

ORIGINAL ARTICLE

Physicochemical Characterization of Kahata Angala (*Dioscorea alata*) Starch and its Potential as a Binder in Losartan Potassium Tablet Formulation

Samarasinghe Arachchillage Nuwani Chathurika Samarasinghe, Sriaandhal Sabalingam*¹,
Banneka Mudiyansele Walawwe Ishara Methsalani Warapitiya, Samamalee Upekshi
Kankanamge¹, Ranjith Nandalal Pathirana¹

¹Department of Pharmacy, Faculty of Allied Health Sciences, General Sir John Kotelawala
Defence University, Werahera, Sri Lanka.

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ABSTRACT

This study focuses on developing a pharmaceutical-grade starch as a natural binder from yam species. The starch was isolated from the yam rhizome of Kahata Angala (*Dioscorea alata*) which is widely found in Sri Lanka. The physicochemical parameters and morphology of the starch were analyzed and compared with maize starch BP. The isolated yam starch was used as a binder to formulate losartan potassium tablets using the wet granulation method with a 10% w/v starch binding solution. Losartan potassium tablets were further assessed for some critical parameters, including weight variation, friability, hardness, thickness, dissolution, and disintegration. The findings indicated that compared to maize starch BP, Kahata Angala starch has greater flow characteristics, suggesting lesser values for compressibility index (22.20 ± 1.39), angle of repose ($38.02 \pm 0.60^\circ$) and Hausner ratio (1.29 ± 0.02) than maize starch BP. Tablets formulated with Kahata Angala starch exhibited a good friability percentage, which was less than 1%. Based on the outcomes, it can be concluded that certain parameters of starch obtained from Kahata Angala is more suitable than maize starch BP. However, further optimization is needed for the disintegration and dissolution profiles.

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*Corresponding author

E-mail: sssabalingam@kdu.ac.lk (Sriaandhal Sabalingam)

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1. INTRODUCTION

Starch is the most abundant and naturally occurring carbohydrate reserve in plants. Native starch occurs in the form of granules that exhibit a semi-crystalline structure. The size, shape, and structure of the granules are characteristic of their botanical sources and are different for each plant. The functional and physicochemical properties of starch and its stability in storage for a prolonged period have made it highly attractive for use as a pharmaceutical excipient in various medicinal formulations (Builders & Arhewoh, 2016). Starches used commercially are primarily derived from tubers (such as *Dioscorea* species and *Solanum tuberosum*), roots (*Manihot esculenta*), and grains (*Oryza sativa* and *Zea mays*), all of which typically contain 40–80% starch by dry weight. These natural sources play a major role in the supply of starch for both the food and pharmaceutical sectors. Due to its affordability and multifunctionality, starch remains one of the extensively used excipients in the pharmaceutical industry (Odeku & Picker, 2007). Starch is a versatile excipient that is commonly used as a binding agent during the wet granulation process of bulking and screening, which is a crucial step in producing solid dosage forms.

The yams are starchy tubers containing about 70-80% dry matter, a dominant factor determining the textural, physicochemical, and rheological characteristics of various yam species (Odeku & Picker, 2007). These tubers are mainly found in tropical and subtropical regions of Africa, as well as parts of Asia, Central and South America, the Caribbean, and the South Pacific Islands. Yams belong to the genus *Dioscorea* which includes more than 600 identified species (Bhattacharjee et al., 2011). Starch is the primary constituent of these yam tubers making up about 60-85% on a dry weight basis (Jayakody et al., 2009).

However, only a few species such as *Dioscorea alata* (water yam), *Dioscorea dumetorum* (bitter yam), *Dioscorea bulbifera* (potato yam), *Dioscorea trifida* (cush-cush yam), *Dioscorea esculenta* (lesser yam), and *Dioscorea cayenensis-rotundata* complex (yellow and white yam) produce edible tubers (Brunnschweiler et al., 2005). Among the ten economically important species within the genus *Dioscorea*, Kahata Angala (*Dioscorea alata*) is notably prevalent in Sri Lanka and is cultivated in all ecological zones of Sri Lanka (Wanasundera et al., 1994). In Sri Lanka, *Dioscorea* is locally referred by its vernacular name, 'Vel-ala'. It is a popular staple in the diets among individuals residing in suburban and rural areas of the island. *Dioscorea alata* is among the most widely cultivated yam species in Sri Lanka. As *Dioscorea* species are seasonal plants, they are commonly cultivated between late March and April, with harvesting taking place from December to February (Senanayake et al., 2013). Kahata Angala, a variant of *Dioscorea alata*, is known for its widespread availability and distribution across Sri Lanka (Jiang et al., 2012).

Losartan potassium is an Angiotensin II receptor antagonist that lowers the blood pressure in hypertensive patients. Losartan potassium is an active ingredient that has very poor flow properties. Therefore, it is not appropriate for a direct compression method and the wet granulation process is most frequently employed to manufacture Losartan potassium tablets (Tadawee g et al., 2018). The studies have proven that *D. alata* and *D. rotundata* are appropriate for tablets that need to dissolve and disintegrate more quickly. The increased swelling capacity could be the cause of the quicker disintegration and breakdown time (Okunlola & Odeku, 2011). The primary target of our study is to incorporate Kahata Angala (*Dioscorea alata*) as a binder in the preparation of losartan potassium 50 mg tablets in the wet granulation process.

2. MATERIALS AND METHODS

2.1 Materials

Pharmaceutical graded losartan potassium BP, lactose BP, talcum powder BP, magnesium stearate BP and maize starch BP were gifted by the State Pharmaceutical Manufacturing Corporation (SPMC), Ratmalana, Sri Lanka. Yam tubers of Kahata Angala (*Dioscorea alata*) and the fresh plant material were collected during the month of March from a local farm from Paththampitiya, Sri Lanka (approximately 7.2928° N, 80.6359° E). Yam tubers were authenticated by the Bandaranaike Memorial Ayurvedic Research Institute, Nawinna, Maharagama. The research was conducted at the Chemistry and Physics laboratory, General Sir John Kotelawala Defence University, Sri Lanka. In addition, the physical tests of tablets were conducted using the facilities available at State Pharmaceutical Manufacturing Corporation, Kandawala road, Ratmalana, Sri Lanka. Particle size analysis using Scanning Electron Microscope (SEM) and Fourier Transform Infrared Spectroscopy (FTIR) was carried out at the University of Moratuwa. The proximate composition of the starches was conducted at the Bandaranaike Memorial Ayurvedic Research Institute, Nawinna.

2.2 Methods

2.2.1 Isolation of starch

Fresh yam tubers were initially rinsed with distilled water, peeled, re-washed, and then cut into small pieces. The pieces were then treated with a 5.0 g/L sodium metabisulphite solution in distilled water to prevent darkening and subsequently cut into small chunks of 2.0 cm-3.0 cm. The pieces were blended with distilled water (1:2 m/v) into a smooth paste in a laboratory blender. The obtained slurry was passed through a muslin cloth for filtration, and the filtrate was left undisturbed to allow sedimentation. After 12 hours, the supernatant was decanted, and the remaining starch suspension was re-dispersed in distilled water. The resulting starch cake was collected after three days and dried in a hot air oven at 60 °C for 48 hours (Okunlola &

Odeku, 2011). The dried material was then ground into a fine powder using a mortar and pestle (Asare et al., 2017).

2.2.2 Characterization of yam starch

2.2.2.1 Starch extraction yield

The starch yield was determined as a percentage by dividing the weight of the extracted starch by the initial weight of the peeled yam rhizomes used in the extraction process.

2.2.2.2 The physical, chemical and physicochemical properties

The identification test was done according to the methods given in British Pharmacopoeia 2023 for maize starch BP. A moisture analyser was used to determine the dried starch sample's residual moisture content.

Crude protein, ash and total dietary fiber and pH were determined according to the methods described by the A.O.A.C International standards.

(i) *Determination of morphology, size and shape of starch granules*

The particle size, shape, and surface morphology of the Kahata Angala (*Dioscorea alata*) and Maize starch granules were examined under scanning electron microscope (SEM). Prior to imaging, the dry starch samples were coated with a conductive layer of gold and polonium using a vacuum evaporation coater. The analysis had been carried out by a Carl Zeiss EVO 18 SEM (Germany) operated at an accelerating voltage of 10 kV, with magnifications of 1KX. Granule dimensions were determined using "Image. j" software for SEM image analysis.

(ii) *Fourier transform infrared (FTIR)*

The infrared (IR) spectrum was recorded using an ALPHA BRUKER 1005151 IR spectrometer. Approximately 1.0 mg of the sample was blended with 100.0 mg of potassium bromide (KBr) and compressed between two pastilles under high pressure to form a clear, undistorted tablet. The analysis was conducted within the spectral range of 400 to 4000 cm^{-1} (Oliveira et al., 2021).

(iii) *Determination of particle size distribution using sieve analysis*

Particle size was analysed by sieve set following mechanical agitation (Dry sieving method) described under British pharmacopoeia 2023 using test sieves of 500 μm , 250 μm , 180 μm , 90 μm , 63 μm .

(iv) *Determination of true density of starch*

The true density of the starch samples was measured using the fluid displacement technique (Bayer et al., 2013).

(v) *Determination of bulk density and tapped density*

An adapted technique, resembling the bulk densitometer method, was employed for the initial determination of bulk density (Obitte and Chukwu, 2007).

(vi) *Determination of Angle of Repose*

The angle of repose was measured using the fixed funnel method as outlined in the British Pharmacopoeia 2023, employing the drained angle of repose technique.

(vii) *Determination of hydration capacity*

This was measured following the method described by Kornblum and Stoopak in 1973 (Emenike et al., 2017).

(viii) *Determination of solubility test*

A 1.0 g sample of starch was dissolved in 10.0 mL of hot distilled water (100°C), cold distilled water (2- 8°C), and 95% ethanol, respectively. The mixtures were shaken and allowed to stand for 24 hours. Afterward, 5.0 mL of the supernatant from each solution was obtained and heated to dryness on a hot plate at 110°C. The weight of the dried residue was calculated as a percentage relative to the volume of the solution, and the solubility of the starch in each solvent was determined (Emenike et al., 2017).

2.2.3 Preparation of losartan potassium tablets BP 50 mg

Tablets were formulated by the wet granulation method after modifying and optimising the preliminary formula described by Rafique et al., 2014. Commercially used maize starch BP was used as the reference material to prepare the positive control tablets to compare the properties of test samples.

A total batch weighing 150 g was prepared, with each tablet formulation containing losartan potassium (50 mg), lactose (200 mesh size, 458.52 mg), and dry Kahata Angala starch (45.6 mg). In the initial step losartan potassium BP and lactose BP were mixed for 5 minutes in a mixing bowl. Kahata Angala starch slurry with a 10% w/v concentration was prepared and heated in a water bath while being stirred until a paste was formed (Okunlola & Odeku, 2011). The prepared starch paste portions were added to produce granules containing two types of starches as binder. Kneading continued for 5 minutes, after which the wet masses were manually sieved through a mesh 12 sieve (1.4 mm) to produce wet granules. The wet granules were then dried in a hot air oven (Memmert REX C700) at 55°C for 5 hours. After drying, the granules were mixed for 15 minutes with 11.4 mg of purified talc powder BP and 4.56 mg of magnesium stearate BP, and stored in an airtight container.

Then the prepared losartan potassium granules were compressed into tablets using a TDP-6N single punch machine in the Chemistry and Physics laboratory. A control batch of losartan potassium tablets was also prepared by compressing a

formulation that included 10% w/w maize starch as the binding agent while all other ingredients were maintained in the same quantities as in the formulation that used Kahata Angala starch as the binder.

2.2.4 Quality tests for losartan potassium tablets BP 50 mg

The thickness of randomly selected ten Losartan potassium tablets was measured using the electrolab hardness tester (EHT-5P). The tablet hardness was measured using an electrolab hardness tester (EHT-5P). Friability of tablets was determined with an ELECTROLAB EF2 friabilator. Disintegration test was carried out in distilled water with the Disintegrating apparatus. A single tablet was placed into each of the six tubes of the basket-rack unit. The diintegration apparatus was operated with distilled water as the immersion fluid, kept at a temperature of $37 \pm 2^\circ\text{C}$.

Dissolution Test

The dissolution test was done as per the methods given in British Pharmacopoeia 2023. Apparatus 2, with the paddle rotating at 75 revolutions per minute, was employed for the test. A total of 900.00 mL of water at 37°C (to resemble the body temperature) was used as the dissolution medium. After 30 minutes, a 10.0 mL sample of the medium was collected and diluted with 10.0 mL of distilled water in a 20.0 mL volumetric flask. The absorbance of the filtered sample was then measured at a wavelength of 250 nm, using distilled water in the reference cell.

Preparation of Losartan Potassium BPCRS (British Pharmacopoeial Chemical Reference Substance) solution, 37.20 g of Losartan Potassium BPCRS was measured and was dissolved in 100.0 mL distilled water. Then another 15.0 mL of solution diluted up to 200.0 mL with distilled water. The absorbance of a losartan potassium BPCRS solution was recorded, using water as the reference in the reference cell. Dissolution rate was calculated using following equations.

$$\text{Absorbance (A)} = \epsilon \times b \times c$$

ϵ =molar absorptive of Losartan Potassium at 250 nm; b =Path length of the cuvette; c = Concentration of Losartan Potassium in the sample (mg/cm^{-3})

Since both b and c are equal in both samples (Solution of Losartan Potassium BPCRS and tested sample),

$$A \propto c$$

If, release rate of Losartan Potassium 50 mg is $x\%$,

$$A1 = \frac{50}{900} \times \frac{10}{20} \times \frac{x}{100}$$

The potency of Losartan Potassium is 99.39 %,

$$A2 = \frac{37.20}{100} \times \frac{15}{200} \times \frac{99.39}{100}$$

Dividing both equations,

$$\frac{A1}{A2} = \frac{\frac{50}{900} \times \frac{10}{20} \times \frac{x}{100}}{\frac{37.20}{100} \times \frac{15}{200} \times \frac{99.39}{100}}$$

3. RESULTS AND DISCUSSION

3.1 Characterization of Kahata Angala (*Dioscorea alata*) starch

The tubers of Kahata Angala were single, larger yams with brown, rough skin featuring prominent markings and ridges. The cutting surface exhibited a darker outer layer compared to the inner layers. Both Kahata Angala and maize starches provided dark blue colour, indicating the presence of starch which disappears on heating and reappears on cooling.

The percentage yield of Kahata Angala starch was within the range of 13%-15% w/w which complied with the results of the other studies. Hingurala and Raja-ala, two more *Dioscorea alata* varieties, exhibited 14.25% and 18.80% of the yield of starch respectively (Jayakody *et al.*,2007). The yield of starch depends on the method of extraction. The present study followed the aqueous extraction method using fresh yam tubers of Kahata Angala as described by Okunlola and Odeku,2011 which is a more cost-effective and environmentally friendly method.

Organoleptic properties such as colour, taste, odour, texture, and appearance can impact the palatability of medications and potentially affect patient compliance. The starch extracted from Kahata Angala is a light pink powder with no taste. It has a similar appearance to maize starch BP with the only noticeable difference being its colour.

3.2 Physico-chemical properties

3.2.1 Microscopic characteristics of starch granules

As per the light microscopic analysis (**Table 1**), Kahata Angala starch exhibited the oval and truncated spade shape granules without having hila similar to other variations of *Dioscorea alata* species (**Figure 1**) such as Raja ala and Hingurala. However, Kahata Angala starch granules were different from maize starch BP which has rounded or spheroid granules of irregular sizes with central hila consisting of a distinct cavity of two to five rayed cleft and no striation

Table 1: Microscopic characteristics of the starch granules

Sample	Shape	Hila	Aggregation	Fissure	Position of hila
Kahata Angala	Oval and truncated spade	Absent	Simple	Absent	
Maize BP	Polygonal	Present	Simple	Centre	



Fig. 1. Light micrographs of Kahata Angala (*D.alata*) (A) and maize starch BP (B) ($\times 400$)

3.2.2 Morphology and size of starch granules

The scanning electron microscope (SEM) images obtained at 1KX magnification and 10kV provided a detailed view of the surface morphology of the particles. SEM analysis revealed that Kahata Angala particles have truncated spade and truncated oval shapes with a mean diameter of $23.88 \pm 3.95 \mu\text{m}$ (Figure 2). Larger granules were ranging from $16.21 \mu\text{m}$ to $34.54 \mu\text{m}$ and the smaller granules were ranging from $8.82 \mu\text{m}$ to $13.191 \mu\text{m}$. Based on these results, it appears that the granule size of the Kahata Angala starch being analysed falls within the range reported for tapioca starch (5 to $35 \mu\text{m}$) in the British Pharmacopoeia 2023. Maize starch particles appeared to have polyhedral granules of irregular sizes with a mean diameter of

$12.97 \pm 2.68 \mu\text{m}$ (Figure 3). It is within the range described in British pharmacopeia, 2023 ($2 \mu\text{m}$ - $23 \mu\text{m}$).

It is implied that the starch granules of Kahata Angala are larger than the maize starch granules and may exhibit different flow and compression properties than maize starch. Since both granules are within the range of 10 - $25 \mu\text{m}$, both can be categorized under medium size granules (Oliveira et al., 2021). The difference in particle diameter between the two starches is statistically significant ($p < 0.05$) which could indicate the differences in the physical properties of the two starches such as composition, gelatinization, pasting properties swelling and solubility.

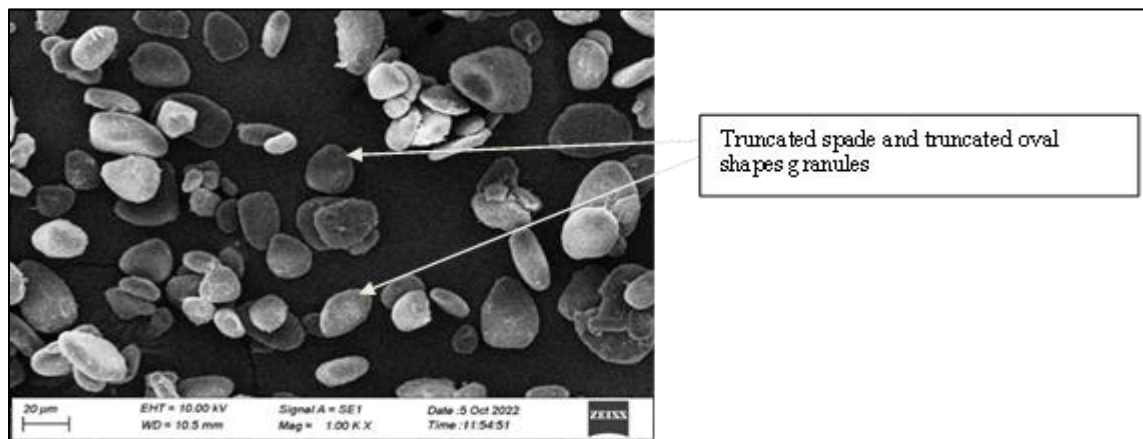


Fig. 2. Micrographs of Kahata Angala (*Dioscorea alata*) starch granules observed under the scanning electron microscope (1.00 KX)

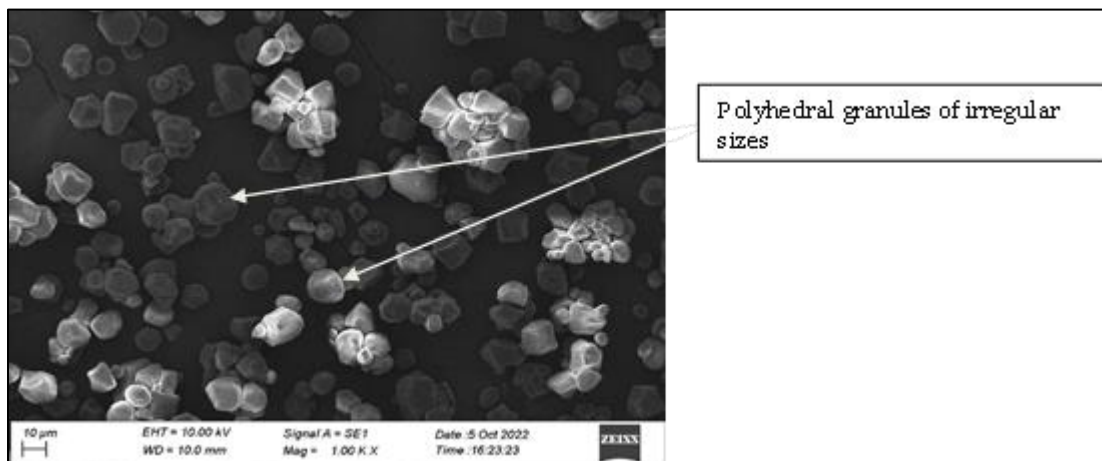


Fig. 3. Micrographs of maize starch BP granules observed under the scanning electron microscope (1.00 KX)

3.2.3 Fourier Transformation Infrared (FTIR) Analysis

Figure 4 shows the infrared spectrum of Kahata Angala starch in the region 4000–400 cm^{-1} , indicating the presence of various functional groups with characteristic bands and peaks. In the FTIR spectrum of Kahata Angala, the broad peak around 3500 cm^{-1} is attributed to the O-H stretching vibrations of the hydroxyl group in starch, while the peak near 3000 cm^{-1} corresponds to the asymmetric stretching of the C-H group. The peaks in the range of 1000 cm^{-1} and 1200 cm^{-1} are attributed to the (C-O) bond of the amylopectin and amylose molecule.

In the FTIR spectrum of maize starch BP, the broad band in the 3000–3500 cm^{-1} range is attributed to the O-H stretching vibration. The band around 3000 cm^{-1} is associated with the C-H bond linked to the hydrogen atoms of the ring methane group. Additionally, the band near 1000 cm^{-1} may indicate the presence of C-O stretching coupled with C-O bending in the C-OH group of the maize starch BP sample.

FTIR analysis provides information regarding the presence of functional groups of a chemical structure. Moreover, the degree of purity and the presence of impurities also can be evaluated. Both Kahata Angala and maize starch BP provided similar FTIR spectra with peaks at 3000–3500 cm^{-1} range, around 3000 cm^{-1} and near the 1000 cm^{-1} (Figure 4, and Figure 5). The broad band within the 3000–3500 cm^{-1} range represents the O-H group in starch. The peak around 3000 cm^{-1} confirms the asymmetric C-H stretching vibrations. The peaks in the range of 1000 cm^{-1} and 1200 cm^{-1} are attributed to the stretching vibrations of (C-O) bonds in C-OH and C-O-C groups in starch. When comparing the FTIR spectra of Kahata Angala and maize starches with Losartan potassium separately, no formation of new peaks was observed. Therefore, no chemical bond formation or chemical interaction occurred between Losartan Potassium (Figure 6) and Kahata Angala and maize starch BP (Figure 7 and Figure 8). This indicates physical compatibility between the excipients and the active pharmaceutical ingredient.

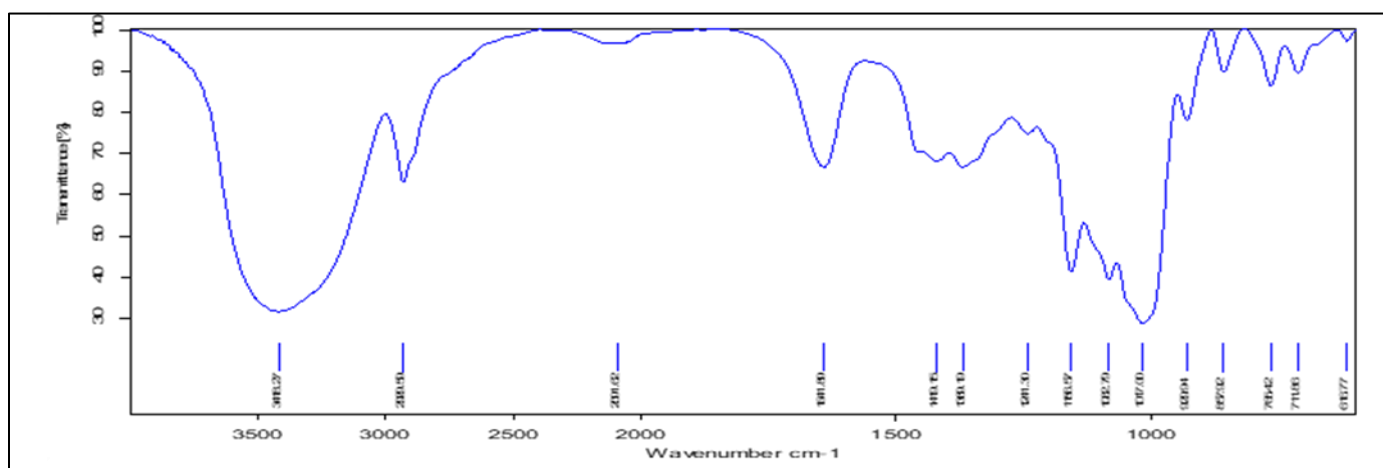


Fig. 4. FTIR spectrum of Kahata Angala starch

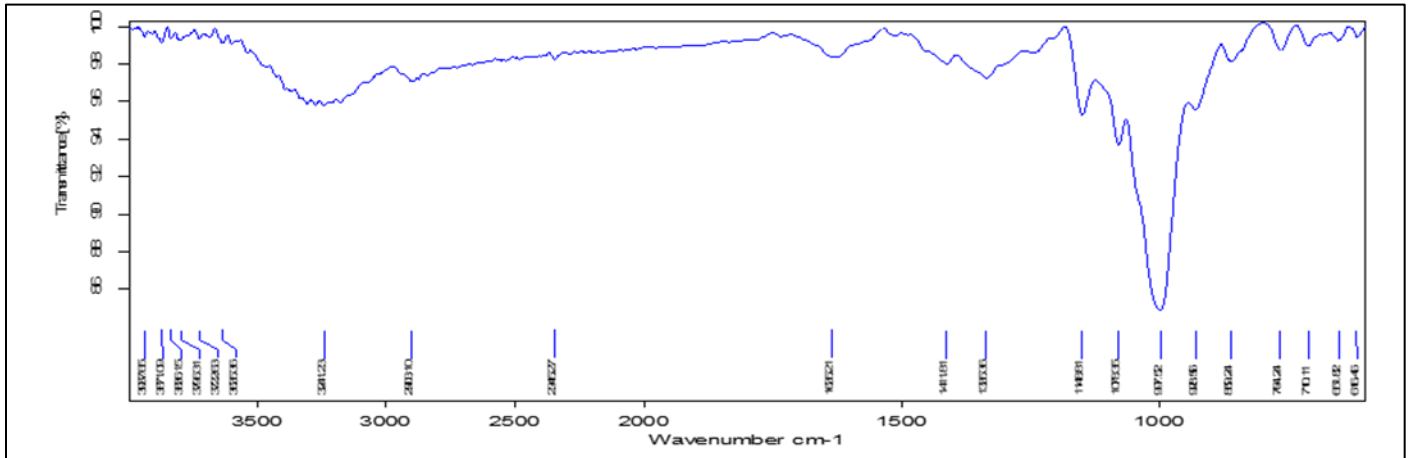


Fig. 5. FTIR spectrum of maize starch BP raw material

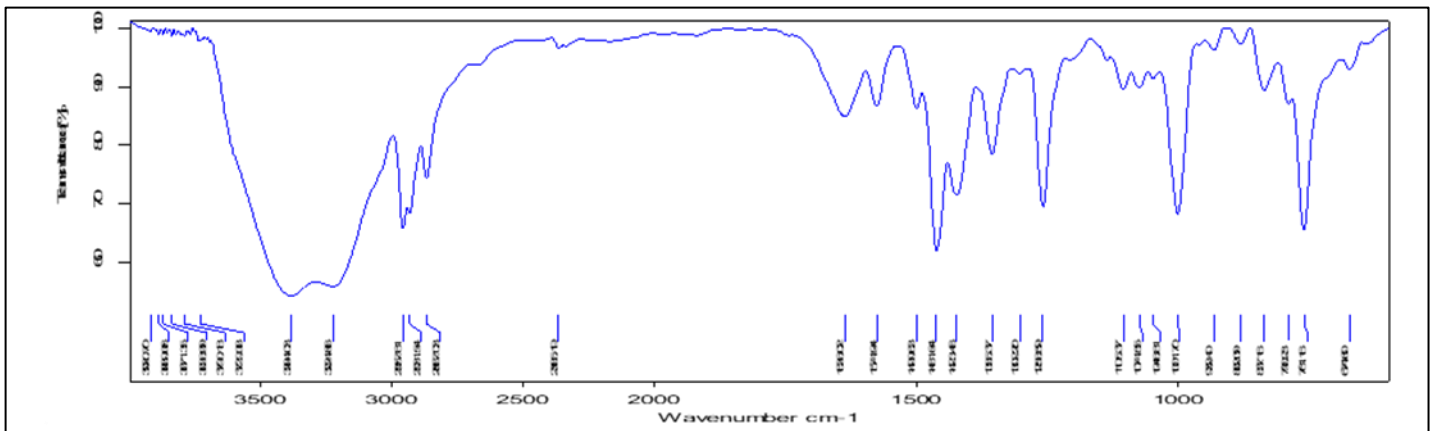


Fig. 6. FTIR spectrum of Losartan potassium BP active pharmaceutical ingredient

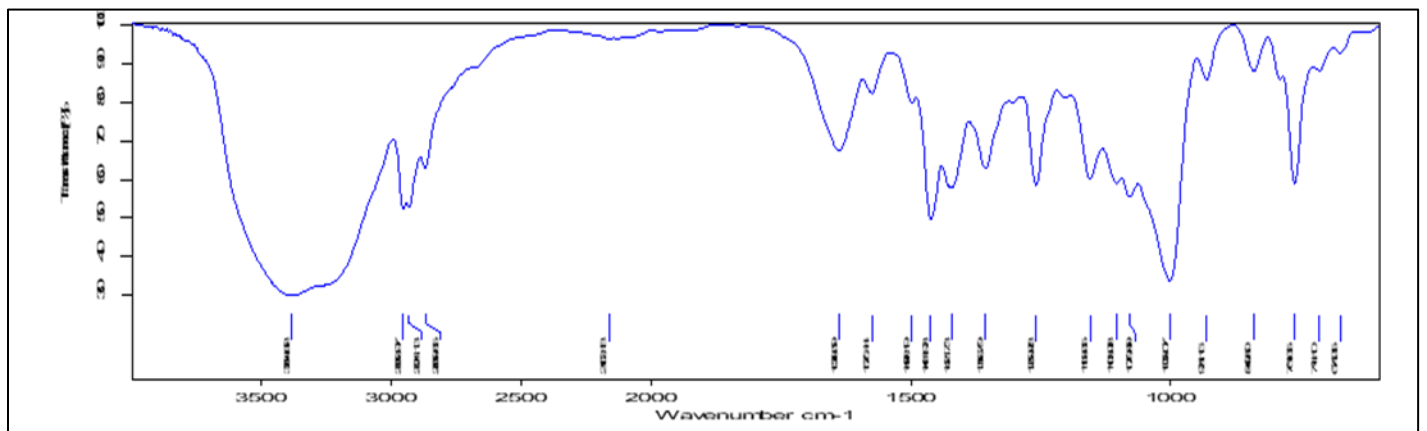


Fig. 7. FTIR spectrum of Losartan potassium BP tablets formulated with maize starch BP binder (1:1)

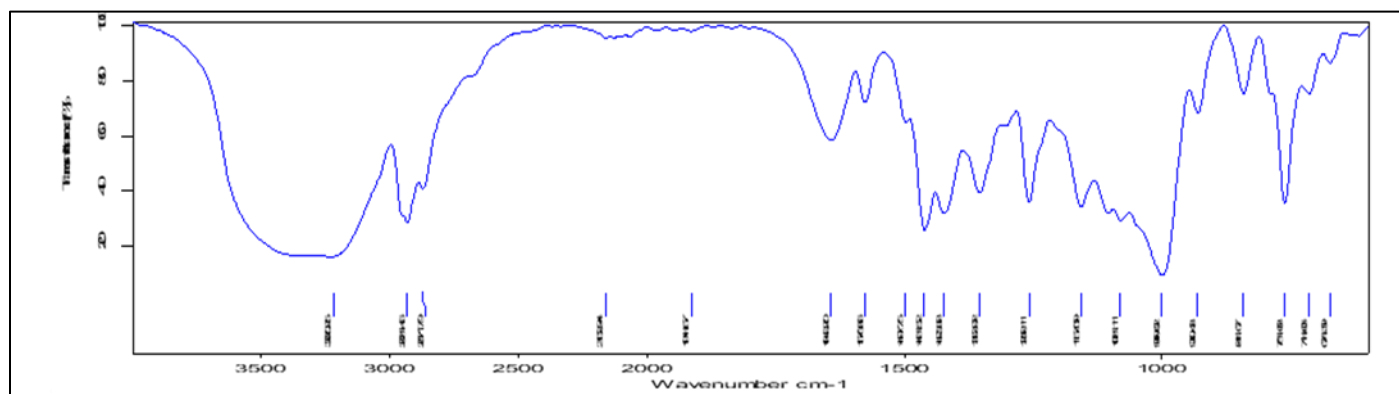


Fig. 8. FTIR spectrum of losartan potassium BP tablets formulated with Kahata Angala binder (1:1)

3.2.4 Physicochemical parameters of Kahata Angala (*Dioscorea alata*) starch compared with maize starch BP

The binding properties of pharmaceutical excipients are influenced by various physicochemical parameters including particle size distribution, granule size, pH, particle size, and hydration capacity (Emenike *et al.*, 2017). According to the results of the physicochemical parameters of the starches (Table 2), the Kahata Angala (*Dioscorea alata*) starch has a higher pH value which is 5.61 ± 0.22 than maize starch BP (4.99 ± 0.04). However, the pH values of both starches are within the standard range (4.00-7.00) given in pharmacopeia.

The hydration capacity of starch creates a significant impact on its binding properties in pharmaceutical formulations. The hydration capacity of starch can also affect the disintegration and dissolution properties of the prepared losartan tablets. The starches with higher hydration capacities have shown low disintegration in tablet formulation. As per the results of the present study, there is a significant difference in the hydration capacity of both Kahata Angala and maize starch BP ($p < 0.05$). Kahata Angala has a lower hydration capacity than maize starch BP. The hydration capacity of both Kahata Angala and maize starch BP is 1.80 g/g and 2.34 g/g, respectively. Therefore, starch of Kahata Angala can absorb and retain less water than maize starch BP.

Both Kahata Angala and maize starch BP are insoluble in cold water and 96% ethanol and slightly soluble in hot water. Starch becomes soluble in hot water when the temperature exceeds its gelatinization point. As the temperature rises, water penetrates the starch granules, weakening the binding forces and enhancing the mobility of starch molecules. This process can also lead to the leaching of soluble components. Furthermore, the hydration capacity and solubility of starch can be influenced by the presence of amylose-lipid complexes and structure of amylopectin.

As per the results, there was a significant difference in the bulk properties of both Kahata Angala and maize starch BP ($p < 0.05$), indicating higher bulk properties by the Kahata Angala starch. The bulk properties of the maize starch BP obtained are closely related to those reported in the Handbook of pharmaceutical excipients and the bulk density and tapped density of Kahata Angala are within the range of those reported for maize starch ($0.50\text{--}0.60\text{ g/cm}^3$; $0.70\text{--}0.80\text{ g/cm}^3$).

The literature suggests that the Hausner ratio could be a useful indicator of the flow properties of pharmaceutical powders. The lower Hausner ratio of Kahata Angala starch compared to maize starch BP indicates that it may have better flow properties, which could be beneficial for certain pharmaceutical applications.

The compressibility index serves as an indirect indicator of several powder properties, including bulk density, surface area, particle size and shape, cohesiveness, and moisture content. Based on the results of the experiment, the compressibility index (%) of Kahata Angala (*Dioscorea alata*) was found to be 22.20 ± 1.39 , while the compressibility index of maize starch BP was 30.78 ± 2.10 . According to the generally accepted scale of flowability given in British pharmacopeia 2023, the compressibility index of Kahata Angala falls within the range of 21-25 % which is categorized as a passable flow character while the compressibility index of maize starch BP is within the range of 26-31% which is described as poor flow character. This indicates that Kahata Angala has a better compressibility index than maize starch BP. In the context of tablet manufacturing, passable flow indicates that the powder may flow reasonably well, making it suitable for compression. In contrast, poor flow suggests a higher likelihood of inconsistent die filling, weight variation, or the need for flow aids such as glidants to ensure uniformity during large-scale production."

The compressibility index of starches can vary depending on their origin, method of processing, and other factors. For instance, maize starch is known to have lower compressibility due to its higher amylose content, which can lead to greater

Table 2: Physicochemical Parameters of Maize starch BP and Kahata Angala Starch

Parameter	Kahata Angala	Maize starch BP	P value
pH	5.61±0.22	4.99±0.04	0.01
Particle diameter (µm)	23.88±3.95	12.97±2.68	0.00
True density (g/cm ³)	1.43±0.00	1.34±0.00	0.00
Tapped density(g/cm ³)	0.82±0.03	0.58±0.02	0.00
Bulk density(g/cm ³)	0.64±0.02	0.40±0.02	0.00
Angle of repose (°)	38.02±0.60	50.37±0.64	0.00
Hausner's ratio	1.29±0.02	1.45±0.04	0.01
Compressibility index	22.20±1.39	30.78±2.10	0.00
Hydration capacity (g/g)	1.80±0.01	2.34±0.02	0.00
Solubility in 95% ethanol	Insoluble	Insoluble	-
Solubility in cold water	Insoluble	Insoluble	-
Solubility in hot water	Slightly soluble	Slightly soluble	-

3.2.5 Proximate properties of the starches

Table 3. Proximate Composition of the two starches

Component	Kahata Angala	Maize starch BP	P value
Moisture (%)	7.00±0.75	6.96±55	0.94*
Crude fat (%)	2.24±0.13	2.34±0.12	0.37*
Crude fibre (%)	Not detectable	Not detectable	-
Crude protein (%)	0.94±0.00	0.38±0.04	0.00
Ash (%)	0.24±0.02	0.14±0.01	0.00
Carbohydrate (%)	89.57±0.89	90.17±0.62	0.39*
Purity (%)	96.32±0.18	96.92±0.12	0.01

*No significant difference (p>0.05). Values show means with standard deviations of triplicate measurements.

particle swelling and decreased inter particulate void space. Furthermore, British pharmacopeia has shown that the compressibility index can be influenced by various factors such as particle size, shape, surface area, and moisture content. Therefore, it is possible that the differences in the compressibility index observed between Kahata Angala, and maize starch BP may be attributed to differences in these properties.

The Yam starch showed 7% moisture, 2.24% Crude fat, 0.94% crude protein, 0.24% ash, 89.57% carbohydrate and 96.32% purity on dry weight basis. The extraction yield was 13%-15% w/w while the maize starch BP showed the 6.96% moisture, 2.34% crude fat, 0.38% crude protein, 0.14% ash, 90.17% carbohydrate and 96.92% purity (**Table 3**).

Overall, the results suggest that the Kahata Angala starch have relatively low moisture content values, which is desirable for their use as pharmaceutical excipients similar to the maize starch BP. The low moisture content can improve their stability and reduce the potential for degradation or microbial growth in the final product. Experimental results reveal that the purity of Kahata Angala (96.32%) is quite similar to maize starch BP (96.92%). The moisture content of Kahata Angala starch was measured as 7%, which is higher than the 2.24% reported for *Dioscorea alata* by Jayakody et al. (2007). This indicates a

comparatively greater water retention capacity in Kahata Angala starch.

3.3 Quality of the formulated tablets

3.3.1 Organoleptic properties of the formulated tablets

Table 4. Organoleptic properties of formulated losartan potassium 50 mg tablets

Shape	Texture	Colour	Odour
Round	Smooth	Light pink	Odourless

Table 5. Results for different quality parameters of formulated tablets

Tests	Results
Thickness (mm)	4.43±0.60
Friability % w/w	0.70
Hardness (kPa)	30.25±5.43
Weight variation (mg)	648.53±4.7
Disintegration (Minute)	37
Dissolution (%)	44.67

Values show means with standard deviation of triplicate measurements

Table 4 and Table 5 show the organoleptic properties and quality evaluation results of the tablets prepared using yam starch. The prepared tablets of losartan potassium tablets using yam starch as a binder were evaluated for parameters such as Thickness, hardness, friability, weight variation, Disintegration and dissolution. Isolated yam starch has shown significant binding property indicating exhibiting a higher hardness value (30.25 ± 5.43 Kp). According to the friability test results tablets have a good friability value of 0.70%. According to the British pharmacopoeia (2023), friability values less than 1% are considered as acceptable for most products. In this study the disintegration time was 37 minutes and dissolution was 44.67 which were not in the range described in British Pharmacopoeia 2023.

Tablets exhibited poor disintegration properties exceeding the acceptable limit of 15 minutes. It is possible that the issue may have arisen due to excessive compressional force during tablet compression and higher binder concentration. To overcome the issue of poor disintegration, it is recommended to adjust the tablet compression process to ensure that the tablets are not subjected to excessive compressional force during compression. Additionally, adjusting the formulation by adding a disintegrant, such as sodium starch glycolate, Crospovidone, or changing binding concentration may help to improve tablet disintegration.

CONCLUSION

This study revealed that the starch of Kahata Angala (*Dioscorea alata*) has a similar appearance to maize starch BP, with the only noticeable difference being its colour. However, this difference can be overcome by a decolorizing agent.

While the physicochemical parameters of Kahata Angala starch are not significantly comparable to maize starch BP, particle size diameter, pH, bulk properties, and solubility fall within the range described in the pharmacopoeia and previous literature. Furthermore, Kahata Angala starch demonstrated better flow properties compared to maize starch BP, as indicated by the angle of repose, hausner ratio, and compressibility index. The study also found that Kahata Angala starch is compatible as an excipient for losartan potassium tablets, a critical factor in the development of a stable and effective pharmaceutical product. The moisture content, carbohydrate content, and crude fat content of Kahata Angala were found to be significantly comparable to maize starch BP, while the purity of maize starch BP was slightly higher than Kahata Angala.

Formulated losartan potassium tablets batch did not meet the official compendial standards in weight variation, disintegration and dissolution tests. Compression force, binder concentration and manual kneading can be reasons for the failures in these tests, which should be overcome in future studies.

In conclusion, the study indicates that various properties of Kahata Angala starch are more favorable as excipient materials

according to pharmacopoeial standards, with some properties being comparable to maize starch BP. However, additional research is needed to enhance the excipient properties, as well as the disintegration and dissolution profiles of tablets formulated with Kahata Angala starch, to confirm its suitability for use as a pharmaceutical excipient.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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