

Full Length Research Paper

Performance of starch obtained from *Dioscorea dumetorium* as disintegrant in sodium salicylate tablets

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Starch obtained from *Dioscorea dumetorium* was employed as a disintegrant in Sodium Salicylate based tablets at concentrations of 5 –15 %w/w. Properties of the starch evaluated include: bulk and tapped densities, water uptake by capillarity, Hausner's quotient and percent compressibility. Compound tablets were evaluated for hardness, friability, disintegration time and dissolution rate. Batches of tablets containing equivalent concentrations of AC-di-sol or maize starch were employed as standards. Results obtained indicate that *Dioscorea dumetorium* starch performed as much better as a disintegrant in sodium salicylate tablets as maize starch but less than Ac-di-sol.

Key words: Disintegrant, starch, *Dioscorea dumetorium*, sodium salicylate.

INTRODUCTION

Disintegrants constitute one of the principal tablets excipients. They cause the intact tablets to rupture when in contact with moisture; hence they oppose the effect of binders. They effect the disintegration of tablets either by swelling, by improving the penetration of aqueous liquid or by the mechanism of effervescent base, Rawlings (1982). In the context of tablet technology, disintegrants are added either intragranularly or extragranularly in specific proportions for effective and optimum activity, Feinstein, (1966). Starches are used extensively in pharmaceutical industries as disintegrants, binders and lubricants in tablets formulations. Some authors have studied the use of starch obtained from banana species and sago as disintegrants in tablet formulations, (Patel and Chulikia, 1983). Similarly, the use of cassava and yams starches as tablet disintegrant have been studied, (Mital and Ocran, 1968). The effect of various starches on the physical standards of sulfaguanidine tablets were studied (Sakr et al., 1967). They showed that all tablets made

with the starches show a decrease in disintegration time with increasing concentration. However, this behaviour could vary depending on type of other ingredients present in the formulation, Wagner (1971). Several authors were able to establish a relationship between disintegration time and water absorption capacity of starches, (Jaminet et al, 1971). Starch is believed to exert its disintegrating property by absorption of moisture and swelling of the grains followed by rupture of tablet core, (Jaminet et al., 1971). Many other mechanisms have been postulated for the disintegration process in tablets. These include wetting, (Nagami et al., 1966) evolution of gases, adsorption, Matsumaru, (1958) porosity, (Higuchi, 1963), deformation, (Lowenthal, 1972; Ingram and Lowenthal, 1972; Lowenthal, 1973). Many authors have continued to assess their disintegrant candidates by water absorption and swelling.

Dioscorea dumetorium, also known as African bitter yam, three-leaved yam, cluster yam or wild cluster yam is widely cultivated and the tuber is eaten in Eastern Nigeria. It has approximate starch content of 20% w/w. The appreciable starch content as well as its local availability motivated this work. We have thus, investigated the disintegrant properties of its starch content and compared

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it with maize starch and Ac-di-sol.

Experimental

Materials

The following materials and chemicals were used as procured from their manufacturers without further purification, sodium salicylate, maize starch BP, Hydrochloric acid, lactose (May and Baker, England), Ac-di-sol (FMC, Philadelphia), acacia, methanol (Merck, Germany) and magnesium stearate (Hopkins and Williams, U.K).

METHODS

Extraction of *Dioscorea dumetorium* starch

Tubers of *D. dumetorium* were obtained locally from Nsukka Central Market in Enugu State of Nigeria. Starch was extracted using a method reported previously, (Mital and Ocran, 1968). The tubers were washed free of soil and then peeled, peeled tubers were cut to small sizes and grated. The grated portion was soaked in water and sieved using a nylon sieve. This ensured the removal of unwanted debris. The starch slurry was collected in a large basin and allowed to settle for 10 h. The supernatant was decanted. The resultant starch slurry was severally washed with distilled water while passing through a 100-mesh sieve. The final starch slurry was allowed to settle for 10 h, decanted and dried to a constant weight in a hot air oven set at 60°C for 2 h. The dried starch was pulverized, passed through a 200 – mesh sieve and stored in well closed container.

Weighed quantity of the starch (100 g) was defatted with 85% aqueous methanol according to the method previously described by Schoch (1942). The starch was subjected to some micromeritic (particle size and particle size distribution) evaluation using standard methods.

Determination of bulk and tapped densities

Exactly 50 g of the *D. dumetorium* starch was weighed on a chemical balance and transferred into a dry 100 ml measuring cylinder. The cylinder was dropped from a height of 2.5 cm three times at 2 s intervals. The volume occupied by the starch was recorded as the bulk volume. The cylinder was then tapped on the wooden platform until the volume occupied by the starch remained constant. This was repeated three times and average bulk volume and tapped volume recorded. The same procedure was repeated for the other starches and results obtained. The Hausner's quotients and Carr's compressibility indices were thus calculated.

Determination of the rate of water uptake

This was done following a modification of the capillary rise method (Singh et al., 1968). Exactly 2 g of *D. dumetorium* starch was dried to a constant weight. A capillary tube of 3.14 mm diameter was filled with the starch and immersed in a container containing 20 ml of amaranth solution. The rise of the solution in the capillary tube was measured at predetermined time intervals. This procedure was repeated, but this time the void spaces in the starch contained in the capillary tube were reduced by tapping to a constant height. In another experiment, 0.1 N Hydrochloric acid (HCl) was employed in place of amaranth solution. Values reported represent means of replicate determinations. Ac-di-sol and maize starch employed as standards were similarly treated.

Preparation of sodium salicylate tablets

Batches of sodium salicylate tablets were prepared using the well-known wet granulation method. *D. dumetorium* starch was employed in concentration of 5, 10, and 15% w/w. Each tablet contained, in addition to the intragranularly added disintegrant, 50 mg of sodium salicylate, 10% w/w of acacia as binder, 1% w/w magnesium stearate as lubricant; all ingredients to a target weight of 120 mg. The prepared granules were compressed at a constant compressional pressure setting in a 15-station rotary tablet punch machine. Tablets containing equivalent concentrations of Ac-di-sol or maize starch were similarly prepared.

In-vitro tablet tests

Uniformity of weight

The BP 1980 method was adopted. Twenty tablets randomly selected from each batch were employed. The average weight of the tablet was estimated and deviation of each tablet from the average weight calculated. Statistical method was used to analyse the data.

Crushing strength and friability test

Crushing strength of prepared tablets were determined 24 h after compression. The Erweka hardness tester (TB- 28 model) was used. Values presented represent mean of ten determinations. Tablet friability was determined by subjecting ten tablets from each batch to shock at 25 rpm for 4 min in an Erweka friabilator (TAR-Model). Percent loss in weight was taken as the friability in each case.

Disintegration time test

The disintegration was determined according to the USP XXI method. The Erweka disintegration apparatus (Erweka apparatus, Type 2T4 GMBH) was used. Disintegration medium consisted of 0.1 N HCl maintained at 37±1°C. Values presented represent mean of six determinations.

Dissolution profile

The magnetic stirrer, static basket method, a modification of the USP method was adopted. Dissolution medium consisted of 500 ml of freshly prepared 0.1 N HCl maintained at 37±1°C. The magnetic stirrer was operated at 100 rpm. One tablet from each batch was placed in the basket. A 5 ml volume of the dissolution medium was withdrawn at predetermined intervals and analyzed spectrophotometrically for sodium salicylate content after colour development with 2 ml of 5% ferric chloride. For each 5 ml withdrawn, 5 ml of 0.1 N HCl the same temperature was added to the content of the dissolution medium.

RESULTS AND DISCUSSION

The bulk density of 0.4766 g/cm³ and tapped density of 0.6767 g/cm³ were obtained for *D. dumetorium* starch compared with values of 0.4597 and 0.6767 g/cm³ respectively obtained for maize starch. Thus, the Hausner's quotient and Carr's compressibility indices for the two starches were 1.4198 and 29.57% and 0.9833 and 32.50% respectively. Ac-di-sol exhibited values slightly

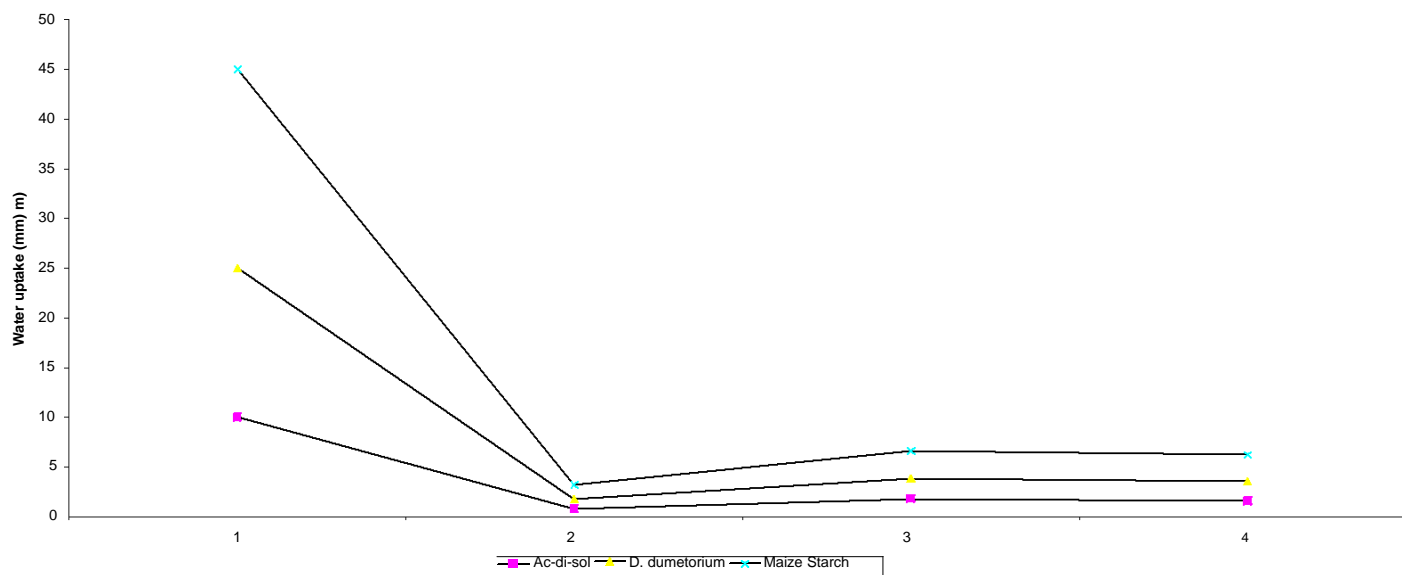


Figure 1. Graph of water uptake Vs. time by capillary method for untapped powder in distilled water.

lower than those exhibited by the two starches, 0.3636 and 0.5263 g/cm³ respectively. Its Hausner's quotient and Carr's compressibility index were 1.4475 and 30.91% respectively.

These values indicate poor flowing powders, (Guyot-Herman and Lebiane, 1985).

Water uptake of *D. dumetorium* starch

Results obtained from the water uptake studies show that water penetration into *D. dumetorium* starch was slightly faster than the penetration obtained with maize starch. The two starches, however, showed a close and similar trend in water uptake. This indicates that both starches may be exerting their disintegrant action by a similar or common mechanism. The slowest water rise occurred with Ac-di-sol, which swelled as it absorbed the water, a behaviour that was absent in *D. dumetorium* and maize starch. There is the indication that Ac-di-sol which is a fast disintegrant act differently and by swelling. The result is presented in Figure 1. Figure 2 and 3 shows the effect of tapping on water penetration into the three disintegrants. Higher water penetration occurred in the tapped powdered starches (*D. dumetorium* and maize starch). For powdered materials whose water uptake is by capillarity, water uptake by capillary attraction is facilitated as the powder particles become more closely packed. This can be achieved by tapping the powder, thereby reducing the air spaces that act as bridges. On the other hand, tapping produced a slight reduction in water uptake by Ac-di-sol. Materials which swell when in contact with water have great tendency to form gelled network that retard water penetration. There was a little reduction in fluid penetration into *D. dumetorium* and maize starches

when 0.1 N HCl was used. A slight increase in fluid penetration occurred in Ac-di-sol. Ac-di-sol has higher affinity for HCl than *D. dumetorium* and maize starch which may undergo hydrolysis in the acid medium.

In vitro tablet properties

All the tablet batches exhibited narrow weight variations as shown by their relatively low value of coefficient of variation (Table 1). They could therefore be considered acceptable on the basis of weight variation test. Gross variations in the weight of tablets would result from improper mixing during the granulation process and from incorrect machine setting. The size and distribution of the compressed granules could also affect the tablet weight.

The mean crushing strength of the tablets shown on Table 1 indicates slight increase in crushing strength with increase in the concentration of maize starch or Ac-di-sol. The crushing strength of tablets containing *D. dumetorium* starch increased as the disintegrant concentration was increased to 10% w/w after which it remained almost constant. All the tablet batches containing *D. dumetorium* or maize starch could be considered acceptable on the basis of their friability values, while only the batch containing 10% w/w of the Ac-di-sol could be considered acceptable. Usually, conventionally compressed tablets exhibiting friability values less than one are considered acceptable (Gordon et al., 1990). While increase in concentration of *D. dumetorium* starch led to increase in the friability values, those containing maize starch or Ac-di-sol did not follow any regular trend. A correlation could not therefore be established between tablet crushing strength and friability in this study.

All the three disintegrants exhibited concentration de-

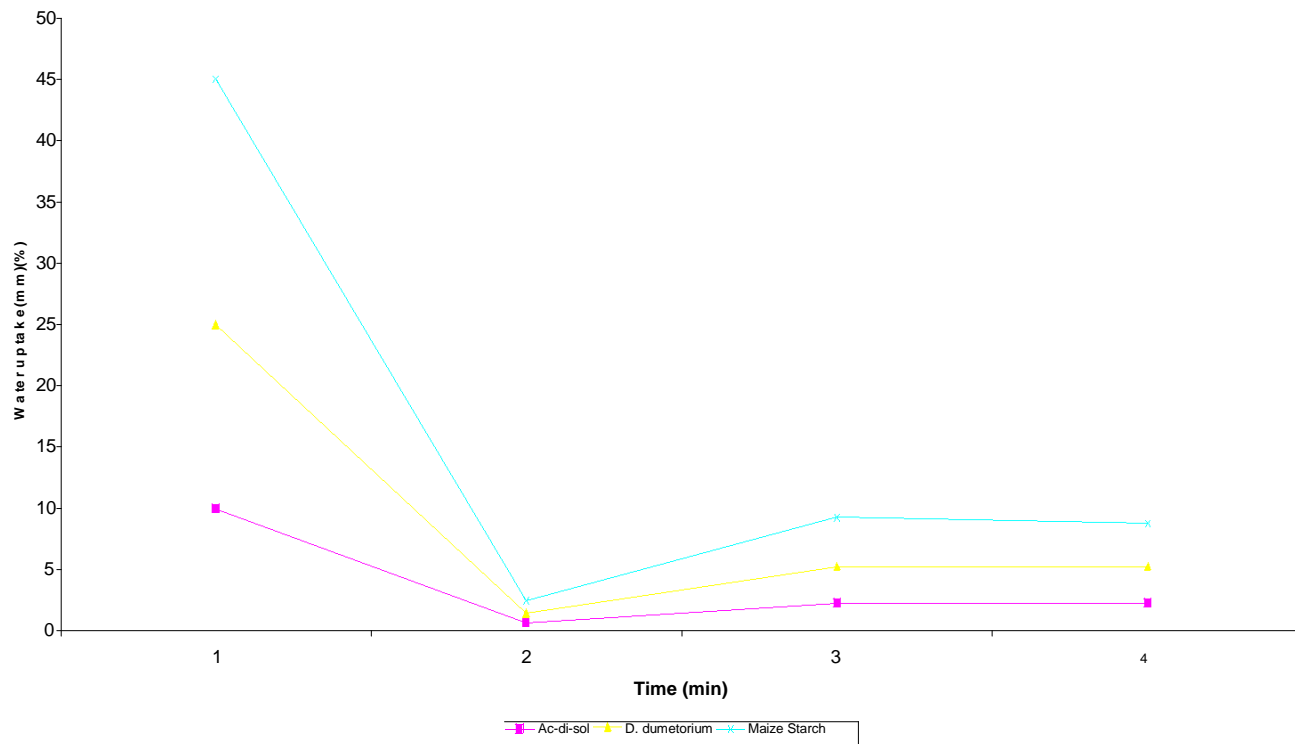


Figure 2. Graph of water uptake Vs. time by capillary method for tapped powder in distilled water

Table 1. Some *in vitro* tablet properties

Parameter	Disintegrant (% w/w)								
	<i>D. dumetorium</i>			Maize starch			Ac-di-sol		
	5	10	15	5	10	15	5	10	15
Mean Crushing									
Strenght (N)	5.00	5.20	5.15	5.17	5.35	5.05	5.55	5.15	5.25
Friability (%)	0.357	0.667	0.667	0.714	0.346	0.984	1.333	0.660	1.034
Uniformity of	293.4	295.3	297.4	297.3	295.1	293.2	293.9	295.7	296.2
Weight* (mg)	(0.505)	(0.606)	(0.463)	(0.593)	(0.597)	(0.581)	(0.664)	(0.516)	(0.624)
Disintegration Time (min)	16.0	13.0	10.0	18.0	15.0	11.0	6.0	4.0	3.0

*Figures in bracket represent coefficient of variation.

dependent disintegration times. Generally, disintegration time decreased with increase in disintegrant concentration. At all disintegrant concentrations, Ac-di-sol possessed the fastest disintegration time. This was followed by *D. dumetorium* starch and maize starch.

Conventionally, uncoated tablets are required to disintegrate within 15 min. On the basis of this, all, except batches of tablets containing 10% w/w *D. dumetorium* starch or maize starch could be considered acceptable. The slight faster disintegration times obtained with *D. dumetorium* starch at all concentrations with the rate of fluid uptake already established for the two starches. Ac-di-sol is a fast disintegrant, which acts by swelling, and its

superior disintegrant action in this study is expected.

The dissolution profile of the tablet batches are shown in Figures 4 - 6. All the tablet batches released nearly all their drug content within 20 min. As should be expected, fastest release of drug occurred in tablets containing Ac-di-sol at all concentrations. This was followed by tablets containing *D. dumetorium* starch and then maize starch. The release of sodium salicylate from the tablets was generally concentration dependent, with faster release occurring as disintegrant concentration was increased. There seem to be a correlation between disintegration time and the dissolution profile of the tablets. In conclusion, *D. dumetorium* starch could successfully be employ-

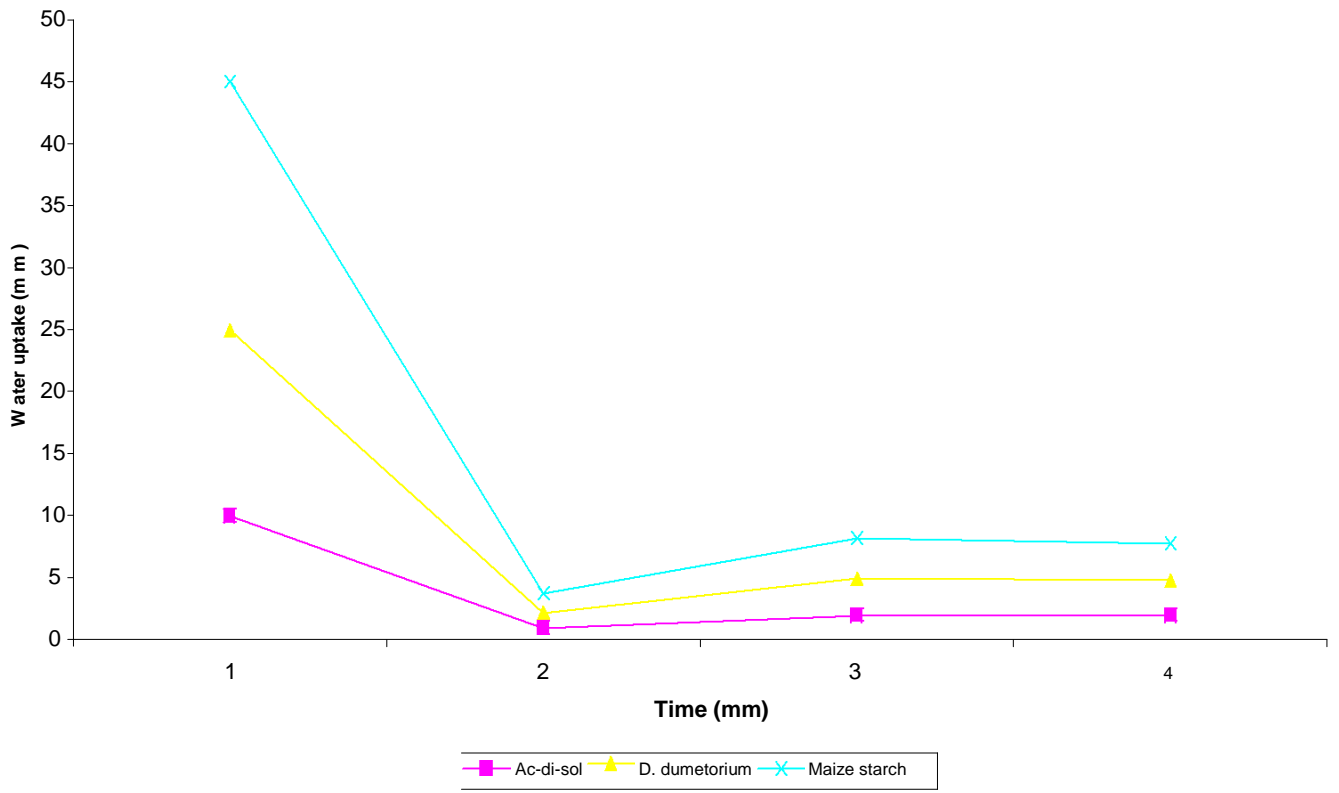


Figure 3. Graph of water uptake Vs. time by capillary method for tapped powder in 0.1 NHCl

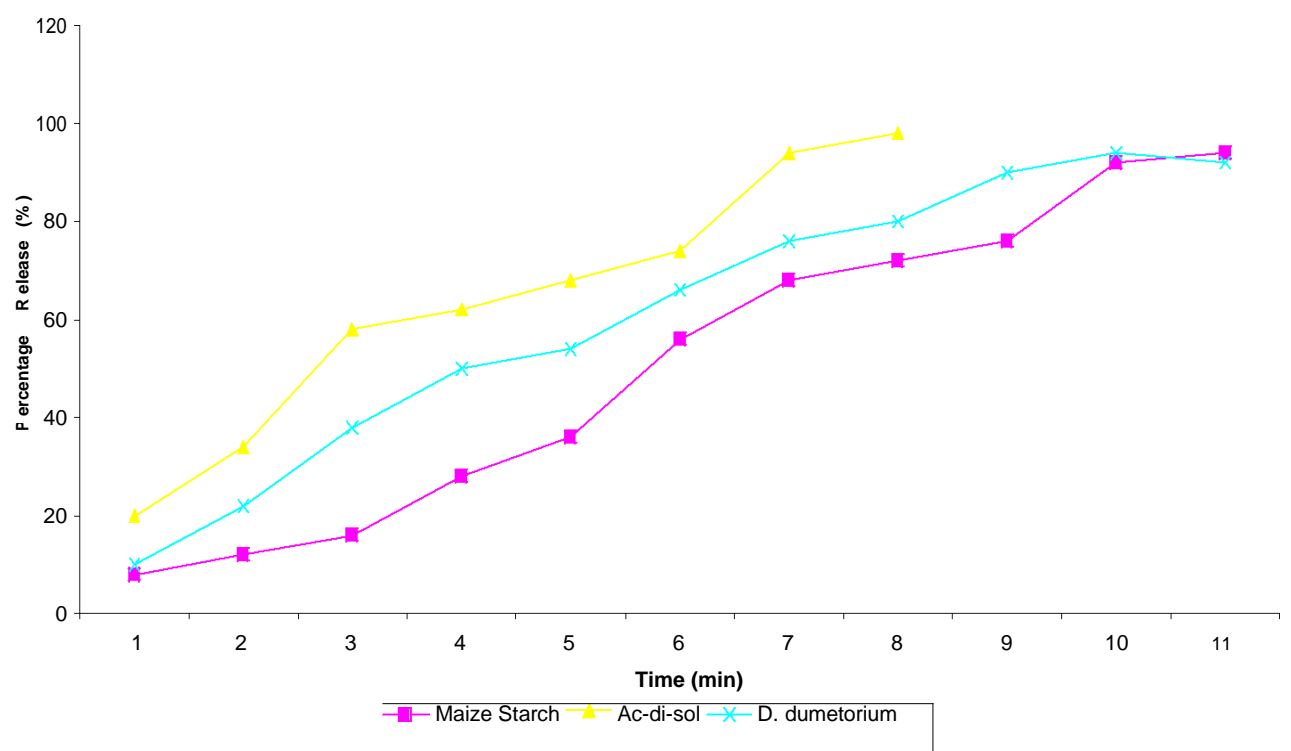


Figure 4. Graph of % Release Vs. time for 5% conc. of different disintegrant in the tablets

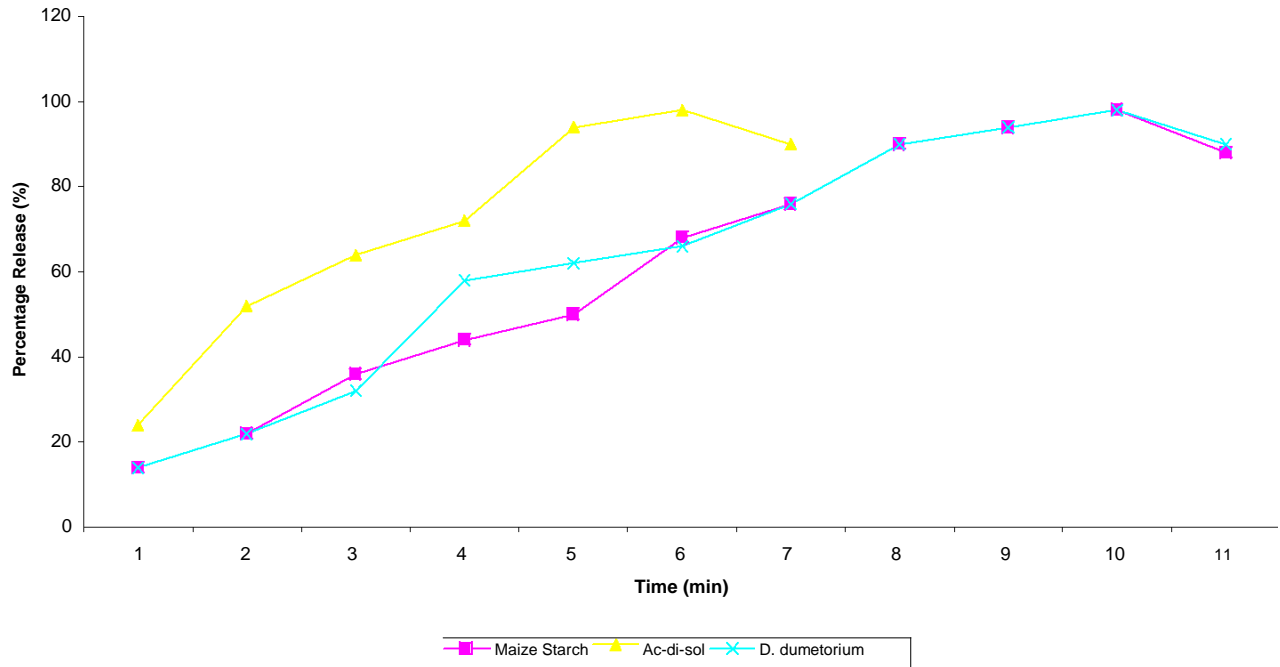


Figure 5. Graph of % release Vs. time for 10% Conc. of different disintegrants in tablets.

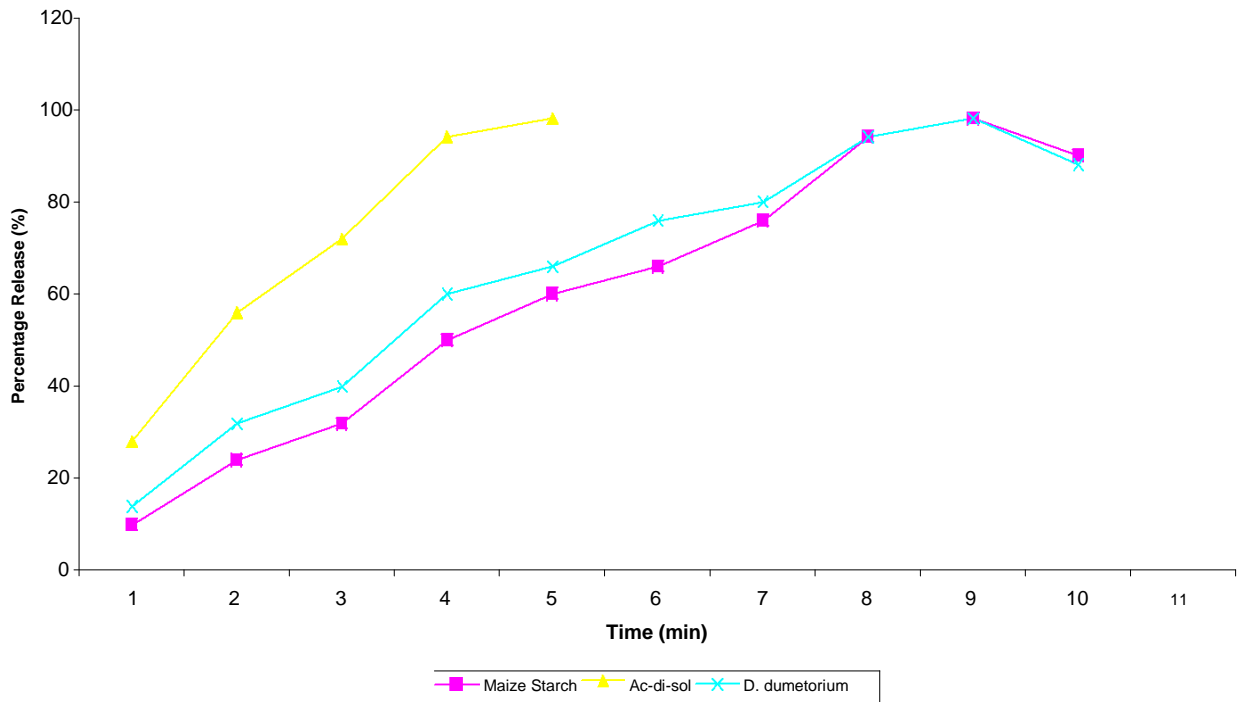


Figure 6. Graph of % release Vs. time for 15% conc. of different disintegrants in tablets.

ed as a disintegrant in a water soluble drug such as sodium salicylate at concentrations generally recommended for official starches. It compared favourably with maize starch, but was inferior to Ac-di-sol.

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