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Comparative Evaluation of Natural Disintegrating Agents from Guava and Papaya in Tablet Formulations



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ABSTRACT

Compared to the various route of administrations oral route of the drug delivery system is the widely accepted one that has been explored for the systemic delivery of drugs. The main objective of the study was to isolate and compare the disintegrating property of natural excipients like starch from unripe fruits of guava and papaya when used in tablet formulation. Pharmaceutical excipients obtained from natural sources are economic. The unripe fruit of guava and papaya has high levels of starch content and hence these are used as raw material for starch isolation. Starch was isolated from guava and papaya fruits by alkaline extraction method using NaOH lye solution. Isolated starches were evaluated and used as a disintegrant in the formulations of tablets using paracetamol by wet granulation method. Studies indicate that tablets with guava starch disintegrate slowly compared with and papayastarch. These tablets also conformed various evaluation parameters including dissolution. Results from various evaluations suggested that guava starch and papaya starch showed adequate disintegrating characteristics and could be used as a disintegrant in tablet formulation.



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INTRODUCTION

In recent years, plant derived products have the greatest interest due to their diverse applications in the pharmaceutical field such as a diluent, binder, disintegrant in tablets. These natural formulation additives are biocompatible, cheap and easily available. These are preferred over other synthetic and non-synthetic because of their low cost, availability, lack of toxicity and non-irritating nature.

In the present study focused on the natural disintegrating agent in tablet formulation. For most tablets, the first important step is to break down the tablet into small particles, a process is known as disintegration. Starch is a relatively cheap raw material with physical and chemical properties that are used as disintegrating agents in the pharmaceutical industry. Starch can be extracted using different methods, depending on the plant source and use of the starch. Starch from various sources has been widely accepted for use in various pharmaceutical formulations. The main objective of this study was to isolate the starch from unripe guava and papaya fruit and use of these as disintegrating agents for the preparation of tablets using paracetamol as a model drug. The wet granulation method was used for the preparation of tablets. The tablets are then evaluated as per IP and compared to the disintegration properties of two different starches.

MATERIALS AND METHODS

MATERIALS

Unripe guava and papaya were obtained from the local market and the extraction of starch was performed in the laboratory. Paracetamol was received from Yarrow Chem product Mumbai and all other chemicals of analytical grade which were obtained from Spectrum reagents and Chemicals Pvt. Ltd. Edayar, Kochi.

METHODS

Isolation of starch:

The extraction of starch from guava and papaya was carried out by the alkaline extraction method using sodium hydroxide Lye solution. The pulp of unripe guava and papaya were isolated and dried, powdered and mixed with 0.5 N NaOH solution to prepare a slurry in a ratio 1:3 (Guava/Papaya: Lye solution). The slurry was held for 3 hrs., and diluted with water

in a ratio of 1:5 (Slurry: Water). The mass was then strained through a 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 becomes clear. This residue was further filtered and centrifuged. The sedimented starch was collected and washed with ethanol followed by water. It was then sieved, dried at room temperature and milled to a fine powder.

Pharmaceutical Characterization of isolated starch:

Identification Test (Iodine Test)

1 g of guava and papaya starch were boiled with 15 ml of water separately. After cooling to 1 ml of the mucilage, 2 drops of 0.1 N iodine solutions were added and the color change was noted.

Particle Size Determination (Optical Microscopy)

A small amount of starch was mixed with liquid paraffin and mounted onto a microscope slide with a coverslip and examined by polarized Optical microscopy. The mean particle size of samples of starch was determined microscopically with the aid of a calibrated eyepiece. The particle size of each sample dispersed in liquid paraffin was determined.

Paste Clarity

The clarity (transmittance % at 650 nm) of starch paste was measured. A 1% aqueous suspension of starch near-neutral pH was heated in a boiling water bath for 30 min with intermittent shaking. After the suspension was cooled for 1 hr. at 25°C, the light transmittance at 650 nm was read against blank.

Moisture Content

A 3 g weight each of guava and papaya starch was heated at 132°C using moisture analyzer and the reading was recorded.

Swelling capacity

The tapped volume occupied by 10 g of each guava powder and papaya starch (Vd) in a 100 ml measuring cylinder was noted. This powder was then dispersed in 85 ml of distilled water

and volume was made up to 100 ml distilled water. After 18 hrs of standing, the volume of the sediment, (V_w) was estimated and the swelling capacity was determined using the formula.

$$\text{Swelling capacity} = V_w - V_d$$

Ash Value of starch.

A total of 2 g quantity of starch was weighed into a silica crucible and incinerated. The determination of ash value was done by measurement of the residue left after complete combustion in a muffle furnace at 550° C.

Flow properties of starch

Angle of repose

It was determined by allowing the powder to flow through a funnel and fall freely on to a surface. Further addition of powder was stopped as soon as the pile has touched the tip of the funnel. A circle was drawn around the pile without disturbing it. The height and diameter of the resulting cone were measured. The same procedure was repeated three times and the average value was taken. The angle of repose was calculated using the following equation:

$$\tan \theta = h/r$$

Where h = height of the powder cone; r = radius of the powder.

Bulk Density

A 30g weight of each of the guava powder and papaya starch was weighed and poured into a 100ml measuring cylinder and the volume was recorded. The bulk density was then calculated.

$$\text{Bulk Density (BD)} = M / V$$

Where M is mass and V is volume

Tapped Density

A 30g weight of each of the guava powder and papaya starch was weighed and poured into a 100ml measuring cylinder and tapped on a hard surface 30 times from about 2cm height and the volume was recorded.

$$\text{Tapped Density (TD)} = M / V$$

Where M is mass and V is volume

Carr's Index

Carr's Index (%) was determined using the following relationship

$$\text{C.I.} = (\text{TD} - \text{BD} / \text{TD}) \times 100$$

Hausner's ratio

Hausner's ratio was determined using the following relationship

$$\text{H. R} = \text{TD} / \text{BD}$$

Where TD is Tapped density, BD is Bulk density

Formulation of Paracetamol Tablet:

Four different batches of tablets each containing 250 mg of Paracetamol were formulated by using the formula in (Table 1). The guava and papaya starch were taken at two different concentrations. The resultant granules were compressed into tablets by using a single punch rotary compression machine. To compare the disintegrant property, controlled tablets were prepared using papaya starch and guava starch as disintegrant agent .50 tablets were prepared for each batch.

Table No. 1: Formulation of tablet by wet granulation

S.NO	INGREDIENTS	F1	F2	F3	F4
1	Paracetamol	250mg	250mg	250mg	250mg
2	Papaya powder	20%	30%	-	-
3	Guava powder	-	-	4%	8%
4	Lactose	96	49	171.2	152.4
5	Starch	QS	QS	QS	QS
6	Talc	15	15	15	15
7	Magnesium stearate	15	15	15	15
8	Total weight	470	470	470	470

Evaluation of Tablets:

Weight variation

The IP weight variation test was performed by taking 20 tablets from a batch. Then 20 tablets, were weighed and the average weight was taken. Then each tablet was weighed individually. The percentage deviation can be determined by using the following formula.

$$\% \text{ Deviation} = \frac{\text{Average weight} - \text{Individual weight}}{\text{Average weight}} \times 100$$

Hardness Test

Pfizer hardness tester was used for measuring the hardness of the formulated Paracetamol tablets. From each batch, five tablets were taken at random and subjected to test. The mean of these five tablets was given in the table.

Friability

It is a measure of tablet strength. The friability was determined by using Roche Friabilator. 10 tablets were taken and their weight determined. Then they were placed in the friabilator and allowed to make 100 revolutions at 25rpm. The tablets were then dusted and reweighed. The percentage of weight loss was calculated by using the following formula.

$$F = 100 \times (1 - w/w_0)$$

Where, w_0 = Weight of tablets before friability

w = Weight of tablets after friability

Drug content Uniformity

The prepared tablets containing Paracetamol was tested for drug content uniformity. Tablets were dissolved in 100 ml of phosphate buffer pH 7.4 in a 100 ml volumetric flask which was previously clean and dry. This solution after suitable dilution was measured for absorbance at 249nm in a UV visible spectrophotometer.

Disintegration Test

Six tablets were taken in the disintegration apparatus. Six glass tubes that are 3 inches long open at the top and held against a 10-mesh screen at the bottom end of the basket rack assembly. To test the disintegration time one tablet was placed in each tube, and the basket rack was positioned in a 1litre beaker of water at $37^{\circ}\text{C} \pm 20\text{C}$ such that the tablets remain 2.5 cm from the bottom of the beaker. A standard motor driver device was used to move the basket assembly up and down through a distance of 5-6cm at a frequency of 28-32 cycles per minute. To meet the USP standard all particles of tablet must pass through 10 mesh screens in the time specified.

Dissolution

Dissolution was carried out using IP dissolution apparatus I (paddle apparatus). The dissolution of tablets was carried out in a 900ml-dissolution medium. The dissolution medium for the Paracetamol tablet was pH 7.4. The temperature of the dissolution medium was maintained at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$. The agitation intensity was 100rpm. The samples of dissolution medium were withdrawn through a filter at different time intervals. An equal volume of a fresh medium having the same temperature was replaced at each time. The samples were suitably diluted and the amount of active ingredient was determined spectrophotometry concerning the reported methods.

RESULTS AND DISCUSSION

The extracted starch was evaluated for various parameters and the results show that starch has better flow properties and is given in Table.2 and the powder turns blue-black color on the addition of iodine solution which indicates the presence of starch. The entire tablets pass the weight variation test as per IP and have hardness within the limit (Table.3). The drug content

of paracetamol determined at 249nm and it ranges from 97.88 to 99.54 and complies the standard as per IP. The tablets prepared from guava starch shows slower disintegration time than papaya starch. Among the four batches, a tablet containing papaya starch 30% shoes good disintegrating property. The In vitro dissolution studies also shows that papaya starch-containing tablets exhibit higher percentage release than with guava starch.

Table No. 2. Pharmaceutical characterization of papaya and guava starch

Sl.No	Characterization of starch	Papaya starch	Guava starch
1	Bulk density (g/ml)	0.43	0.77
2	Tapped density (g/ml)	0.54	0.89
3	Carr's index	18.86	12.5
4	Hausner's ratio	1.24	1.14

Table No. 3. Evaluation of Paracetamol Tablet

Parameters	F1	F2	F3	F4
Hardness (Kg)	6.3	6.1	4.5	6.0
Friability (%)	0.692	0.476	0.493	0.232
Weight variation (%)	2.5	2.3	2.6	3.6
Disintegration(min.)	5.2	4.0	6.4	6.1
Dissolution (% after 1 Hr)	88.98	93.14	79.24	83.74

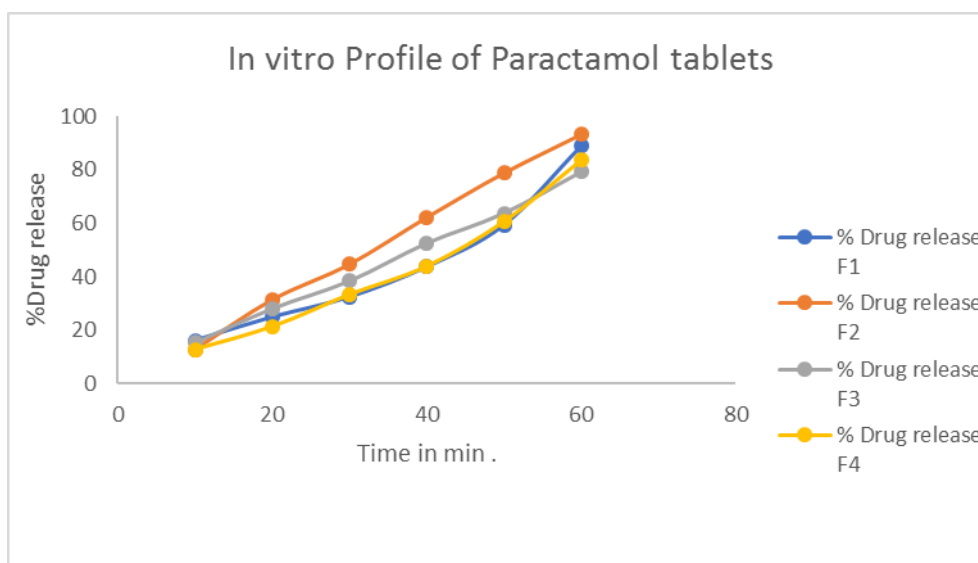


Figure No. 1: In-vitro dissolution study of Paracetamol tablets

CONCLUSION

The present study focused on evaluating the disintegration properties of guava and papaya starch and compared their disintegration properties. The results showed that papaya starch has greater disintegrant property than guava starch. It was concluded that guava starch and papaya starch were having excellent disintegration property which can be used as a natural disintegrating agent in tablet formulation.

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REFERENCES

1. Sunitasonarriya, Dr. Shikhaagarwal. Formulation and evaluation of ibuprofen tablet using isolated starch from unripe papaya fruit as a disintegrant. *Int.J.Adv.Res.*2018;6(6):792-804.
2. Puri AV, Puranik VK, Kamble MD, Tauro SJ. Formulation and evaluation of Diclofenac sodium tablet using isolated starch from unripe papaya fruits as disintegrant. *Indo. Am.j.pharm.res.*2013;3(11):9183-9189.
3. Olayemi OJ, Ekunboyejo A, Bamiro OA, Kunle OO. Evaluation of disintegrant properties of Neorautanenia Mitis Starch. *Journal of Phytomedicine and Therapeutic* 2016;15(2):52-63.
4. Arunraj R. Comparative evaluation of potato starch and banana powder as disintegrating agents in aceclofenac tablet formulation. *International Journal of Pharmacy and Pharmaceutical Sciences* 2013;5(2):204-07.
5. Barad R, Soni P, Upadhyay S, Upadhyay U. Withaniacoagulans and Psidiumguajava- an overview. *International Research Journal of Pharmaceutical and Applied Sciences*, 2013; 3(3):42-47.
6. Ebere, OI., Austinline, C., Ekweogu, Ugochukwu E. Oruna. Effects of palm bunch potash, trona and their modified cashew gum-corn starch composite on the physicochemical properties of furosemide. *J Pharm Pharmacogn Res*, 2017. 15-28.
7. Philip, F., Builders and Mathew I. Arhewoh. Pharmaceutical applications of native starch in conventional drug delivery. *www. starchjournal.com*, 2016. 864 –873.
8. Barmi, H., Sriwidodo, M., Abdassah, A., Yohana, C., Starch as Pharmaceutical Excipient. *Int. J. Pharm. Sci. Rev. Res*, 2016. 59-64.
9. Schwartz J.B, Zelinskie J.A. The binding and disintegrant properties of the corn starch fractions: amylose and amylopectin. *Drug Dev.and Ind. Pharm* 2008;4(5):46383.
10. Lachman, H.A. Lieberman, and J.L Kanig. *The Theory and Practice of Industrial Pharmacy*, Third edition Lea and Febiger, Philadelphia. 1990. pp: 296-303; 336-342.
11. *The Indian Pharmacopoeia*. Volume I, the controller of publication, Ministry of Health and Family Welfare, Government of Indian, 2007 pp: 175-184.
12. Allen, L.V., N.G. Popovich and H.C. Ansel. *Pharmaceutical dosage forms and drug delivery systems*. Eighth edition, Wolters Kluwerslippincott Williams & Wilkins Philadelphia. 2008. pp: 148-50; 227-259.
13. Jain, N.K., 2006. *Pharmaceutical product development*. First edition, CBS publishers and distributors, New Delhi and Bangalore, Reprint 2008, pp: 100.
14. Banker, G.S. and C.T. Rhodes. *Modern Pharmaceutics*, Third Edition Revised and Expanded, Marcel Dekker. New York, 1996. pp: 385
15. Martin A; *Micromeritics*. In: Martin A, ed. *Physical pharmacy*. Baltimore, MD: Lippincott. Williams & Wilkins. 2001; 423.