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Review Article

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## Comparison of Starch from Locally Grown Food Crops as a Pharmaceutical Excipient: A Systematic Review

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### Abstract

Starch is a widely used material with various applications in many starch based industries like pharmaceuticals, food and textiles, breweries and distillers due to its adhesive, gelling, thickening, swelling and film forming properties, making it to be used as a binder and disintegrant in pharmaceutical industries, but as a country becomes more industrialized, demand for both native and modified starches increases but these demands are currently being somewhat met through imports instead of locally made starch yet the sources of the starches are Maize, Cassava, Irish potato among others, so this review evaluated the available evidence on use of maize, cassava, and potatoes as sources of pharmaceutical grade starch in order to comprehensively prove with evident the possibility of their application and identify the best option by properties respectively using Articles containing Starch from these sources used as Pharmaceutical and conclusively, there was a strong evidence that all the sources produced starch which met the pharmacopeial grade standard and maize having the highest yield.

**Keywords:** Starch, Pharmaceutical, Excipient, Binder, Disintegrant, Pharmacopeia

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## 1. Introduction

Starch is a widely used material with various applications in many starch based industries like pharmaceuticals, food and textiles, breweries and distillers due to its adhesive, gelling, thickening, swelling and film forming properties, making it to be used as a binder (Eze and Alozie, 2015). In the pharmaceutical industry, native and modified starch are majorly utilized (Kundu *et al.*, 2011).

Starch and its derivatives (native starches and modified starches, e.g., sodium starch glycolate) are principally used as disintegrants in pharmaceutical tablet formulations. As a disintegrant, starch acts through

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a swelling mechanism (Ikechukwu *et al.*, 2013); it can also be used as a diluent, binder, glidant, and thickener. Disintegrants are pharmaceutical excipients included in the tablet formulation with the aim of facilitating the breakup of the compressed tablets into small fragments in aqueous media. The enhanced splitting of the tablets in aqueous medium improves the dissolution, absorption, and bioavailability of orally administered drugs (Adjei *et al.*, 2017). Other substances employed as disintegrants in tablet formulation include; microcrystalline cellulose, sodium starch glycolate which increase the porosity and wettability of the compressed tablet matrix, resin and its derivatives, croscarmellose sodium, carboxymethylcellulose, and crospovidone, which cause swelling in the presence of aqueous fluids. Thus tablet disintegration induced by these agents is due to the increase in the internal pressure within the tablet matrix upon contact with the aqueous environment (Okpanachi *et al.*, 2013).

Native starches derived from botanical sources are commonly employed as disintegrants in pharmaceutical tablet formulations usually in a concentration range of 2-10% w/w (Adjei *et al.*, 2017). The addition of starch and other disintegrants in tablet formulations may be performed intragranularly and extragranularly or in combination. In intragranular addition, starch is included in the powder mixture and granulated while in extra granular addition, dry starch powder is added external to the prepared granules. On the other hand, in combined addition, half starch is added intragranularly and the other half extragranularly. The mode of incorporation of a disintegrant influences its disintegrant effectiveness. Starch exhibits faster disintegrant action when added extragranularly than intragranularly (Adjei *et al.*, 2017). However disintegrants which are added to tablet formulations both intra- and extragranularly give the best disintegrant performance. Other factors which affect disintegrant effectiveness are particle size, moisture content, and the compression force applied (O.J *et al.*, 2016).

Binders are pharmaceutical excipients used in tablet formulation to impart cohesion on the powder mix, the resultant cohesiveness ensures that the tablet remains intact after compression (Satyam *et al.*, 2010b). Binders are used either in solutions or dry form depending on the other ingredients in the formulation and the method of preparation especially in wet granulation. The quantity of binders used has a considerable influence on the characteristics of the compressed tablets; increasing the binder concentration invariably rises the disintegration times. Important materials used as binders are starch, gelatin, natural gums, sugar, acacia sodium alginate, methyl-cellulose, microcrystalline cellulose, polyethylene glycol, waxes and water (Chitedze *et al.*, 2012).

Maize and potato starches have been in common use and recently cassava starch appeared in the British Pharmacopoeia (BP) as an official starch for use as binder (Satyam *et al.*, 2010a).

The composition, physicochemical properties, morphology, and pharmaceutical uses of starches from different sources are well documented (Builders and Arhewoh, 2016). Thus, this systematic review involved comparison of existing data on starch properties from these locally grown food crops.

According to a report of survey done by CEHURD in June 2013, the starch that is used by Ugandan pharmaceutical industries as binder, disintegrant and diluent is not got from the local sources but rather imported (almost 90% from India, Egypt and other countries). Yet the sources of these imported starches are maize, potato and cassava (Satyam *et al.*, 2010b) which are all grown in Uganda. For instance, maize is the dominant grain crop (75%) grown in every part of Uganda with 2.81 million metric tons of production. In south western Uganda (Mbarara), almost 80% of households grow maize (MoA, 2016). This implies that there is sufficient evidence to suggest that starch from locally grown maize can be used as an alternative to the expensive imported starches. But due to the environmental factors like soil content in different areas, the quality of these starches from local sources in terms of binding and disintegrating properties may not be known, since starch from different botanical sources could yield pastes with different characteristics due to variation in amylose-amylopectin ratio, which results in different binder substrate interactions (Abdallah *et al.*, 2014a). Such interaction makes it still a challenge for pharmaceutical industries in Uganda to formulate tablets using these starches from local sources.

As a country becomes more industrialized, demand for both native and modified starches increases but these demands are currently being somewhat met through imports instead of locally made starch (Ezeocha

and Okafor, 2016). But available evidence shows that the sources of the pharmaceutical grade starch imported from other countries are all readily available within Uganda. For instance, maize, which is an important source of pharmaceutical grade starch imported into the country, has had its production increase from 2.8 million metric tons to 4 million metric tons between 2015 and 2017. Uganda, with its favorable climate that can support two cropping seasons in a year (Wakabi Kasajja, 2018), is able to increase production capacity of maize, cassava and potatoes annually. Thus, reviewing existing data on starch from locally grown food crops (evidence in support) in Uganda would help in guiding the pharmaceutical industries on how to reliably add value to local starch for use in pharmaceutical production as viable alternatives to the expensive imported starch. This will in turn lead to significantly cheaper but quality pharmaceuticals on the market, reduce the existing balance of payment deficit, and promote government strategies for local industrialization for economic development.

## 2. Objective

This systematic review focused on comparing starch from locally grown food crops to be used as pharmaceutical excipient (binders and disintegrants) in pharmaceutical formulation. Data on starch from maize, cassava, sweet potato and irish potato was collected, analyzed for their starch and their starch yields, flow and bulk properties of the starches. The formulation properties as binders and disintegrants were also analyzed. Finally, the data collected were manipulated in table form, with the mean and standard deviation of each outcome measures of each source calculated.

## 3. Materials and Methods

### 3.1. Search Procedures

#### 3.1.1. Search Strategies

Sources of Starch	Properties
Cassava	Binding
Maize	Disintegration
Sweet potatoes	Flow/bulk properties
Irish potatoes	Pharmaceutical formulation like Disintegration time, hardness

The keywords to be included when searching in the engine are starch from each different sources (maize, cassava, sweet potatoes, and irish potatoes) with their properties (bulk, flow, binding, disintegration) in pharmaceutical formulation.

#### 3.1.2. Search Sources

- PubMed
- Embase
- Google scholar

#### 3.1.3. Study Design

This systematic review was based on existing data on the starch from the four locally grown crops; maize, cassava, and potatoes for comparison

#### 3.1.4. Inclusion Criteria

On the search for the existing data, only articles containing starch from the different selected sources, evaluation of yields, and properties of the starches, and being used as pharmaceutical excipients. Only current and updated articles of 2010 and above, English translated were selected for review.

#### 3.1.5. Exclusion criteria

- Review articles,

- Missing 30% of outcome measures,
- Articles containing properties of modified starch,
- For corn, articles containing corn starch BP.

### 3.1.6. Population

Sources of starch from locally grown crops like maize, cassava, and potatoes (evidence in support)

## 3.2. Data Extraction

Existing data was searched from the sources identified. Each individual was assigned something to research on and after the articles and findings checked either removed or added or affirmed by the second person for legibility. Some discrepancies which arise were cleared by a third person.

## 3.3. Outcome Measures

- The percentage yield of starch from each source using their mean, standard deviation, confidence interval.
- The physico-chemical properties of starch extracted from each source (swelling index, hydration capacity).
- Flow properties (angle of repose, carr's index, and hausner's ratio).
- Bulk properties (bulk and tapped density).
- Binding properties (tablet hardness, dissolution, friability).
- Disintegration properties.
- Tablet weight uniformity.

## 3.4. Risk of Bias

Risk of bias tool for assessing quality and internal validity, to establish transparency of evidence synthesis results and findings in qualifying the articles was double checking by every group member.

Also expected outcomes in the exclusion criteria, i.e., all the articles selected have the required 50% of the expected outcomes helped us in minimizing bias.

## 3.5. Data Synthesis

The data from the different articles were combined and manipulated in a table form and the averages, i.e., mean (central value of a discrete set of numbers) and the standard deviation, SD (measure of the amount of variation or dispersion of a set of values, low SD indicates values are closed to the mean and high SD indicates that values are spread over a wider range) of the values of the properties and yield were gotten, recorded, analyzed and compared.

The data were analyzed using a one-way ANOVA (Microsoft excel and Microsoft word).

## 4. Results and Discussion

Properties	Nwachukwu and Ubieko (2020)	Obarisiagbon aj, okorr and uhumwangho mu (2018)	Kemas, U.C. et al. (2013)	Adjei et al. (2017)	Chitedze et al. (2012)	Total (Mean ± SD)
Bulk density	0.36	0.45	0.60	0.63	0.52	0.512 ± 0.110
Tapped density	0.42	0.64	0.80	0.70	0.66	0.638 ± 0.140
Carr's index	14.28		24.8	11.42	28.2	19.675 ± 8.087

Properties	29.0	46	46.2	41.01		40.550 ± 8.067
Angle of repose	29.0	46	46.2	41.01		40.550 ± 8.067
Hausner's ratio	1.17	1.42	1.33	1.13	1.21	1.252 ± 0.120
Swelling index	2.45	1.22				1.835 ± 0.870
Friability	0.91		4.39	0.59	0.37	1.565 ± 1.896
Disintegration time	4.92	4.30	6.33	10.47	7.73	6.750 ± 2.466
Tablet weight	601.37			594.00	405.84	533.737 ± 110.823
Yield	24.50			13.1		18.800 ± 8.061
Hardness	5.32		9.33		113.35	7.325 ± 2.835

Properties	Ogbonna <i>et al.</i> (2019)	Mahadi <i>et al.</i> (2012)	Kusuma <i>et al.</i> (2014)	Arun (2013)	Nwachukwu and Ubieko (2020)	Bayor <i>et al.</i> (2013)	Total (Mean ± SD)
Bulk density, g/ml	0.56	0.77	0.7	0.46	0.36	0.54	0.57 ± 0.15
Tapped density, g/ml	0.83	0.9	0.89	0.54	0.41	0.79	0.73 ± 0.2
Carr's index	31.96	14.4	24.7	14.81	12.19		19.61 ± 8.42
Angle of repose, (°)	30.26	33	25.67	38.13	27	38.2	32.04 ± 5.39
Hausner's ratio	1.47	1.16	1.32	1.17	1.14	1.47	1.29 ± 0.15
Swelling index		0.63	0.64		2.87		1.38 ± 1.29
Friability	1.29			0.48	0.63		0.8 ± 0.43
Disintegration time	8.23			44	1.77	2.99	14.25 ± 20.03
Tablet weight	404.82				610.92	575	530.25 ± 110.1
Yield			13.8		18.2		16.0 ± 3.11
Hardness	6.0			5.6	6.33		5.98 ± 0.37

Properties	Ogbonna <i>et al.</i> (2019)	Mahadi <i>et al.</i> (2012)	Kusuma <i>et al.</i> (2014)	Nwachukwu and Ubieko (2020)	Kemas <i>et al.</i> (2013)	Uwazuoke <i>et al.</i> (2014)	Total (Mean ± SD)
Bulk density	0.49	0.88	0.4	0.36	0.53	0.3	0.49 ± 0.21
Tapped density	0.66	0.96	0.57	0.41	0.76	0.62	0.66 ± 0.19
Carr's index	26.35	8.3	31.02	12.19	30.4	51.61	26.65 ± 15.51
Angle of repose	30.22	31.38		30.00	53.3	40.0	36.98 ± 10.02
Hausner's ratio	1.36	1.09	1.45	1.14	1.44	2.0	1.41 ± 0.33

Properties		0.5	0.6	2.8			1.3 ± 1.3
Swelling index							
Friability	1.29			0.69	0.78	1.05	0.95 ± 0.27
Disintegration time	12.05			2.75	2.33	8.05	6.30 ± 4.64
Tablet weight	404.67			605.02			504.85 ± 141.67
Yield		48.8		62.0			55.4 ± 9.33
Hardness	5.93			5.97	9.33		7.08 ± 1.95

Properties	Hassan <i>et al.</i> (2014)	Muazu <i>et al.</i> (2012)	Kusuma <i>et al.</i> (2014)	Total (Mean ± SD)
Bulk density	0.69		0.64	0.67 ± 0.04
Tapped density	0.89		0.86	0.88 ± 0.02
Carr's index	22.4		13.4	17.9 ± 6.36
Angle of repose	34		38.7	36.35 ± 3.32
Hausner's ratio	1.2		1.16	1.18 ± 0.03
Swelling index				
Friability		0.64		0.64
Disintegration time		8.15		8.15
Tablet weight		632.11		632.11
Yield				
Hardness				

Properties	Cassava	Sweet Potato	Maize	Irish Potato
Bulk density	0.512 ± 0.110	0.56 ± 0.15	0.49 ± 0.21	0.67 ± 0.04
Tapped density	0.638 ± 0.140	0.73 ± 0.20	0.66 ± 0.19	0.88 ± 0.02
Carr's index	19.675 ± 8.087	19.61 ± 8.42	26.65 ± 15.51	17.9 ± 6.36
Angle of repose	40.550 ± 8.067	32.04 ± 5.39	36.98 ± 10.02	36.35 ± 3.32
Hausner's ratio	1.25 ± 0.120	1.29 ± 0.15	1.41 ± 0.33	1.18 ± 0.03
Swelling index	1.835 ± 0.870	1.38 ± 1.29	1.3 ± 1.3	
Friability	1.565 ± 1.896	0.80 ± 0.43	0.95 ± 0.27	0.64
Disintegration time	6.750 ± 2.466	14.25 ± 20.03	6.30 ± 4.64	8.15
Tablet weight	533.737 ± 110.823	530.25 ± 110.10	504.85 ± 141.67	632.11
Yield	18.800 ± 8.061	16.00 ± 3.11	55.4 ± 9.33	
Hardness	7.325 ± 2.835	5.98 ± 0.37	7.08 ± 1.95	

## 5. Discussion

### 5.1. Percentage Yield of Maize, Cassava, Sweet Potato, and Irish Potato Starch

The percentage yield of maize starch (55.4 ± 9.33) (Table 3) was high compared to cassava and sweet potato. But many factors affect the yield like the crop variety, processing factors, the extraction method employed, and the season of harvest of the crop

## 5.2. Bulk and Flow Properties of the Starch

The bulk properties describe the density, consolidation, and flow of a powder mass. It also denotes how well the starch powders can be compressed since smaller particle sizes resist free flow because of adhesion between the powders (JPHA).

## 5.3. Bulked and Tapped Densities

The bulk and tapped densities of the starch powder cassava, sweet potato, maize and Irish potato were shown in Table 5. The tapped density which is indicative of the powder packing properties was seen to be higher than the bulk density. Maize starch was seen to have the lowest mean bulk and tapped densities compared to sweet and Irish potato (Table 4), and cassava starch, but they are all in the range considering the standard error. This implies the particles of maize starch do not easily pack to fill up voids within the powder bed compared to the other starch. This decrease in densities increases the flow properties of the granules compared to the powders due to the resultant increase in particle size which leads to decrease in surface free energy of the granule and frictional forces between the granules.

## 5.4. Angle of Repose, Hausner's Ratio and Carr's Index

These are all indirect methods used in predicting powder flow properties under specific conditions. Hausner's ratio is an indicative of inter-particle friction while Carr's index shows the aptitude of a material to diminish in volume. As the values of these indices increases the flow of the powder decreases. In general a Hausner's ratio less than 1.25 which is equivalent to 20% Carr's compressibility index indicates good flow while that greater than 1.5 equivalent to 33% Carr's compressibility index indicates poor flow. Angle of repose is a measure of the powder resistance to flow under gravity due to frictional forces resulting from the surface properties of the granules. Usually, when it is less than or equal to 30° indicates free flowing powders while that greater than or equal to 40° suggests a poor flowing powder. Maize starch has a hausner's ratio of 1.49 implying poor powder flow and cassava starch with angle of repose of 40 and above, (Table 1).

## 5.5. Physicochemical Properties of Tablets

### 5.5.1. Weight Uniformity

The individual weight of the tablets from the different sources does not deviate from the mean more than is permitted since all showed a low coefficient of variation below 5% according to the standard in the national pharmacopoeias for tablets greater than 324 mg. Compliance with the standard ensures that uniformity of dosage is achieved across all the starches.

### 5.5.2. Tablet Hardness

The results show that tablets containing sweet potato starch as binder (Table 2) had a smaller compared to tablets containing maize or cassava starch as binder. Despite the fact that tablets containing maize, cassava, sweet potato starch disintegrant gave tablets of recommended hardness (4-7 KgF) for uncoated conventional tablets, the tablets for maize, and sweet potato were nonetheless not as hard as tablets containing cassava starch disintegrants, meaning cassava is a strong binder.

### 5.5.3. Friability

The results (Table 5) show that all the tablets from the different crops had a mean weight loss of less than 1% except cassava, which is acceptable according to the standard in the British Pharmacopoeia, implying that the tablets can withstand handling and transportation conditions without much reduction in weight and change in appearance of the tablets. It must be noted that while tablets containing maize starch were not as hard as tablets containing cassava starch. Friability values of less than 1% show efficiency of dosage form formulation and development

### 5.5.4. Disintegration Time

The British Pharmacopoeia recommends a disintegration time of not more than 15 min for conventional (plain uncoated) tablets. From Table 5, tablets containing cassava, and maize starch binders disintegrated

within 15 min and therefore pass the disintegration time test for conventional tablets. Such tablets will be expected upon oral administration to disintegrate within expected time to release the pharmaceutical active for systemic absorption. The speed with which this disintegration will occur can be seen to vary with the type of starch binder. Although sweet potato except for one research which had an outlier of 44 mins, it therefore exhibit well binding properties and will probably be applied at low concentrations in conventional tablets formulations.

The fast disintegration rates will accelerate the dissolution of the tablets by exposing large surface areas of the solid particles to the dissolution medium (jpha).

This result show that cassava starch when incorporated in tablet formulations will promote rapid disintegration of the dosage form compared to maize and sweet potato starch. The disintegrant action of starch is attributable to a combination of capillary action followed by rapid swelling when in contact with moisture. Capillarity may increase the rate at which water is introduced into the tablet and it is influenced by the porosity of the tablet (Kusuma *et al.*, 2014).

## 6. Conclusion

The results of this study provide some insights into the relative effectiveness of the starch from the locally grown cassava, sweet potato, irish potato and maize as binder and disintegrant, with maize starch having the highest yield, cassava starch with the lowest disintegration time, sweet potato having the lowest friability but there was a clear evidence that the starches from all the sources can be used as Pharmaceutical excipients.

## Conflicts of Interest

No conflict of interest declared by both authors.

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