

EVALUATION OF SORGHUM STARCH AS A TABLET EXCIPIENT

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ABSTRACT

The suitability of sorghum starch as a binder and disintegrant at various concentrations in diverse tablet formulations have been investigated. Sodium bicarbonate and calcium carbonate were used as soluble and insoluble inorganic medicinal substances in various tablet formulations.

The effect of sorghum starch on the physical properties of the tablets were compared with those formulated with maize starch using the same concentrations of binder and disintegrant under the same experimental conditions.

The observations show that sorghum starch can be used as binder and disintegrant in tablet formulations. The indication is that the starch exhibit about twice the disintegrant power and about the same binding efficacy compared to maize starch.

INTRODUCTION

Starch is one of the most widely distributed substances in nature, occurring in most plants and sometimes in abundant quantity. It is the most commonly employed adjuvant in the formulation of tablets.

The suitable physico-chemical nature of starch and its relative inertness favour the choice of this substance among other excipients as a binding agent, disintegrant and diluent.

In recent years, Pharmaceutical Scientists have been giving increasing attention to the extraction, development and use of starches in the formulation of solid dosage forms.

No significant work has been reported on the potentials of sorghum starch for pharmaceutical utilization. The fundamental aim of this study is to ascertain the usefulness or otherwise of sorghum starch as a binder and disintegrant in tablet formulations.

EXPERIMENTAL MATERIALS

Sodium bicarbonate and Talc were obtained from BDH Chemicals Ltd., Poole, England. Calcium Carbonate (Shermond, Sussex, England). Magnesium stearate from Hopkins and William's United Kingdom.

Maize starch used was obtained from May and Baker Ltd., Dagenham, England.

The sorghum starch was prepared in the Laboratory using a modified method of starch extraction.⁴

METHODS

Method of Starch Analysis

The wet granulation method was used to prepare granules of the drugs. All ingredients except the binding agents were dry mixed using pestle and mortar for 10 minutes. In the first batches, the binder concentration was kept constant, while the percentages of disintegrant were varied.

In the second batches, the percentage of disintegrant was kept constant, while the concentrations of binder were varied. In both batches the disintegrants were added as endo- and exo-disintegrant.

A constant massing time of 8 minutes was used for all the batches, using sufficient quantity of binder.

The wet masses were passed through a mesh sieve of 1.60mm size in an oscillating granulator (Erweka apparatebau Type F.G.S. made in Western Germany). The granules were dried at 40°C for four hours in a hot air oven (Gallenkamp Oven BS size three) and resieved again through 1.60mm size sieve.

The exo-disintegrant and 0.25% w/w of 1:1 Talc and magnesium stearate mixture were added and thoroughly mixed by rotating in plastic bottle at different angles for 10 minutes.

COMPRESSION

300mg tablets of sodium bicarbonate and calcium carbonate were prepared by compressing granules (250µm - 1.00mm size fractions) in a single punch tableting machine (Manesty) fitted with 10.00mm die per minute and a fixed compression pressure setting at 3.0 units for sodium bicarbonate and 5.0 units for calcium carbonate.

Evaluation of Tablets

The tablets formulated from both sorghum and maize starches respectively were evaluated on the basis of hardness, friability, and disintegration time.

Hardness: The hardness of the tablets were determined using Monsanto hardness tester, 24 hours after ejection to allow elastic recovery and hardness. Ten tablets were tested for each batch.

Friability Test: The friability values were determined by rotating twenty weighed tablets in a Roche friabilator at 25 r.p.m. for 5 minutes.

Disintegration Test: The test was carried out by the method prescribed in the British Pharmacopoeia, 1980, using the Manesty tablet disintegration test unit.

The medium was distilled water thermostated at the temperature of $37 \pm 1^\circ\text{C}$. The mean disintegration times of six tablets were determined.

TABLE 1

Effect of the Starches Employed as Disintegrant on Physical Properties of the Tablets

Types of Disinte-grant	Disintegrant Conc. % w/w	Hardness KgF		Friability %		Disintegration Time (min)	
		A	B	A	B	A	B
Sorghum	2.50	13.13	7.60	0.64	0.69	6.22	3.93
Starch	5.00	13.94	7.90	0.62	0.55	4.00	3.00
	7.50	15.00	8.40	0.52	0.46	3.85	1.87
	10.00	16.70	10.10	0.46	0.40	3.48	1.87
Maize	2.50	13.43	7.80	0.49	0.52	10.63	5.83
Starch	5.00	14.75	8.40	0.42	0.40	8.20	4.13
	7.50	15.20	12.10	0.48	0.50	7.00	3.58
	10.00	16.86	13.25	0.34	0.39	6.58	2.90

Note: The binder concentrations of both starches were kept constant at 10% w/w.

Keys: A = Sodium bicarbonate 300mg tablets

B = Calcium carbonate 300mg tablets

TABLE 2

Effect of the Starches Employed as Binder on Physical Properties of the Tablets.

Type of Binder	Binder Conc-entration %	Hardness Kgf		Friability %		Disintegration Time (min)	
Sorghum	5.00	11.31	6.01	0.79	0.75	2.20	1.80
Starch	10.00	13.13	7.60	0.64	0.59	6.22	3.93
	15.00	16.20	11.50	0.46	0.39	7.80	4.85
Maize	5.00	12.20	6.85	0.50	0.69	8.16	3.97
Starch	10.00	13.43	7.80	0.49	0.52	10.63	5.83
	15.00	16.87	12.80	0.40	0.35	13.00	7.33

Note: The percentage of disintegrant in both starches were kept constant at 2.50% w/w

Keys: A = Sodium bicarbonate 300mg tablets

B = Calcium carbonate 300mg tablets

RESULTS AND DISCUSSION

The size distributions of the granules prepared from both starches were comparable. The granules became larger and showed wider size distribution with increase in binder concentration. This can be ascribed to an increase in the number of bond formation with increasing concentration of the binders or to the increase in the penetration, covering or wetting of the drug particle by binder mucilage.¹

The values of moisture contents in all the batches were less than 2% w/w. This eliminated the effects of moisture on the consolidation of granules and the quality of tablets.

Flowability results show the granules prepared from sorghum starch as binder and disintegrant had faster flow than granules prepared with maize starch.

Granules had slight decrease in tapped bulk density and flow times with increasing concentrations of the starch mucilages. This seems to be consistent with the observed increase in granule sizes. Tables 1 and 2 summarizes the results of the effects of both sorghum and maize starch on the hardness and friability.

When the starches were employed as binder, increasing their concentration increased the hardness of the tablets. The concentration of binding agent determines the amount of solid bonding that takes place between the particles due to asperity melting, plastic and elastic deformation of the particles. The number and strength of bonds formed depend on the nature and amount of binder employed. Since the tablets in this study were compared at a constant compression pressure, the higher the concentration of starch mucilage used, the greater the amount of bonding taking place and the harder the tablets.^{2,3}

A significant correlation was observed between the concentration of starch mucilages employed as binder and the friability values. There was a decrease in friability, with increase in starch mucilage concentration.

Increase in starch mucilage concentration will therefore result in a corresponding increase in interparticulate cohesive-

ness, strength of tablets and a resulting decrease in friability values as observed in this study.

The hardness and friability values of tablets formulated with sorghum starch as binder were comparable with those of maize starch.

It was also observed that increasing the concentration of binder extended disintegration times. The increase was higher in formulations prepared with maize starch than sorghum and can be ascribed to the formation of a thin film of the starch mucilage around the granules with varying thickness depending on the quantity of mucilage employed.

CONCLUSION

A comparative study of the binding and disintegrating properties of sorghum and maize starch in tablet formulations containing inorganic medicinal agents has been made.

Various concentrations of the starches as binder and disintegrant were used and the possible effects of concentration changes were observed.

Sorghum starch compared favourable with maize starch as binder and disintegrant with respect to all the parameters used to evaluate the tablets and in some cases gave more satisfactory results especially in terms of disintegrating efficiency.

The study indicates the good potential of sorghum starch for use as a binder and disintegrant in tablet formulation.

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