependent dissolution optimization and stability assessment, to establish the design space and identify the composition providing the optimal balance between manufacturability, mechanical performance and reproducible extended drug release.

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