

Comparative Evaluation of *Zea mays* (L.) and *Ipomoea batatas* (L.) as a Pharmaceutical Excipient

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Abstract: This investigation aims at comparing starches from two grains: Maize (*Zea mays*) and Sweet potato (*Ipomoea batatas*) grains. These grains are used mainly as foods and they contain high amount of carbohydrate. The presence of starch in these grains varies and thus their use as pharmaceutical excipients will vary to the degree of their starch functionality. The powders obtained were characterized for their particle size, particle size distribution. The organoleptic and physicochemical characterization such as viscosity, hydration capacity, swelling capacity, moisture sorption capacity, pH, flow rate and porosity, Carr's index and Hausner's ratio were evaluated. Maize starch showed the least Carr's index, Hausner ratio, porosity, moisture sorption capacity and the greatest flow rate. Sweet potato starch showed the highest hydration capacity and swelling capacity. The results obtained showed that between the two starches in relation to their flowability, maize starch possesses the best flow property. Compatibility of Etoricoxib with maize and sweet potato starch was evaluated by IR spectra and found that both Etoricoxib is compatible along with maize and sweet potato starch. This knowledge of starch properties will help to explain the behavior of these starches when used as tablet excipients.

Key words: Starch, Carbohydrate, Flow ability, Etoricoxib.

I. Introduction

The characterization of pharmaceutical excipients using a material science approach has helped to design drug formulations to obtain a desired set of performance properties. For tablets, a better understanding of the compression properties of the material alone and in combination with other potential components helps in developing desirable formulations as well as acceptable products (1). When formulating tablets, the choice of excipients is extremely critical. It must fulfill certain requirements such as compressibility, good binding functionality, powder crystallinity, flowability and acceptable moisture content. Moreover, it is essential to have a well designed particle size distribution for favorable mixing conditions with drugs (2, 3).

Starch is widely used as thickening, stabilizing, gelling and/or filling agent in many food applications and it considered as the most used excipients in pharmaceutical formulations. It has many pharmaceutical applications and it is used mainly in tablets as filler, binder or disintegrant (4). Starch is the major carbohydrate reserve in plant tubers and seed endosperm where it is found as granules. It contains mainly two types of polymer molecules; several million of highly branched amylopectin molecules (normally 70-80%) accompanied by a higher number of largely linear amylose molecules (normally 20-30%) (5). Starches obtained from different botanical sources may not have identical properties with respect to their use for specific pharmaceutical purposes. Examples of starch sources are maize, rice, potato and wheat (6). Currently, only few materials meet the criteria to allow starch classification as tablet excipient and to study the relation between their pharmaceutical properties and their source, cultivation and production (7, 8). An understanding of the physicochemical properties of starch is critical for its proper use.

The aim of this study is to investigate the properties of starches and also study their advantages and disadvantages relative to each other. The objectives therefore are, to extract maize and sweet potato starches from their natural plant sources and process them to pharmaceutical grade starch and to compare the physical properties of these starches in the powdered state relative to each other.

II. Materials and Methods

Collection and Identification of Starches

Maize (*Zea mays*) and Sweet potato (*Ipomoea batatas*) were purchased from BADC market at Mohahammadpur in Dhaka and were identified by Department of Botany, Faculty of Biological Sciences in Jahangirnagar University, Bangladesh.

Extraction of Maize and Sweet potato starches

The outer layer of sweet potato was peeled off and the white part was washed and cut into the pieces. Then it was powdered in a blender (Philips HR2001, China). Then it was washed with enough quantity of distilled water. The washing steps were repeated until the supernatant was clear and the starch was free of color. The starch was then dried in an air oven at 105°C. The procedure was also same for the maize or corn flower powder. (9).

Characterization of Starch

Solubility test

1g of each starches (Maize and Sweet Potato) were weighed and poured into a beaker containing 1ml, 2ml, 10ml, 1L and 10L distilled water at 25°C and was stirred, and the solubility was observed. Same procedure was repeated using 65% alcohol as a solvent.

Iodine test

Using BP (2010) starch identification test, 1g of each starches (Maize and Sweet Potato) were boiled with 15ml of water and allowed to cool. A few drops of 0.1N Iodine solution were added to 1ml of the mucilage and the color changes recorded.

Determination of P^H

One gram (1g) of the individual starches was made into mucilage with 100mls of distilled water and the pH was determined in an electronic P^H meter.

Moisture Content Determination

One gram (1g) of the powder was weighed and then dried in an oven at 105°C for about 1 hour and then weighed again until constant weight was gotten and the percentage of loss on drying was calculated.

$$\text{Moisture content} = (W_f / W_i) \times 100 \text{ ----- (i)}$$

Where, W_f is final weight of powder after drying and W_i is initial weight of powder before drying.

Microscopic Determination

A small quantity of each starch was mounted in a drop of glycerol on a glass slide and covered with a slip. The size and shape of starch particles were determined with a microscope (Olympus, Germany) equipped with a micrometer using 40 × magnification.

Determination of flow properties of starch

Angle of repose

Angle of repose was measured for the starch batches before granulation, as to observe the flow properties of starch particles. The method employed a funnel secured with its tip at a given height (*h*), above the graph paper placed on horizontal surface. Starch powders were poured through the funnel until the apex of the conical pile touches the tip of the funnel. The angle of repose was calculated using the following formula:

$$\tan \theta = h / r \text{ ----- (xii)}$$

Where, θ is the angle of repose and *r* is the radius of conical pile.

The mean angle of repose was calculated from three determinations. This method is known as fixed height method.

Determination of Starch density

Bulk and Tapped densities

Bulk and Tapped densities were determined by using 50g (*W_p*) of the starch powder. This was gently poured through a short stemmed glass funnel into a 100ml graduated cylinder. The volume occupied by the powder is taken as *V_p*. The powders were tapped on a wooden surface at height of 7 inches until no further change in volume was observed. This volume (*V_{pT}*) was taken as the tapped volume.

$$B_d = (W_p / V_p) \text{ ----- (iii)}$$

$$T_d = (W_p / V_{pT}) \text{ ----- (iv)}$$

Where, B_d = Bulk density and T_d = Tapped density

Carr's Index

The difference between the tapped and bulk density divided by the tapped density was calculated and ration expressed as a percentage.

Hausner Ratio

The ratio of tapped density to bulk density was calculated for all starches.

Determination of starch true density

The specific gravity bottled method was adopted, and xylene was used as displacement fluid. The bottle was cleaned and filled with xylene, all spilled over liquid (xylene) was wiped off with an absorbent cloth. The weight of the bottle filled with xylene was noted as (a), the bottle was emptied and cleaned, 2 g of starch was weighed into the specific gravity bottle, the weight of the starch powder was noted as (w). The specific gravity bottle containing the starch was almost filled with xylene, stirred with glass rod and allowed to stand for 10 minutes for air bubbles to be released. The bottle was then carefully filled with xylene and the final weight of the bottle was noted as (b). Starch true density was calculated as:

$$l = w / [(a + w) - b] S \dots\dots\dots (v)$$

Where, l is the particle density of starch and the specific gravity of xylene, S = 0.86

Swelling capacity

The swelling capacity of the starch powders were determined by the method of Iwuagwu and Okoli (10). The tapped volume occupied by 5g of the powder V_x was noted. The powder was then dispersed in 85 ml of distilled water and the volume made up to 100 ml with more water. After 24 hours of standing, the volume of the sediment, V_v was estimated and the swelling capacity, S, was computed as:

$$S = [(V_v - V_x) / V_x] \times 100 \dots\dots\dots (vi)$$

Moisture sorption capacity

Moisture sorption capacity of the starch was determined by modified method of Ohwoavworhwa *et al*, (11). Two grams (2g) of the individual starch powders (W) were weighed and put into a tarred Petri dish. The samples were then placed in a desiccator containing distilled water at room temperature and the weight gained by the exposed samples at the end of a five-day period (W_g) was recorded and the amount of water absorbed (W_a) was calculated from the weight difference as:

$$W_a = W_g - W \dots\dots\dots (vii)$$

Hydration capacity

A 1g weight of starch was in placed 15ml plastic centrifuge tube, 10ml distilled water was added and then closed. The contents were shaken for 2 min and then allowed to stand for 10 min and immediately centrifuged at 1000 rpm for 10 min in a bench centrifuge. The supernatant water was decanted and the weight of the wet starch was recorded. The hydration capacity was determined using the equation below:

$$\text{Hydration capacity} = W_s / W_D$$

Where, W_s and W_D are the weights of the sediment formed and weight of the dry sample respectively.

Porosity

The powder porosity (E) was calculated by the method of Ohwoavworhwa and Adelokun (12) as:

$$E = [1 - (B_d / D_t)] \times 100 \dots\dots\dots (ix)$$

Where, B_d is bulk density, D_t is true density of starch.

Packing fraction

The packing fraction (P_f) was expressed as the ratio between the bulk density (B_d) and the true density (D_t);

$$P_f = (B_d / D_t) \dots\dots\dots (x)$$

FT-IR compatibility test

Compatibility of Etoricoxib, a widely prescribed NSAIDs in Bangladesh with maize starch and sweet potato starch was studied by IR spectra (Shimadzu FT-IR 8400S, Japan).

III. Result and Discussion

The percentage yield obtained from extracting starch from Maize (*Zea mays*) and Sweet potato (*Ipomoea batatas*) was 48.8 and 40.8 respectively. The higher yield and low cost of these starches indicate that it can be potential source of pharmaceutical raw material.

The identification tests carried out showed that Maize and Sweet potato starches were insoluble in water and alcohol (95%) at room temperature. The starches were all positive to mucilage and iodine tests. Sweet potato starch was more acidic than the maize starch as shown in table 1. The nearness of the starches to pH 7 could be an advantage because neutral pH might decrease tendency of interaction of excipients with active pharmaceutical ingredient. The pH was all within the acceptable limit of 4.5-8 [13]. The color, odor, taste, solubility test for this two starches were within the official recommendation (BP. 2010). There is no color and taste was found in both starches (Table 1).

Table 1: Results of identification tests of Maize and Sweet Potato starch

Parameter	Maize	Sweet Potato
Color	White	Yellowish
Odor	Odorless	Odorless
Taste	Tasteless	Tasteless
Test for mucilage	Positive	Positive
Solubility test	Insoluble	Insoluble
Iodine test	Positive	Positive
pH	5.96	6.22

Microscopy of starch

Figure 1 - 2 shows the photomicrograph of the starches at X40 magnification. Maize starch particles were small angular polyhedral and round (Fig.1). The particle shapes of the sweet potato starch were mainly spherical and polyhedral. The large particle size is an advantage because large particles have a smaller surface area and hence smaller surface activity. Larger particles flow better than smaller particles because particulate flow is more of a surface phenomenon by generation of resistance to flow. The smaller particles (large surface area) having more surface energy to attract with one another tend to adhere together and have more resistance to flow [14]. It is however pertinent to note that not only particle size that is involved in the flow of powders, other characteristics of excipients such as densities and moisture content may also affect flow properties of powder.

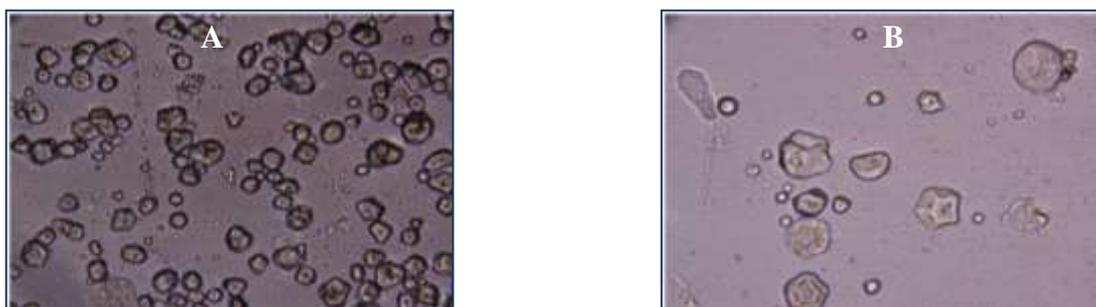


Figure 1: Photomicrograph of maize starch (A) and sweet potato starch (B) at X40 magnification.

Physicochemical parameters of starch

The physicochemical parameters of the starch were presented in table 2. The hydration capacity of starch sweet potato starch was higher than that of the maize starches. It is assumed that the hydration of starch represents the water absorbed by the particle or the particle surface (14). As observed earlier, the smaller the particle size, the larger the surface area for absorption of water. The sweet potato starch has higher moisture content than maize starch; this might be as a result of the larger particle size of the potato starch. Regulation of moisture in formulation is very important as high moisture content may interfere with the active ingredient (15). The moisture sorption capacity is a measure of moisture sensitivity of a material and it reflects the relative physical stability of the tablets formulated with the material when stored under humid conditions (16). The results show that maize starch absorbed the least moisture, followed by sweet potato starch. This could indicate that maize starch when used in tablet formulation would absorb the least moisture and thus eventually give tablets with better physical stability than sweet potato. The common feature of all theories of disintegration is that penetration of water (or liquid medium) must precede disintegration and this can be assessed by the determination of hydration capacity, swelling capacity, and porosity (17). The hydration capacity of the starches indicates that both maize and sweet potato starch are capable of absorbing two times their own weight of water. The swelling capacity, which reflects an increase in volume of the starches, showed sweet potato starch having the highest increase in volume, followed by maize. This suggests that sweet potato starch may be a better disintegrant than the other starch and if incorporated in tablet formulation as a disintegrant, would probably produce tablet disintegration by two mechanisms: capillary or wicking and swelling.

Also from the results of bulk, tapped densities, porosity, and packing fraction in Table 2, maize starch exhibited the largest maximum volume reduction due to packing, while sweet potato starch exhibited the lowest. The flow characteristics of the starch were measured using the angle of repose. The angle of repose of sweet potato starch was greater than those of maize starch. An angle of repose above 50° is an indication of poor flow characteristics of powder. Both of the starches were within the limit.

The Carr's index and Hausner ratio predict the flow and compressibility of powders. Hausner ratio below 1.25 and Carr's index above 5-15% indicates good flow or good compressibility.

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The swelling power of sweet potato starch was higher than that of Maize starch this parameter is an indicator of disintegrating property of starch. It means that sweet potato starch may have better disintegrating property than other starches. But it is important to note that it is not the only mechanism of disintegration (15).

Table 2: Comparative studies of phytochemical properties of both starch powder.

Parameter	Maize	Sweet potato
Viscosity (pa-sec)	5.34	8.28
Bulk Density(gm/ml)	0.88	0.77
Tapped Density(gm/ml)	0.96	0.90
Carr's Index	8.3	14.4
Hausner Ratio	1.09	1.16
Moisture content (%)	09	11
Moisture sorption capacity (%)	2.5	7.5
Swelling capacity (%)	50	62.5
Hydration capacity	2.29	2.41
Angle of repose	31.38	33
Porosity (%)	21.43	45.77
Packing fraction	0.79	0.54
True density (gm/cm ³)	1.12	1.42

Compatibility of Etoricoxib with maize and sweet potato starch was evaluated by IR spectra and found that both Etoricoxib is compatible along with maize and sweet potato starch (Fig. 2-3).

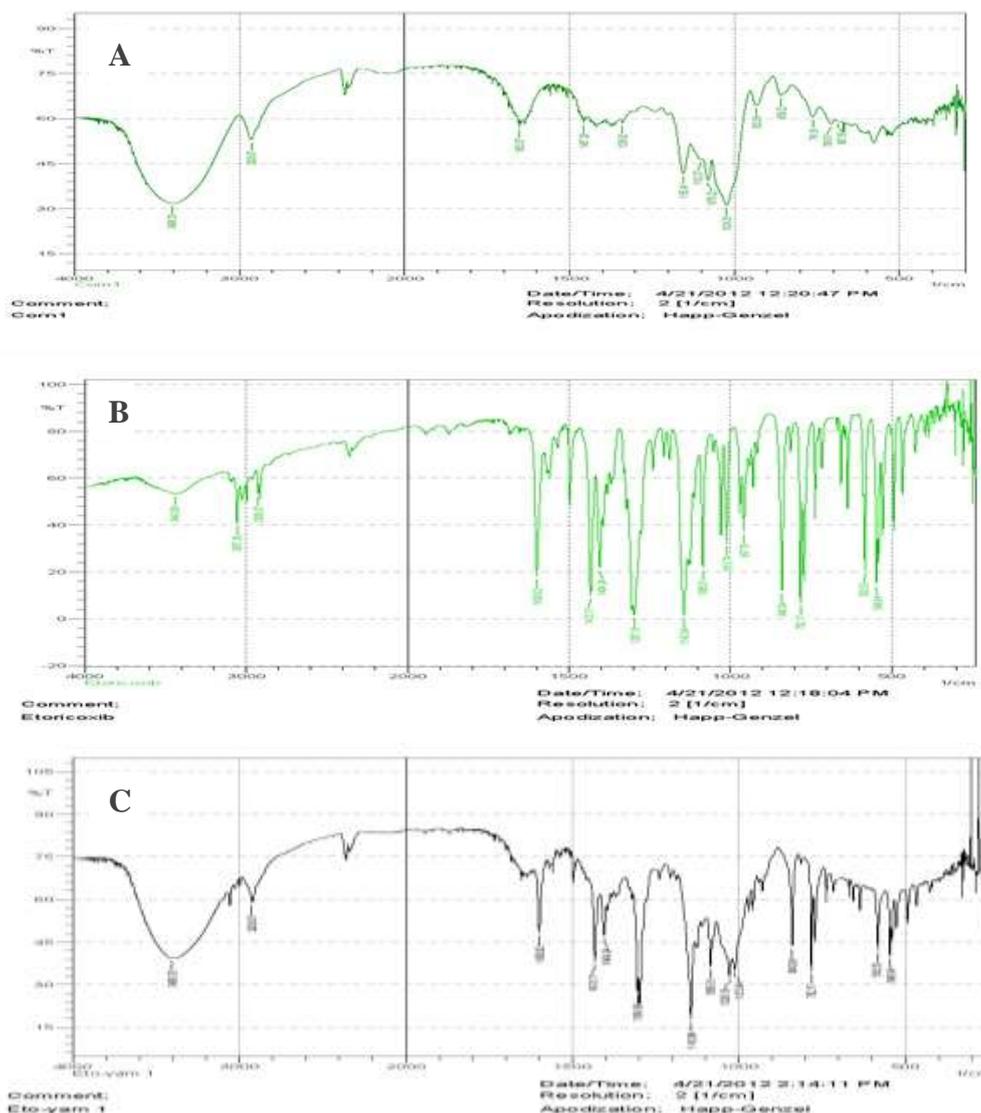


Figure 2: IR spectra of starch compatibility studies (A. Maize starch, B. Etoricoxib, C. Etoricoxib and Sweet potato starch).

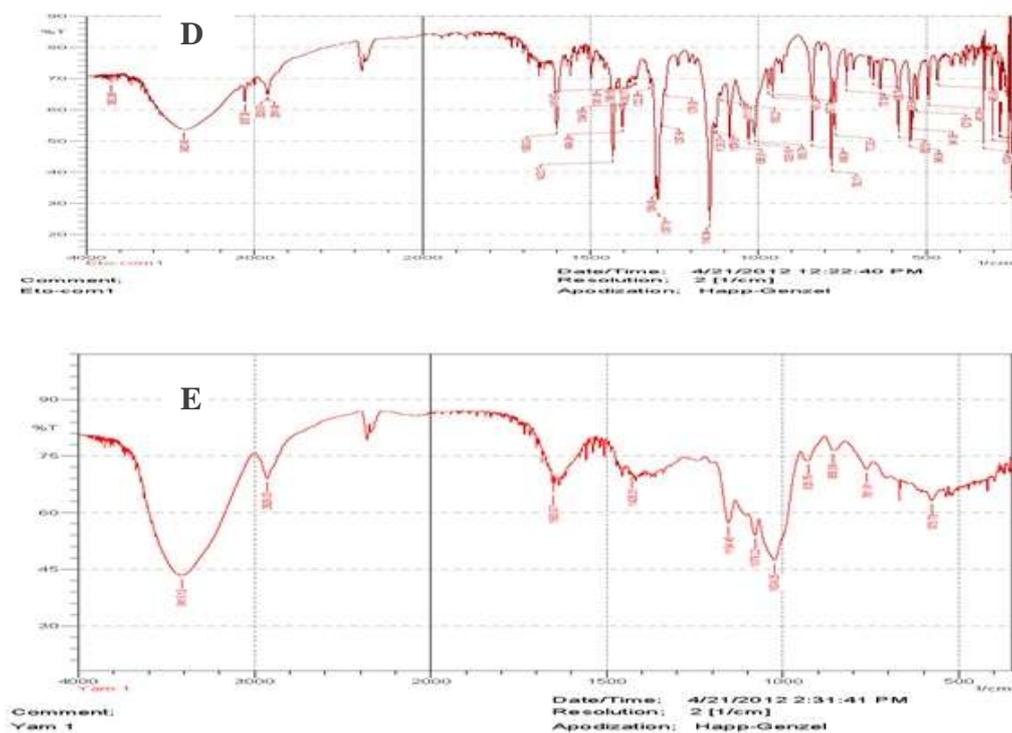


Figure 3: IR Spectra of starch compatibility studies (D. Etoricoxib and Maize starch E. Sweet Potato starch).

IV. Conclusion

Sweet potato starch compared well to maize starch in physicochemical properties and could therefore serve as an alternative to maize starch as an excipient in the pharmaceutical industries especially in the manufacture of solid dosage forms.

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