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PRODUCTION OF PREGELATINISED MAIZE STARCH COMPARED WITH MAIZE STARCH AS INGREDIENT IN PHARMACEUTICAL SOLID DOSE FORMS

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Abstract

Pregelatinised maize starch was prepared from evaporating to dryness 8%w/v of maize starch mucilage and pulverising it. Its physicochemical properties were compared with maize starch powder. Its higher and tapped densities resulted in lower Carr's index. Its higher particle flow rate lower angle of reponse could render it a better candidate in capsule filling and tablet compression. The later properties could allow more uniform dose distribution by weight and lower power consumption for compression. Its higher intraparticulate porosity and more amorphous disruption by the gelatinisation could cause dose form faster disentegration and therefore enhanced faster dissolution for faster drug bioavailability.

Keywords: Pregelatinised starch; Maize starch; Physicochemical properties, Comparative pharmaceutical excipient.

INTRODUCTION

Starch a polysaccharide, it is an important pharmaceutical raw material found in abundance in many plants growing in Nigeria. It is most popularity used in pharmaceutical solid dosage forms as diluents and disintegrants, it is obtained from cereals and tubers (Edward et al 1990). Starch has a great affinity for water and swells most possibly by capillary action when moistened. Its slippery feeling has been utilised as a glidant by promoting fluidity in granular flow into tableting presses. Its thus, facilitates the rupture of the tablet matrix. Many non-official starches found in abundant quantities in Nigeria, have been tested and found to be useful as tablet binders and disintegrants. These include the starch from yam, coco yam cassava (Nasipuri and Akala (1986) and sorghum starch, (Deshpande and Panya 1987). Some starches can also be modified for better pharmaceutical or chemical properties in order to achieve some designed objectives such includes sodium starch glycollate which has been desented as a super tablet disintegrant (Vivastar by JRS Germany).

This study is aimed at preparing or producing pregelatinised starch from maize starch, and also to compare the physicochemical characteristics of the two in order to ascertain whether there is any advantage of producing the former from the later.

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MATERIALS AND METHODS

Materials: Maize starch (East Anglia Chemicals), xylene (BD Chemical, England) and distilled water. Glassware used include measuring cylinders, funnels, beakers produced by Pyrex England, stainless steel bowl 12 litres, trays.

Preparation of pregelatinised starch (PGS). For the purpose of preventing encapsulated lump formation some 100ml of water was initially added to and mixed with 450g of starch powder placed in 12L narrow base, stainless steel bowl tared to 5.625L volume . Hot water at 60^0C was added with stirring until the mark was reached. The bowl was kept on a heating mantle while contents were being stirred until a translucent mucilage was formed. The mucilage was poured into a 30cm diameter stainless steel tray which was placed in Gallenkamp hot air oven (Gallenkamp machines, model size 3, Birmingham, England) subjected to at 50^0C until a constant weight was obtained over 48 hours period. This is pregelatinised starch in the form of flakes. The flakes were milled through 1000μm sieve in Christy and Horns milling machine (Chemford England) to pulverise. The product was sieved through 180μm seive onto the pan with Endecott sieves and shaker (London, England). This was stored in airtight jar. The yeild Y was calculated from the original weight W_1 of the maize starch and the final weight which is the weight of the pregelatinised starch, W_2

$$Y = 100(W_2/W_1)$$

Determination of hygroscopicity and efflorescence: 2 grammes W_1 of pregelatinised starch or maize starch in an evaporating dish was exposed to atmospheric condition by placing in open space and left for 24 hours but observed at 8 hourly intervals. The final weight W_2 of the sample was recorded after exposure and percentage difference calculated.

$$H = 100 [1- (W_2/W_1)$$

If the value of H, hygroscopicity value, is minus or negative it means it absorbed some moisture and if it has a positive value it means it lost some moisture. The average relative humidity of the room was also taken into account and noted.

Solubility Determination

The pregelatinised starch powder and maize starch were mixed respectively in a 50ml of distilled water to produce a suspension, that is, having excess powder undissolved in water. The water was stirred with a magnet bar over a magnetic hot plate (Erweka, Germany) warned slightly above room temperature of about 40^0C for 5 hours for any soluble components to dissolve to saturation. The suspension was filtered through 0.3μm pore size of millipore membrane filter via a suction pump. 10ml of the filtrate was pipetted into a clean and dried evaporating dish of weight W_1 without the solution. The dish with its supectant was kept in 500ml beaker in Gallenkamp hot air oven thermostated at 70^0C overnight. The dried evaporating dish was weighed W_2.

The weight of any solute dissolved in the 10ml was any weight $\in W$ in excess of the empty weight of the evaporating dish.

$$S = 100(\in W)/ 10$$

which is the solubility S expressed as weight by percentage volume.

Moisture Content Determination

Three-gramme (3g) weight of each sample of the powders was taken in respective evaporating dish of known weight, W_1 which were then transferred into the oven (Gallenkamp oven) and dried at 105^0C until a constant weight W_2 was obtained, denoting that all the moisture presenting the powder had evaporated. The moisture content as a percentage of the original weights of the powder was taken. The experiment was repeated twice with the samples of powders.

$$M_C = 100\,[1 - (W_2/W_1)]$$

Where M_c = moisture content; W_1 is the initial weight of the powder sample taken; W_2 is the final weight of the powder sample after drying to constant weight.

The moisture content of all the powder samples was also determined in a similar manner.

Powders Characterisation

The Powders were characterized as follows.

Particle size distribution

The sieve analysis method was employed. One hundred gramme (100g) weight of the powders was used for the analysis, it was mechanically vibrated for 30minutes on an Endecott test sieve shaker (Endecott Ltd London). The weight of the powders that was retained on each of the sieve mesh 1400μm, 1000μm 710μm, 500μm, 250μm, 180μm and the percentage weight (%wt) calculated. The percent cumulative under size (Fig. 1). The mean powders size (MGS) was also calculated.

$$MGS = \Sigma(\mu m)$$

Where μ is the sieve mesh size retaining the granules and w is the percent weight of the granules retained on the sieve.

Determination of Angle of repose

One hundred gramme (100g) weight of each powder was allowed to flow through a funnel from a fixed height onto a flat surface. The radius (r) and the height (h) of the powders heap was then determined. The angle of repose (θ) was calculated from the equation:

$$\tan\theta = h/r$$

Where θ = is the angle of repose

Determination of Carr's index

A 50g quantity of the powder sample was gently poured into a 100ml measuring cylinder graduated in 10ml units. The initial V_1 of the powder was recorded. The cylinder was tapped 50 times on a hard top wooden table. The tapped volume V_2 was recorded Carr's index I as described by Staniforth (1985), and Staniforth (1993) which is the percentage difference between the tapped and bulk densities was calculated as

$$I = 100[1 - (V_1/V_2)]$$

For each sample, the I values for 3 determinations were obtained and the mean calculated.

Determination of Flow Rate

A 50g quantity of each powder was poured into the funnel of Erweka (model TA – 3R type GDT, Germany) particulate flow meter. The meter was started and the time t in seconds taken by W grammes of the powder to flow through the orifice was recorded.

$$\text{Flow rate } F_R = W/T$$

Three flow rate determination for each powder was undertaken and the mean value calculated.

Determination of particle density, packing fraction and porosity of the powders.

Specific gravity bottle method was used. The bottle was cleaned and filled with the liquid (xylene) to be used. The spilled over liquid was wiped off with funless absorbent cloth. The weight of the bottle filled with the liquid was noted as X and the bottle was emptied and cleaned. One gramme of the powder was weighed into the specific gravity bottle which was initially calibrated. The weight of the powders was noted as W. The specific gravity bottle containing the powder was then almost filled with the liquid xylene, stirred with a glass rod and allowed to stand for 10 minutes for the air bubbles to be released and allowed to escape. The bottle was then filled with the liquid. Any spilled over liquid was wiped off and the final weight of the bottle with the content was noted as Y.

Particle density of the powder,

$$e = WS/\,[(X + W) - Y]$$

where e is the density of the powder, S the specific gravity of xylene.

RESULTS AND DISCUSSION:

The results obtained in the various xperiments are shown in Table 1 and Figure 1. The yield obtained from gelatinising maize starch formed from 8% W/V mucilage was 83%. Any loss from the product could have ensured by envisaged processing losses. Pre-gelatinization involves the rupture of the organised structure of the starch particles to form a granule. Gelatinisation involves the disorganisation of this crystalline – like, lattice arrangement into a disorganised, amorphous form (Ocheja, 2000). It is also possible that the heat applied for evaporation of the water in the mucilage could partially lead to some level of hydrolysis of the starch into a partially depolymerised form. If at all that was the case, it must have been very negligible as any extensive hydrolised form could have been soluble in the solubility determination which did not reveal any soluble constituents as Table 1 result showed under solubility.

The particle size of the milled dried mucilage flakes showed a mean granule size of 108 μm, much larger than the 21μm size of the maize starch. This larger mean size of the pregelatinised starch showed a high flow rate of 5.7g/sec compared to 1.2g/sec for maize starch (Table 1). This has also been shown as lower angle of repose (19.6^0) of the heap of PGS while that of MS was 45.7^0. *Larger particles have smaller surface area to volume ratio. Since particulate function is more of a surface phenomenon by generation of resistance to flow. This resistance is directly, related to the surface area of particles.

Most pharmaceutical granules have specific gravity of about 1 or less. Having an admixture with higher bulk and tapped densities, increases the inertia of such mixtures which causes higher densification. Bring in the work or publication of staniforth who showed the range of values of angles of repose, Carr's indices particle sizes that favour flow and ease of packing which favour good glident properties required of granules for filling into the die cavity and therefore higher flow rate.

Nabintu (2001) has shown how close packing had reduced the compaction force needed to density the granules which preceeds solidification into compacts. This ease to closer packing is shown with the higher bulk and packed densities of 0.75 and 0.91 g/cm^3 for PGS compared with those of MS were 0.44 and 0.61g/cm^3 respectively (Table 1).The percentage yield of 83% of pregelatinized starch was apprenciatively high enough. This shows that the maize starch did not contain a higher amount of other materials other than starch. This contributed to the high yield of pregelatinized starch (Table 1).

Table 2 shows that pregelatinized starch (PGS) has a higher flow rate than that of maize starch. The physical characteristics that make pregelatinised starch, flow or pack more easily to enhance better tableting properties are exhibited the following characteristics there was a lower angle of response, higher powder flow rate due to lower cohesive forces, Martin, et al (1983), Neuman (1976), Carter (1972). Lower difference between bulk and tapped densities and therefore lower value of Carrs packing or consolidating indices. – The lower moisture content, higher packing fraction, lower porosity, and larger mean powder size of PGS result of which are shown on Table 1, all favour more desirable tableting prerequisite. The size distribution of pregelanized starch powder produced from maize starch compared with maize starch powder is shown in Figure 1. The particle size of maize starch powder was not significantly different (P>0.05) compared with pregelatinised starch. 15 to 21um and 108 um are by means significantly different pregelatinised starch

(PGS) was found to be a good disintegrant in tablets, because, of its excellent pharmaceutical properties when compared with Maize Starch (Musa 2002; Musa, 1999).

Table 1: Comparative physico-chemical characteristics of pregelatinised starch powder produced from maize starch and maize starch.

Parameter	Pregelatinised starch (PGS)	Maize starch (MS)
Yield	83	12.8
Moisture content (%)	7.3	12.8
Mean particle size (μm)	108	21
Efflorescence (%)	1.2	2.1
Solubility	Insoluble	Insoluble
True density (g/cm^3)	1.50	2.13
Flow rate (g/sec)	5.70	1.2
Bulk density (g/cm^3)	0.75	0.44
Tapped density (g/cm^3)	0.91	0.67
Percentage Compressibility (%)	17.6	34.8
Angle of repose (0^0)	19.6	45.7
Powder porosity (%)	50	80
Packing fraction	0.5	0.2

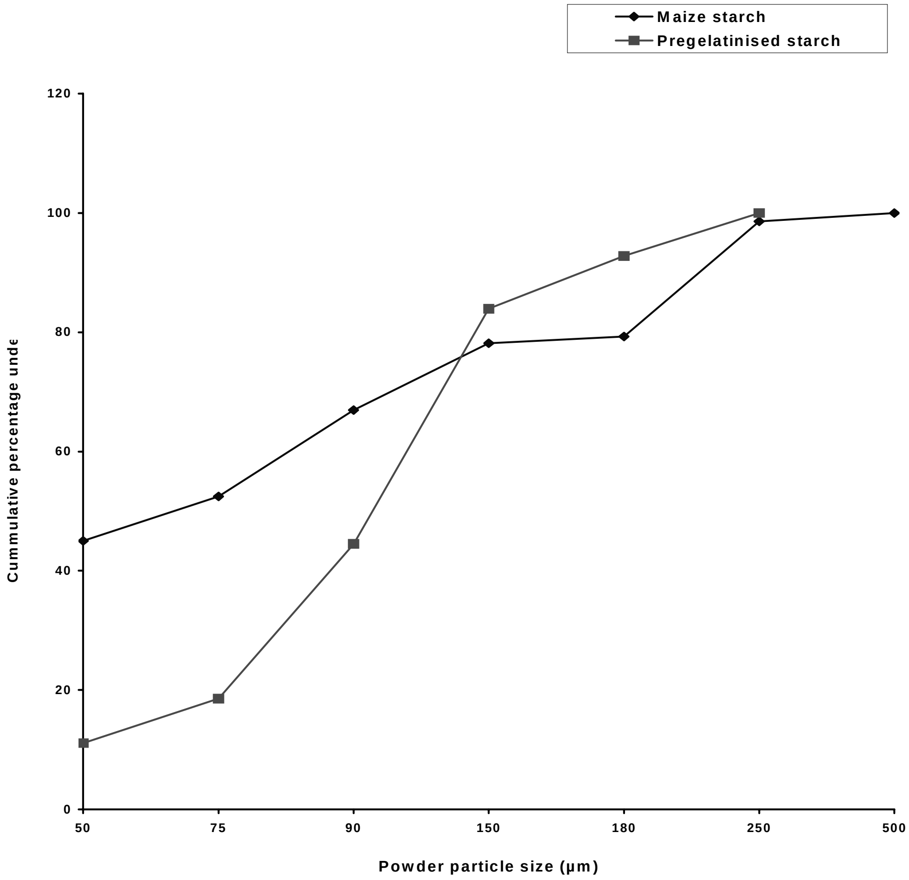

Fig. 1: Size distribution of maize starch powder and pregelatinised starch powder produced from maize starch

CONCLUSION

Nearly all the physical characteristics that favour densification and therefore easier rate of packing in capsule filling and tablet compression such as lower Carr's index, low angle of repose and larger mean particle size were found to be more inherent in pregelatinized maize starch then in maize starch. The move porous PGS and amorphous form favours shorten disintegration time which usually precedes access to faster dissolution of active ingredients and therefore makes the medication more bioavailable the simple nature of PGS production favours its industrial production even locally.

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