J. Pharm. Pharmacol. 1982, 34: 761–765
Received March 18, 1982

0022–3573/82/120761–05 $02.50/0

An evaluation of starch obtained from plantain *Musa paradisiaca* as a binder and disintegrant for compressed tablets

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The binding and disintegrant properties of plantain starch obtained from *Musa paradisiaca*, family Musaceae, have been evaluated. Its effect in tablets of paracetamol and chloroquine phosphate on their physical properties such as hardness, friability and disintegration time was compared with tablets prepared with maize starch. The results show that plantain starch can be used both as a tablet binder and disintegrant in the preparation of tablets and the indication is that plantain starch has about twice the binding efficiency and about half the disintegrant power of maize starch.

Paracetamol and chloroquine phosphate tablets formulated to contain 500 and 250 mg drug per tablet respectively, with appropriate amounts of starch and other excipients are now made in Nigeria by many indigenous manufacturers. They most frequently use maize starch in the preparation of these tablets and it is divided into two portions before adding to the formulations. One part is added to the powdered formula before granulation and acts as a disintegrant and the remainder is incorporated in the form of a mucilage and acts as a binder.

This method has been adopted for the evaluation of plantain starch as a disintegrant and as well as a binder in the two tablet formulations.

Plantain (*Musa paradisiaca*, family Musaceae), is a herbaceous plant closely related to the banana but its fruit is longer and more starchy than the banana. These plants grow abundantly in Nigeria and are used extensively as food. The mature unripe fruits contain the highest amount of starch in the plant (Shantha 1970). Patel & Joshi (1959) have evaluated banana starch as a possible disintegrant in some tablet formulations. But only the swelling, solubility patterns and rheological properties of plantain starch have been reported (Rasper 1969).

Since plantain is a locally available bulk produced commodity from which the starch can be easily obtained we have compared it with maize starch as a tablet disintegrant and binder.

MATERIALS AND METHODS

Materials

The materials were pharmaceutical grades of paracetamol and chloroquine powders obtained from May & Baker (W. Germany); maize starch from BDH Laboratories (U.K.); magnesium stearate was from Hopkins & Williams (U.K.); talc was from E. Merck (W. Germany).

All other chemicals were of reagent grade and were used as supplied.

Preparation of plantain starch

The unripe fruits of plantain purchased from the local market were peeled, washed, cut into pieces and reduced to a fine pulp in a liquidizer with a small amount of water added. The pulped material was passed through fine muslin to remove the cell debris and the milky liquid collected, filtered through a fine sieve and allowed to settle. The sedimented starch was washed several times with water followed by sieving each stage of the washing. Crystals of L-cystine were added to inhibit the enzyme responsible for discolouration of starch on exposure to air (Montgomery & Sgarbieri 1975). The starch was again washed several times with water to remove the L-cystine. It was sieved and dried at 50 °C for 24 h then reduced to powder and again sieved. The powder so obtained complied with the specifications laid down in the B.P. 1980 for starches.

Preparation of formulation and granules

The compositions of the two standard tablet formulations (paracetamol and chloroquine) are given in Table 1.

Batches (90 g) of the mixture were prepared by weighing out all the ingredients except the binding agent, dry-mixing them in a planetary mixer for 10 min. An appropriate quantity of freshly prepared maize or plantain starch mucilages was added as the

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Table 1. Standard formulations for paracetamol and chloroquine phosphate per tablet used (in mg).

	Paracetamol 500	Chloroquine phosphate 500
A. Maize and plantain starches used in the form of mucilage (i.e. as binders)		
Starch (as disintegrant)	25 (5%)	50 (10%)
Starch mucilage (as binder)	31·5; 52; 72; 10·5 (3%, 5%, 8%, 10%)	15·8; 31·5; 52; 72 (1·5%, 3%, 5%, 7%)
Talc	10·80	16
Magnesium stearate	0·80	0·80
Note: The starch concentrations used as disintegrants were kept constant as stated above.		
B. Maize and Plantain starches used as disintegrants		
Starch (as disintegrant)	15; 25; 35; 50 (3%, 5%, 7%, 10%)	15; 25; 50; 75 (3%, 5%, 10%, 15%)
Starch mucilage (as binder)	72·5 (10%)	52·5 (7%)
Talc	10·80	16
Magnesium stearate	0·80	0·80

granulating agent and mixed for a further period of 5 min.

The wet masses were then granulated by passing through a No. 10 mesh sieve, dried at 60 °C for 12 h, and resieved through a No. 16 mesh sieve. Finely sifted magnesium stearate and talc were weighed, added to the granules and intimately mixed.

Compression of tablets

Tablets were compressed in a single punch machine (The Kilian and Co. GMBH, KOLN-NIEHI Type K5) fitted with 12·5 mm flat-faced punches. The granules were compressed into tablets containing 500 mg of paracetamol and chloroquine phosphate respectively in each tablet. The machine compression force dial was kept constant at 7·25 units when the starches were employed as binders and at 7·5 units when they were used as disintegrants.

Hardness determination

Hardnesses of the tablets were determined using the Schleuniger Hardness Tester. Ten tablets from each batch were used in each determination and the mean and the standard error were calculated.

Friability determination

An improvised friabilator was made from a Gallenkamp flask shaker. Ten tablets from each batch were placed in a flask, clamped to the shaker and allowed to run for 10 min at the rate of 100 rev min^{-1}. The percent loss in weight was calculated as the friability.

Disintegration time measurement

The Manesty Tablet Disintegration Test Unit was used. The disintegration medium was distilled water maintained at 37 ± 1 °C. The mean and standard error were calculated from the results for ten tablets from each batch.

RESULTS AND DISCUSSION

The effects of the starches in the form of mucilage (i.e. as binders) on the hardness of the paracetamol and chloroquine phosphate tablets with one concentration of disintegrant starch are shown in Fig. 1. Increasing the starch mucilage concentration increased the hardness of the tablets. This is consistent with previous work on starches and other binders (Yen 1964; Sakr et al 1972; Davis & Gloor 1972; and Esezobo & Pilpel 1976). This is to be expected as it has been shown (Pietsch 1967; York & Pilpel 1972, 1973) that the amount of bonding that takes place between the particles due to asperity melting and plastic and elastic deformation of the particles, and hence the hardness of the tablets, depends on the compressing force and the amount of binding agent present. Since the tablets in the present study were compressed at a constant compression force, it is assumed that the greater the amount of starch mucilage employed, the greater the amount of bonding taking place, and, therefore, the harder the tablets.

It is also seen in Fig. 1, that for both drugs, the hardness of their tablets varied with the type of starch employed. Tablets prepared with plantain starch mucilage gave tablets with greater hardness than those made with maize starch mucilage. With paracetamol tablets, a 3% w/w plantain starch mucilage gave the same hardness as 5% w/w maize starch mucilage while, for chloroquine tablets, 1·5% w/w plantain starch mucilage gave hardness values equivalent to 3% w/w maize starch mucilage indicating that plantain starch has about twice the binding efficiency of maize starch.

When the starches were used as disintegrants (Fig. 2) and their binder concentration was kept constant, increase in disintegrant concentrations increased the hardness of the tablets, up to a maximum—probably to a point where better packing of the granules in the tablet structure was attained—and then remained more or less constant with further addition of starch. The reason for the initial slight increase in hardness with both formulations is due to small proportion of the starch added to the formulation that was wetted during the granulation stage and acted as a binder (King 1970; Pilpel et al 1978).

The graphs showing the effect of the starch mucilages on the friability of the tablets (Fig. 1) show a decrease in friability with increase in starch

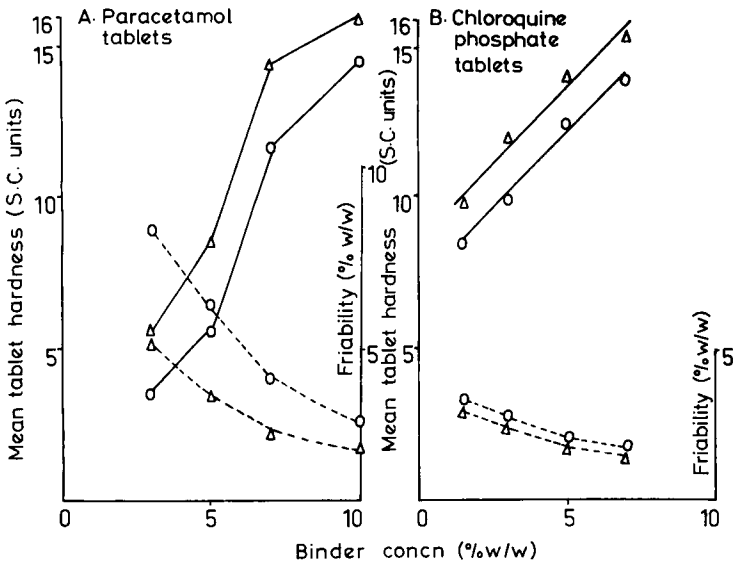

FIG. 1. Effects of concentration of the starches employed as binders on the hardness (——) and friability (– – –) of the tablets. A Paracetamol tablets. B Chloroquine phosphate tablets. △ Plantain starch; ○ Maize starch.

mucilage concentration. This result accords well with those of Hill (1976) and the result is as expected since friability is a measure of interparticulate cohesiveness in tablets and could be a function of tablet hardness. Hence it is sometimes employed as an alternative approach in assessing the hardness of tablets. Thus, increase in the starch mucilage concentration results in a corresponding increase in interparticulate cohesiveness and strength of the tablets and therefore a decrease in friability with starch mucilage concentration. Tablets prepared with maize starch mucilage were generally more friable than those made with plantain starch mucilage.

The disintegrant effect on the friability of the tablets is shown in Fig. 2 where it is seen that the

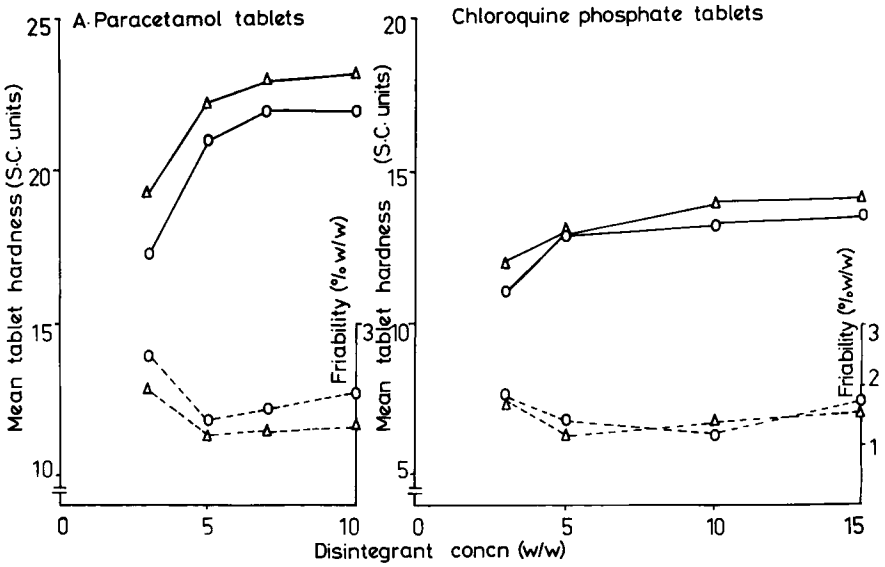

FIG. 2. Effects of concentration of the starches employed as disintegrants on the hardness and friability of the tablets. The symbols as in Fig. 1.

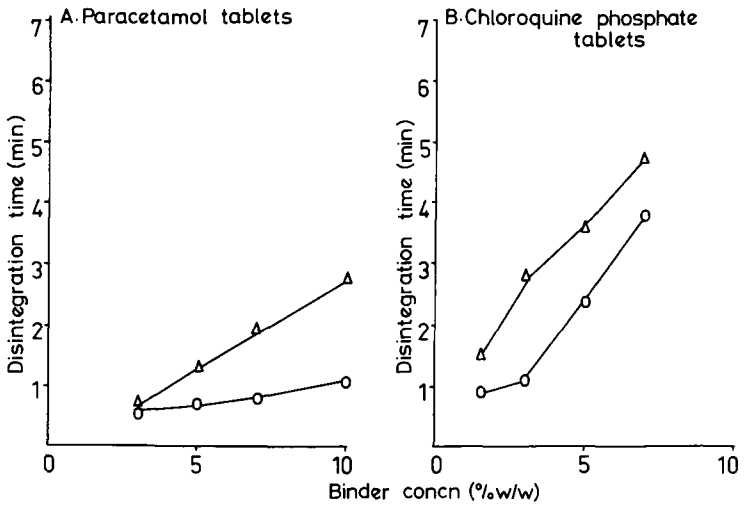

FIG. 3. Effects of concentration of the starches employed as binders on the disintegration of the tablets. △ Plantain starch. ○ Maize starch.

friability of both tablets decreased and attained a minimum value and then remained more or less constant with further starch added. Although for chloroquine tablets, the friability values are closely similar for both starches, for paracetamol tablets, plantain starch clearly produced the less-friabile tablets. This corresponds, again, to their effects on the hardness of the tablets.

From the disintegration results, it is seen (Fig. 3) that increasing the starch mucilage concentration, resulted in an increase in disintegration time; the increase being much higher with plantain starch than with maize starch. The increase in disintegration time with increase in starch mucilage or binder concentration has been shown by various workers (Yen 1964; Esezobo & Pilpel 1976; Pilpel et al 1978)

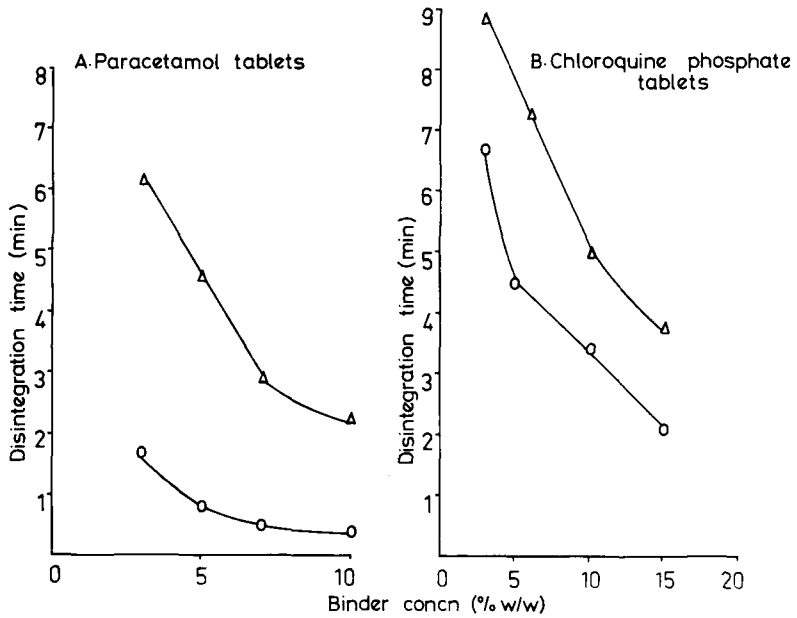

FIG. 4. Effects of concentration of the starches employed as disintegrants on the disintegration of the tablets. △ Plantain starch, ○ Maize starch.

and is attributed to the formation of a thin film of the starch mucilage around the granules with a thickness depending on the quantity of mucilage employed. In the presence of water this thin film is converted into a mucilagenous, viscous barrier between the granules and the water (Huber et al 1966), retarding the disintegration of the granule (Pilpel et al 1978). Thus, at the same concentration, plantain starch forms a thicker film round the granules and hence causes longer disintegration times than maize starch.

The addition of starch as a disintegrant to both formulations produced a decrease in the disintegration times of the tablets (Fig. 4). Tablets formulated with maize starch as disintegrant giving faster disintegration times than those formulated with plantain starch.

For all samples investigated, tablets of paracetamol (a relatively water insoluble drug—solubility is 1 in 70) disintegrated faster than tablets of chloroquine phosphate (a relatively water-soluble drug—solubility is 1 in 4). Similar observations have been reported by Shteingart et al (1970) and has been ascribed to the diminished water absorbing capacity of the starches in the later case.

Conclusion

Plantain starch compares favourably with maize starch and could be a good substitute for maize starch in the formulation of paracetamol and chloroquine phosphate tablets. Plantain starch is a better binder since it gives harder, glossier and less friable tablets than maize starch but it is a poorer disintegrant. The study also indicates that tablets of paracetamol (a relatively less soluble drug than chloroquine phosphate) disintegrated faster with both plantain and maize starches than tablets of chloroquine phosphate.

Acknowledgements

The authors wish to thank Miss Anna O. Ehighakhuo for carrying out part of the work.

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