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Formulation and Evaluation of Ibuprofen Tablets Using *Musa acuminata* Starch as a Binder by Wet Granulation

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ABSTRACT

The granule was evaluated and had fair flow properties using tests such as bulk density. Ibuprofen tablets of 400mg were then formulated from granules by compression. The process of tableting was carried out at Mbarara University of science and technology using the Pharmbiotrac laboratories. The tablet properties such as friability test, disintegration test, hardness test was carried out and the results were fairly good. Unfortunately, only one Batch was able to pass the dissolution test and all batches were not able to yield about 95% drug concentration on drug assay. The study's primary goal was to formulate tablets of ibuprofen where Musa acuminata starch is used as a binder using wet granulation method. The *Musa acuminata* starch was used to form a mucilage which was used as a binder in the formulation. *Musa acuminata* starch showed good binding properties, this is seen in the hardness test. The formulated tablets had a good crushing strength. The disintegration of the tablets was fair. But the batches were not able to pass the drug assay test, the tablets contained 80% of the active ingredient.Musa acuminata starch has good physical properties and is a good binder and could be a competitor of corn starch as a binder however compatibility tests are required to prove its compatibility with active ingredient ibuprofen.

Keywords: Formulation, Evaluation, Ibuprofen, *Musa acuminata*, Starch, Binder and Wet Granulation

INTRODCTION

Tablets are solid dosage forms containing one or more active ingredients and excipients. Tablets are oral dosage forms. Excipients are necessary components of a dosage form that are included to increase volume, facilitate flow, enable compactness, and make a medication easy to deliver. Additionally, they can be employed to alter drug release, which affects drug incorporation's bioavailability and subsequent absorption. Excipients are essential ingredients of a dosage form which are added to increase volume, aid flow, enable compactness and make a drug convenient to administer [1].Tablet quality is dependent on the physicochemical properties of the active pharmaceutical ingredient , excipients used as well as the conditions applied while manufacturing [2]. In tablet dosage form, the US Pharmacopeia- National Formulary (USPNF) classifies excipients based on their use at the time of formulation, such as binders, disintegrants, and fillers [3]. One of the most utilized excipient is starch, used as filler, binder, and disintegrant in the manufacture of solid dosage forms. Starch is a relatively cheap raw material with physical and chemical properties that impart multiple uses in pharmaceutical industry like binding agent [2]. Starch is a compound that has a high molecular weight consisting of glucose polymers which are branched together with glycosidic bonds [3].

Binders are pharmaceutical excipients that are normally used in tablet formulations to mix the powders properly and form proper granules and consequently improve the flow properties of the granules [4]. Binders are either sugar or polymeric material [5]. Among the carbohydrates that plants store is starch, which is present in a variety of plant tissues including seeds, roots, fruits, and tubers [3]. Starches of numerous sources used as binder in its mucilage or dry powdered form have been studied and effectively assessed [6].Starches commonly used include maize starch , rice starch , corn starch , wheat starch [7]. The choice of a specific binder depends on the binding force required to form granules and how compatible the binder is with other ingredients in the formulation [8]. The family Musaceae includes the banana, which has more than 700 variations and perhaps over 30 well-known species [6]. Bananas are widely farmed in subtropical and tropical areas. Green banana is rich in starch as a main component that prevents ripening [7]. Bananas are widely grown in this community [Uganda] and are widely available. Banana in a mature green stage is a great source of starch. The green banana pulp contains up to 70–80% starch on a dry weight basis [9]. Banana starch can be extracted from the bananas, the starch is colorless, a viscous mucilage [6]. Commercially, banana may be an alternative source for starch that can be used as a binder in pharmaceutical setting [7]. Banana starch have been reported to be resistant to α-amylase and glucoamylase hydrolysis, and has been shown to have health benefits similar to dietary fiber [10]. Banana starch was found to compare favorably with corn starch as the binding agent in tablet formulations [10]. Green banana contains a large amount of starch throughout its unripe stage, which consists of around 20-25 % in the pulp of the fruits [7] starch is deposited in the fruit in within the shape of granules, partially crystalline, whose morphology, chemical composition, and super molecular structure are characteristic of each particular plant species [7]. The banana has favorable physicochemical properties, so banana has great potential to be an additional material in the pharmaceutical field, either in the form of original starch or in a modified form [11]. Banana starch's application as a tablet excipient is not well understood [6]. Native banana starch has higher resistant starch content (65–98%) [7–9] than other native starches such as aracca starch (17.5%), cassava starch (1.8%), cush-cush yam starch (55.8%), potato starch (48.5%), and taro starch (13.8%) [9]. Ibuprofen is a key medication on the WHO's "Essential Drugs List," which is a list of essential medicines for a minimally adequate healthcare system [12]. Ibuprofen is a common and widely used non-steroidal anti-inflammatory drug (NSAID) [13]. Ibuprofen, a BCS class II drug, shows poor water solubility and high permeability across the intestinal membrane. Apart from its low intrinsic solubility in aqueous media [14].

When used at a modest dose, ibuprofen is just as effective as aspirin and paracetamol for conditions that are often treated with OTC drugs. As an analgesic, an anti-inflammatory, and an antipyretic, ibuprofen is used Ibuprofen at low dose is as effective as aspirin and paracetamol for the indications usually treated with over-the-counter (OTC) medications [15]. Ibuprofen is mostly used to relieve mild to moderate pain associated with osteoarthritis, rheumatoid arthritis, headaches, migraines, and post-operative pain [15]. Ibuprofen is a potent inhibitor of prostaglandin (PG) synthesis that can manage a number of pain types and possess anti-inflammatory activity [15]. Ibuprofen has been selected for this study because of its poor compressibility and hence it requires a binder among other excipients to form tablets of sufficient tensile strength [16].

MATERIALS AND METHODS

Study design

An experimental design was used to perform the study where by different quality parameters were carried out to analyze the quality of Ibuprofen tablets formulated using starch derived from *Musa acuminata* to investigate its suitability for use as a pharmaceutical excipient (binder).

Study setting

The study was conducted at Kampala International University-western campus pharmaceutics laboratories and Mbarara university pharmaceutics laboratories.

Sample Size

Seventy pieces of *Musa acuminata* were collected to give the starch.

Methods

Collection of *Musa acuminata* plant

The plant was collected from a garden in Bwejiragye, Bushenyi in Western Uganda.

Extraction of starch

The extraction of the starch derived from *Musa acuminata* was carried out following the method, adopted from [17]. Seventy fresh unripe bananas were weighed individually using an analytical balance. The bananas were washed with distilled water then peeled. Peeled bananas were washed with water and weighed. Peeled bananas were cut into small pieces using a sharp knife. The pieces were blended. The blended bananas were filtered and passed through a muslin cloth. To filtrate (1200ml), sodium hydroxide was mixed with distilled water and added to the filtrate. The

filtrate with Sodium hydroxide was left to settle (decant) for 12 hours. The starch was washed repeatedly using distilled water to remove alkali completely. The starch was then dried in the oven at 50C for 5 hours. The starch was then finally passed through a sieve of 480micrometer. Then stored in an airtight container.

Characterization of *Musa acuminata* starch powder

1. PH

The pH of the starches was determined by a pH meter whereby 5.0g of starch were added to 25mI of carbon dioxide free water followed by shaking for 60 second then the solution was Allowed to settle for 15minutes.

2. Moisture content

Using a hot air oven, the moisture content of the starch samples was ascertained. Starch powder that has been precisely weighed and distributed across the pan is 1 g. The samples were then dried for 90 minutes at 130°C. Calculated and reported as a percentage moisture content, the weight difference caused by moisture loss.

3. Bulk density

A modified method simulating the bulk densitometer was used in the initial bulk density determination. In a 25 ml measuring cylinder, 10 g of starch powder was put. . The upper surface was carefully flattened out and the volume was noted. Bulk density was calculated using the relation:

Bulk density (DO) (g/cm3) = mass of starch ÷Bulk volume

4 .Tapped density

The 10 g starch powder was gently tapped 150 times on a padded bench and the final volume was noted. Tapped or final bulk density was then be calculated using the relation:

Tapped density (g/cm3) = Weight of starch÷ Tapped volume

5. Powder flow properties

The angle of repose, Hausner's ratio and Carr's compressibility index was used in estimating the flow properties of the matooke banana starch powders [17].

Angle of repose

The funnel was held with its tip 2 cm above a petri dish that was 9 cm broad. The starch powders were then allowed to pass through the funnel until the cone's apex barely touched the funnel's tip. The average diameter (D) of the powder cone's base was measured, and the tangent of the angle of repose (8) was computed using the formula Tan =h/r, where h stands for the pile's height and r for its radius.

Hausner's ratio

This was calculated as the ratio of tapped density to bulk density of the starches.

Carr's compressibility index

Carr's index was calculated from the bulk and tapped density data using the relation: Carr's index = {(Tapped density- Bulk density) ÷ (Tapped density)} ×100

Swelling capacity = Va/Vb

Where, Va = tapped volume, Vb = volume of sediment after 24 h.

Preparation of starch mucilage

1 gram of starch was weighed and placed small beaker containing 2ml of water and mixed thoroughly. The mixture was heated using a water bath while adding distilled water slowly to make the mucilage up to 10ml volume.

Mucilage for the different concentration of starch binder was prepared following the above method

Preparation of granules and tablets

Tablet formulation were prepared by wet granulation technique. Ibuprofen tablets contain 308 mg of ibuprofen was prepared using five different concentrations of the banana starch (binder).308 mg of Ibuprofen (API) was weighed accurately. Granules was be prepared by mixing of Ibuprofen, corn starch and lactose in mortar, banana starch mucilage was added as required. Granules was obtained by passing the dump mass through a sieve No. 186 micrometer and dry in hot air oven at 45 °C for 40min and again granules were sieved through No. 186 micrometer. Magnesium stearate [% w/w] and Talc was used as lubricant and glidant. The compositions of the batches are shown in Table 3:

The process of tableting making

Filling: In this step the number of granules was dispensed into a hopper or a die cavity.

Compression: This is the application of balance inward (pushing forces) to different points on the material.

Ejection of the tablet lastly.

The machine used was Sunita implex Eco- station suite #1201.

Evaluation of the Prepared Ibuprofen Granules

1 .Bulk Density

Pouring the mixture into a graduated cylinder allowed us to calculate the apparent bulk density. The bulk volume (Vb) and powder weight (M) were calculated. Pb = M/Vb was used to calculate the bulk densitym

2 .Tapped Density:

Using density equipment, the measurement cylinder containing a known mass of blend was tapped 100 times. Measurements were made of the blend's weight (M) and the minimum value (Vt) that the cylinder could hold. Pt = M/Vt was used to calculate the tapped density.

3 .Compressibility Index:

The easiest approach to quantify a powder's flow is by its compressibility. The Compressibility (Carr's) index (I), which is computed as follows, provides an indication of how easily a material may be made to flow I = 100 - Pb/Pt - Pt

4 .Hauser's Ratio:

A non-direct measure of powder flow is Hauser's ratio. The formula used to calculate it is as follows: Pt/Pb = Hr.

5 .Angle of Repose:

Angle of Repose was calculated using the funnel approach in item number five. The mixture was poured via a funnel that could be lifted vertically until it reached a particular cone height (h). The formula = tan-1 (h/r) was used to calculate the angle of repose () and measure the radius of the heap (r).

Evaluation of the batches of tablet

Tests were conducted in order to compare the quality and effectiveness of the batches of ibuprofen granules with various starch concentrations. These tests cover weight uniformity, hardness, friability, dissolving time, and disintegration**.**

1. Uniformity of weight and diameter of tablets

Twenty tablets were chosen at random from each batch and evaluated one at a time. Calculations were made to determine the mean weight and standard deviation.

2. Hardness test

This test was conducted to find out whether the pills could endure pressure while being handled, packaged, and transported. The mechanical strength of the tablets was assessed using a Monsanto tablet hardness tester. We will determine the typical force needed to break each batch of pills.

3. Friability testing of tablets

A total of ten tablets were randomly chosen from each batch, dusted, and weighed in order to assess the level of friability. The pills were put in a Roche friabilator and tumbled for four minutes at a rate of 25 revolutions per minute. The tablets were then powdered once more and weighed once more to measure the percentage of weight reduction.

4. Disintegration studies on the tablets

A Disintegration Apparatus was used to conduct disintegration tests on six tablets from each batch in distilled water at a temperature of 37 °C. The moment at which there were no more granules of any tablet remaining on the device' mesh was considered the disintegration time.

5. In vitro drug release studies

Dissolution studies were done using USP apparatus I (basket method). The dissolution medium was 900 mL of 900ml of 7.2 pH phosphate buffer, at 37 to 37.5 degrees celcisus and 50 rpm. Six tablets were selected from each batch. A sample (10ml) of the solution was withdrawn from the dissolution apparatus at 5minutes, 10minutes, 15 minutes, 30 minutes and 45 minutes and the samples were replaced with fresh dissolution medium. The samples were filtered through filter paper and diluted to a suitable concentration with 7.2 pH phosphate buffer.Absorbance of these solutions was measured at 230 nm using a UV spectrophotometer at 37˚C.

6. Assay of Ibuprofen

The method involving acid base titration was modified and used. Three tablets were chosen randomly from a batch of the formulation and weighed. A quantity of the powder equivalent to 0.5g Ibuprofen was extracted with 20ml chloroform for 15 minutes and then filtered using filter paper. The residue was washed thrice with 10ml each of chloroform and the filtrate gently evaporated to dryness. The residue was dissolved in 100ml of 96% ethanol and the solution titrated against 0.1M NaOH upon addition of 2 drops of phenolphthalein as indicator. The end point (pink color) was noted and content of ibuprofen calculated.

RESULTS

Table 1: Characterization of Granules

PARAMETERS	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6
Bulk density (g/cm³)	0.4325	0.4138	0.398	0.348	0.3370	0.388
Tapped density(g/cm³)	0.4675	0.4427	0.4294	0.3715	0.3589	0.466
Hauser's ratio	1.08	1.06	1.07	1.06	1.064	1.2
Carr's compressibility index	7.48	6.5	7.3	6.3	6.10	16.738

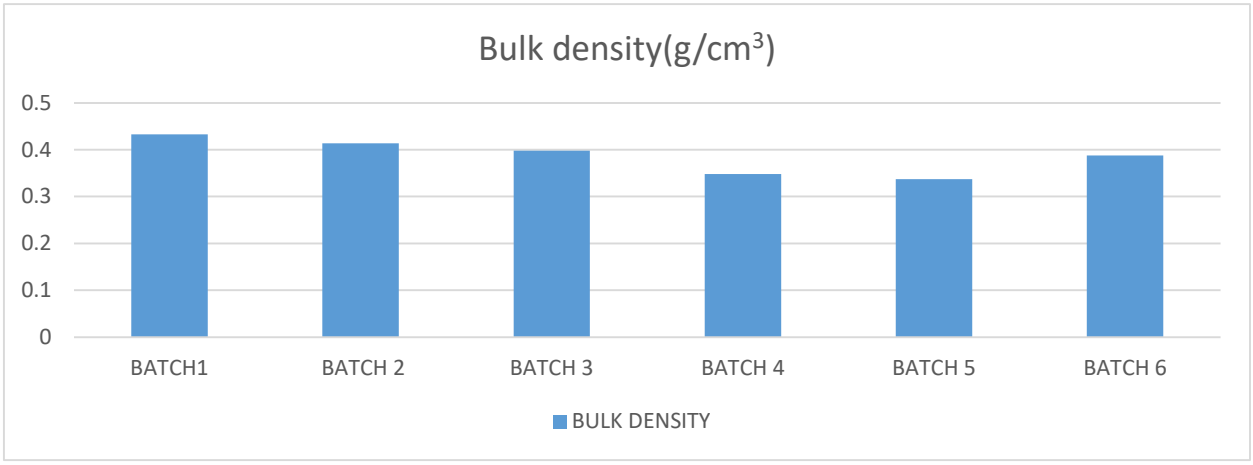

Figure 1: Bulk Density

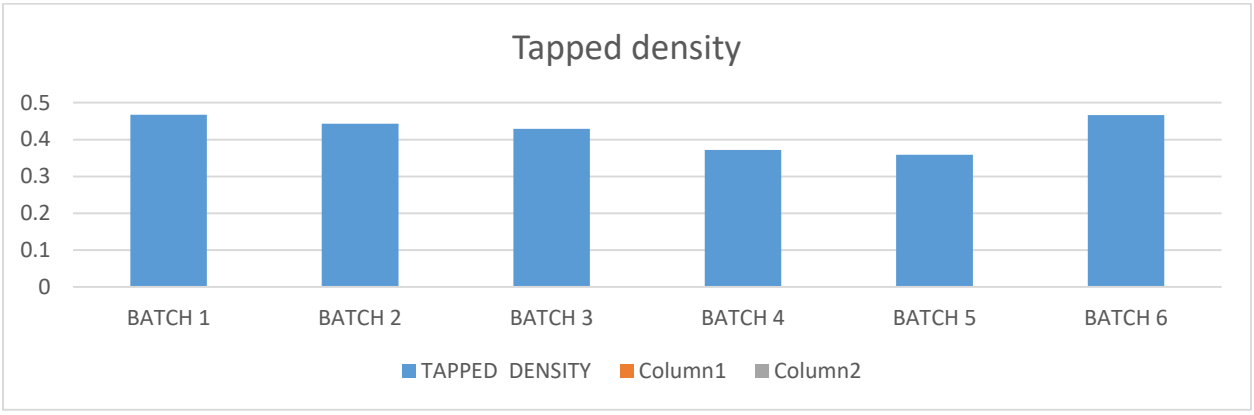

Figure 2: Tapped Density

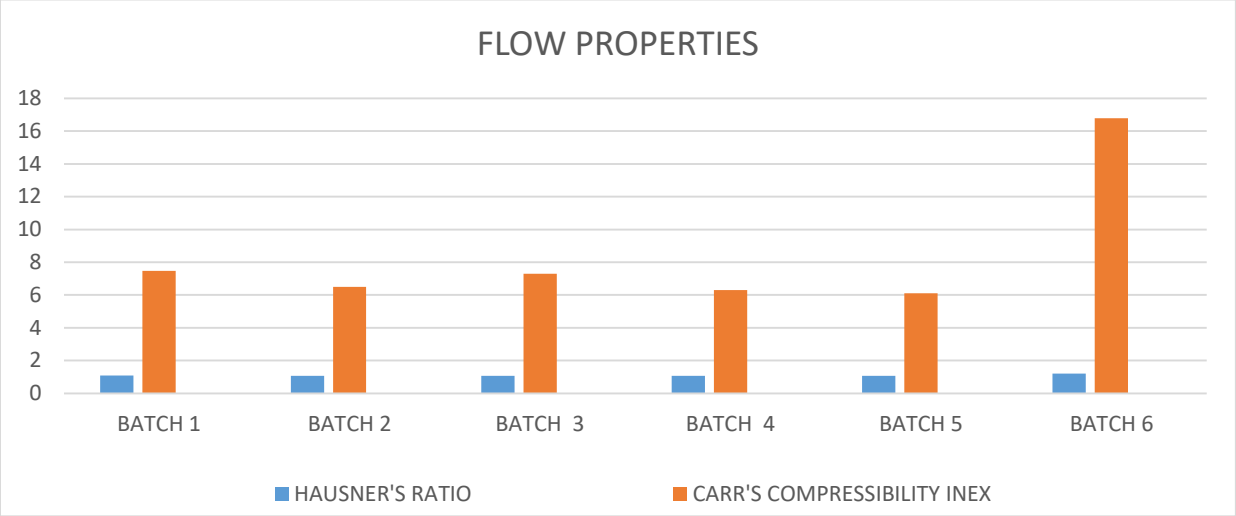

Figure 3: Flow properties

Table 2: Physical Properties of Ibuprofen 400mg Tablets Prepared

Tablet Property	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6
Average weight (mg) (n=20)	402.555 ±4.2069	403.460± 4.035813	403.933 ± 3.766651	402.469 ± 4.953433	405.525 ± 4.409339	404.059 ± 5.172858
Thickness (n=10)	2.978 ± 0.068	2.887 ± 0.218	3.015 ± 0.234	2.975 ± 0.068	3.027 ± 0.0748	3.249 ± 0.1930
Friability (%) (n=6)	0.7	0.82	0.9	0.9	1.0	0.83
Hardness (KgF) (n=6)	7.478 ± 1.1110	6.84 ± 1.033	7.046 ± 0.911	7.672 ± 0.825	8.63 ± 1.353	6.734 ± 1.311
Disintegration (min) (n=6)	7.166667 ± 0.408	7.5 ± 1.048809	7.33 ± 0.5164	8.5 ± 1.3784	8.167 ± 1.16	7.2 ± 0.52
Drug content (%)	64.84501	82.70934	80.39452	89.13647	87.59058	83.5004

Values are mean ±S.D.

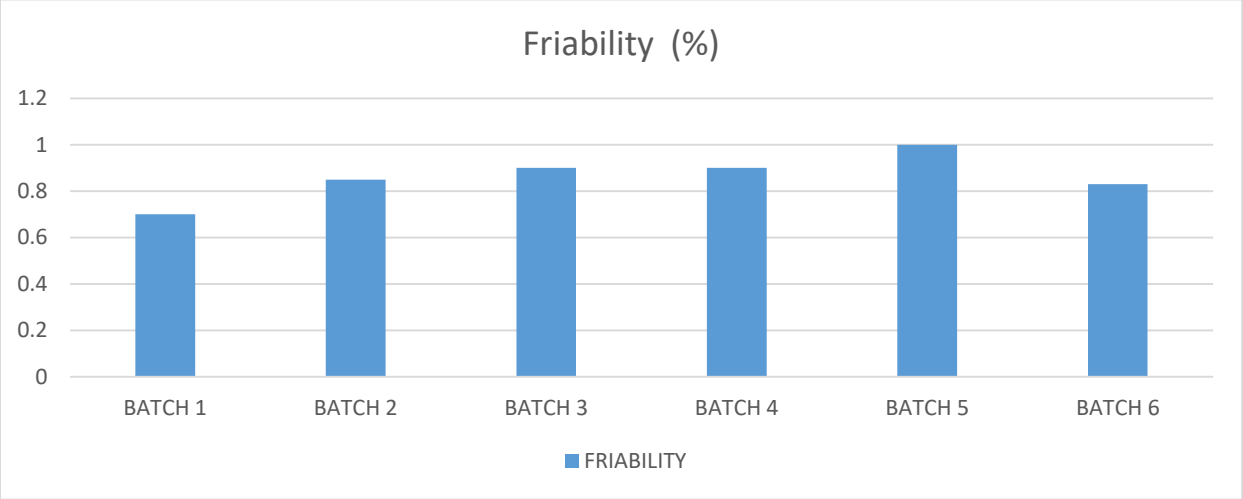

Figure 4: Friability

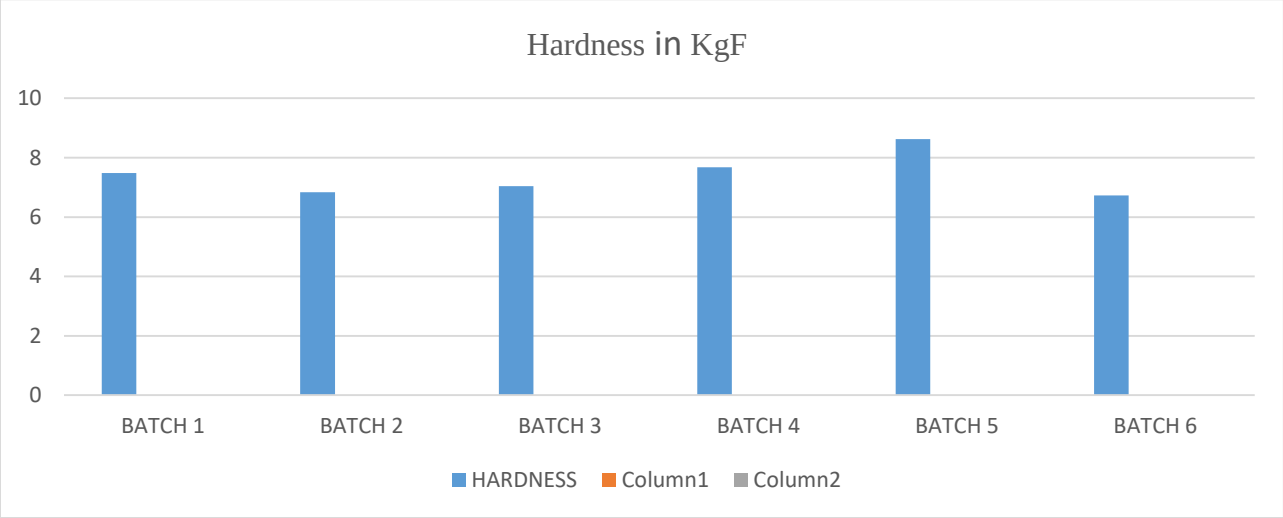

Figure 5: Hardness

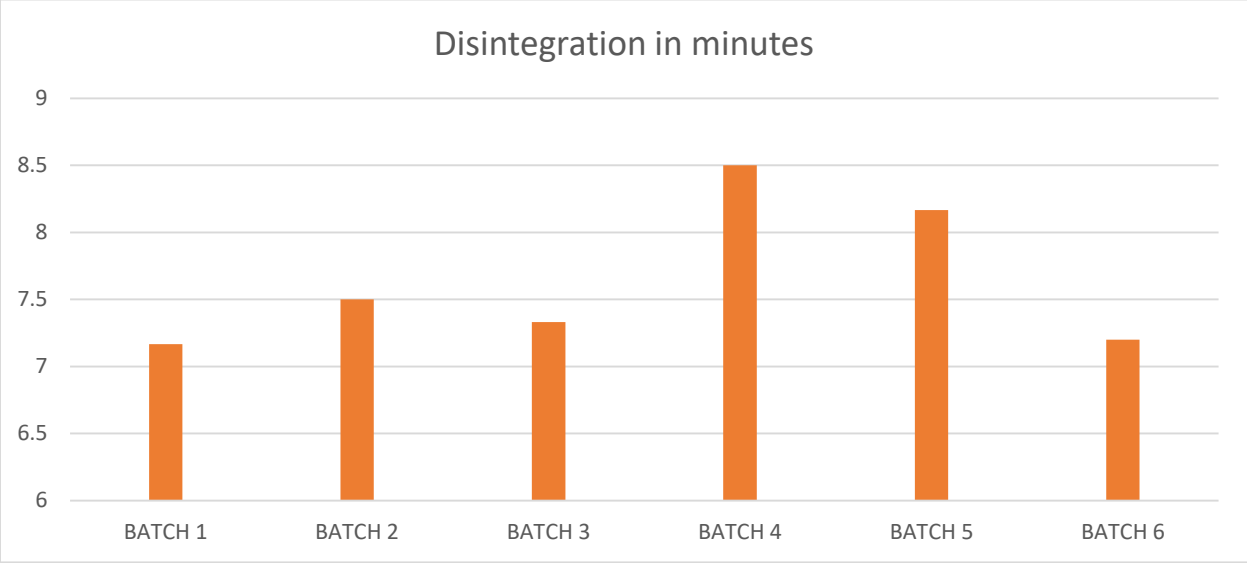

Figure 6: Disintegration time

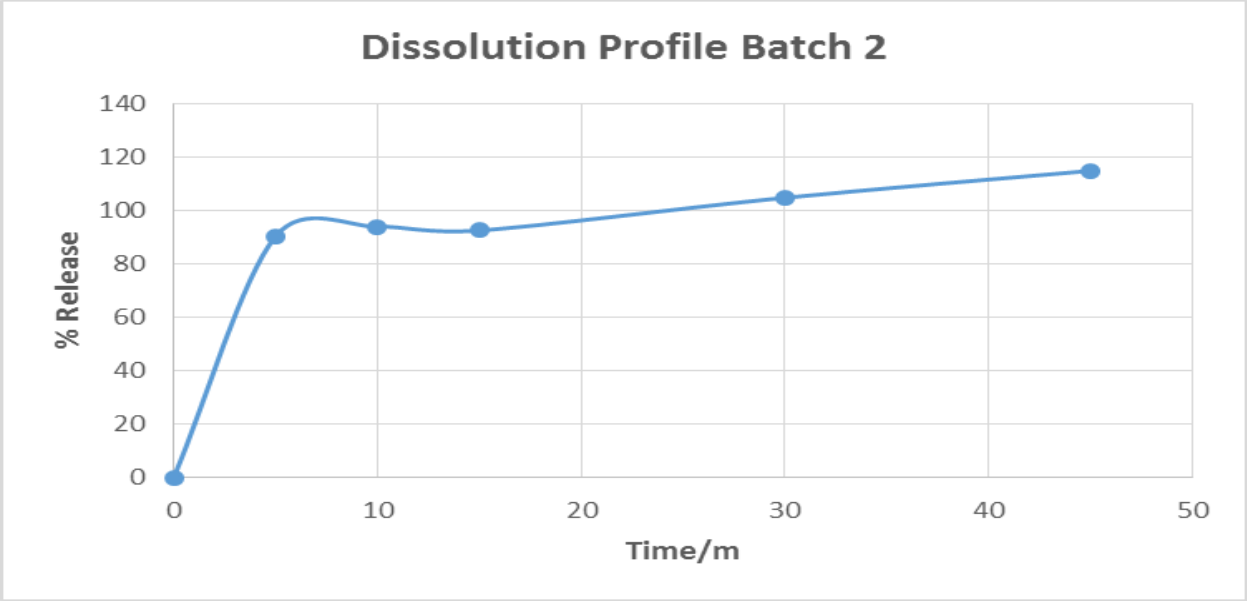

Figure 7: Dissolution profile

DISCUSSION

Musa acuminata's starch powder was white, flavorless, and odorless. The PH of *Musa acuminata* powder was 6.98 which is within the BP specification of 4.0 t0 7.0 for starch PH [17]. The pH of starch was slightly acidic but almost neutral which makes it a good candidate for an excipient as a binder. The moisture content was 10.84%. According to the British Pharmacopeia of 2011, moisture content should be less than 15% [17]. Therefore, the moisture content of the extracted *Musa acuminata* starch is with the specified specifications. The bulk density as shown in the above table which is above 0.5 and tapped density of 0.600. Hausner's ratio was below 1.25 for the starch powder. Hausner's ratio below 1.25 indicates good flow [17]. The results indicates that the starch has a good flow property and hence can make good standard tablets. Tapped density of the batches ranged from 0.4675 to 0.3587 for batches one to six. The tapped density of batch six containing corn starch as a binder did not vary a lot from the batches that containing *Musa acuminata* starch as a binder.

Hausner's ratio was below 1.25 for all the six batches. Hausner's ratio below 1.25 indicates good flow [17]. The results of Hausner's ratio ranged from 1.08 to 1.2, which indicates that the batches have a good flow property and hence can make good standard tablets. Carr's compressibility index in the range of 5 to16% indicates good flow [17]. All the batches had Carr's compressibility index ranging from 16.78 to 7.48, with batch six the one containing corn starch having the highest index. Compressibility of granules is determined in order to assess the ability of the granules to compact and decrease in volume when pressure is applied. This is needed to ensure that the suitability of the granules for tableting in order to produce strong tablets which can withstand pressure [1].Therefore for granules to have a good Carr's compressibility index enables the suitability of the granules for tableting in order to produce strong tablets that can withstand pressure. The flow properties of granules have been determined because of their effect on the uniformity of weight of tablets. From the result shown above on table, the weight uniformity test on the tablets showed no significant difference (SD > 0.05) in the weights of tablets from the six tablets batches and hence conformed to the British Pharmacopoeia (BP., 2011) specifies that no more than two of the individual weights may differ from the average weight by more than 5%, and no weight may deviate by more than 10%. The weight variance of tablets weighing 250 mg and more is allowed by BP standards, and all of the tablets in the five batches had an average weight range of 400 mg to 425 mg. Hardness generally measures the tablet crushing strength [18]. In addition to affecting table strength, a tablet's hardness affects how quickly it dissolves and how long it takes [1]. As the concentration of the binder increases, the crushing strength increases but batch two has a slightly lower hardness than batch one which could have been due to mixing. Batch six contains corn starch binder 10% has a lower crushing strength than batch five containing *Musa acuminata starch* of similar concentration hence the *Musa acuminata* starch could be having better binding ability than corn starch hence a greater crushing strength value.
A tablet with compendia has the mechanical attribute of friability [1]. The friability test is used to assess a tablet's resistance to abrasion during handling, packaging, and shipping procedures. The common consensus is that a weight reduction of no more than 1% is acceptable. The results from the table above show that the average friability of all the formulations varied from 0.7 to 1.0%, which was likewise within the BP limit of less than 1% for uncoated tablets. This demonstrates that the tablets' shock-resistance formulation. Disintegration time for uncoated tablets should be within 15 minutes implying that tablets which do not comply with this standard failed disintegration test [18-20]. A key stage in the release of medications from immediate release dosage forms is disintegration. The rate of dissolution is inversely correlated with the rate of disintegration. The pace of disintegration is influenced by the rate of water infiltration into the tablets, which is influenced by their porosity. Excipients also have an impact on disintegration [1] .The disintegration test was passed by batches I through 6. Since no batch's disintegration time exceeded 15 minutes, no batch failed this test. This indicates that the tablets have the ability to crumble, allowing the medicine to dissolve. Dissolution test; only one batch that is Batch two was able to pass the dissolution test. Other batches had erratic dissolution profile, batch three tried to have a fair dissolution profile. The rate of dissolution affects how quickly and how much a medicine is absorbed, as well as how well it works therapeutically. The type and concentration of the binder, hardness, surface area, diffusion distance, solubility of the medication, manufacturing technique (wet granulation, dry granulation, or direct compression), and diluents can all have an impact on the dissolution test [1].The drug's solubility became irregular as the binder concentration rose, with various concentrations present at different periods rather than increasing over time This is could due to the effect of the binder, may be the binder was not effectively mixed and also increased concentration of the binder could have hindered drug release from the dosage form. Within 45 min, only the tablets formulated with 4% w/v of *Musa acuminata* starch did release not less than 100% of the drug. Batch 6 that was formulated with corn starch 10% had 90% drug release at 60minutes compared to batch 3, 4and 5 formulated with Musa acuminata starch that had less than 90%drug release. Therefore, concentration of the binder could have had an effect of drug release.

CONCLUSION

The study's major goal was to formulate tablets of ibuprofen where Musa acuminata starch is used as a binder using wet granulation method. The *Musa acuminata* starch was used to form a mucilage which was used as a binder in the formulation. *Musa acuminata* starch showed good binding properties, this is seen in the hardness test. The formulated tablets had a good crushing strength. The disintegration of the tablets was fair. But the batches were not able to pass the drug assay test, the tablets contained 80% of the active ingredient.

Musa acuminata starch has good physical properties and is a good binder and could be a competitor of corn starch as a binder however compatibility tests are required to prove its compatibility with active ingredient ibuprofen and higher concentration of the starch binder yielded poor dissolution profile. Lastly Ibuprofen used for this study was not coated.

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