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Evaluation of *Musa acuminata* Starch as a Diluent in Paracetamol Tablet Formulations

Tansah Mbunwe
School of Pharmacy Kampala International University, Uganda

ABSTRACT

Tablet formulation, a widely used dosage form, relies on excipients like diluents to ensure product quality. This study investigates the potential of *Musa acuminata* (matoke banana) starch as a diluent in paracetamol tablets. Starch was extracted from matoke bananas and formulated into three batches using wet granulation, with concentrations of 5%, 10%, and 15% w/w. Comparative analysis was conducted with maize starch. Physiochemical properties of starch and granules, as well as tablet characteristics, were evaluated. Results indicated comparable properties between matoke and maize starches. Tablets formulated with matoke starch exhibited optimal disintegration time, hardness, friability, and weight uniformity, suggesting its potential as a cost-effective and accessible alternative diluent.

Keywords: Matoke, *Musa acuminate*, Starch, Active pharmaceutical and ingredients

INTRODUCTION

Among all available dosage forms, tablet is the most popular dosage form existing today because of its convenience of self-administration, compactness and easy manufacturing [1]. Tablet remains popular as a dosage form because of the advantages afforded both to the manufacturer (e.g. Simplicity and economy of preparation, stability and convenience in packing, shipping, and dispensing) and the patient (accuracy of dose, compactness, baldness of taste and ease of administration) [2] and diverse drug delivery systems [3, 4].

Active pharmaceutical ingredients (APIs) and a variety of additional components, together referred to as additives or excipients, are typically found in tablet formulations [5]. Inert materials called excipients are employed as diluents or delivery systems for drugs. Diluents, disintergrants, and other substances are included in the pharmaceutical business [2]. When the medication dose is insufficient to create the necessary bulk for the tablet, diluents—fillers made up of a diverse range of substances—are used to make up the missing volume [6]. Diluent may be added to tablet formulation to improve tablet qualities such cohesiveness, direct compression manufacturing, and flow characteristics [2].

Carbohydrate substances such as sugars, starches and celluloses may also function as binders during wet granulation process, whereas when used in direct compression system, they serve as the diluent [7]. Starch is one of the most widely used excipient as fillers (diluent), binders and disintegrants in the manufacture of solid dosage forms [8]. Starches from different plants have shown different functional properties such as gelling, swelling, and water binding capacity, which are related to their capacity to function effectively as binders and disintegrants in solid dosage forms [9], and are widely used and researched in the pharmaceutical and food industry as excipients and additives due to their low toxicity, biodegradable, availability and lowcost [10].

*Musa acuminata*is a member of the genus Musa (previously Eumusa). It is a member of the Zingiberales order and Family Musaceae [11]. Although this type of banana is indigenous to Southeast Asia, it is currently grown in more than 100 nations worldwide [12]. The second-largest banana grower in the world is Uganda. Nonetheless, it is among the lowest exporters, with the majority of its harvests going towards domestic use [13]. It grows best in warm, humid tropical and subtropical regions [14]. *Musa acuminata* is rich in carbohydrate with starch being the principal component of green banana accounting for about 70 to 80% dry weight basis [15].

Researchers have evaluated local starches for use as pharmaceutical excipients to address the importation of starch for tableting [16]. Some non-pharmaceutical starches have been investigated, such as cassava starch (*Manihotutilissima*), yam starch (*Diascorearotundata*), plantain (*Musa paradisiaca*) starch, African bitter yam (*Diascoreadumetarum*) and White yam (*Diascorearotundata*) starches and cocoyam starch (*Colocasiaesculenta*) have been found

to be suitable for tableting purposes [17, 18, 19, 20, 21, 22]. However, *Zea mays* starch showed superiority in some properties such as moisture absorption capacity and angle of repose [23].

This study aimed to evaluate the quality of paracetamol tablets manufactured using *Musa acuminate* (matoke banana) starch as a diluent.

METHODOLOGY

Plants collection

Unripe healthy Matoke banana was obtained from Ishaka market, Bushenyi, western, Uganda.

Raw materials

Raw materials were obtained from Rene pharmaceuticals, Bushenyi, western, Uganda.

Research Design

An experimental design was used to perform the study whereby different quality parameters were carried out to analyze the quality of the paracetamol tablets manufactured using starch derived from Matoke banana (*Musa acuminata*).

Sample size

30 pieces of matoke banana yielded 200g of starch.

Extraction of starch

The starch was extracted following the method implemented by Babalola et al. [24].

Characterization of *Musa acuminata* starch powder

pH, moisture content, bulk density, tapped densitytests were carried out to determine the integrity of the starch powder.

Powder flow properties

The angle of repose, Hausner's ratio and Carr's compressibility index was used in estimating the flow properties of the matoke starch powders [25].

Tablet Formula

- Paracetamol (API), 77%w/w l25mg
- Matoke banana starch (Diluent), 5, 10 and 15%w/w --7.5mg, 15mg and 22.5mg
- Aerosil 200(Extra granula Pharmaceutical Excipient) 2.5, 5 and 7.5%w/w -3.75mg, 7.5mg, 11.25mg
- Maize starch B.P (binder) 5%w/v QS
- Magnesium stearate (Lubricant) 0.5%w/w - -0.75mg
- Theoretical weight of tablet 137±5mg, 148.25±5mg and 159.5±5mg
- The paracetamol granules were then compressed into tablets using a tableting machine.

With a fill weight of 137±5mg, 148.25±5mg and 159.5±5mg, formulations for investigational batch of 100 tablets were made for each batch.

A reference batch of paracetamol tablets was also compressed from a formulation containing starch 1500 (15%w/w) (starch BP) as diluent.

Evaluation of tablets

Uniformity of weight, Disintegration time test, Tablet friability test and Hardness test were carried out as stipulated by BP [26].

Data analysis

The data was analyzed according to qualitative statistic using Microsoft Excel and the obtained results shall be presented in tables and graphs. The results were expressed as Mean ± SD.

Inclusion criteria

Unpolluted / unadulterated matoke banana from (*Musa acuminata*) species were used.

Exclusion criteria

Banana that was unhealthy or contaminated, Cross breeds or other banana species apart from matoke banana (*Musa acuminata*) were excluded.

Outcome procedures

The validity of the tools of data collection conformed to the WHO pre-requisite of cGMP for equipment

Limitations to the study

It was not possible to conduct dissolution test and stability studies on the manufactured tablets because of limited time.

RESULTS

Table 1. Comparative Characterization of Matoke Starch and maize starch powder

Parameters	Matoke starch	Maize starch BP	Specification (BP,2011)
pH	6.00	6.00	(4.0-7.0)
Moisture content (%)	14.34	11.89	(:SIS%)
Bulk density (g/cm3)	0.42	0.42	
Tapped density (g/cm3)	0.44	0.44	
Angle of repose	36.53	37.66	(25-40) good flow
Hausner's ratio	1.07	1.07	S1.25(good flow), > 1.25 indicates poorflow
Carr's compressibility index (%)	6.25	6.25	(5 to 16%) good flow, 18 to 21 % (fair flow), ► 38% very poor flow

Table 2: Comparative Characterization of Paracetamol Granules using Banana and Maize Starch a diluent

Parameters	Fl	F2	F3	MF4	BP Specification (BP,2010)
pH	6.00	6.00	6.00	6.00	(4.0 -7.0)
Moisture content (%)	0.89	3.00	1.99	2.32	(1.6-3.6%)
Bulk density (g/cm3)	0.50	0.45	0.47	0.42	
Tapped density (g/cm3)	0.53	0.45	0.50	0.45	
Angle of repose	36.53	34.59	34.02	34.94	(25-40) good flow
Hausner's ratio	1.06	1.04	1.02	1.05	1.25(good flow) >1.25 indicates poor flow
Carr's compressibility index (%)	5,7	6.25	6.00	6.67	(5to16%) good flow, 18 to 21 % (fair flow), ►38% very poor flow

F1, F2 and F3 are Paracetamol granules prepared with 5 %, 10% and 15% of *Musa acuminata* Starch as diluent respectively and MF4 with maize starch as diluent in 15% w/v.

Table 3: Properties of Paracetamol tablets

Parameters	F1	F2	F3	MF4	BP Specification (BP, 2010)
Weight uniformity Test	136.9±2.03	147.8±1.47	158.6±0.83	158.5±1.99	80-250mg (: G.5%)
Disintegration time (min)	0.26	0.47	0.57	0.20	(s15min)
Friability test (%	0.24	0.41	0.54	0.40	(S1%)
Crushing strength test (kgt)	15.32	10.76		8.43	(4-16kgf)

*Mean for 20 tablets; SD - standard deviation. F, F2 and F3 are paracetamol granules prepared with 5%, 10% and 15% *Musa acuminata* starch as diluent respectively. Tablets manufactured with maize starch as diluent is MF4

DISCUSSION

Diluents are substances frequently added to tablet formulations for secondary purposes, such as improving tablet qualities like cohesiveness, enabling direct compression manufacture, improving flow, and adjusting the tablet's weight in accordance with die capacity [27].To determine if a substance can serve as diluent, various parameters are examined such as pH, moisture content, bulk density, and tapped density for the intergrity while the angle of repose, Hausner's ratio and Carr's compressibility index are used to estimate the flow properties [28, 29].

The pH of the *Musa acuminata* powder was weakly acidic (6) similar to that of the commercial maize starch powder (6), falling within the limits of 4.0-7.0 as recommended by the British Pharmacopoeia [30].

The amount of moisture absorbed by drugs and excipients affects the flow, compression characteristics and hardness of tablets. Water interacts with pharmaceutical solids at virtually all stages of manufacture [31]. Therefore, water-powder interaction is a major factor in the formulation, processing and performance of excipients and solid dosage forms [32]. The moistures capacity of the matoke starch (14.34) were significantly higher than the values obtained for corn starch (11.89) both falling within the limits of less than 15% as recommended by the British Pharmacopoeia [30]. The moisture decreases tablet adhesion to the die wall and allows easy tablet ejection. It also increases the ease with which the individual particles can slip and flow during

compression [33]. However, it is important that the moisture content be kept as low as possible during storage to prevent microbial spoilage, hydrolysis and enzymatic decomposition [34].

The blending process with a powder with low flowability is terrible, and would not be possible to assure the content uniformity for each pill. The compression process, tableting, would give as a result a huge weight variation [35]. The flow characteristics of a powder are crucial in assessing its appropriateness as a direct compression excipient. The Hausner ratio and Carr's index are regarded as indirect indicators of powder flowability [36]. Hausner's ratios greater than 1.25 indicate poor flow while Carr's index below 16% indicates good flowability and values above 35% indicate cohesiveness [34]. In this study, the values of Hausner's ratio and Carr's in Figure 4.2, showed that matoke starch had a good flow and values obtained were within the specified limits for the production of good quality tablets. When the Carr's compressibility index and Hausner's ratio are adequate, the powder flows at minimum bulk density. A high bulk density, that is a low porosity, will result in a low deformation potential, a lack of space for deformation during compression will cause less intimate contact between the particles within the tablets, resulting in weaker tablets [32].

The results of angle of repose, showed matoke starch having an angle of repose of 36.56°compared to the commercial maize starch powder which had 37.66° both within the required range for pharmaceutical powder which is 25 to 40. From the results, the granules had angle of repose that ranged from34.02°to36.53°. These results show that the granules had fairly low inter-particulate friction and hence a fairly good flow [37].

Tablet weight uniformity test is a very important quality control test because variation in tablets weight will lead to variation in drug content and the overall bioavailability of the drug will be affected [38]. The result showed that the tablets passed the weight uniformity test.

The tablets disintegration time results show that the tablets all complied with BP (2009) specifications for uncoated tablets. i.e. disintegration within 15 min. Tablets disintegration time ranged from 0.2 to 0.57 minutes for all tablets. From the result, increase in the concentration of the starch disintegrant significantly increased the disintegration time of the Paracetamol tablets. Tablets containing banana starch generally showed higher disintegration time than the one containing maize starch disintegrant. However statistical analysis showed that there were no significant differences in the disintegration time for tablet containing the various starch disintergrants.

The results of tablets friability test showed that the tablets passed friability test according to BP specifications therefore the tablets could be able to withstand shock and vibrations during the packaging, transportation and use [39].

The results of tablet hardness of paracetamol tablets formulated showed a good hardness profile and conformed to BP specifications for tablets hardness. The tablets hardness ranged from 7.49 to 15.32 kgf. This reportsuggested that the mechanical properties of the tablets would not be compromised during packaging, transportation and use [40].

The results of the drug release profile of Paracetamol tablets formulated with different concentrations of Musa acuminate starch as disintegrant are shown in Figure 4.6 From the results, all the batches showed a good drug release profile.

CONCLUSION

The results obtained indicate that the physiochemical and material tablet properties of the banana and corn starches were comparable. When used as diluent in paracetamol tablet formulations, banana starch had longer disintegration time than those containing corn starch although there were no significant differences in the disintegration time. The results showed that banana starch compared well with corn starch B. P as diluent, therefore starch obtained from *Musa acuminata* could be used to formulate tablets given its optimum disintegration time, hardness, friability and weight uniformity as it is relatively cheap and easily accessible.

Recommendations

Further studies should be conducted by Pharmaceutical industries and PIPID to evaluate and carry out further tests to ascertain the suitability of starch derived from *Musa acuminata* as a pharmaceutical excipient. If these studies are proved to be positive, drugs manufactured using this excipient can finally be release to the market for use.

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