



**FORMULATION AND CHARACTERIZATION OF PARACETAMOL GRANULES
UTILIZING *BOMBAX CEIBA* MUCILAGE AND CORN STARCH CO-PROCESSED
WITH *BOMBAX CEIBA* MUCILAGE**

*¹Mshelia S. M., ¹Kwari J. H., ²Aji. M. M.

¹Department of Pharmaceutics and Pharmaceutical Technology, Faculty of Pharmacy,
University of Maiduguri, Borno State

Corresponding Author Email; suleimanmshelia@unimaid.edu.ng +2348039280238

Abstract

This study evaluates the binding properties of mucilage extracted from the calyx of Bombax ceiba and its co-processed form with corn starch, comparing their performance to corn starch in paracetamol granules formulation. The mucilage was extracted using hot-water extraction, characterized for physicochemical and phytochemical properties, and combined at varying ratios (90/10, 80/20, 70/30, 60/40, 50/50, 100/0, 0/100) with corn starch through co-fusion to produce a co-processed binder. Granules were formulated via wet granulation and assessed for flow indices, density parameters, hydration capacity, and moisture sorption, particle size analysis and dissolution. Results showed that Bombax ceiba mucilage possesses high swelling capacity (583%), high hydration capacity (999%), and moderate flowability, indicating strong binding potential. The co-processed binders demonstrated improved flow, reduced cohesiveness, and balanced hydration compared to the crude mucilage. The particle size analysis revealed that CS 100% had the most uniform particles, while 100% BCM granules had the largest size variation due to the high binding solution of Bombax ceiba mucilage. The USP (2005) sets standards for uniformity of content, requiring: $\geq 9/10$ units within 85-115% of label claim, no units outside 75-125% of label claim and $RSD \leq 6.0\%$ and this study found that all batches had $RSD < 6\%$, meeting the USP standards. 100% CS granules had the fastest release (100% in 45 minutes) due to low swelling capacity and moderate water-binding ability. 100% BCM granules had the slowest release (90% in 45 minutes) due to high swelling and mucilage-forming properties. Blended formulations (BCM + CS) had intermediate release rates, with higher BCM proportions slowing down dissolution. All formulations met pharmacopeial standards for immediate-release granules. This study concludes that Bombax ceiba mucilage is a promising natural binder; while co-processing with corn starch significantly optimizes its performance, which potentially provide a cost-effective, locally sourced multifunctional excipient for granule formulation.

Key Words: Paracetamol, Bombax ceiba, granules, binders, co-processed excipients.

INTRODUCTION

In the production of pharmaceutical dosage forms, granulation is achieved by agglomeration technique and is one of the most significant unit operations (Shanmugam, 2015). Granulation is mostly employed in tablet and capsule production.

The aim of granulation is to transform powders into free flowing, dust free granules to facilitate compression (Jannat *et al.*, 2016). Granulation process can be divided into two types: wet granulation that utilize a liquid in the process and dry granulation that requires no liquid (Saad Ali

et al., 2019). Granulation poses numerous challenges due to high quality requirement of the formed granules in terms of content uniformity and physicochemical properties such as granule size, bulk density, porosity, hardness, moisture, compressibility, etc. together with physical and chemical stability of the drug and like any other scientific field (Agiba and Eldin, 2019). Pharmaceutical granulation technology also continues to change, and arrival of novel and innovative technologies are inevitable (Patra *et al.*, 2017).

Binders are critical formulation components in tablet production made by either direct compression or dry as well as wet granulation. Binders ensures appropriate plasticity, compact-ability and also binding ability (Dharani *et al.*, 2015). Traditionally, binder selection has been an empirical experience and preference of companies and individuals. However, advances in understanding mechanistic and quantitative particle engineering and materials science aspects of granulation and tablet binding now allow a more rational and science-based binder selection process (Stewart *et al.*, 2016). One important characteristic of the binder is its ability to be effectively and evenly distributed through the interparticulate voids in a compound tablet. Characteristics such as high plasticity, low elasticity and a small particle size were associated with a more even distribution and a consequent pronounced effect on pore structure and marked improvement in tablet strength (Janssen *et al.*, 2024). Over the years, various plants has been used as source of gums and mucilage in the pharmaceutical industry, one plant of interest is the *Bombax ceiba*.

Bombax ceiba is commonly known as silk cotton tree. It is a large deciduous tree, fast growing, native to tropical and subtropical Asia. It has bright red or orange flowers. It grows as high as 45 meters. *Bombax ceiba* has diverse medicinal uses, with different plant parts like the roots, bark, flowers, and gum being used to treat a wide range of ailments (Vaijanath Tambare *et al.*, 2023). Various parts of the tree are used in traditional medicine to treat a wide range of ailments. Studies have also indicated potential benefits such as anti-inflammatory, antioxidants and hypoglycemic effects (Karole *et al.*, 2016). The edible parts such as the young leaves, flowers, buds and fruits can be cooked and eaten as vegetables. The tree is widely planted in south eastern Asian countries such as in Myanmar, Nepal, Thailand, Vietnam, Malaysia (Janssen *et al.*, 2024). It is also widely found in some parts of Nigeria including Benue, Jos and southern part of Borno State (Aguoru *et al.*, 2015).

This study introduces the application of *Bombax ceiba* mucilage and its co-processed form with corn starch as a binder in paracetamol granules, exploring their potential as natural, cost-effective alternatives to synthetic binders. The research provides new insights into the physicochemical properties and performance of these co-processed excipients, contributing to the development of innovative pharmaceutical formulations and expanding the utilization of natural polymers in drug delivery systems.

MATERIALS AND METHOD

Collection and Identification

The flowers of *Bombax ceiba* were collected from Sakwa Bura region of

Hawul LGA, Southern Borno, Borno State and were authenticated at University of Maiduguri. The authentication number is UMM/FPH/MAV/010 as of 2024.

Isolation of Mucilage from *Bombax ceiba* flower petals.

Conventional Method

Hot water extraction method was used. The completely dried *Bombax ceiba* calyx were separated from the flowers and size reduced for 5 mins using a mechanical blender. They were soaked in water and boiled for 1 hr. with occasional stirring; it was then kept for 24h hrs. to release the mucilage into the water. The material was filtered through a clean muslin clothe. Equal volume of acetone was added to the filtrate to precipitate the mucilage and oven dried. It was then powdered, weighed kept in an air tight container before subjecting it to chemical tests to confirm identity.

Characterization of Mucilage

Physical Analysis of Mucilage Powder

The dried mucilage of *Bombax ceiba* was studied for Appearance, Solubility, Bulk and Tapped Density, Compressibility Index and Hausner's ratio, Ash Value, Angle of Repose, Moisture Content, Hydration, Swelling Capacity and Flow Rate.

Organoleptic Properties

The colour, odour, texture, and taste of the mucilage extracted were observed using the

organoleptic senses of look, smell, feel, and taste.

Solubility Test

The solubility profile of the mucilage extract was carried out using standard methods as described by Evans (2009). One gram of the extracted mucilage was weighed and dissolved in 2 ml of various solvents including cold distilled water, hot distilled water, ethanol and acetone. The solubility profile of the mucilage was determined and recorded.

Ash Value Determination

A clean crucible is obtained and heated to remove any residual moisture, ensuring that a constant weight is achieved. The crucible is weighed after heating and the weight is recorded. This process of heating and weighing is repeated every 15 minutes until a constant weight is observed over three consecutive measurements. Once the crucible has achieved a constant weight, the mucilage, is added to the crucible. The crucible containing the mucilage is then heated until it is burnt into ash and free of carbon. After the heating process, the crucible with the ash is weighed. This heating and weighing process continues at regular intervals until the crucible and the ash reach a constant weight over three consecutive measurements. Finally, the constant weight is recorded, and the procedure was repeated three times.

$$\frac{WA}{WSP} \times 100 = \text{percentage ash value equation 1}$$

Where WA and WSP are weight of ash formed and initial weight of powdered mucilage respectively.

Determination of Moisture Content

Moisture content test was carried out using a digital moisture analyzer (Sartorius,

Germany). Three grams (3g) of the mucilage powder was weighed and put into the moisture content analyzer. The machine was then set to $130\text{ }^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 5 min. The readings were noted when the machine automatically stopped. This procedure was done in triplicate and the mean was determined (Chitedze-Kumatso and Mweta, 2020)

Determination of Hydration Capacity

The hydration capacity of the extracted mucilage was carried out as described by Muazu *et al.*, (2014) One gram of the mucilage powder was weighed and placed in a tarred 20 ml stoppered centrifuge tube. The weight of the tube was noted; 10 ml of distilled water was added and shaken vigorously for 2 min. It was then allowed to stand for 10 min during which it was mixed by inverting the tube three times at the end of 5 and 10 min. The sample was then centrifuged at 1000 revolutions per minute for 10 min. The aqueous supernatant was then carefully removed and the tube with the sediment was re-weighed. The

hydration capacity was calculated as the ratio of the weight of the sediment to the initial weight of dry powder. The procedure was done in triplicate and the mean was calculated.

Determination of Swelling Index

The method of Muazu *et al* (2014) was used and the tapped volumes occupied by 5 g of the mucilage was noted. The mucilage was then dispersed in 85 ml of distilled water and the volume made up to 100 ml with more distilled water. It was allowed to stand for 24 h. The volume of the sediment was then determined and the swelling capacity was calculated from the difference in volumes.

Determination of Bulk Density

The method of (Fegade *et al.*, 2023) was adopted. Fifty grams of the powder was weighed and poured into a 100 ml measuring cylinder. The volume occupied by the powder is noted and recorded. It is expressed in g/ml and is given by;

$$\text{Bulk density} = \frac{\text{weight of powder}}{\text{volume occupied by powder}} \dots \text{eqaution 2}$$

Determination of Tapped Density

The method of (Fegade *et al.*, 2023) was adopted. Fifty grams of the weighed powder in the cylinder was tapped gently by lifting it up to a height of about 2 cm and

allowing it to fall freely onto a wooded base. Continue tapping until no further reduction in volume is detected (after about 50 taps). Calculated the tapped density using the formula;

$$\text{Tapped density} = \frac{\text{weight of powder}}{\text{Tapped volume of the powder}} \dots \text{eqaution 3}$$

Determination of Compressibility Index and Hausner's ratio

The compressibility index and Hausner's ratio were calculated using the formulae:

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100\% \dots \dots \text{eqaution 4}$$

$$\text{Hausner's ration} = \frac{\text{Tapped density}}{\text{Bulk density}} \dots \dots \text{eqaution 5}$$

Measurement of Angle of Repose

A glass funnel was clamped to a retort stand at 10 cm from the tip end of the funnel to the base of the flat surface. A 50-gram

weight of the powder was gently poured through the funnel until a heap was formed, whose height and diameter were obtained by measurements. And the angle of repose was calculated using the formula:

$$\Theta = \tan^{-1} \frac{\text{height of the cone } h}{\text{radius of the cone } r} \dots \dots \dots \text{eqaution 6}$$

The experiment was repeated two times for each and the mean was recorded (Fegade *et al.*, 2023)

Preparation of Co-processed Excipient Using Corn Stach and *Bombax ceiba* Mucilage

Preparation of the Co-processed Excipients

A 100g batch of co-processed excipients of corn starch and *Bombax ceiba* at varying ratios (90/10, 80/20, 70/30, 60/40, 50/50, 100/0, 0/100) were prepared using co-fusion method. *Bombax ceiba* was dispersed in sufficient quantity of distilled water to form a viscous, homogenous dispersion while heating over a water bath. Distilled water was added to corn starch in a beaker to form a slurry. The dispersion of *Bombax ceiba* mucilage was added to the corn starch slurry whilst stirring for 20 min at low heat. The resulting homogenous mass was dried in a Gallen Kamp hot air oven (Model: BS 250, UK) at 60°C for 48 hours (Olubunmi *et al.*, 2024). The dried mass was then milled, sieved with a 250 µm mesh and stored in well - sealed containers.

Preparation and Evaluation of Paracetamol Granules

Paracetamol granules were prepared as described using the formula in Table 2. *Bombax ceiba* mucilage in varying concentrations (2.5%, 5%, 7.7%, and 10%) as a binder and the co-processed excipients prepared at different ratios of corn starch to *Bombax ceiba* mucilage (90/10, 80/20, 70/30, 60/40, 50/50, 100/0, 0/100) were used in the formulation of paracetamol granules.

Formulation of Granules by Wet Granulation

Twelve batches of granules were produced. Four batches for *Bombax ceiba* mucilage as a binder, five batches for the co-processed excipients using corn starch and *Bombax ceiba* and a batch for corn starch as standard.

The mucilage was prepared by dispersing the *Bombax ceiba* in 10 ml of distilled water at binder concentrations of 2.5 %, 5 %, 7.5 % and 10 % w/w for *Bombax ceiba*, 5%w/w for all the varying concentration of the co-processed binder (CS/BCM) and 5 %w/w for corn starch as the standard. The mucilage was added to 50 g paracetamol powder. Calculated amounts of lactose as indicated in Table 2 and Table 3 were triturated in geometric order were added

and dampened thoroughly. The granules were then obtained by forcing the damp mass through a 1.7 mm screen and dried in a drying cabinet at 60 °C for 30 min. The

dried granules were screened through a sieve carrying a 1 mm mesh and bottled for further investigation.

Table 1: Formula for the Preparation of Co-Processed Excipient Using Corn Starch and *Bombax ceiba* Mucilage.

CS/BCM	90/10	80/20	70/30	60/40	50/50	100/0	0/100
CS	90	80	70	60	50	100	0
BCM	10	20	30	40	50	0	100

CS: Corn Starch, BCM: *Bombax ceiba* Mucilage, CS/BCM: ration of Corn starch to *Bombax ceiba*

Table 2: Preparation of Paracetamol Granules using different concentrations of *Bombax ceiba* Mucilage.

Percentage (%)	PCM (mg)	Lactose (mg)	Corn (mg)	Binder (mg)
BCM 2.5	500.00	62.25	65.00	16.25
BCM 5	500.00	46.00	65.00	32.50
BCM 7.5	500.00	29.75	65.00	48.75
BCM 10	500.00	13.50	65.00	65.00
MS 5	500.00	46.00	65.00	32.50

MS: Corn Starch, BCM: *Bombax ceiba* Mucilage

Table 3: Preparation of Paracetamol Granules Using the Co-processed Excipient

Percentage (%)	PCM (mg)	Lactose (mg)	Corn (mg)	Binder (mg)
CS/BCM 90	500.00	46.00	65.00	32.50
CS/BCM 80	500.00	46.00	65.00	32.50
CS/BCM 70	500.00	46.00	65.00	32.50
CS/BCM 60	500.00	46.00	65.00	32.50
CS/BCM 50	500.00	46.00	65.00	32.50
BCM 100	500.00	46.00	65.00	32.50
CS 100	500.00	46.00	65.00	32.50

CS: Corn Starch, BCM: *Bombax ceiba* Mucilage, CS/BCM: ration of Corn starch to *Bombax ceiba*

Physicochemical Test of Granules

Various physicochemical test for granules was carried out including enumeration of microbial count, bulk and tapped density, compressibility index and Hausner's ratio, determination of angle of repose, and also hydration capacity to determine the flow properties of the granules.

Enumeration of Microbial Count

Inoculation by pour plate method was carried out after serial dilutions of the powdered starch samples from 1 in 10 to 1 in 10,000 using 1 g sample. One milliliter of the diluted sample was then aseptically aspirated into the nutrient agar media. The media was aseptically poured into a sterile

petri dish at 40 to 45 °C. This is then swirled and allowed to solidify for incubation at 37 °C for 24 hr. (Uniscope, England). Typical colonies of microbial growth on plates were counted with an electronic colony counter at the end of incubation and the result presented as colony forming unit per gram [cfu/g] (Esoje *et al.*, 2016).

Characterization of Prepared Granules Determination of Bulk and Tapped Density

A quantity of 20-gram weight of the granules was transferred into a 100 ml measuring cylinder in which the volume was noted, and the bulk density was calculated as thus:

$$\text{Bulk density} = \frac{\text{weight of powder}}{\text{volume occupied by powder}} \dots \text{eqaution 7}$$

For the tapped density, the measuring cylinder containing the 20g weighed powdered Mucilage was tapped 50 times at

2cm from the level of the table surface, and the volume was noted. The tapped density was calculated as thus:

$$\text{Tapped density} = \frac{\text{weight of powder}}{\text{Tapped volume of the powder}} \dots \text{eqaution 8}$$

Compressibility index and Hausner's Ratio.

The compressibility index and Hausner's ratio of the granules were calculated using the formulae:

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100\% \dots \text{eqaution 9}$$

$$\text{Hausner's ration} = \frac{\text{Tapped density}}{\text{Bulk density}} \dots \text{eqaution 10}$$

Determiration of Angle of Repose

A glass funnel was clamped to a retort stand at 10cm from the tip end of the funnel to the base of the flat surface. A 50-gram weight

of the granules was gently poured through the funnel until a heap was formed, whose height and diameter were obtained by measurements. And the angle of repose was calculated using the formula:

$$\Theta = \tan^{-1} \frac{\text{height of the cone } h}{\text{radius of the cone } r} \dots \text{eqaution } \dots \dots \dots 11$$

Determination of Hydration Capacity of the Mucilage.

The method of Muazu *et al.*, (2018) was adopted. The weight of an empty 20 ml tarred centrifuge tube was obtained, and a 1-gram weight of the mucilage was placed into the tube. The mucilage was solubilized to 10 ml of distilled water and shaken

vigorously for 3 minutes. It was allowed to stand for 10 minutes and mixed again by inverting three times, which was then centrifuged at 1000 revolutions per minute for 10 minutes. Afterwards the aqueous supernatant was separated, and the sediments reweighed. The hydration capacity was extrapolated by the formula:

$$\text{Hydration capacity} = \frac{\text{weight of the sediments}}{\text{weight of dry sample}} \dots \text{equation 12}$$

Particle Size Analysis

Sieve test method was used to determine the degree of fineness of the granules. This was done by sieving them through sieves of 1.20 mm, 1.02 mm and 0.75 mm placed one on another on a laboratory sieve shaker. The mass of granules was controlled in every 5 minutes. The test lasted 15 minutes. A percentage m/m passing the sieves were calculated after that.

then crushed together, mixed, and then an aliquot equivalent to 500 mg of paracetamol was weighed out. The aliquot was then dispersed in 100 ml of 0.1 N HCl and analyzed spectrophotometrically to determine the absorbance and hence concentration, from which the drug content was calculated according to the Beer-Lambert's relationship

$$a = K \times C \dots \dots \dots (13)$$

Drug Content, Uniformity of Content

From this, we get

Beer's Calibration Curve

$$C = a / K \dots \dots \dots (14)$$

To get the Beer's curve for paracetamol in 0.1 N HCl, 100 mg of paracetamol was dissolved in 100 ml of 0.1 N HCl to get 100 mg% solution. This stock solution was then appropriately diluted to get 0.1, 0.2, 0.3, 0.4, 0.5, and 1 mg% solutions of paracetamol. The absorbance of each solution was read of in the spectrophotometer at a wavelength of 245 nm. Absorbance values were then plotted against concentration and the Beer's calibration constant was calculated.

a = Absorbance, K = a constant, C = concentration

K is obtained as the slope of the graph when absorbance is plotted against concentration in the Beer- Lambert's relationship. The drug content was then calculated as

$$\text{Drug content} = C \times \text{Volume} \dots \dots \dots (15)$$

Granule Drug Content Determinations

Granules were randomly picked 10 times from different parts of the granules batch such that the granule quantity picked each time was supposed to contain the target dose of 500 mg of paracetamol. They were

The percentage deviation from the label dose was calculated as

$$\text{Percentage deviation} = 100 (500\text{mg} - \text{drug content}) / 500 \text{ mg} \dots \dots \dots (16)$$

Granule Uniformity of Content Determinations

Here 10 aliquots of granules as in the Drug Content Assay were randomly picked from different parts of each granule batch. Each

was then crushed, dispersed in 100 ml of 0.1 N HCl spectrophotometrically and analyzed to determine the absorbance and hence concentration, from which the drug content was calculated according to the Beer-Lambert's relationship. The mean and standard deviation of the drug content for each granule batch was calculated. The Relative Standard Deviation (RSD) was calculated as

$$\text{RSD} = 100 S / X_{\text{mean}} \dots\dots\dots(17)$$

where S = sample

$$\text{and } S = [\sum (X_i - X_{\text{mean}})^2 / (n-1)]^{1/2} \dots \dots (18)$$

X_{mean} is the mean of the values obtained from the units tested expressed as a percentage of the label claim; n is the number of units tested;

$X_1, X_2, X_3, \dots X_n$ are the individual values (X_i) of the units tested expressed as a percentage of the label claim.

Dissolution Test for the Formulated Granules

Calibration Curve Preparation

A calibration curve was prepared using aspirin as the reference standard. A stock solution was prepared by dissolving 1000mg of standard Paracetamol powder in 0.1 N sodium hydroxide to achieve a concentration of 100 mg/mL. Serial dilutions of the stock solution were made to obtain ten different concentrations. The absorbance of these solutions was measured at 257 nm using a UV-Vis spectrophotometer, and a graph of absorbance versus concentration was plotted to establish the standard curve (British Pharmacopoeia, 2009).

Dissolution Rate Determination

The dissolution rate was evaluated using a USP dissolution apparatus, with phosphate buffer (pH 6.8) as the medium. The medium was thermostatically maintained at $37^\circ\text{C} \pm 0.5^\circ\text{C}$, and the basket was set to rotate at 50 rpm, positioned 25 mm above the base of the jar and the quantity of granules equivalent to 500 mg paracetamol from each batch was placed in the apparatus, and 5 mL samples of the dissolution medium were withdrawn at specified intervals over 45 minutes. The withdrawn samples were analyzed spectrophotometrically at 257 nm to determine the concentration of paracetamol released into the medium (British Pharmacopoeia, 2009). The procedure is repeated 3 times and the mean taken.

Data Analysis

Data collated was analyzed on Microsoft Excel 2016 and the means and standard deviations for replicate measurements were determined. All the values are expressed as mean \pm standard deviation.

RESULTS

Percentage Yield

The yield of *Bombax ceiba* mucilage was 17.13 %

Organoleptic Properties of *Bombax ceiba* mucilage extract

The results for organoleptic properties show *Bombax ceiba* has brown colour, fine texture, sour taste and musky odour as presented in Table 4 while corn starch is white and tasteless. *Bombax ceiba* mucilage reacted positive for the all the chemical tests carried out. It reacted positive to carbohydrates, alkaloids, flavonoids, saponins and tannins as indicated in Table 5

Table 4: Identification and organoleptic properties of extracted *Bombax ceiba* mucilage

Parameter	<i>Bombax ceiba</i> Extract	Corn Starch
Taste	Sour	Tasteless
Color	Brown	White
Texture	Fine particulate powder	Fine particulate powder
Odor	Musky	Odorless

Table 5: Chemical Test of *Bombax ceiba* extract

Test	Reagent	Observation
Carbohydrate	Molisch's	Positive
Alkaloid	Mayers, Wagner's, and Dragendorff's	Positive
Flavonoids	Ferric Chloride	Positive
Saponins	Ferric Chloride	Positive
Tannin	Foam test	Positive

Physicochemical Properties of *Bombax ceiba* Mucilage and Corn Starch

The flow properties of the *Bombax ceiba* extract and corn starch were determined

and recorded as indicated in Table 6. Also, the flow properties of the formulated granules were using Bombax determined and recorded as indicated in Table 8

Table 6: Physicochemical Properties of *Bombax ceiba* mucilage extract and Corn Starch

Test	<i>Bombax ceiba</i> Extract	Corn Starch
Bulk density (g/ml)	0.48	0.46
Tapped density (g/ml)	0.63	0.59
Angle of Repose (°)	33.35	33.11
Carr's index (%)	23.84	22.62
Hausner's Ratio	1.31	1.29
Swelling capacity (%)	583.00	200.00
Ash Value (%)	15.00	1.00
Hydration Capacity (%)	999.00	101.00
Moisture Sorption (%)	6.45	2.84

Table 7 Microbial count of *Bombax ceiba* mucilage Extract

Sample Concentration mg/MI	BCM (cfu/mL)
100	508.50 ± 10.31
10	330.50 ± 12.91
1	213.00 ± 15.60
0.1	69.00 ± 1.410

BCM: *Bombax ceiba* mucilage, cfu: colony forming unit

Table 8: Table of Flow Property of granules prepared using *Bombax ceiba* mucilage, co-processed corn starch and *Bombax ceiba* mucilage and corn starch

Parameter	100% CS	100% BCM	5% CS	2.5% BCM	5% BCM	7.5% BCM	10% BCM	90:10 CS/BCM	80:20 CS/BCM	70:30 CS/BCM	60:40 CS/BCM	50:50 CS/BCM
Bulk Density (g/ml)	0.56	0.51	0.54	0.53	0.53	0.52	0.51	0.53	0.50	0.49	0.51	0.50
Tapped Density (g/ml)	0.59	0.54	0.57	0.56	0.55	0.55	0.54	0.54	0.53	0.50	0.53	0.606
Angle of Repose (°)	33.37	34.33	34.00	34.50	35.00	35.50	36.00	31.46	33.69	36.19	37.64	32.23
Carr's index (%)	5.40	5.10	5.30	5.40	5.20	5.00	4.90	2.77	4.92	2.40	2.47	17.49
Hausner's Ratio	1.06	1.05	1.06	1.06	1.06	1.05	1.05	1.03	1.05	1.03	1.02	1.21
Hydration Capacity (%)	83.00	207.00	87.00	92.00	100.00	114.00	123.00	103.00	123.00	134.00	140.00	147.00

KEY: BCM= *Bombax ceiba* mucilage extract CS= Corn Starch, CS/BCM: ratio of corn starch to *Bombax ceiba* mucilage

Table 9: Particle Size Analysis of granules prepared using *Bombax ceiba* mucilage, co-processed corn starch and *Bombax ceiba* mucilage and corn starch

The fineness of granules particles				
A percentage m/m passing the sieves (%)				
Granules	Fraction 1.6 > 1.2 mm	Fraction 1.2 > 1.02 mm	Fraction 1.02 > 0.75mm	Fraction < 0.75mm
100% CS	95,48	3,47	1,03	0,09
100% BCM	71,85	20,12	6,43	2,07
5% CS	74,13	18,12	6	1,99
2.5% BCM	75,79	17,22	5,78	1,84
5% BCM	75,99	17,02	5,55	1,59
7.5% BCM	80,07	16,23	3,29	1,07
10% BCM	80,44	15,98	2,99	0,87
90:10 CS/BCM	89,17	8,57	2,03	0,63
80:20 CS/BCM	86,23	11,02	2,54	1,01
70:30 CS/BCM	84,98	10,23	2,99	1,23
60:40 CS/BCM	83,98	9,98	4,59	2,01
50:50 CS/BCM	78,92	15,05	4,79	1,73

KEY: BCM = *Bombax ceiba* mucilage extracts; CS = Corn Starch; CS/BCM: ratio of corn starch to *Bombax ceiba* mucilage

Table 10: Results of Drug Content of granules prepared using *Bombax ceiba* mucilage, co-processed corn starch and *Bombax ceiba* mucilage and corn starch

Gum/Mucilage	Concentration	Mean Drug Content	SD
100% MS	100%	502.27	0.95
100% BCM	100%	500.99	0.77
5% MS	5%	499.40	-0.14
BCM	2.5%	501.07	0.77
	5%	499.43	-0.17
	7.5%	501.33	0.35
	10%	503.47	0.81
CS/BCM	90:10	502.27	0.95
	80:20	501.07	0.87
	70:30	501.33	0.82
	60:40	499.37	-0.16
	50:50	497.37	-0.16

KEY: BCM = *Bombax ceiba* Mucilage extracts; CS = Corn Starch; CS/BCM: ratio of corn starch to *Bombax ceiba* mucilage

Table 11: Results of Uniformity of Content Test for granules prepared using *Bombax ceiba* mucilage, co-processed corn starch and *Bombax ceiba* mucilage and corn starch

Gum/Mucilage	Concentration	SD (%)
100% MS	100%	2.43
100% BCM	100%	1.99
5% MS BCM	5%	1.56
	2.5%	2.14
	5%	1.99
	7.5%	1.97
CS/BCM	10%	2.02
	90:10	2.14
	80:20	2.12
	70:30	2.04
	60:40	1.98
	50:50	1.99

KEY: BCM = *Bombax ceiba* Mucilage extracts; CS = Corn Starch; CS/BCM: ratio of corn starch to *Bombax ceiba* mucilage

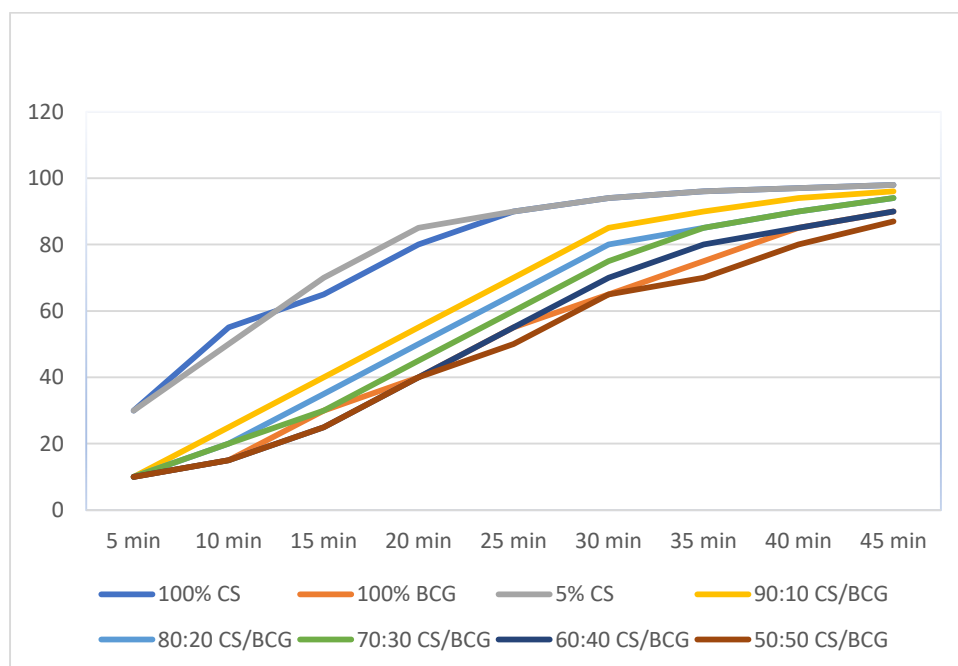


Fig 1: Dissolution Profile of Granules prepared using co-processed corn starch and *Bombax ceiba* mucilage (100% CS, 100% BCM, 5% CS, 90:10 CS/BCM, 80:20 CS/BCM, 70:30 CS/BCM, 60:40 CS/BCM, and 50:50 CS/BCM) and corn starch (5%)

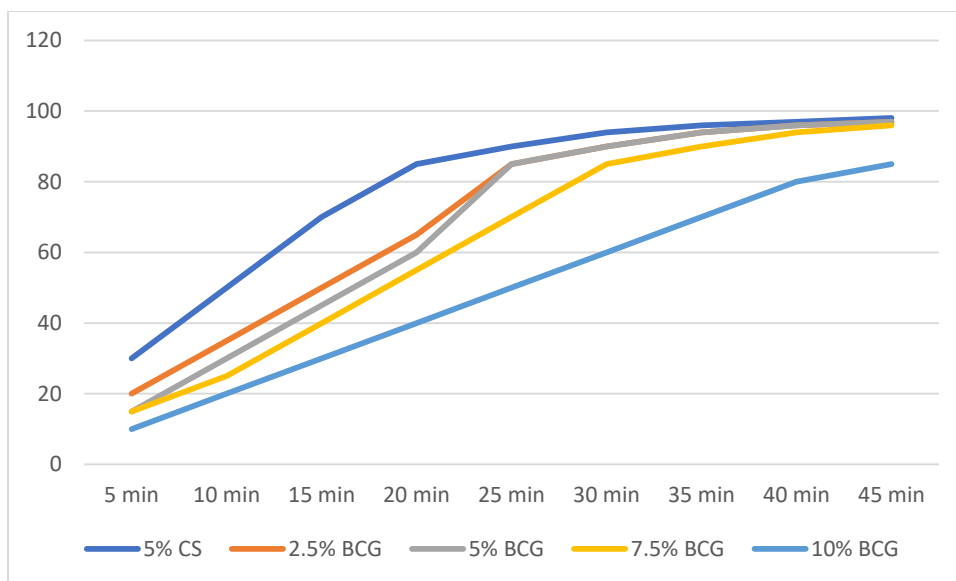


Fig 2: Dissolution Profile of Granules prepared using *Bombax ceiba* (2.5%, 5%, 7.5% and 10%) mucilage and corn starch (5%)

DISCUSSION

The percentage yield of *Bombax ceiba* mucilage, as obtained from the dried calyx of *Bombax ceiba* is 17.13 %. This is considered a good yield as claimed by (Audu-Peter *et al.*, 2011) that the hot extraction process gives more yield than cold water extraction. The little variation could be due to differences in specie, time of collection, method of extraction and ecological factors.

Bombax ceiba mucilage powder appears chocolate-brown in colour with a characteristic musky smell, bland taste, and fine texture. Comparatively, corn starch was found to be white, odorless, tasteless and similarly fine texture following the stipulations in B.P. (2009).

The ash value for *Bombax ceiba* (15%) is markedly higher than corn starch (1%), reflecting a higher mineral content in the plant extract. This is typical for plant-based excipients and can influence the formulation's physicochemical stability and compressibility (Pal and Raj, 2023)

The phytochemical screening revealed the presence of major secondary metabolites including carbohydrates, alkaloids, flavonoids, saponins, and tannins. The positive Molisch's test confirms that the sample contains carbohydrates, which is consistent with previous reports that mucilage-producing plant materials usually contain high levels of polysaccharides (Pal and Raj, 2023). The presence of alkaloids, as indicated by Mayer's, Wagner's, and Dragendorff's reagents, suggests that the plant material possesses nitrogen-containing compounds. Alkaloids are commonly found in many medicinal plants and contribute to biological activity, including antimicrobial and analgesic effects (Patwal and Nautiyal, 2022). The positive ferric chloride test for flavonoids further demonstrates the presence of polyphenolic compounds that may contribute antioxidant or anti-inflammatory properties. This is consistent with earlier phytochemical evaluations of *Bombax ceiba*, which documented flavonoids among its major constituents (Fegade *et al.*, 2023). Similarly, saponins were detected,

which aligns with the known phytochemical profile of several mucilage-containing plants. Saponins are associated with foaming ability and can influence excipient performance in pharmaceutical formulations by enhancing disintegration and solubility (Kwari *et al.*, 2024). Finally, the positive foam test for tannins confirms the presence of astringent polyphenols. Tannins have been reported in *Bombax ceiba* and related species and may contribute to physicochemical characteristics such as binding strength and moisture interaction (Chaudhary *et al.*, 2014). Overall, the results agree with previous phytochemical studies on *Bombax ceiba* and related natural excipients, supporting its suitability for pharmaceutical applications

The bulk and tapped densities of *Bombax ceiba* extract (0.48 g/ml and 0.63 g/ml, respectively) are slightly higher than those of corn starch (0.46 g/ml and 0.59 g/ml), indicating a relatively denser powder for *Bombax ceiba*. The Carr's index (23.84% for *Bombax ceiba* and 22.62% for corn starch) and Hausner's ratio (1.31 and 1.29, respectively) suggest that both powders exhibit fair to passable flow properties, with *Bombax ceiba* showing slightly poorer flowability (Szumilo *et al.*, 2017; Okunlola, 2018). The angle of repose values (33.35° and 33.11°) further support that both powders have moderate flow, suitable for granulation and tableting processes (Ssemakula, 2023). The swelling capacity of *Bombax ceiba* (583%) is significantly higher than corn starch (200%), indicating a strong water-absorbing ability. This property is crucial for binder and disintegrant functions in tablets, as it can facilitate granule cohesion and rapid disintegration upon hydration (Kale *et al.*,

2022; Berton *et al.*, 2002). Lastly, the hydration capacity of *Bombax ceiba* (999%) far exceeds that of corn starch (101%), demonstrating its excellent water retention and mucilage-forming ability, which is desirable for granule binding and tablet integrity (Audu-Peter *et al.*, 2011; Kwari *et al.*, 2024). Overall, these results indicate that *Bombax ceiba* possesses promising swelling and hydration properties compared to corn starch, supporting its potential as a natural binder and disintegrant in solid dosage formulations. The moisture sorption study shows a progressive increase in moisture uptake over five days for all samples. *Bombax ceiba* exhibited higher moisture absorption (6.45%) compared to corn starch (2.84%). This trend indicates that *Bombax ceiba* has a greater affinity for water, likely due to its high mucilage content and polysaccharide composition, which readily interact with water molecules (Kale *et al.*, 2022; Pal and Raj, 2023). The relatively low and gradual moisture uptake of corn starch reflects its lower water-binding capacity, consistent with its physicochemical profile (Berton *et al.*, 2002). The increase in moisture content over time is typical of hydrophilic excipients and must be considered during storage, as excessive moisture can affect tablet stability, flow, and compressibility (Szumilo *et al.*, 2017; Kwari *et al.*, 2024). Overall, the results highlight the higher water absorption behavior of *Bombax ceiba*, which could enhance its performance as a binder and disintegrant in tablet formulations, but also suggests a need for careful moisture control processing and during storage.

Table 7 presents the results of microbial count in the *Bombax ceiba* samples. The

microbial integrity of the *Bombax ceiba* samples was within specified pharmacopeial limits and slightly showed lower counts compared to the native starch. Also, total aerobic microbial count for the samples studied was less than the upper limit (103cfu/g) as required by the B.P., (2013) for corn starch.

The bulk density, tapped density, flowability, and hydration capacity of granules prepared with varying ratios of corn starch (CS) and *Bombax ceiba* mucilage (BCM). Bulk and tapped densities of the granules ranged from 0.49 – 0.56 g/ml and 0.5 – 0.61 g/ml, respectively. Formulations containing higher proportions of BCM generally show slightly lower densities compared to 100% CS, indicating that *Bombax ceiba* mucilage produces fewer compact granules, likely due to its high swelling and water-binding capacity (Audu-Peter *et al.*, 2011; Okunlola, 2018). Angle of repose increases with higher BCM content, ranging from 31.46° to 37.64°, suggesting a slight reduction in flowability as the mucilage content increases. However, all values remain within the acceptable range for fair to good flow (Ssemakula, 2023; Szumilo *et al.*, 2017). Carr's index (2.4–17.49%) and Hausner's ratio (1.02 – 1.21) indicate that all formulations, except the 50:50 ratio, exhibit good compressibility and flow properties. The increase in Carr's index and Hausner's ratio at the 50:50 ratio may reflect granule aggregation or excessive water retention, which slightly hinders flow (Okunlola, 2018; Kwari *et al.*, 2024). Hydration capacity increases progressively with higher BCM content, from 83% for 100% CS to 147% for the 50:50 mixture. This confirms the superior water-absorbing and mucilage-forming ability of *Bombax ceiba*

mucilage compared to corn starch (Kale *et al.*, 2022; Audu-Peter *et al.*, 2011).

Formulations with co-processed or blended ratios (e.g., 90:10, 80:20) show intermediate hydration capacities, demonstrating that co-processing CS with BCM can modulate water absorption while maintaining acceptable flow and compressibility. This is advantageous for formulating tablets that require controlled disintegration and optimal hardness (Singh *et al.*, 2024).

The particle size showed that the most uniform particles were in CS 100%. The granule batches of 2.5% to 10% BCM have similar particle size; the particles of the co-processed excipients also have similar size. The 100% BCM granule showed the largest variations of sizes between fractions of particles and this feature distinguished it from the other granules. This is caused by high binding solution of the *Bombax ceiba* mucilage used in production of these granules.

The United States Pharmacopoeia (2005) states that the paracetamol content should not be less than 90.0 % of the label claim, and should not be more than 110.0 %. This translates to a deviation of not less than -10 % and not more than 10 % of the label claim of 500 mg/dose. The results of the drug content tests are shown in Table 10, which showed that the least deviation was - 0.14 % and the highest was 0.95 %. These values are within the admissible limits of drug content. Thus, all the granulation of paracetamol conformed to the acceptable limits. This confirms to similar test obtained by (Osonwa and Chukwu, 2010) (Hassan and Kadhim, 2018).

In the test for uniformity of content, The United States Pharmacopoeia (2005) states that, unless otherwise specified in the individual monograph, the met if the amount of the active ingredient in not less than 9 of the 10 dosage units as determined from the Content Uniformity method lies within the range 85.0 % to 115.0 %, and no unit is outside the range 75.0 % to 125.0 % of the label claim or if the relative standard deviation of 10 dosage units is less than or equal to 6.0 %. If 2 or 3 units are outside the range of 85.0 % to 115.0 % of the label claim but not outside the range of 75.0 % to 125.0 % of the label claim, or if the relative standard deviation is greater than 6.0 % or both conditions prevail, 20 additional units should be tested. The requirement is met if not more than 3 units of the 30 are outside the range of 85.0-125.0 % of label claim, and the Relative standard deviation of the dosage units does not exceed 7.8 %. No batch had a Relative standard deviation of drug content of more than 6 % (Table 11). Thus, they all conformed to acceptable limits and could facilitate dosage precision and regulatory compliance by (Osonwa and Chukwu, 2010) (Hassan and Kadhim, 2018).

The dissolution test study was carried out for granules produced. 100% CS granules exhibited the fastest release, with complete dissolution (100%) achieved by 45 minutes. This rapid release reflects the low swelling capacity and moderate water-binding ability of corn starch, which allows the granules to disintegrate quickly and release the drug efficiently (Ssemakula, 2023; Berton *et al.*, 2002). 100% BCM granules had the slowest dissolution, reaching only 90% at 45 minutes. The delayed release can be attributed to the high swelling and mucilage-forming properties of *Bombax*

ceiba, which create a gel-like barrier that slows drug diffusion (Kale *et al.*, 2022; Audu-Peter *et al.*, 2011). Blended formulations (e.g., 5–10% BCM with CS) exhibited intermediate dissolution rates, indicating that co-processing or blending BCM with CS can modulate drug release. For instance, 5% BCM formulations reached 97% dissolution at 45 minutes, demonstrating a balance between binding strength and disintegration rate (Mohammed *et al.*, 2019; Kwari *et al.*, 2024). Increasing the proportion of BCM generally slowed the dissolution, reflecting its strong water absorption and gel formation. Formulations with higher BCM ratios (70:30, 60:40, 50:50) showed slower early-stage release but reached 85–90% by 45 minutes, which is still acceptable for immediate-release granules according to pharmacopeial standards (Therapeutic Goods Administration, 2021; World Health Organization, 2020).

CONCLUSION

The study demonstrates that *Bombax ceiba* mucilage and its corn-bombax co-processed binder as compared to corn starch was found to show promising binding properties. The study confirms *Bombax ceiba* mucilage as an effective, eco-friendly binding agent with comparable and complementary properties to corn starch. Its potential to enhance drug formulation quality while reducing costs and environmental impact underscores its value in pharmaceutical development.

Declaration of Interest

The authors declared no conflict of interest.

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