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COMPARATIVE EVALUATION OF PAPAYA AND BANANA STARCH AS DISINTEGRANT IN DICLOFENAC SODIUM TABLET FORMULATION

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ABSTRACT

Objective: *The objective of this research was to characterize, formulate, evaluate and compare the disintegration properties of natural excipients alike papaya and banana starch in tablet formulation.* ***Methods:*** *The starch was isolated from unripe papaya and banana fruit and used as a disintegrant in diclofenac sodium tablets. Isolated starch from papaya and banana was subjected to evaluation of physicochemical properties like melting point, solubility, iodine test, paste clarity, moisture content, swelling capacity and ash value. Flow properties of starch were determined as an angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio etc. Tablets were then formulated by direct compression method using disintegrant and In-vitro release characteristic of the prepared tablets was analyzed. The disintegration time of the formulated tablets was then compared to determine the disintegration properties of starches.* ***Results:*** *The result showed that the disintegration rate of tablet formulations by using starch from different sources decreased in the following order Corn>Banana>Papaya. The physicochemical properties showed by all starches passed prescribed evaluation test for tablets viz. weight variation, hardness, friability, and content uniformity.* ***Conclusion:*** *Studies indicated that starch so obtained from banana shows qualitatively and quantitatively good disintegration characteristic as compared to papaya starch. These tablets also confirmed significant degree dissolution as per the standards. Evaluations also indicated that banana starch showed adequate disintegrating characteristics in comparison to corn starch and can be used as a disintegrant in tablet formulation.*

KEY WORDS

Carica papaya Starch, Banana Starch, Corn Starch, Diclofenac sodium, Disintegration properties.

INTRODUCTION

Starch is a moderately economic crude material with physical and chemical properties that have numerous utilizations in the pharmaceutical industry. Starch is one of the most commonly used binders, lubricant and disintegrant in the formulations of solid dosage forms. Even though corn starch is one of the most extensively used starches in pharmaceutical preparations, starches from other botanical sources have revealed diverse functional properties such as swelling, gelling and water holding capacity which are related to their capacity to function effectively as a disintegrant. Owing to their powerful disintegrant property starch is found valuable in the preparation of insoluble drug substances [1]. Starch from different sources has been generally utilized for different reasons as a part of pharmaceuticals. Additionally, the yield in isolated starch so as to be economically feasible must be refined without critical change to the starch granules [2]. The extraordinary demand for starch as an excipient in pharmaceuticals due to its low cost, extensive availability and adaptability make it valuable to frequently explore new sources of pharmaceutical grade starch with possibly greater formulation properties [3]. The multidimensional uses of starch necessitate the exploration of new

possible sources. Starch is abundantly distributed in natural sources. The grain size (μ) physicochemical properties of starch vary with sources. *Carica papaya* is a semi-woody tropical herb which displays a strong apical dominance comprises of numerous biologically active compounds. Subsequently, every single portion of the papaya tree owns economic value; it is grown on a commercial scale [4]. Unripe papaya fruit pulp can be graded as a rich source of carbohydrate due to the presence of its high polysaccharide and starch contents. About 43% of starch is present in unripe papaya fruit [5]. Starch acquired from unripe banana *(Musa paradisiaca)* fruit is of never-ending interest as a basis of eco-friendly resources. The unripe banana fruit pulp consists of 80% starch on basis of a dry weight with a percentage that is equivalent to another source of standard starch [6]. Disintegration test is passed out to determine whether tablet disintegrates within the acclaimed time as soon as it is sited in a liquid medium in a precise experimental condition. Starches are hypothetical to an extent its disintegrating property by the fascination of moisture and spelling of the grains follow-on by the rapture of tablet core [7]. Hence, this research work was directed to investigate standard corn starch and isolated starch from the unripe papaya and banana fruit pulp. For diclofenac sodium tablet as a model formulation isolated starch was used as a disintegrant. Suitable wet granulation method was used for the formulation of tablets. The tablets then were evaluated and compared as per standards.

MATERIALS AND METHODS

Materials

The unripe Papaya and Banana were procured from a local market and starch were isolated in the laboratory. Corn starch, Diclofenac (Korten Pharma Pvt. Ltd.) and all other chemicals were of analytical grade which was obtained from SIGMA, Loba chemicals Pvt. Ltd Mumbai.

Isolation of Starch from unripe fruit of Papaya

Extraction of starch from unripe papaya was carried out by alkaline extraction method using sodium hydroxide as Lye solution. The pulp of unripe papaya was isolated and dried, powdered and mixed with 0.5N NaOH solution to prepare a slurry in ratio 1:3 (Papaya: Lye solution). The slurry was held for 2-3 hrs., then diluted with water in ratio 1:5 (Slurry: Water). The mass was then passed through a muslin cloth and washed with the saline solution numerous times to eliminate sugar, mucilage, and soluble substances. The mass obtained was then washed repeatedly until the supernatant solution was clear. This residue was further filtered and centrifuged at 5000rpm for 45min. The sedimented starch was collected and washed with ethanol followed by water until the pH was neutral. It was then sieved, dried at room temperature and milled to fine powder [8].

Isolation of Starch from unripe fruit of Banana

Alkaline extraction method using sodium hydroxide as a lye solution. A banana was thoroughly washed to remove adhered foreign materials. The bananas were peeled off weighed and washed. The washed bananas were slices into pieces and pulverized using a blender. Enough quantity of water was added to the pulp which then passed through a sieve. The filtrate was allowed to settle down and different concentration of sodium hydroxide was added to a solution. Excess sodium hydroxide was removed by washing several times with distilled water. The clear supernatant solution was decanted and sediment containing starch was collected in a tray. It was then dried at room temperature [9].

Pharmaceutical characterization of Starch

Identification test (Iodine Test)

1g of papaya, banana and corn starch was boiled with 50mL of water separately. After cooling to 1mL of the mucilage, 2 drops of 0.1N iodine solutions were added and the change in color was observed [10].

Particle size determination (Light Microscopy)

A small amount of papaya, banana and corn starch was separately mixed with glycerol and mounted onto a microscope slide with a coverslip and examined by polarized light microscopy. The mean particle size of samples of both starches was determined microscopically with the aid of a calibrated eyepiece. The particle size of each sample dispersed in glycerol was determined [11].

Paste clarity

The clarity (transmittance % at 650nm) of papaya, banana and corn starch paste was measured. A 1% aqueous suspension of starch adjacent neutral pH was heated in a boiling water bath for 30min with intermittent shaking. After the suspension was cooled at 25°C for 1hr., the light transmittance at 650nm was read against water blank [12].

Moisture content

A 3g of each papaya, banana and corn starch was placed in the oven at 105°C for 3hrs. and weighed. Triplicate determinations were made, the mean was calculated

then the ratio of the final weight to the initial weight was expressed as a percentage [13].

Swelling capacity

The tapped volume occupied by 10g of each papaya, banana and corn starch (V_d) in a 100mL measuring cylinder was noted. This powder was then dispersed in 85 mL of distilled water and volume was made up to 100mL with distilled water. After 18hrs of standing, the volume of the sediment, (V_w) was estimated and the swelling capacity was determined as; [14]

Swelling capacity = $V_w - V_d$

Ash Value of starch

A total 2g quantity of papaya, banana and corn starch was weighed into a silica crucible and incinerated. Determination of ash value was done by measurement of the residue left after complete combustion in a muffle furnace at 550°C [15].

Flow properties of starch [16-19]

Angle of repose

It was determined by allowing papaya, banana and corn starch 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. An angle of repose was calculated by using the following equation:

$\tan \theta = h/r$

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

Bulk density

A sufficient quantity of papaya, banana and corn starch was passed through a 1mm (no.18) screen to break up agglomerates that may have been formed during storage to complete the test. Into a dry 250mL cylinder, approximately 100g of the test sample (M) was introduced. The cylinder was filled carefully and level of powder was adjusted without compacting and the unsettled apparent volume (V_o) was noted. Bulk density was calculated, in g/mL.

Using the formula: **Bulk density = M/V_o**

Tapped density

An accurately weighed quantity of papaya, banana and corn starch was introduced into a measuring cylinder. Cylinder comprising of the sample was then tapped by raising the cylinder and allowing it to drop below its own weight by means of an appropriate mechanical tapped density tester at a minimal rate of 300 drops/min. The cylinder was tapped 500 times and the tapped volume (V_a) was measured. The procedure was repeated for an additional 750 tapings and again the tapped volume was measured as (V_b). If the difference between V_a and V_b was <2%, V_b was the final tapped volume (V_f). If the difference was higher, the tapings were repeated for an additional 1,250 times, and then the tapped density was calculated using the following formula:

Tapped density = M / V_f

Where M = weight of the sample taken; V_f = final tapped volume

Carr's index

The compressibility index of papaya and banana starch granules was determined using Carr's compressibility index, as follows:

$$\text{Carr's index} = \frac{(\text{Tapped density} - \text{Bulk density})}{\text{Tapped density}} \times 100$$

Hausner's ratio

The Hausner's ratio of papaya and banana starch was determined using the following formula:

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Formulation of a tablet by wet granulation [20]

Tablets were prepared by wet granulation process using isopropyl alcohol as the granulating fluid. Granules were prepared using a formula in (Table1). Prepared granules were evaluated for following parameters Bulk density, Tapped density, Carr's index, Angle of repose, Hausner's ratio [16-19]. Tablet of 225mg was prepared by compressing evaluated granules using a single punch tablet compression machine. Three batches F1, F2 (5% and 10% Papaya starch), F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch) were prepared.

Evaluation of Tablets [21-24]

Hardness Test

Monsanto hardness tester was used for measuring the hardness of the formulated tablets. From each batch, five tablets were taken at random and subjected to test. The mean of these five tablets is 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 the weight was determined. Then they were placed in the friabilator and allowed to make 100 revolutions at 25rpm. The tablets were then dusted,

reweighed and the percentage weight loss was calculated.

Weight variation

The weight variation test of the tablets was performed as per Indian Pharmacopoeia. Twenty tablets of each type were weighed and average weights were calculated.

***In-vitro* disintegration time**

The *in-vitro* disintegration time was determined using a disintegration test apparatus. Six tablets were taken in disintegration apparatus. A tablet was placed in each of the six tubes of the apparatus with 3 inches long opened 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°C ± 2°C in such way that the tablets remain 2.5cm above from the bottom of the beaker. A typical motor driven 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 IP standard all particles of tablet must pass through 10 mesh screen in the time specified.

Dissolution studies

Dissolution was carried out using IP dissolution apparatus I (paddle apparatus). Dissolution of tablets was carried out in 900mL-dissolution medium. The dissolution medium for diclofenac tablet was phosphate buffer pH 6.8. The temperature of the dissolution medium was maintained at 37°C ± 2°C. The agitation intensity was 100rpm. The samples of dissolution medium were withdrawn at every interval of 10min for 80 min. 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 with respect to the reported methods.

RESULTS AND DISCUSSION

In this study, attempts have been made to comparatively evaluate the disintegrating properties of papaya, banana and corn starch. Starch extracted from *Carica papaya* had a light yellowish tinge hence bleaching was carried out with ethanol whereas banana starch on isolations yielded white starch. On a dry basis, 31.5% papaya starch and 41.8% banana starch was obtained. Size of papaya starch was found to be smaller in comparison to banana starch (Fig. 1a, 1b, 1c). The shape of papaya starch grains is oval, banana starch grains is lenticular whereas corn starch grains is subspherical in shape. A very little difference was observed in the loss on drying, acidity, ash value, pH values of papaya, banana and corn starch as there is no substantial difference in their composition. The loss on drying and acidity values of all starches were well within official ranges. The bulk density, angle of repose and compressibility index of all the starches was comparable. In all the cases the values of angle of response were ≤30°, which indicate that all the starches were free-flowing (Table 2). Evaluation of formulated granules showed a significant increase in bulk and tapped density with increase in the concentration of starches and the good correlation was observed between concentrations of disintegrant. The bulk and tapped densities (0.75 ± 0.01, 0.62 ± 0.005 g/mL) exhibited by papaya granules was lower compared to banana and corn starch granules (0.90 ± 0.21, 0.92 ± 0.025 g/mL resp.) (Table 3). Diclofenac tablets prepared with papaya, banana and corn starch passed the friability test and was found to be well within acceptable limits for all the formulation. The friability test showed that the papaya starch had slightly less binding strength compared to banana and corn starch (Table 4). Disintegration time observed was less with banana and corn starch at all the concentrations employed compared to those of papaya starch which may be due to higher swelling capacity (Table 5). Weight variation test carried showed no tablet deviated from average weight by 7.2%. Thus, all tablets pass the weight variation test as per official limit. One-point dissolution data of all the tablets prepared with all starches confirmed to dissolution specifications of I.P. (Table 6). The result of *in-vitro* % drug release for F1 and F2 formulated tablet with papaya starch shows slow % drug release 38.5 and 65.5 in comparison to banana and corn starch tablet. While in the case of formulation F3, F4 the % drug release was 89.6 and 94.7 and for F5, F6 the % drug release 97.2 and 98.3 observed was respectively. Whereas papaya starch shows poor disintegrating properties with a comparison to papaya and corn starch. The range of 5 to 10 % concentration of corn and banana starch is an acceptable range of starch incorporation in tablet formulation as a disintegrating agent (Fig 2). To analyze the dissolution data and mathematical models were employed. To evaluate dissolution rate data both empirical and semi-empirical

models were applied. Formulations F1, F2, F3, F4 F5, and F6 were then analyzed for their drug release kinetics as well as their mechanism of drug release. The data obtained from *in-vitro* release studies [Table 6] were subjected to zero-order model [Table 7 and Figure3], first-order model [Table 7 and Figure 4], Higuchi's model [Table 7 and Figure 5] Hixson Crowell [Table 7 and Figure 6] and Korsmeyer's models [Table 7 and Figure 7] to assess their release kinetics. From the regression coefficient values [Table 8] the mechanism of drug release was tested by Hixson Crowell plots of the dissolution data were found to be linear (Table 3) with all formulation. The disintegration is occurring from discretely suspended particles. This might have also contributed to the enhanced disintegration of the tablet. The correlation coefficient values of the Hixson Crowell's cube root model are found to be (R^2 = 0.946 to 0.982) slightly higher when compared to the zero (0.976- 0.943) and first order (0.893-0.9002) (Table 8) release model. Hence the release of drug from the formulation followed predominantly Hixson-Crowell cube root law compared to zero and first order kinetics. Thus, it can be concluded that unripe banana fruit possesses disintegrating properties comparable to corn starch.

Table 1: Formulation of tablet by wet granulation

Sr. No.	Ingredients mg/Tablet	Formulation					
		F1	F2	F3	F4	F3	F4
1.	Diclofenac sodium (mg)	50	50	50	50	50	50
2.	Lactose (mg)	145.75	152.5	145.75	152.5	145.75	152.5
3.	Starch (mg)	22.50	11.25	22.50	11.25	22.50	11.25
4.	Talc (mg)	4.5	4.5	4.5	4.5	4.5	4.5
5.	Magnesium stearate (mg)	2.25	2.25	2.25	2.25	2.25	2.25
6.	Isopropyl alcohol (mL)	QS	QS	QS	QS	QS	QS

F1, F2 (5% and 10% Papaya starch) F3, F4 (5% and 10% Banana starch)
F5, F6 (5% and 10% Corn starch)

Table 2: Pharmaceutical characterization of starch

Sr. No.	Characterization of Starch	Papaya Starch	Banana Starch	Corn Starch
1.	Iodine test	+ Ve	+ Ve	+ Ve
2.	Paste clarity (%)	14.9	11.67	9.67
3.	Average Grain size (μ)	12.23	45.3	27.3
4.	Ash Value (% w/w)	16.2 ± 0.8	12.2 ± 0.6	15.3 ± 0.2
5.	Moisture Content	5.93 ± 0.3	4.26 ± 0.4	6.24 ± 0.4
6.	Swelling capacity	2.147 ± 0.86	2.538 ± 0.42	2.037 ± 0.52
7.	Angle of repose	30.25° ± 1.45	26.21° ± 1.18	24.43° ± 1.34
8.	Bulk Density(g/mL)	0.43 ± 0.38	0.58 ± 0.17	0.44 ± 0.47
9.	Tapped Density(g/mL)	0.49 ± 0.28	0.67 ± 0.82	0.50 ± 0.62
10.	Carr's Index (%)	18.86 ± 0.12	13.68± 0.34	12.00 ± 1.44
11.	Hausner's ratio	1.23 ± 0.29	1.15 ± 0.66	1.13 ± 0.66

Table 3: Evaluation of granules

Sr. No	Batch	Tapped Density (g/mL)	Bulk Density (g/mL)	Carr's Index (%)	Angle of repose	Hausner's ratio
	F1	0.8 ± 0.05	0.75 ± 0.002	6.25 ± 0.005	21°	1.15 ± 0.12
	F2	0.7 ± 0.01	0.62 ± 0.005	11.42 ± 0.020	16.23°	1.14 ± 0.15
	F3	1.0 ± 0.01	0.81 ± 0.005	10.0 ± 0.057	17..25°	1.17 ± 0.14
	F4	0.9 ± 0.21	0.92 ± 0.025	12.42 ± 0.020	15.31°	1.15 ± 0.25
	F5	0.5 ± 0.01	0.58 ± 0.005	9.32 ± 0.020	12.23°	1.15 ± 0.11
	F6	0.8 ± 0.01	0.67 ± 0.005	10.36 ± 0.020	17.23°	1.11 ± 0.16

F1, F2 (5% and 10% Papaya starch), F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch)

Table 4: Friability test and Hardness Test

Sr. No	Batch	Friability (%)	Hardness (kg / cm^2)
1.	F1	0.7 ± 0.013	4.1
2.	F2	0.7 ± 0.025	4.2
3.	F3	0.8 ± 0.012	4.7
4.	F4	0.8 ± 0.046	4.4
5.	F5	0.6 ± 0.012	3.8
6.	F6	0.5 ± 0.046	4.1

F1, F2 (5% and 10% Papaya starch), F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch)

Table 5: Disintegration Test

Sr. No	Diclofenac Sodium Tablet	Disintegration time (min)
1.	Marketed Tablet	2.28
2.	Batch F1	5.21
3.	Batch F2	4.52
4.	Batch F3	3.57
5.	Batch F4	3.13
6.	Batch F5	3.18
7.	Batch F6	2.53

F1, F2 (5% and 10% Papaya starch), F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch)

Table 6: Dissolution study of tablet formulation

Time (min)	% Drug release					
	F1	F2	F3	F4	F5	F6
10	16.3	25.4	25.8	28.9	29.9	30.7
20	19.8	33.2	31.2	37.9	42.5	43.2
30	23.5	36.4	38.4	45.1	58.7	55.8
40	25.8	39.7	44.7	54.2	65.2	66.5
50	27.2	43.5	58.5	67.8	72.5	78.2
60	29.6	46.8	66.8	78.9	84.8	88.3
70	30.3	51.3	78.4	88.3	89.2	91.8
80	38.5	65.5	89.6	94.7	97.2	98.3

F1, F2 (5% and 10% Papaya starch), F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch)

Table 7: Drug release kinetics of formulations F3, F4, F5, and F6

Time (h)	Cumulative% drug release				Log cumulative% drug remaining to be released				Square root of time	Log cumulative% drug release				Log time	Wo-Wt			
	F3	F4	F5	F6	F3	F4	F5	F6		F3	F4	F5	F6		F3	F4	F5	F6
0	0	0	0	0	2.000	2.000	2.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
10	25.8	28.9	29.9	30.7	1.870	1.852	1.846	1.841	3.162	1.412	1.461	1.476	1.487	1.000	0.440	0.499	0.519	0.534
20	31.2	37.9	42.5	43.2	1.838	1.793	1.760	1.754	4.472	1.494	1.579	1.628	1.635	1.301	0.544	0.682	0.782	0.798
30	38.4	45.1	58.7	55.8	1.790	1.740	1.616	1.645	5.477	1.584	1.654	1.769	1.747	1.477	0.693	0.841	1.185	1.106
40	44.7	54.2	65.2	66.5	1.743	1.661	1.542	1.525	6.325	1.650	1.734	1.814	1.823	1.602	0.832	1.064	1.377	1.418
50	58.5	67.8	72.5	78.2	1.618	1.508	1.439	1.338	7.071	1.767	1.831	1.860	1.893	1.699	1.180	1.461	1.624	1.848
60	66.8	78.9	84.8	88.3	1.521	1.324	1.182	1.068	7.746	1.825	1.897	1.928	1.946	1.778	1.428	1.879	2.165	2.372
70	78.4	88.3	89.2	91.8	1.334	1.068	1.033	0.914	8.367	1.894	1.946	1.950	1.963	1.845	1.857	2.372	2.432	2.625
80	89.6	94.7	97.2	98.3	1.017	0.724	0.447	0.230	8.944	1.952	1.976	1.988	1.993	1.903	2.459	2.898	3.233	3.449

F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch)

Table 8: Regression coefficient (R^2) values of formulations F3, F4, F5 and F6

Sr. No	Formulation code	First order R^2	Korsmeyer Peppas n-value	Zero order R^2	Higuchi R^2	Hixson Crowell
1.	Batch F1	0.8845	0.9227	0.8480	0.9641	0.8737
2.	Batch F2	0.9004	0.9140	0.8725	0.9559	0.9006
3.	Batch F3	0.8937	0.9559	0.9763	0.9433	0.9466
4.	Batch F4	0.9120	0.9517	0.9708	0.9708	0.9678
5.	Batch F5	0.9031	0.9463	0.9393	0.9942	0.9765
6.	Batch F6	0.9002	0.9477	0.9430	0.9928	0.9826

F3, F4 (5% and 10% Banana starch), F5, F6 (5% and 10% Corn starch)

Figure 1: Strach grains at 40X objectives under microscope

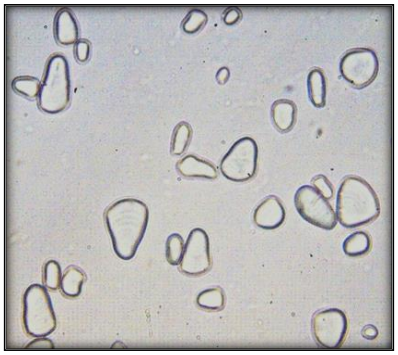


Figure 1a: Papaya starch

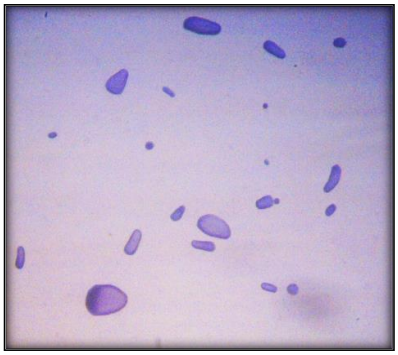


Figure 1b: Banana starch

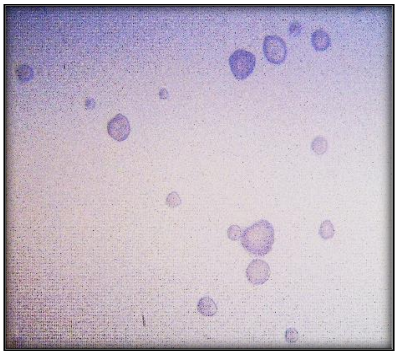
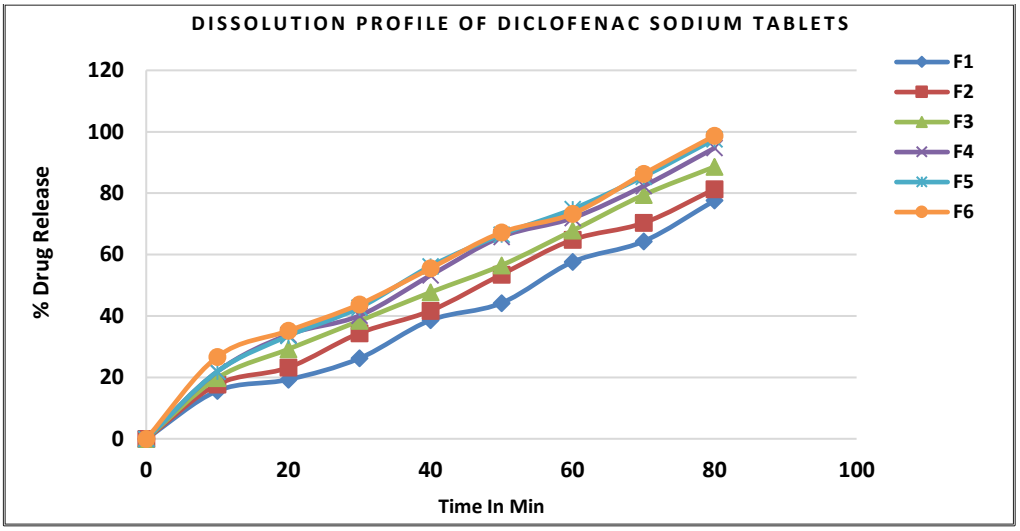


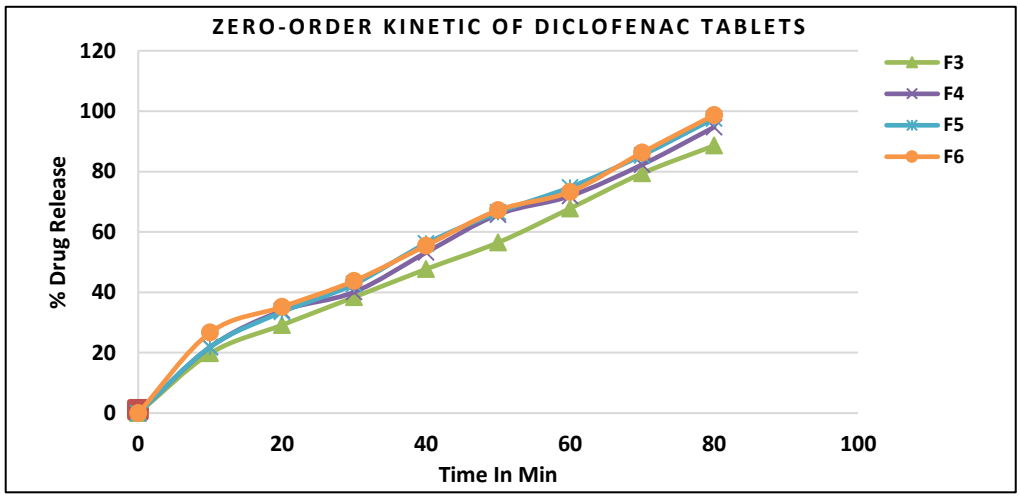
Figure 1c: Corn starch

Figure 2: *In-vitro* release of drug in presence of papaya, banana and corn starch as a disintegrant



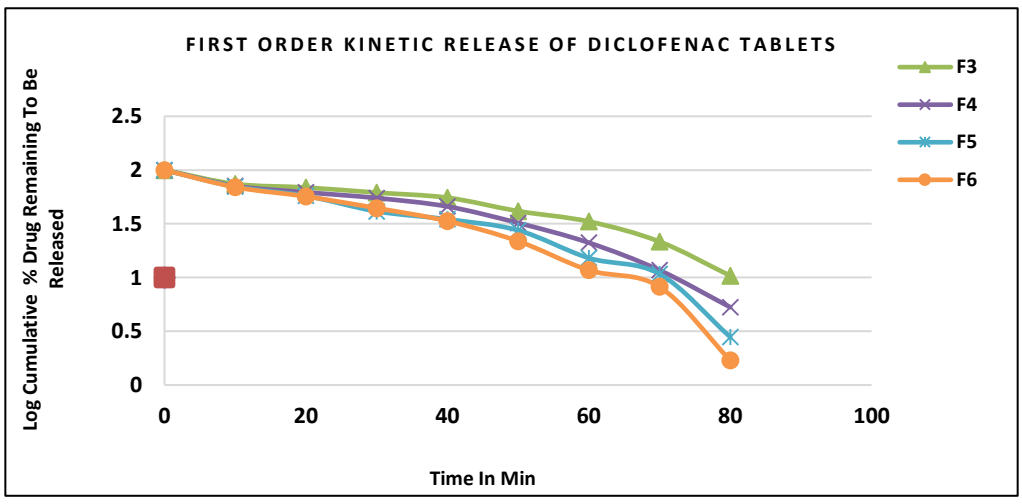
F1, F2 (5% and 10% Papaya starch), F3, F4 (5% and 10% Banana starch), F5,F6 (5% and 10% Corn starch)

Figure 3: Zero-order kinetic release model for formulations F3, F4, F5 and F6



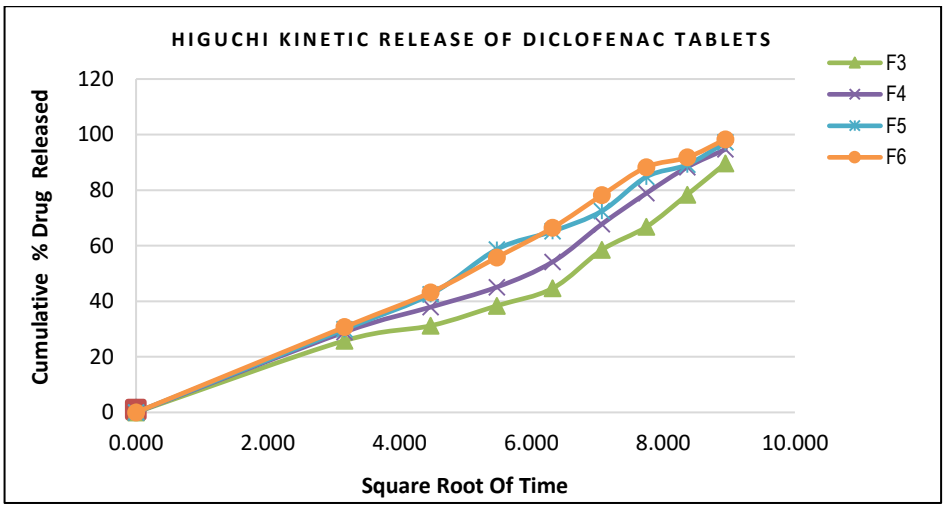
F3, F4 (5% and 10% Banana starch) F5, F6 (5% and 10% Corn starch)

Figure 4: First-order kinetic release model for formulations F3, F4, F5 and F6



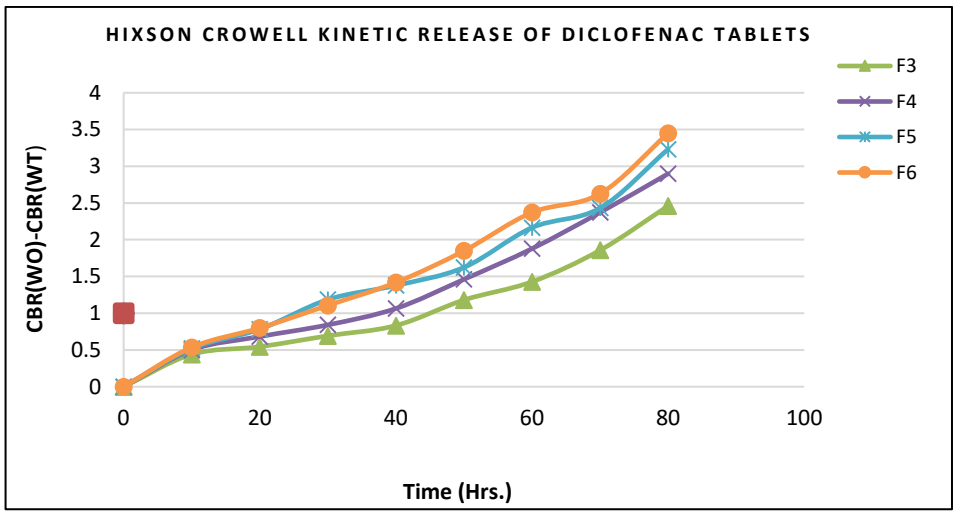
F3, F4 (5% and 10% Banana starch) F5, F6 (5% and 10% Corn starch)

Figure 5: Higuchi kinetic release model for formulations F3, F4, F5 and F6



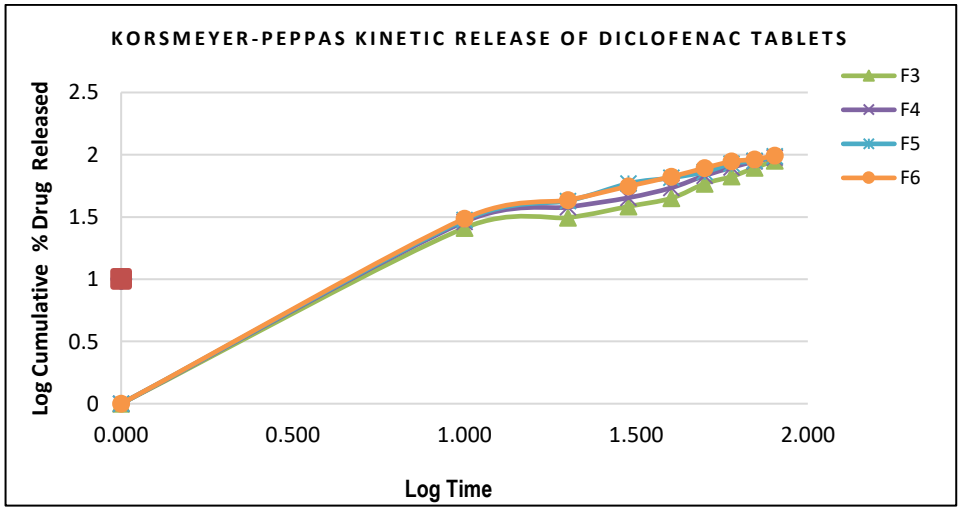
F3, F4 (5% and 10% Banana starch) F5, F6 (5% and 10% Corn starch)

Figure 6: Hixson Crowell release model for formulations F3, F4, F5 and F6



F3, F4 (5% and 10% Banana starch) F5, F6 (5% and 10% Corn starch)

Figure 7: Korsmeyer–peppas kinetic release model for formulations F3, F4, F5 and F6



F3, F4 (5% and 10% Banana starch) F5, F6 (5% and 10% Corn starch)

CONCLUSION

The results of the present study have highlighted the potential of a banana starch as a source of disintegrant agent over other starches. It has also been observed that it maintains its mechanical strength of tablets in terms of friability and hardness. The dissolution studies suggest that tablets (batch F3 and F4) containing 5% and 10% banana starch gives 89.6 % and 94.7 % of drug release after specified dissolution test time i.e. higher than papaya starch and comparable with corn starch. The study of the disintegrating property of all the formulations showed that the disintegration time for the tablets prepared with banana starch was less than that of papaya starch reflecting its good disintegrating characteristic. The *in-vitro* dissolution of diclofenac sodium tablets containing banana starch in comparison to corn starch was found to follow Hixson-Crowell model (R^2 = 0.946 to 0.982) equally. This also signifies drug release was due to starch which was used as the disintegrant. Thus it can be concluded that the starch isolated from unripe banana fruit owns significant disintegrating properties and has an exceptional scope as a disintegrant in pharmaceutical formulations. Banana starch could be used as a promising pharmaceutical excipient in tablet technology as it showed adequate physicochemical, disintegrating properties and drug release kinetics.

DECLARATION OF INTEREST

The authors declare that they have no conflict of interest.

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