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Research Article

COMPARATIVE EVALUATION OF TAPIOCA SAGO AND POTATO STARCHES AS DISINTEGRATING AGENTS IN TABLET FORMULATION

Patil Basawaraj S.[1]*, Kodli Mohan V.[1], Kolla Durga Rao[2], Gulam Rabbani[1]
[1]R.M.E.S's College of Pharmacy, Gulbarga, Karnataka, India
[2]Luqman College of Pharmacy, Gulbarga, Karnataka, India

*Basawaraj S.Patil**,** Professor, Department of Pharmaceutics**,** RMES College of Pharmacy, Old Jewargi road, Balaji Nager, Gulbaraga, Karnatka, India. E-mail: bspatilglb17@rediffmail.com
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ABSTRACT
In the present study Tapioca sago starch was employed as a disintegrating agent in Chloroquine based tablets at concentration of 5–15% w/w. Properties of the starch were evaluated for angle of repose, bulk density, tapped density, carr's compressibility index, hausner's ratio, hydration capacity and swelling capacity. The granules were evaluated for moisture content, angle of repose, bulk density and tapped density, carr's compressibility index and hausner's ratio. The tablets were evaluated for thickness, weight variation, crushing strength, friability, disintegration time and dissolution profiles. Batches of tablets containing equivalent concentration of potato starch were employed as standard. Results obtained indicate that as a disintegrant Tapioca sago starch showed comparable results in Chloroquine phosphate tablets with the standard.

KEY WORDS: Tapioca sago starch, Chloroquine phosphate, Potato starch, Disintegrating agent, Tablets.

INTRODUCTION
Disintegrants constitute one of the principal tablets excipients. They cause the intact to rapture when in contact with moisture; hence they oppose the effect of binders. They effect the disintegration tablets either by swelling, by improving the penetration of aqueous liquid or by the mechanism of effervescent base[1]. In the context of tablet technology, disintegrants are added either intragranularly or extragranularly in specific proportions for effective and optimum activity[2]. Starches are used extensively in pharmaceutical industries as disintegrants, binders and lubricants in tablet formulations. The effect of various starches on the physical standards of sulfaguanidine tablets was studied[3]. They showed that all tablets made with starches show a decrease in disintegration tine with increasing concentration. However, this behavior could vary depending on type of other ingredients present in the formulation[4]. Several authors were able to establish a relationship between disintegration time and water absorption capacity of starches[5]. Starches are believed to exert its disintegrating property by absorption of moisture and swelling of the grains followed by rapture of tablet core[5]. Many other mechanisms have been postulated for the disintegration process in tablets. These include wetting[6], evolution of gases, adsorption[7], porosity[8], and deformation[9-11].Many authors have continued to assess their disintegrants candidate by water absorption and swelling.

Tapioca sago starch is obtained from the rhizomes of Manihot utilissima pohl. This grows mainly in equatorial climates. Depending on the region of growth, plants may be known as mandioca, yucca, cassava or tapioca[12]. Tapioca sago starch contains about 27% of the amylose[13]. Swelling property of the starch is responsible for disintegration activity of the starch. Tapioca sago starch contains high amount of amylase than other starches so it is assumed that it should have more swelling capacity and hence better disintegration property than starch from other sources. Tapioca sago starch is tasteless, odorless, white amorphous powder practically insoluble in cold water and ethanol (96%)[14]. Soluble starch is obtained by

heating ordinary starch with 10% HCl for 24 hours and then precipitating with alcohol. Starch granules vary in shape and size with source. Tapioca sago starch is very fine powder, which creaks when pressed between the fingers.

In the present work, Tapioca sago starch has been evaluated as a disintegrating agent in Chloroquine phosphate tablets formulations in compression with standard disintegrating agent, potato starch. Chloroquine phosphate was used as the model drug for the present work. The results are reported here.

MATERIALS AND METHODS

The following materials were obtained from the manufacturers, used without further purification. Chloroquine phosphate (Gift sample from Wintech Pharmaceuticals, Mumbai), Talc (BDH chemicals Ltd.), Magnesium stearate (CDH chemicals Ltd.), Potato starch (S.D. Fine chemicals Ltd.), Tapioca sago shiny beads purchased from local market and powdered in laboratory.

Evaluation of Tapioca sago starch

Bulk and tapped densities

Exactly 50 gm of Tapioca sago starch was weighed on chemical balance and transferred into a 100 ml measuring cylinder. The cylinder was dropped on a wooden platform from a height of 2.5 cm three times at 2 seconds interval. The volume occupied by the Tapioca sago starch was recorded as the bulk volume. The cylinder was then tapped on the wooden platform until the volume occupied by the Tapioca sago starch remained constant. This was repeated three times for Tapioca sago starch powder. The data generated was used in calculating the Carr's compressibility index (CI) and Hausner's ratio (HR) for the Tapioca sago starch and potato starch.[15]

$$CI = (TD - BD)100/ TD$$

$$HR = TD /BD$$

Swelling capacity

The swelling capacity of the starch powder was estimated by a modification for the method of Okamafe et al.[16] In this method the tapped volume occupied by 10 gm of the powder Vx, was noted and the powder was dispersed in 85 ml of water and the volume made upto 100 ml with water. After 24 hours of standing, the volume of sediment Vv was measured. The swelling capacity was then computed as the ratio of Vv/Vx.

Hydration capacity

A 10 gm sample was placed in each of four 15 ml plastic centrifuge tubes to which 10 ml of distilled water aws added and then stopped. The contents were mixed on a cyclometer for 2 minutes. The mixer was allowed to stand for 10 minutes and then centrifuged at 1000 for 10 minutes on absented centrifuge. The supernatant was carefully decanted. The stopper replaced and the sediment weighed. The hydration capacity (H) was taken filled in equation;[17]

$$H = \text{Sediment weight / Dry sample weight}$$

Angle of repose

50 gm of the powdered Tapioca sago starch was placed in a plugged glass funnel which had a distance of 10 cm from the flat surface. The Tapioca sago starch was then allowed to flow through the 8 mm funnel orifice by removing the cotton plug from the funnel orifice. The height of the heap (h) formed as well as the radius of the heap (r) was noted. The angle of repose (θ) was calculated as;[18]

$$\theta = \tan^{-1} h/r$$

Preparation of granules

Chloroquine phosphate were passed through sieve # 40 and mixed for 20 minutes using laboratory scale double (twin) cone mixer. Granules were prepared by wet granulation method using acacia gum solutions in concentration of 5%w/v, the damp mass was passed through sieve # 12 and granules were dried at 50^0 C for 1hour in a tray drier. The dried material was then passed through sieve # 16.

Granule analysis

Moisture content analysis

1 gm of the granules was put into a crucible and dried to constant weight in a hot air oven at 105^0C. the moisture content(MC) was deduced as difference between the initial(Wo) and final weight (Wf) of the granules expressed as a percentage and calculated as;[19]

$$MC = (Wo - Wf)100/ Wo$$

Angle of repose

50 gm of the granules was placed in a plugged glass funnel which had a distance of 10 cm from the flat surface. The granules were then allowed to flow through the 8 mm funnel orifice by removing the cotton plug from the funnel orifice. The height of the heap (h) formed as well as the radius of the heap (r) was noted. The angle of repose (θ) was calculated as;[18]

$$\theta = \tan^{-1} h/r$$

Bulk and tapped densities

Exactly 50 gm of granules was weighed on chemical balance and transferred into a 100 ml measuring cylinder. The cylinder was dropped on a wooden platform from a height of 2.5 cm three times at 2 seconds interval. The volume occupied by the granules was recorded as the bulk volume. The cylinder was then tapped on the wooden platform until the volume occupied by the Tapioca sago starch remained constant. This was repeated three times for granules. The data generated was used in calculating the Carr's compressibility index (CI) and Hausner's ratio (HR) for the Tapioca sago starch and potato starch.[15]

$$CI = (TD - BD)100/ TD$$

$$HR = TD /BD$$

Preparation of tablets

The different batches of the granules specified amount of disintegrating agent i.e. Tapioca sago and potato starches were than mixed with calculated equal quantities of magnesium stearate (0.5%) and talc (0.5%) then compressed into tablets using Rotary punching machine.

Characterization of tablets[20]

Tablet thickness

The thickness of 10 tablets each selected at random from the formulated tablets was determined using a vernier caliper and the mean of these readings was taken as the mean tablets thickness

Tablet weight uniformity

Twenty tablets were weighed individually using a digital balance with the precision of 0.05 mg and readability of 0.1 mg, from which the mean was calculated and percentage deviations determined

Crushing strength

The crushing strengths of tablets were determined individually with the Monsanto hardness tester, following 10 tablets were used and the mean crushing strength was calculated.[21]

Friability

The friability of 10 tablets was determined using Roche friabilator (Electrolab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula;

$$F = (1 - Wo / W) \times 100$$

Disintegration test

The disintegration time of tablets was determined according to the method described in the British Pharmacopoeia 1998. Six tablets were placed in each compartment of the disintegration apparatus, with water thermostated at 37 ± 1^0 C as the medium. The tablets were considered to have passed the test after the 6 tablets passed through the mesh of the apparatus in 15 minutes.

Calibration curve for Chloroquine phosphate

A stock solution of Chloroquine phosphate was prepared by dissolving 100 mg of the drug in 100 ml of 0.1 HCl. Various dilutions of the stock were made and absorbance of the various dilutions were the taken at mass of 343 nm using a UV-Visible spectrophotometer. A plot of absorbance, 'A' against

concentration, 'C' of the drug was made and the calibration curve 'K' was determined from the slope of the graph.

Dissolution tests

Drug release from different formulated tablets was performed using USP XXII, type II apparatus. 900ml of 0.1 N HCl was dissolution medium; paddle was rotated at 75 rpm with bath temperature of 37 ± 1^0. At every 10 minutes interval 5 ml of sample was withdrawn from the dissolution medium to maintain the volume constant. After filtration and appropriate dilution, the sample solutions were analyzed at 343 nm using a UV-Visible spectrophotometer. The amount of drug present in the samples was calculated.

RESULTS AND DISCUSSION

Table 1 shows the various properties of the Tapioca sago starch in comparesion to the official potato starch. Swelling which is generally accepted as an indication of tablet disintegration ability can be assessed by the determination of hydration and swelling capacity profile. The hydration as well as swelling capacity is slightly higher compared to potato starch. This due to crystallinity and arrangement of amylase and amylopectin as well as their proportion in starch granules.

The bulk and tapped densities of both Tapioca sago starch and potato starch indicate that both materials were not highly porous and are poor flowing powders. The confirmation of the non free flowing nature of Tapioca sago starch and potato starch were gotten from the fact their Hausner's ratio of 1.3394 and 1.4401 respectively and these were greater than 1.2 which indicate low inter particulate friction powder.[22] However, Tapioca sago starch possessed better flow properties than potato starch was confirmed by Carr's compressibility index of 25.3440 and 30.5608% respectively. This index as a one – point measurement does not always show the ease of consolidation of powder granules.[23] The angle of repose is known to be a measure of flowability and the angle of repose of Tapioca sago starch and potato starch were 32.49^0 and 35.25^0, it indicate poor flowing properties of powders.[24]

The precompresion parameters data for Chloroquine phosphate granules are shown in Table 2. The analysis of granules moisture content was showed that formulations has the highest moisture content and this could be attributable to the fact that it has larger average grain size[25] which implies that there are large pore size which may trap water and result in high moisture contents. Investigations have shown that moisture contents of 3-5% w/w were appropriate to produce maximum disintegration and dissolution for tablets[26].

The bulk and tapped densities exhibited by Tapioca sago starch and potato starch granules shows that both granules were good flowing. From the Hausner's ratio which are almost equal to 1.2 indicate free flowing granules. In case Carr's compressibility index, all granules possess better flow properties. The angle of repose for granules was between 23^0 to 25^0 that indicate free flowing properties of granules.[24]

The post formulation study of Chloroquine phosphate tablets were prepared with different concentration of Tapioca sago starch as well as potato starch as per the formula mentioned in Table 4. On comparing the physical property of tablets, it clear that tablets prepared from both starches showing nearly equal hardness i.e. The hardness of the tablets was within the acceptable range of 5-7 kg/cm^2, but the friability of potato starch is slightly higher as compared to tablets prepared with Tapioca sago starch. All the batches passed the uniformity of weight test. Both the disintegrants exhibited concentration dependent disintegration time decreases with increasing concentration of disintegrants. At all disintegration concentration, potato starch possesses faster disintegration time as compared to Tapioca sago starch.

The tablet thickness of all the formulations was similar and this can be attributed to their similar bulk and tapped densities and same compressional force used. The drug content is more than 98% in all tablet formulations.

Results obtained from the dissolution studies of Chloroquine phosphate tablets using Tapioca sago starch and gelatin, the drug release profile were show in fig.1. It was found that increase in the disintegrating agent concentration, the increase in the drug release. However, all the batches of the tablets were passed B.P. (2002) dissolution specification. That is that at least 70% of the drug should be released with in one hour.

The crushing strength to friability ratio (CSFR) can be used as a measure of mechanical strength of the formulated tablets. The CSFR and CSFR/DT values decreased with increasing disintegrating agent concentration.

CONCLUSION

From the foregoing, it can be concluded that Tapioca sago starch showed nearly comparable disintegrant properties with that of potato starch but at higher concentration. Thus Tapioca sago starch can be employed as an alternative source of starch for use as tablet disintegrating agent.

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Table 1: Properties of Tapioca sago starch and potato starch

Properties	Tapioca sago starch	Potato starch
Bulk density (gm/ml)	0.5750	0.5510
Tapped density (gm/ml)	0.7702	0.7935
Hausner's ratio	1.3394	1.4401
Carr's compressibility index (%)	25.3440	30.5608
Angle of repose (degrees)	32.49	35.25
Hydration capacity	0.590	0,780
Swelling capacity	26.10	1.690

Table 2: Formulation of Chloroquine phosphate tablets

Ingredients (mg)	Tablets formulated with Tapioca sago starch	Tablets formulated with Potato starch
Chloroquine phosphate	250	250
Acacia gum (binder %)	5	5
Starch (disintegrant %)	5, 10, 15	5, 10, 15
Talc (%)	0.5	0.5
Magnesium stearate (%)	0.5	0.5

Table 3: Pre compression parameters data for Chloroquine phosphate granules

Parameters	Tablets formulated with Tapioca sago starch			Tablets formulated with Potato starch		
	5%	10%	15%	5%	10%	15%
Bulk density (gm/ml)	0.5480	0.5467	0.5456	0.5014	0.5440	0.5834
Tapped density (gm/ml)	0.6612	0.6317	0.6489	0.6129	0.6542	0.6788
Hausner's ratio	1.2065	1.1554	1.1893	1.2223	1.2025	1.1635
Carr's index (%)	17.1203	13.4557	15.9192	18.1922	16.8450	14.0542
Moisture content	3.0	3.5	3.0	3.5	3.0	3.0
Angle of repose (degrees)	24.67	24.55	24.55	24.60	23.15	23.50
Formulation code	T1	T2	T3	P1	P2	P3

Table 4: Post formulation study of Chloroquine phosphate tablets

Parameters	Tablets formulated with Tapioca sago starch			Tablets formulated with Potato starch		
	5%	10%	15%	5%	10%	15%
Hardness(kg/cm^2)*	5.1±0.20	5.8±0.45	6.5±0.15	4.6±0.23	5.0±0.25	5.5±0.53
Friability (%)*	0.45±0.04	0.66±0.04	0.71±0.02	0.52±0.05	1.10±0.07	1.25±0.03
Average weight variation (%)*	1.92	2.51	2.33	1.42	1.75	2.56
Disintegration time(minutes)*	14.05±0.75	13.30±0.44	11.10±0.69	13.20±0.81	11.25±0.15	10.12±0.43
Thickness (mm)	3.25	3.25	3.33	3.26	3.29	3.30
Content uniformity (%)*	98.99±1.15	99.83±0.43	99.11±0.49	98.89±0.11	98.96±0.57	98.78±0.14
Dissolution time (After 60 minutes)*	80.25±0.24	87.16±0.28	92.11±0.21	75.29±0.13	84.45±0.54	88.12±0.36
Dissolution time (After 90 minutes)*	90.10±0.42	94.01±0.28	99.90±0.33	85.18±0.27	93.05±0.55	97.15±0.19
CSFR	11.334	8.788	9.155	8.846	4.545	4.400
CSFR/DT	0.806	0.6607	0.824	0.670	0.404	0.434

* All values are expressed as mean ±SD, n=3.

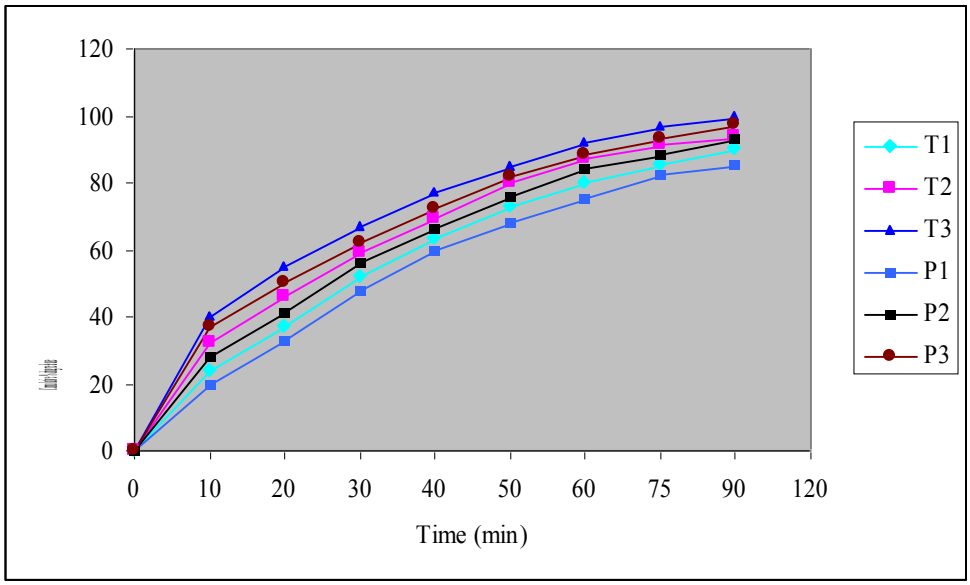

Fig. 1: Comparison of *In-vitro* dissolution profiles of different formulations.

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