THE POTENTIAL OF THE FRUIT PULP OF PARKIA BIGLOBOSA (AFRICAN LOCUST BEAN) AS AN EXCIPIENT IN SOLID PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT
Nature has provided us with a wide variety of materials and the world today is increasingly interested in natural drugs and excipients. *Parkia biglobosa* (African locust bean) fruit pulp was processed into flour and its physico-chemical and functional properties evaluated as a potential pharmaceutical excipient for use in solid dosage forms. The effects of the fruit pulp as a binder and disintegrant were investigated on Paracetamol tablet formulations, using Acacia gum and Sodium starch glycolate as reference binder and disintegrant, respectively. The *P. biglobosa* fruit pulp was soluble in water with a resultant pH of 6.31; but insoluble in organic solvents. By all the indicators, Tapped density (0.24 g/ml), Bulk density (0.18 g/ml), Angle of repose (45.0°), Hauser’s ratio (1.67), Carr’s index (40 %); the fruit pulp did not show satisfactory inherent flow properties. The *P. biglobosa* fruit pulp had a very high water binding capacity (446 %) and swelling profile (4.25), holding up to about five times its own weight of water, which suggested it could serve as a good disintegrant. The proximate data (moisture content 8.66 %, ash value 2.40 %, crude fat 0.13, crude fibre 8.75 %, protein 6.64 %, carbohydrate 76.80 %, and sugar 3.66°Brix); showed it could be a good source of macronutrients. However, it’s pasting profile (pasting temperature 60.70°C, breakdown viscosity 7.5 RVU, setback viscosity 15 RVU, peak viscosity 9.0 RVU and final viscosity 15.50 RVU); indicated the absence of starch and lack of inherent viscosity. The appearance, tensile strength, friability and disintegration of Paracetamol tablets formulated with the fruit pulp as binder were not significantly different from compacts containing acacia gum at similar binder concentrations (>3 %w/w), but released the drug significantly faster (P < 0.05) (96 % in 30 minutes) compared to formulations with acacia gum (94 % in 45 minutes). The results established the potential of *P. biglobosa* fruit pulp as a thickener and an effective pharmaceutical binder, at least comparative to the commercially available Acacia gum.

KEYWORDS: *Parkia biglobosa*, fruit pulp, excipient, binder, diluent, disintegrant.

INTRODUCTION
The successful formulation of a stable and effective solid dosage form depends on the careful selection of the excipients which are added to facilitate processing and administration, promote the consistent release and bioavailability of the drug and protect it from degradation.[1] Today’s consumers opt for natural ingredients in food, drug and cosmetics, believing that they are safer and devoid of side effects as compared to synthetic ones.[2] even though synthetic polymers offer a broad range of properties that can be reasonably well “built-in” by design and modified by altering polymer characteristics.[3] Plant products are therefore attractive alternatives to synthetic products. Furthermore, novel excipients offer patent holders opportunities to upgrade their products and thereby extend their patent lives. Development of excipients from natural sources which are known to be utilized for food consumption may also reduce the regulatory requirements for approval.

The excipients used to make compressed tablets are numerous and can be classified by their use or function as; fillers, binders, disintegrants, lubricants, glidants, wetting agents, preservatives, colouring agents or flavouring agents.[4] Being inexpensive, environmentally friendly, fairly free from side effects, bioacceptable with a renewable source, local availability, better patient tolerance as well as public acceptance, are some of the advantages of plant-based excipients. They improve the native economy by providing inexpensive formulations to people by using locally available materials in a sustainable manner.

*Parkia biglobosa* (Mimosoideae - Leguminosae) commonly called African locust bean tree, has long been
widely recognized as an important indigenous fruit tree in anglophone and francophone West Africa. These trees are not normally cultivated but can be seen in populations of two or more in the savannah region of Ghana. For centuries, the *P. biglobosa* tree has been an integral part of life in Northern Ghana. Each and every part of the tree (bark, leaves, root, seed, wood and fruit) is utilized. The trees of the Parkia species are usually carefully preserved by the inhabitants of the area where they grow, because they are valuable sources of reliable food. A matured *P. biglobosa* fruit pod contains yellow, dry and powdery pulp (locally called ‘Dorowa’ in Hausa) in which dark brown or black seeds are embedded. The pulp which is rich in carbohydrates, minerals and vitamins, is licked for its sweet taste but only to a small extent. The pulp of the sweet varieties are usually dried, powdered and preserved for use in the lean season, when it is made into a lumpy porridge and other food products and eaten to combat hunger and food insufficiency.

Although the *P. biglobosa* seed has been extensively exploited, studied, and used in foods in a form locally referred to as ‘dawadawa’ in Ghana, the fruit pulp which constitutes about 60-70% of the pod content has not attracted much attention. As such little or no information is available concerning the use of the *P. biglobosa* fruit pulp as a pharmaceutical excipient, despite its abundance, food safety and long history of traditional use. Therefore, as a successful validation of usefulness of an excipient is contingent on data obtained from pre-formulation studies, this study sought to process *P. biglobosa* fruit pulp, evaluate its physicochemical and functional properties, incorporate it into tablet formulations and assess its effects and potential as an excipient in solid pharmaceutical dosage forms.

**Materials and Methods**

The dry fruit pods of *Parkia biglobosa* were collected into jute bags, from four (4) different locations in Ghana, namely: Bunkpurugu in Bunkpurugu/Yunyoo District, in the Northern Region (A), Wid at Bawku in the Bawku District, in the Upper East Region (B), Jirapa in the Jirapa/Lambussie District, in the Upper West Region (C) and Dawadawa No.1 in the Kintampo District, in the Brong Ahafo Region (D); during the March/April, 2011 fruiting season. The fruits pods were authenticated by Dr. G. H. Sam of the Department of Herbal Medicine, Faculty of Pharmacy and Pharmaceutical Sciences, KNUST; where a voucher specimen of each sample was deposited. They were then stored in a cool dry place in the laboratory store room until used. Acacia gum powder BP, Mannitol BP, Povidone BP and Magnesium stearate BP were all obtained from BDH Laboratory Chemicals Limited, Poole, England. Paracetamol BP was obtained from Trade Winds Chemists Ltd., Kumasi. All reagents used were of analytical grade.

**Methods**

**Preparation of *P. biglobosa* fruit pulp flour**

The *P. biglobosa* fruit pods were sorted, cleaned and manually split open. The yellow pulp along with attached seeds was removed, sun dried for 3 days and pounded lightly in a mortar with a pestle. The pulp was separated from the seeds and then thoroughly pounded and passed through a 40 mesh sieve. The fruit pulp samples were packed in high density polyethylene (HDPE) bags, labelled appropriately and stored in a refrigerator until required. The physical, chemical and functional properties of the pulp flour were determined.

**Phytochemical analysis**

Phytochemical tests were conducted on the fruit pulp for the presence of; carbohydrate, reducing sugars, deoxy sugar, ketones, pentoses, starch, tannins, glycosides, saponins, alkaloids and flavonoids.

**Solubility Test**

The *P. biglobosa* fruit pulp was evaluated for solubility in water, acetone, chloroform and ethanol in accordance with standard BP specifications.

**pH determination**

This was done by shaking 1 %%/v, dispersion of the sample in water for 5 minutes and the pH determined using a digital pH meter.[8]

**Particle size distribution of the fruit pulp flour**

Particle size determination was carried out with 150 g of the powdered sample shaken through a stark of sieves (size 75 to 850 μm) arranged in descending order, with a collector pan at the bottom; on an electromagnetic sieve shaker at amplitude 70 for 5 minutes. The percentage weight of the flour retained on each sieve was determined and the results analyzed.[9]

**Powder flow characterization**

**Angle of Repose**

The static angle of repose (θ) was measured according to the fixed funnel and free standing method. The mean diameter (D) of the base of the powder cone formed was determined and the angle of repose calculated using the relation; Tan θ = 2h/D, (where h, is the height of the cone).

**Bulk and Tapped densities; Hausner’s ratio and Carr’s index (%)**

Ten gram (10 g) of sample was weighed into 50 ml graduated measuring cylinder and the volume occupied by the sample without tapping (V) and after 150 taps on the table (V150), were recorded. The bulk (Db) and tapped (Dt) densities were calculated as the ratio of weight to volume (V and V150), respectively. The Hausner’s ratio was calculated as the ratio of tapped density to bulk density (Dt/Db) of the samples. Carr’s index (% compressibility) was calculated as: [(Dt-Db)/ Dt x 100].[6]
Swelling capacity
Swelling power was determined by the method described by Leach et al.,[10] with modification for small samples. 1g of the sample pulp was mixed with 10ml distilled water in a centrifuge tube and heated at 80°C for 30 minutes with continuous shaking. The suspension was centrifuged at 3000 rpm for 10 minutes, the supernatant decanted and the weight of the paste determined. The swelling power was calculated as the ratio of wt. of paste to wt. of dry sample.

Moisture sorption capacity
2 g of sample was evenly distributed over the surface of a 70 mm tarred petri dish, and then placed in a large desiccator containing distilled water in its reservoir (RH= 100%) at room temperature. The weight gained by the exposed samples at the end of a five day period was recorded as the amount of water sorbed.[13]

Water binding capacity
Water binding capacity was determined using a modified method of Medcaf and Gilles.[12] 1g of sample was suspended in 10 ml of distilled water and centrifuged at 3000 rpm for 10 minutes. The weight of the centrifuge tube and content was determined after decanting the water and allowing it to drain. The bound water was determined by the change in weight and the water binding capacity (WBC) calculated as the ratio of bound water (g) to wt. of sample (g) and expressed as a percentage.

Proximate properties of P. biglobosa fruit pulp
Moisture, ash, fat, fibre, crude protein, carbohydrate and sugar contents were determined by the AOAC official methods.[13]

Pasting characteristics P. biglobosa fruit pulp
A smooth paste was made with 40 g of the P. biglobosa flour in 420 ml distilled water for viscoelastic analysis using Brabender Viscoamylograph equipped with a 1000 cmg sensitivity carriage. The smooth paste was heated at a rate of 1.5°C/min1 to 95°C and maintained for 15 minutes. It was then cooled at the same rate and maintained for 15 minutes. Viscosity profile indices were recorded for pasting temperature, peak temperature, peak viscosity, viscosity at the end of the holding time at 95°C, viscosity at the end of the holding time at 50°C, breakdown and setback viscosities.[14]

Evaluation of binder and disintegrant quality
Table formulations
Wet granulation method was used to prepare granules for the compression of tablets containing various concentrations of P. biglobosa pulp as binder or disintegrant, using Paracetamol BP as model drug. The composition of the different formulations contained 500 mg Paracetamol per 600 mg tablet. Water was used as thegranulating fluid. The wet mass was screened through a 1700 µm mesh sieve, dried at 60°C for 30 minutes in a hot air oven and rescreened with a 1180 µm mesh sieve. The tablets were compressed on a single punch tableting machine (DP -30, Pharmao Industries), fitted with concave punches of 12 mm diameter and a fixed compression load of 11 kN was applied.

Two sets (A and B) of formulations were prepared. Set A had six batches (Table 1). The first five (A1 – A5) had standard ingredient but with varying concentrations (1%, 3%, 5%, 8%, 12% w/w) of the P. biglobosa fruit pulp as binder, whilst the sixth batch (A6) had acacia gum (5% w/w) as reference binder. Mannitol was used as a diluent to adjust tablet weight. Set B had five batches (Table 2). The first four (B1 – B4) made of standard ingredients but with different concentrations (2%, 4%, 6% and 8% w/w) of the P. biglobosa fruit pulp as intra-granular disintegrant and the fifth (B5) had 4% w/w Sodium starch glycolate as reference disintegrant.

Table 1: Composition of Paracetamol tablet formulations with varying concentration of P. biglobosa fruit pulp as a binder.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight of Ingredients (mg)</th>
<th>Batches</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A1</td>
<td>A2</td>
</tr>
<tr>
<td>Paracetamol BP</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>P. biglobosa fruit pulp</td>
<td>6 (1%)</td>
<td>18(3%)</td>
</tr>
<tr>
<td>Mannitol</td>
<td>70</td>
<td>58</td>
</tr>
<tr>
<td>Sodium starch glycolate (4% w/w)</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Acacia gum (5% w/w)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total weight per tablet (mg)</td>
<td>600</td>
<td>600</td>
</tr>
</tbody>
</table>

Figures in brackets represent concentration of binder (%w/w).
Table 2: Composition of Paracetamol tablet formulations with varying concentration of P. biglobosa fruit pulp as disintegrant.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight of ingredients (mg)</th>
<th>Batches</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>B1</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>500</td>
<td>500</td>
</tr>
<tr>
<td>P. biglobosa fruit pulp</td>
<td>12 (2%)</td>
<td>24 (4%)</td>
</tr>
<tr>
<td>Polymethylmethacrylate</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Polyvinylpyrrolidone (PVP) (3% w/w)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manitol</td>
<td>76</td>
<td>64</td>
</tr>
<tr>
<td>Sodium starch glycolate (4% w/w)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total weight per tablet (mg)</td>
<td>600</td>
<td>600</td>
</tr>
</tbody>
</table>

Figures in brackets represent concentration of disintegrant (% w/w).

**Tablet hardness**

Tablet hardness was determined using a manually operated Monsanto hardness tester (VEEGO HT-01, Progressive Instruments). Ten (10) tablets were randomly selected from the different batches of tablets and each positioned vertically on the lower immovable anvil of the machine. The upper anvil was gently moved down by rotating the head screw in anticlockwise direction, such that the two anvils just held the tablet vertically. The main and follow pointers on the gauge were then set to zero and diametral load manually applied to the tablet by moving the head screw anticlockwise at a rate of 0.1 kg per turn. Hardness values of the paracetamol tablets were recorded on the gauge in kg/cm² (1 kg/cm² or kgf/cm² = 98066.5 N/m² or Pascal) by the follow pointer, while the main pointer went back to zero after the tablets cracked or crushed.

**Tablet friability**

The friability of fifteen tablets weighing approximately 6.5 g was determined in a friabilator (Erweka, TA 20, Germany). The drum was rotated at 25 rpm for 4 minutes. Loss of tablet weight with respect to the initial weight was then calculated as percentage friability.

**Disintegration time**

A tablet was placed in each of the six tubes of the disintegration apparatus (ZT 4, Erweka - Germany) and the time taken for all tablets to completely disintegrate in distilled water maintained at 37 ± 2°C were determined.

**Dissolution test (In vitro drug release)**

The dissolution of the compressed tablets was determined using an Erweka six vessel rotating paddle USP type II apparatus. The dissolution medium was 900 ml of phosphate buffer pH 5.8 at 37.0 ± 0.5°C; with paddle speed of 50 rpm and sampling time of 5, 10, 15, 30, 45, 60 minute intervals. The samples were assayed spectrophotometrically at 257 nm, using 0.1M NaOH in the reference cell.

**Statistical analysis**

The results were expressed as Mean ± SD. Statistical analysis was done by One-way analysis of variance (ANOVA) and Post hoc multiple comparisons were carried out using Tukey’s Multiple comparison test. The statistical package GraphPad Prism version 5.01 for Windows (GraphPad Software Inc., San Diego - California) was used and the level of significance set at p < 0.05.

**RESULTS AND DISCUSSION**

Organoleptic properties are important considerations in the development of solid oral dosage forms as they can influence consumer preference and compliance. The Parkia biglobosa fruit pulp samples had characteristic odour, yellow colour and sweet taste with sample D (collected from Dawadawa N[1]) showing the best physical properties that the rural households require and use when selecting P. biglobosa fruits for keeps and use, especially during the arid season. The phytochemical screening of the P. biglobosa fruit pulp samples showed the presence of carbohydrates, reducing sugars, saponins and glycosides in all the samples. However, alkaloids, starch and tannins were absent. There were no marked differences in the physical and phytochemical properties exhibited by the four P. biglobosa fruit samples, which suggested that the different vegetational locations had little or no effect on the physical nature and phytochemical composition of the fruit pulp. Sample D was then selected for subsequent evaluation.

The P. biglobosa fruit pulp flour was soluble in water, sparingly soluble in chloroform but insoluble in acetone and alcohol. The pH obtained for the P. biglobosa fruit pulp was 6.31, which is higher than 5.22 reported by Gernah et al.[15]. Knowledge of the pH of an excipient is an important parameter in determining its suitability in formulations, as the stability and physiological activity of most preparations depends on pH.[16] The near neutral pH of the P. biglobosa fruit pulp implies that when used in uncoated tablets, it may be less irritating to the gastrointestinal tract.

The particle size and size distribution of powders affect the compactibility and rearrangement of particles.[17] The flow properties of an excipient will improve when the particle sizes are large. However large particle sizes lead to less strong tablets due to low surface.
area for bond formation as compared to smaller particles. Therefore, optimal particle size and size distribution will be required to obtain good flow properties, compaction and hardness, and also reduce weight variation. The *P. biglobosa* fruit pulp had geometric mean diameter \( d_{50} \) of 420 ± 1.43 μm (Table 3), which indicated that the particles are relatively fine and the flour may exhibit cohesiveness. The bulk properties describe the density, packing and flow of a powder mass. The *P. biglobosa* fruit pulp showed a bulk density (0.18 g/ml) and tapped density (0.24 g/ml) which were suggestive of a good flow material. However, the high angle of repose (45°), Hausner’s ratio (1.67) and compressibility index (40) (Table 3) confirmed its poor flow properties and probably its lack of suitability as a direct compression vehicle.

**Table 3: Physicochemical, proximate and pasting profile of the *P. biglobosa* fruit pulp**

<table>
<thead>
<tr>
<th>Physicochemical properties</th>
<th>Proximate composition (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.31</td>
</tr>
<tr>
<td>Angle of repose (°)</td>
<td>45.0</td>
</tr>
<tr>
<td>Bulk density (g/ml)</td>
<td>0.18</td>
</tr>
<tr>
<td>Tapped density (g/ml)</td>
<td>0.24</td>
</tr>
<tr>
<td>Hausner’s ratio</td>
<td>1.67</td>
</tr>
<tr>
<td>Compressibility index (%)</td>
<td>40.0</td>
</tr>
<tr>
<td>Particle size ( d_{50} ) (μm)</td>
<td>420</td>
</tr>
<tr>
<td>Swelling power (g/g)</td>
<td>4.25</td>
</tr>
<tr>
<td>Moisture sorption capacity (%)</td>
<td>42.50</td>
</tr>
<tr>
<td>Water binding capacity (%)</td>
<td>446</td>
</tr>
</tbody>
</table>

**Pasting characteristics of the *P. biglobosa* fruit pulp and Acacia gum.**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Peak viscosity (RVU)</th>
<th>Final viscosity (RVU)</th>
<th>Breakdown (BU)</th>
<th>Set back viscosity (RVU)</th>
<th>Peak time (min.)</th>
<th>Pasting temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>P. biglobosa</em> fruit pulp</td>
<td>9.0 ±7.07</td>
<td>15.5 ± 3.54</td>
<td>7.5 ± 4.95</td>
<td>15.0 ± 1.41</td>
<td>7.08 ± 8.59</td>
<td>60.70 ± 12.02</td>
</tr>
<tr>
<td>Acacia gum</td>
<td>5.5 ± 0.71</td>
<td>7.5 ± 1.41</td>
<td>0.0±0.00</td>
<td>1.5 ± 0.71</td>
<td>21.53±30.44</td>
<td>72.35 ± 31.61</td>
</tr>
</tbody>
</table>

The water binding capacity of the *P. biglobosa* fruit pulp (446%) indicated that it is capable of absorbing about five times its own weight of water, and could be a reflection of its amorphous nature. Swelling is generally accepted as an indication of tablet disintegration ability. The swelling capacity of the *P. biglobosa* fruit pulp was 4.25 g/g which indicated that if the *P. biglobosa* fruit pulp was incorporated in a tablet formulation, it would probably assist disintegration by capillary action or wicking and swelling. Also the relatively high hydration and swelling capacity of the fruit pulp could possibly be due to high powder porosity, all suggesting it could be a good disintegrant. Moisture sorption capacity is a measure of the moisture sensitivity of a material. The value obtained for the *P. biglobosa* fruit pulp was high (42.50%). This could be due to the hydrophilic nature of the molecules of the powder. It indicated a possibly high susceptibility to moisture induced changes which may affect flow, compression behaviour and mechanical strength of tablets. This result is indicative of the sensitivity of the fruit pulp to atmospheric moisture and the need to be stored in air-tight containers. The low moisture content of the *P. biglobosa* fruit pulp (8.66 %), was comparable to 8.41 % reported by Gernah et al., and within the limit of 4 - 12 % indicated by Olayemi. This suggested that the fruit pulp may be less prone to microbial attack, have good shelf stability, less interaction with moisture sensitive drugs and possibly high ability to absorb water to facilitate disintegration. The ash content of the *P. biglobosa* fruit pulp (2.40 %) was higher than (1.0 %) obtained for the Mediterranean species by Stein but within the range for most legumes (2.0-5.0 %) as reported by Gernah et al.,. It is a commonly applied parameter for the detection of impurities, adulteration and substitution. Therefore, the value indicated low levels of contamination during gathering, processing and handling of the fruit pulp. Crude fat was 0.13 %. This conformed to those reported for most legumes. Ihekoronye and Ngoddy reported that most legumes have less than 3.0 % fat with lentils having as low as of 0.60 %. Stein also reported a fat content of 0.50 % in the Mediterranean species. This low fat content is an indication that the fruit pulp can be stored for long periods without undergoing rancidification, which is characteristic of many legumes. The crude fibre of 8.75 % was low compared to 22.73 % reported by Dahouenon – Ahoussi et al.,. This makes the fruit pulp a poor source of fibre. The protein content of the *P. biglobosa* fruit pulp (6.64%) was higher than (4.29 %) reported by Dahouenon – Ahoussi et al., and comparable to 6.56 % by Gernah et al.,.

The major component of the *P. biglobosa* fruit pulp was carbohydrate (76.80 %) (Table 3). In their study, Akoma et al., found the content of carbohydrate to be 67.30%. The high content of carbohydrate can explain the noticeable sweet taste of the pulp. The sugar content was 3.66’Brix. Sugars such as sucrose, glucose and
fructose are abundantly used as basic ingredients in the food industry and as excipients in the pharmaceutical industry due to the quality attributes they contribute to the final products, such as sweet taste, flavour, texture, binder, bulking agent and carrier function of active pharmaceutical components. Therefore, the *P. biglobosa* fruit pulp may be a potential ingredient in the pharmaceutical industry due to its high carbohydrate and sugar content.

The *P. biglobosa* fruit pulp exhibited low pasting peak viscosity of 9.0 rapid viscosity units (RVU) and Acacia gum produced 5.5RVU (Table 3). The pasting temperature gives an indication of how fast flour swells. The relatively high pasting temperature of the fruit pulp (60.70°C) and Acacia gum (72.35°C) could be attributed to strong associative forces in the pulp powder and the gum, as such forces are known to be responsible for viscosity stability. The *P. biglobosa* fruit pulp had breakdown, setback and final viscosities of 7.5 RVU, 15.0 RVU and 15.5 RVU, respectively. The low setback values suggest the paste formed may have cohesive property. The low breakdown viscosity shows that the pulp may have undergone a low degree of swelling, but the actual swelling capacity of the fruit pulp was rather high. Generally, the pasting profile confirmed the absence of starch and a lack of inherent viscosity in the *P. biglobosa* fruit pulp.

The post compression evaluation showed that the tablets of the various formulations were of uniform thickness and weight. Tensile strength as a property of a tablet that is measured to assess its resistance to permanent deformation. It also influences the disintegration time and rate of dissolution. As the concentration of the fruit pulp as binder increased, the mechanical strength of the tablets increased and friability decreased. Conventional compressed tablets of acceptable hardness (39.2 - 73.5 N) and friability (≤1 %) are essential for handling during packaging, transportation and administration. By this, the tablets compressed with the *P. biglobosa* fruit pulp (>3 %) and acacia gum (5 %) as binder (Table 4), as well as those with the fruit pulp (>2 %) and Sodium starch glycolate (4 %) as disintegrant (Table 5), all possessed sufficient hardness and resistance to friabilisation.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>B1</th>
<th>B2</th>
<th>B3</th>
<th>B4</th>
<th>B5</th>
<th>Acacia gum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness (mm)</td>
<td>6.2 ± 0.1</td>
<td>6.2 ± 0.1</td>
<td>6.2 ± 0.1</td>
<td>6.3 ± 0.1</td>
<td>6.3 ± 0.1</td>
<td>6.2 ± 0.1</td>
</tr>
<tr>
<td>Uniformity of weight (g)</td>
<td>0.597 ± 0.004</td>
<td>0.600 ± 0.006</td>
<td>0.602 ± 0.006</td>
<td>0.602 ± 0.005</td>
<td>0.596 ± 0.004</td>
<td>0.605 ± 0.006</td>
</tr>
<tr>
<td>Hardness (N)</td>
<td>19.60 ± 3.01</td>
<td>29.40 ± 2.51</td>
<td>39.20 ± 2.73</td>
<td>44.10 ± 3.34</td>
<td>49.00 ± 2.83</td>
<td>39.20 ± 4.13</td>
</tr>
<tr>
<td>Friability (%)</td>
<td>1.27 ± 0.05</td>
<td>0.78 ± 0.08</td>
<td>0.60 ± 0.08</td>
<td>0.11 ± 0.00</td>
<td>0.11 ± 0.00</td>
<td>0.37 ± 0.07</td>
</tr>
<tr>
<td>Disintegration time (min)</td>
<td>0.74 ± 2.12</td>
<td>1.52 ± 0.02</td>
<td>3.30 ± 0.03</td>
<td>9.04 ± 0.03</td>
<td>10.24 ± 0.02</td>
<td>1.39 ± 0.01</td>
</tr>
</tbody>
</table>

The disintegration times of the formulated Paracetamol tablets with varying concentration of *P. biglobosa* fruit pulp and with Acacia gum as binder were less than 15 minutes (Table 4), with significant differences (p < 0.05) existing among the former. The British Pharmacopoeia recommends a disintegration time of 15 minutes or less for immediate release tablets. The disintegration times obtained for tablets with varying concentration of the *P. biglobosa* fruit pulp as disintegrant showed a decrease in disintegration time (80.8 - 29 minutes) with increasing pulp concentration (Table 5), but did not meet the BP specification for disintegration. The tablets with Sodium starch glycolate met this specification with a significant difference (p < 0.05) in disintegration time compared to those with the fruit pulp. Both batches of tablets had similar hardness but compared to the Sodium starch glycolate the fruit pulp may not have an inherent ability to disintegrate.
Rather it showed a great propensity to agglutinate, suggesting that the *P. biglobosa* fruit pulp may not be a good disintegrant.

Figure 1: *In vitro* drug release profile of the formulated Paracetamol tablets

Disintegration of tablets plays a vital role in the dissolution process. The paracetamol tablets prepared with *P. biglobosa* fruit pulp as a binder (5%) released the drug significantly faster (P<0.05) (96% within 30 minutes), than formulations with acacia gum (94% in 45 minutes) at the same binder concentration (Fig. 1). The British Pharmacopoeia states that the quantity of drug released should not be less than 85% of the labelled amount of Paracetamol in 45 minutes. Hence the tablets formulated with *P. biglobosa* fruit pulp and Acacia gum as binders complied with this specification and would be appropriate for use.

In all, the *P. biglobosa* fruit pulp and Acacia gum showed comparative effectiveness as binders, and in allowing drug release from the paracetamol tablets. The results strongly demonstrated the potential of *P. biglobosa* fruit pulp for use in the pharmaceutical industry, either for its high water sorption or as a thickener and binding agent.

CONCLUSION

The *P. biglobosa* fruit pulp demonstrated poor flowability. However, Paracetamol tablets formulated with it as a binder satisfied all the specifications including hardness, resistance to friability, disintegration and *in vitro* release of drug, with comparative effectiveness to commercially available Acacia gum, in similar concentrations. Therefore, the *P. biglobosa* fruit pulp could be a good binder for the manufacture of solid dosage forms.

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