



TO COMPARE THE DISINTEGRATING PROPERTY OF PAPAYA STARCH AND SAGO STARCH IN PARACETAMOL TABLETS

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ABSTRACT

Unripe papaya is a rich source of starch. It contains 43% of starch. In this study unripe papaya was taken and the pulp obtained from fresh fruit was lyophilized to obtain the pulp powder. The starch was extracted from unripe papaya pulp powder and used as disintegrant in paracetamol tablets. Sago starch is used as a second disintegrant and the *in vitro* release data of the tablets prepared from papaya pulp powder and sago starch was compared to determine the disintegrant properties of both starch. The physical properties (bulk density, true density, tapped density, angle of repose, swelling power and paste clarity) of both starches were also evaluated. For the comparison of disintegrating property ten batches were prepared using 2%, 4%, 6%, 8%, and 10% concentration of both the starch as disintegrant. The disintegration time of the tablets formulated was determined and it was found that tablets with sago starch disintegrate more rapidly than the tablets with papaya starch. The disintegration time of tablets with papaya starch was found to be 43.5, 41.7, 36.4, 34.6 and 32.3min respectively for 2%, 4%, 6%, 8% and 10% papaya starch as disintegrant. The value of disintegration time for tablets with sago starch as disintegrant was 39.8, 37.9, 36.7, 35.3 and 29.9min respectively for 2%, 4%, 6%, 8% and 10% sago starch. Other properties of the tablets (hardness, friability, weight variation and *in-vitro* release) were also evaluated.

Keywords: Papaya starch, Sago starch, Paracetamol, Disintegration time.

INTRODUCTION

Papaya fruit (*Carica papaya*) is a rich source of starch. Unripe papaya fruit contains about 43% of starch¹. Sago starch is obtained from the pith of the plant *Metroxylon sagu*². Sago starch contains about 27% of the amylose³. Swelling property of the starch is responsible for disintegration activity of the starch. Sago starch contains high amount of amylose than other starch so it is assumed that it should have more swelling capacity and hence better disintegration property than starch from other sources. Disintegrating agents are the hydrophilic substances which when comes in contact of saliva or gastric fluid absorb water, swells and cause disintegration of tablets⁴. Various types of starch from different sources have been previously screened for its disintegrating property in tablets^{5,6}.

Phytochemical screening of mature unripe pulp of *Carica papaya* (dry weight) showed the presence of saponins and cardenolides while chemical analysis revealed the presence of potassium (223.0mg/100g) as well as sodium, calcium, iron, phosphorus, zinc, copper, magnesium and manganese in considerable quantities. Proximate analysis of the pulp showed that it contained starch (43.28%), sugars (15.15%), crude protein (13.63%), crude fat (1.29%), moisture (10.65%) and fibre (1.88%). The proximate analysis shows that unripe pulp of *Carica papaya* can be ranked as carbohydrate rich fruit due to its high carbohydrate and starch contents⁴.

MATERIALS AND METHODS

Materials

Unripe papaya was obtained from local market and starch was isolated in laboratory. Sago starch was obtained from the local market in Meerut (India). Polyvinyl pyrrolidone, calcium carbonate, magnesium stearate, Talc (Central Drug House New Delhi). Paracetamol was kindly donated by Unicure Pharmaceutical limited Roorkee India.

Extraction of papaya starch

Unripe papaya purchased from a local market in Meerut and the starch was isolated using the method of Singh et al⁷. The pulp of unripe papaya was isolated and dried by lyophilisation, powdered and mixed with 0.05% w/v NaCl solution. The mass was then strained through muslin cloth and washed with saline solution several times to remove soluble substances, sugar and mucilage present. The mass obtained was then washed repeatedly until the

supernatant solution was clear. The sediment starch was washed with distilled water until the pH was neutral. It was then sieved, dried at room temperature and milled to fine powder.

Evaluation of starch

Bulk and tapped density of starch

Exactly 50 gm of starch powder 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 second interval. 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 for starch powder. The data generated was used in calculating the compressibility index for the starch.

Swelling power

Starch was accurately weighed (2 g) into a dry tarred pre-weighed 250 ml centrifugal bottle. Distilled water was added to give a total volume of water equivalent to 180 g. The starch was completely suspended by stirring at 200 rpm using a magnetic stirrer. After taking out the stirrer, the bottle was immediately placed in a temperature-controlled water bath at 85 ± 2 °C with continuously shaking at 200 rpm for 30 minutes. The centrifuge bottle was then dried and placed on a balance followed by the addition of distilled water to bring to a total weight of 200 g. After capping, the bottle was centrifuged for 15 minutes at 1000 rpm for 15 minutes. To measure solubility, 50 ml of the supernatant was then pipetted and transferred into an evaporating petridish and dried overnight in a hot air oven at 105 °C. The dried residue was then cooled in desiccator and weighed for soluble starch. To measure the swelling power, the residual supernatant was carefully removed and discarded. The bottle with the sediment paste was then weighed to give the weight of swollen starch granules. The result was expressed by the calculation⁸.

Paste clarity

The clarity (transmittance % at 650 nm) of sago and papaya starch paste was measured using the procedure of Kerr and Cleveland (1959) cited by Lim and Seib (1993). A 1% aqueous suspension of starch near neutral pH was heated in a boiling water bath for 30 min with intermittent shaking. After that the suspension was cooled for 1 hr at 25°C and the light transmittance at 650 nm was read against water blank⁹.

Table 1: Table shows micromeritics study of papaya starch

S.No.	Properties	Papaya starch	Sago starch
1	Bulk density (g/cm ³)	0.4126	0.57142
2	Tapped density (g/cm ³)	0.5214	0.76923
3	Carr's index (%)	20.924	25.7513
4	Angle of repose (degree)	37.22	32.39
5	Swelling power	22.12	26.10
6	Paste clarity (%)	14.9	8.47
7	Viscosity (Pascal)	32.24	34.16
8	Yield stress (Pascal)	52.15	57.493
9	% solubility	0.63	0.56

Formulation and evaluation of paracetamol tablets

Formulation of paracetamol tablets

For the evaluation of the starch as disintegrant, polyvinylpyrrolidone was used as a binder in the prepared paracetamol tablet. The composition of tablet formulation containing paracetamol is given in Table 2.

Wet granulation and compression

Wet granulation method was used for all tablet production. The calculation is made for 30 tablets in each batch. Accurately weighed

quantities of each ingredient were mixed in a mortar and an appropriate quantity of the PVP solution (10% w/v in distilled water) was added as a granulating agent and mixed for 20 min in a mortar. The damp mass was sieved with sieve no. 22 and dried at 50°C in an oven for 6 hrs. The dried granular mass was passed through sieve no. 40 to obtain uniform sized granules. The different batches of the granules specified amount of the disintegrant i.e. papaya and sago starch were then mixed with calculated equal quantity of magnesium stearate (0.5%) and talc (0.5%) then compressed into tablets under constant pressure with a sixteen station rotary tablet machine⁷.

Table 2: Table shows formulation of paracetamol tablet

S.No.	Ingredient	Amount
1	Paracetamol(mg)	250
2	PVP Solution (binder %)	10
3	Starch (disintegrant %)	2,4,6,8,10
4	Talc (%)	0.5
5	Magnesium stearate (%)	0.5

Table 3: Table shows evaluation of Paracetamol tablets

S.No		Papaya starch					Sago starch				
		2%	4%	6%	8%	10%	2%	4%	6%	8%	10%
1	Avg. Weight variation (%)	2.23	3.07	1.92	2.51	1.57	1.42	2.56	3.22	3.51	1.72
2	Hardness(kg/f)	6.5	6.4	6.4	6.6	6.8	6.5	6.5	6.3	6.2	7.0
3	Friability(%)	0.91	0.45	0.56	0.76	0.67	0.23	0.85	0.62	0.78	0.44
4	Disintegration time(min)	49.4	36.5	26.4	22.6	17.8	51.4	40.1	32.2	24.3	15.6
5	Drug content(mg)	246.42	247.78	248.34	247.89	249.1	248.5	249.54	248.67	246.66	249.1
6	T _{50%} (min)	43.5	41.7	36.4	34.6	32.3	39.8	37.9	36.7	35.3	29.9
7	T _{70%} (min)	59.4	57.8	48.7	45.9	46.4	55.3	49.8	45.1	43.4	40.0

Table 4: Table shows *in-vitro* dissolution data of paracetamol tablets

S.No	Time (min)	% cumulative drug release									
		Papaya starch					Sago starch				
		2%	4%	6%	8%	10%	2%	4%	6%	8%	10%
1	0	0	0	0	0	0	0	0	0	0	0
2	10	4.27	5.82	6.77	10.64	11.14	5.68	6.97	9.82	11.82	13.17
3	20	20.01	22.00	25.12	33.12	34.57	22.82	24.82	29.11	32.82	36.92
4	30	32.65	35.12	40.22	42.29	44.82	34.68	39.92	44.12	46.24	50.46
5	40	44.10	48.22	57.29	62.75	64.89	49.21	55.27	60.81	65.87	70.07
6	50	59.28	62.49	72.88	76.81	79.03	64.22	70.81	74.92	79.11	82.17
7	60	70.18	74.89	87.14	90.43	93.82	77.29	84.11	90.12	92.46	96.72
8	90	90.12	92.76	94.83	97.82	99.75	95.23	97.82	98.12	99.11	99.82

Evaluation of tablets

Hardness test

Five tablets were selected at random from each batch to perform this test. Pfizer hardness tester (Elite, Mumbai, India) was used to measure the hardness.

Tablet was placed between spindle and anvil of the tester and the calibrated scale adjusted to zero, then diametric compression force was applied on the tablet and the position on the calibrated scale at which the tablet broke was recorded in kg units. A mean hardness was calculated for each batch.

Weight uniformity test

Twenty tablets were selected randomly from each batch and weighed. The mean weights were calculated for each batch.

Friability test

Ten tablets were selected randomly, dusted, weighed together and then placed in the friabilator. The machine was operated for 100 rotations at 25 rpm and then stopped. The tablets were dusted and again reweighed. The percentage losses were calculated.

Disintegration time

According to the method specified in the USP/NF (1980), 100 ml of 0.1 N HCl was used as disintegration medium at temperature $37 \pm 2^\circ\text{C}$ throughout the experiment. Randomly selected five tablets from each batch were placed one in each of the cylindrical tubes of the basket but no disc was used. The time taken for each tablet to break up into small particles and pass out through the mesh was recorded. Mean disintegration time was calculated for each batch.

In vitro dissolution test

The *in vitro* dissolution test of the compressed paracetamol tablet was performed using USP II dissolution apparatus. Phosphate buffer (pH 7.4) was used as dissolution medium. The temperature was maintained at $37 \pm 2^\circ\text{C}$ using rotation speed 100 rpm. Samples were withdrawn at regular intervals up to 1.5 h, replacing equal amount of fresh dissolution medium (phosphate buffer pH 7.4). Samples were analysed using UV spectrophotometer and % cumulative drug release was calculated.

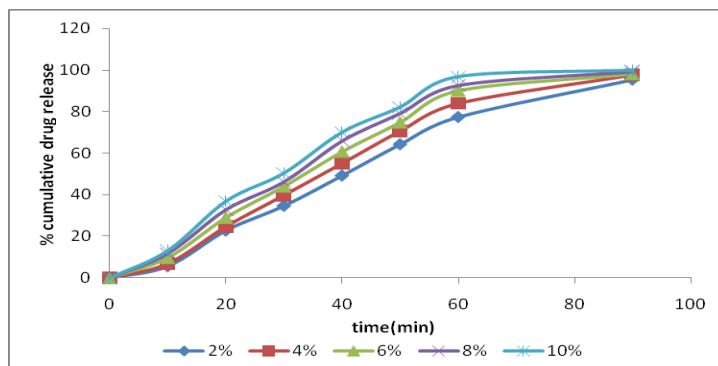


Fig 1: It shows *in-vitro* release of drug in presence of sago starch as disintegrant

RESULTS AND DISCUSSION

Table 1 shows the Micromeritics and other properties evaluated for papaya and sago starch powder. The prepared tablets of paracetamol with papaya and sago starch as disintegrant were evaluated for parameters such as avg. weight variation, hardness, friability, disintegration, drug content, $T_{50\%}$ and $T_{70\%}$. Sago starch showed significant disintegrant property. Results in Table-3 indicate that disintegration time decreases with the increase in the concentration of starch and it was found that at the equal concentration of both starch, sago starch possess greater

disintegrant property. The *in vitro* drug release from the tablet is shown in table-4. The average weight variation of the formulated tablets was found to be within acceptable limits. The hardness and friability of the tablets was found to be within acceptable limits. Time to release 50% of drug ($T_{50\%}$) and time to release 70% of drug ($T_{70\%}$) were found to be decreased with the increasing concentration of starch. % cumulative release was found to increase with the increasing concentration of starch and was found to be greater with sago starch in comparison to papaya starch. Sago starch shows higher swelling power than papaya starch and hence the disintegrating power of sago starch is more than that of papaya starch.

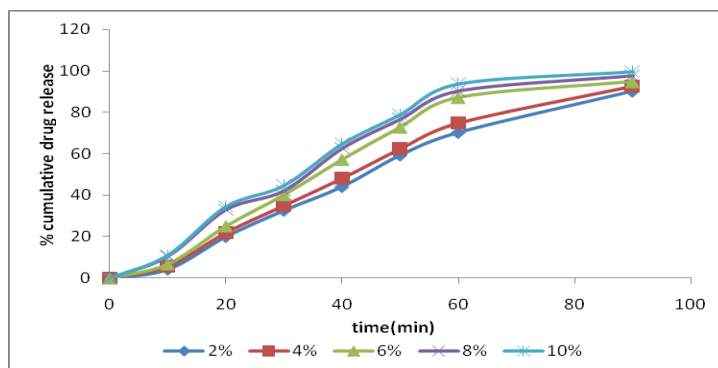


Fig 2: It shows *in-vitro* release of drug in presence of papaya starch as disintegrant

CONCLUSION

It can be concluded from the study that both papaya and sago starch possess significant disintegrating properties and can be used as disintegrating agent. But from the study it was observed that sago starch possesses higher disintegrating property than papaya starch.

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