Research Article

Evaluation of *Musa paradisiaca* (Banana peel) Mucilage as Pharmaceutical Excipient

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ABSTRACT

The objective of the present work is extraction of mucilage from banana peel and further characterization for useful as alternative pharmaceutical excipient. The mucilage was subjected to phytochemical and physicochemical characterization of its safety and suitability to use as binding and suspending agent. FT-IR spectroscopy, DSC studies were performed for drug, banana peel mucilage powder, prepared tablet and suspension formulations. Aceclofenac tablets were prepared by wet granulation method containing mannitol as diluent; using 2.5, 5, 7.5 and10 %w/w of banana peel mucilage powder and 7.5 %w/w of PVP (reference) as binding agents in the tablet formulation. Aceclofenac suspensions were prepared with banana peel mucilage powder at 0.5, 1, 1.5 and 2 %w/v as suspending agent and 1.5 %w/v of sodium CMC as reference suspending agent. Pharmaceutical properties of granules and tablets such as carr's index, Haunser's ratio and angle of repose and post compression parameters like friability, hardness,and disintegration time studies were determine and found satisfactory. The evaluation tests of suspension like sedimentation volume, redispersibility, pH, degree of flocculation were found satisfactory. In vitro release studies shows that release rate of drug is decreased with increase in the banana peel mucilage powder percentage in the formulation. Banana peel mucilage powder showed good binding and suspending properties at 10 %w/w and 2 %w/v, respectively.

Keywords: Banana peel mucilage powder, Aceclofenac, suspension, tablets.

INTRODUCTION

Mother Nature has gifted India with great variety of flora and fauna. For centuries man has made

effective use of materials of natural origin in the medicinal and pharmaceutical field. Natural materials have advantages over synthetic materials because they are nontoxic, less expensive, freely available, biodegradable and edible sources[1]. They are used as binding, thickening, emulsifying, suspending, stabilizing agents in pharmaceutical industries and used as matrices for sustained release of drugs[2,3].

Mucilage are polysaccharide complexes formed from sugar and uronic acid units. Mucilage will form slimy masses with water. Mucilage are used as binding agent, suspending agent, thickening agent, humidifying, disintegrating, gelling agent and release controlling properties in medicines. The sources of mucilage are *Musaparadisical* pulp, acacia emicel, *Abelmoschues esculentus* mucilage etc. Botanical name of banana fruit is *Musaparadisiaca* belongs to family Musaceae. Banana peel is thickening and adhesive in nature. In the present study, attempts shall be made to utilize dried powder of banana peel mucilage as binding and suspending agent[4].

The term "Mucilage" is meant those substances which are soluble or at least swell very perceptibly in water and which, upon the addition of alcohol, are precipitated in a more or less amorphous or granular mass. Mucilage originates in the plant either as a part of the contents of the cell or as a part of the wall such as bark, seeds, sap, roots, rhizomes, fruits and leaves. Mucilage is used for their binding, thickening and stabilizing agent[5].

MATERIALS AND METHODS

Materials

Aceclofenac is purchased from Yerrow Chem, Pvt. Ltd and banana peel mucilage powder was extracted in the lab. mannitol, sodium starch glycolate, magnesium stearate, talc, sodium CMC, methyl paraben, propyl paraben and vanillin flavor are of analytical grade.

METHODS

Extraction of banana peel mucilage

The fresh and ripe bananas are purchased from the local market. The peel are removed from the fruit and washed with water and dried it for one day. 200 g of peel were cut into small pieces, crushed with mixer soaked in the 1 liter of water containing 1% w/v of sodium metabisulphate for 7-8 h and after boiled for

30 min and left to stand for complete removal of mucilage into the water. The marc was removed from the solution by using muslin cloth. The solution was centrifuged at 3000 rpm for 5 minutes and the mucilage was precipitated three volumes of acetone and collected the mucilage from the superinate precipitation through filtration. The crude mucilage was treated with 10 ml of tri chloro acetic acid then the mucilage was centrifuged at 3000 rpm for 5 min and neutralized with 1N NaOH (15 ML) and then dialyzed for 1 h against with 100 ml of distilled water. The mucilage was again precipitated with 300 ml of ethanol in quantities of three times of the volume and filter the solution with vacuum dryer for complete removal of ethanol and mucilage was dried with air dry and powder it, passed through the sieve No. 60 and 65 g of mucilage was obtained, stored in a desiccator until use[6].

Preliminary phytochemical screening of banana peel mucilage powder

The phytochemical properties such as presence of alkaloids, carbohydrate, glycosides, tannins, proteins and amino acids were determined[7] as shown in Table 1.

Physicochemical characterization of banana peel mucilage powder

The physico chemical characterization of banana peel mucilage powder such as solubility, pH, loss on drying, viscosity and ash values were determined as shown in Table 2.

FT-IR Studies

Pure drug aceclofenac, banana peel mucilage powder, prepared tablet formulations and suspension formulation are studied for FT-IR spectra. Aceclofenac suspension formulation was filtered using Whatman filter paper and the residue was used for the FT-IR study[8].

Scanning Electron Microscopy

Extracted banana peel mucilage powder is subjected for SEM studies to understand its surface morphological characters.

Differential Scanning Calorimetry

DSC studies were carried out for pure aceclofenac, banana peel mucilage powder and tablet formulation F4 to find out any chemical interactions among them.

Preparation of Aceclofenac Tablets

Aceclofenac was used as model drug, wet granulation method was used for preparation of the aceclofenac tablets. Drug and excipients are passed through the sieve no.60 individually. Aceclofenac, banana peel mucilage powder, mannitol and sodium starch glycolate were added and mixed uniformly. Distilled water in a sufficient quantity was added to form a wet mass and it was passed through the sieve no. 12. Distilled water was added as granulating fluid. The same procedure was followed to prepare the granules with different concentrations of banana peel mucilage powder (2.5, 5, 7.5 and 10 %w/w) and 7.5 %w/w concentration of PVP as synthetic binding agent for comparison shown in Table 3. The prepared granules were subjected to evaluate pre compression parameters. Granules were lubricated with magnesium stearate, talc and were compressed into the tablets of 200 mg, using 10 station rotary tablet compression machine (Shakti Pharma Tech, Ahmadabad)[9].

Evaluation of Aceclofenac Granules

Angle of repose

The angle of repose was calculated using the formula,

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

Where

θ = angle of repose

h = height of pile,

r = radius of the base of the pile.

Compressibility Index

Tapped bulk density and untapped bulk density was measured using measuring cylinder.

Evaluation of the Tablets

Weight Variation Test

Randomly selected twenty tablets were weighed individually and together in a single pan balance. The average weight was noted and percentage deviation.

Hardness, Thickness

Six tablets were taken randomly and hardness was measured by the Monsanto hardness tester. Hardness was expressed in Kg/cm^2. The thickness and diameter of the tablet was measured using vernier calipers.

Friability

Twenty tablets selected randomly from each batch were tested at a time. Tablets collective weight was determined before (W_1 g) and after (W_2 g) the test.

Drug content

Five tablets were weighed individually and powdered collectively. The powder equivalent to average weight of tablets was weighed and drug was extracted in phosphate buffer pH

6.8, the drug content was determined spectrophotometrically. In case of suspension, 5 ml was subjected to extraction with phosphate buffer pH 6.8 and measured the absorbance after suitable dilution using a UV spectrophotometer at 274 nm.

Disintegration Test

Disintegration test was carried out according to I.P. method. Six tablets were placed in glass tubes of disintegration apparatus. Disintegration fluid temperature was maintained at 37 °C and time required for disintegration was noted.

***In vitro* Dissolution Studies**

The dissolution of aceclofenac tablets & suspension was carried out using phosphate buffer pH 6.8 at 37 °C & rotation speed of the paddle was maintained at 50 rpm for tablets and 25 rpm for suspension. Samples were withdrawn at every 10 min until 120 min in case of tablets, whereas in case of suspension samples were withdrawn at every 2 min until 24 min in case of suspensions. Dissolution media was replaced each time to maintain 900 ml volume constant. Samples were analyzed using UV Spectrophotometer at 274 nm. Similarly a marketed tablet, Acenac also studied for dissolution studies for comparison purpose[10].

Preparation of Aceclofenac Suspension

Aceclofenac (1 g) and banana peel mucilage powder (0.25 g) are triturated to get a fine powder, little quantity of distilled water was added and continued trituration. Methyl paraben, propyl paraben and vanillin are added in sufficient quantities and volume was made up to 50 ml using distilled water and stored in a well closed dispensing bottle (Table 4). Similarly aceclofenac suspensions were prepared with different concentrations of banana peel mucilage powder (1, 1.5 and 2 %w/v). A reference aceclofenac suspension was prepared using 1.5 %w/v sodium CMC as synthetic suspending agent for comparison purpose[11].

Evaluation of Aceclofenac Suspension

pH Measurements

The pH measurements of the suspensions were done weekly for three weeks using a digital pH meter.

Sedimentation Volume[12]

Each suspension (50 ml) was placed in a 100 ml measuring cylinder and stored for 7 days at room temperature. The volume of the sediment at every hour for 7 hr and then every 24 hr for 7 days was noted. Marketed product IMOL was selected for comparison. The sedimentation volume of different suspensions was calculated by the equation

$$F = Vu / Vo;$$

Where

F is the sedimentation volume.

Vu is the ultimate volume of the sediment and

Vo is the original volume of the of suspension.

Redispersibility

Fixed volume of each suspension (50 ml) was kept in stoppered dispense bottles which was stored at room temperature for 7 days. At regular interval, one bottle was taken and turned upside down until there was no sediment at bottom of the bottle and numbers of turns were noted.

Determination of Flow Rate

10 ml of suspension was taken in a pipette and time required to flow was noted to calculate flow rate of suspension.

Flow rate (η) = volume of pipette (ml) / flow time (min)

Viscosity

The viscosity (in poise) of the samples was determined at 25 °C using the Brookfield Synchroelectric viscometer; model LVF at 25 & 50 rpm (Spindle #2).Determinations were in Triplicate[13].

Particle Size Analysis[14,15]

Particles size of prepared suspensions was measured by microscopic method. A slide of suspension was prepared and size of particles was measured using calibrated eye piece micrometer.

Degree of Flocculation

The degree of flocculation was determined using the equation

$$\beta = F/F_{\infty}$$

Where

F is ultimate sedimentation volume in flocculated suspension.

F_{∞} is ultimate sedimentation volume in deflocculated suspension.

Stability Studies

Stability studies of optimized formulations were done as per ICH guide-lines, by storing the tablets for 3 months.

RESULTS AND DISCUSSION

Phytochemical characterization of banana peel mucilage powder results indicates presence of carbohydrates and reducing sugar in the banana peel mucilage powder. Negative results were shown for alkaloids, tannins, glycosides, proteins and amino acids. As per physico chemical characterization banana peel mucilage powder was soluble in water and insoluble in acetone and other organic solvents. Total ash, water soluble ash and acid insoluble ash (%) was 6.25, 5.89 and 0.89, respectively. FT-IR spectra for pure aceclofenac, banana peel mucilage powder, optimized aceclofenac tablet formulation F4 & aceclofenac suspension formulation F9 are shown in the Fig. 1. There is a no changes in the absorption peaks of drug in the final formulation was observed. Hence, there is no interaction of the drug with the banana peel mucilage powder as well as other excipients used.

DSC thermogram of aceclofenac (Fig. 2) shows sharp endothermic peak at 156.25 °C, this shows the crystalline nature of the aceclofenac sodium. SEM photos of banana peel mucilage powder shown in Fig. 3. The banana peel mucilage powder particles are asymmetric and smooth surface observed. The size range of particles was from 50- 200 µm approximately.

Angle of repose of granules found to be 26 to 29° indicates good flow of granules. Carr's index was found to be 10.24-13.64. Haunser ratio was in the range of 1.09-1.13 shown in Table 5. These values are satisfactory for granules to be compressed. Hardness of aceclofenac tablets were 3.05 - 5.89 kg/cm2. Friability was found in the range of 0.42 - 0.91 %. Thickness was 2.21 – 3.17 mm shown in Table 6. Particle size of the all suspension formulations were range of 8 - 18 µm determined by microscopic method. Drug content of suspension formulations prepared with banana peel mucilage powder was found to be in the range 97.15 to 101.06 % shown in Table 7.

Sedimentation studies percentage sedimentation volume of aceclofenac suspensions was directly proportional to suspending agent concentration. However, in each suspension percentage sedimentation volume inversely proportional to time in days. In case of F6 formulation as the time increased from zero to 7 days the percentage sedimentation volume decreased from 100 to 64 [Table 8], (Fig. 4). Whereas formulation F9 shows 98 % sedimentation volume. Hence, F9 was selected as an optimized formulation. Redispersibility and pH was found to be in the range of 1 - 3 turns and 5.28 - 6.82 [Table 9]. In vitro release studies of aceclofenac tablet showed that 97.52 % drug released within 60 minutes in case of formulation F1. Whereas formulation F2 released 99.55 % within 80 minutes, formulation F3 released 99.69 % within 100 minutes, whereas formulation F4 released 99.86 % within 120 minutes. As percentage of banana peel mucilage powder increased in the formulation, more amount of time taken to release about 98 % of the drug from different tablet formulations. Formulation F5 prepared with synthetic binding agent PVP released the drug 99.22 % within 90 minutes; marketed product released 99.32% within 90 minutes of dissolution studies [Table 10], (Fig. 5). Formulation F4, is optimized even through formulation F1, F2 & F3 released 98 % of the drug earlier to the formulation F4 because formulations F1, F2 & F3 did not posses enough hardness and did not pass for the friability test.

In vitro release studies of suspension showed that 97.34 % drug released within 16 minutes in case of formulation F6. Whereas formulation F7 released 97.12 % within 18 minutes, formulation F8 & F9 released 98.72 and 99.39 % within 22 and 24 minutes. As percentage of banana peel mucilage powder increased in the formulation increase amount of time taken to release about 98 % of the drug from different suspension formulations, shown in the [Table 11], (Fig. 6). Formulation F9 is optimized even though formulation F6, F7 & F8 released 98 % of the drug earlier to the formulation F9 because formulations F6, F7 & F8 did not show enough percentage sedimentation volume. Release kinetics of optimized tablet and suspension formulations was followed zero order kinetics and non fickian model. The stability studies for optimized formulations were carried for 3 months. There was no significant change in the physical property and drug content during the study period.

CONCLUSION

The banana peel mucilage powder exhibited good binding and suspending properties for the aceclofenac tablets and suspension. The increased concentration of mucilage showed small retardation in drug release from tablet and suspension. Therefore, banana peel mucilage powder can be used as a pharmaceutical excipient in tablets and suspension preparations. Banana peel mucilage powder 10 %w/w and 2 %w/v were optimized as binding and suspending agents, respectively.

Table 1: Phyto chemical Characterization of banana peel mucilage

S.NO	Name of the test		Observation
1	Test for alkaloids	Mayers test	-
		Dragon draffs test	-
		Wagner test	-
		Hagers test	-
2	Test for carbohydrates	Molish test	+
		Fehlings test	-
		Benidicts test	-
3	Test for Glycosides	Liebermann- Burchard	-
		Legals test	-
4	Test for mucilage	Ruthenium red test	+
5	Test for tannins	Ferric chloride test	-
		Lead acetate test	-
		Aquous bromine test	-
6	Test for proteins and amino acids	Millons test	-
		Biuret test	-
		Ninhydrin test	-
7	Tests for Saponins	Foam test	-
8	Test for Polysaccharides	Iodine test	+
9	Tests for Flavonoids	Shinoda test	_

Table 2: Physicochemical Characterization of banana peel mucilage

S.NO	Charecteristics	Observation
1	Colour	Pale brown colour
2	Odour	Characteristic
3	Nature	Crystalline
4	Solubility	Soluble in water and insoluble in organic solvents
5	pH	7.16±0.26
6	Angle of repose	29.11°±0.09
7	Bulk density (g/cc)	0.69±0.05
8	Tapped density (g/cc)	0.77±0.09
9	Carr's index	14.12±0.17
10	Hausner's ratio	1.125±0.25
11	Viscosity (5%&7.5%)	38.96 & 35.28
12	Melting point ° C	175
13	Microbial count	0
14	Loss on drying %	9 ± 0.78
15	Total ash %	8.46±0.89
16	Water soluble ash %	6.69±0.45
17	Acid insoluble ash %	0.78±0.89

Table 3: Formulation of Aceclofenac tablets at different amounts of banana peel mucilage as binding agent

Ingredients	F1	F2	F3	F4	F5
Aceclofenac (mg)	100	100	100	100	100
Banana peel mucilage powder (mg)	5	10	15	20	--
PVP (mg)	--	--	--	--	15
Mannitol (mg)	85	80	75	70	75
Sodiumstarchglycolate(mg)	4	4	4	4	4
Magnesium stearate (mg)	4	4	4	4	4
Talc (mg)	2	2	2	2	2
Total (mg)	200	200	200	200	200

Table 4: Formulation of Aceclofenac suspensions at different percentages of banana peel mucilage as suspending agent

Ingredients	F6	F7	F8	F9	F10
Aceclofenac (g)	1	1	1	1	1
Banana peel mucilage powder (g)	0.25	0.5	0.75	1.0	--
Sodium cmc (g)	--	--	--	--	0.75
Methyl paraben (g)	0.15	0.15	0.15	0.15	0.15
Propyl paraben (g)	0.1	0.1	0.1	0.1	0.1
Vanillin flavuor (g)	0.005	0.005	0.005	0.005	0.005
Purified water q.s to ml	50	50	50	50	50

Table 5: Pre compression parameters of aceclofenac granules by using banana peel mucilage as tablet binder

S.No	Parameters	Formulation code				
		F1	F2	F3	F4	F5 (PVP)
1	Percentage yield	96.56	93.43	95.43	95.56	94.32
2	Angle of repose (θ)	27°17'±0.25	28°32'±0.29	28°12'±0.37	27°26'±0.85	26°72'±0.65
3	Bulk density(g/cc)	0.55±0.01	0.51±0.01	0.53±0.005	0.59±0.01	0.54±0.01
4	Tapped density(g/cc)	0.61±0.01	0.59±0.05	0.60±0.01	0.65±0.01	0.60±0.005
5	Carr's index	10.27±0.91	12.63±0.94	11.58±1.47	9.14±0.15	10.50±1.01
6	Hausner's ratio	1.11±0.01	1.13±0.04	1.13±0.02	1.09±0.005	1.11±0.01

Table 6: Post compression parameters of aceclofenac tablets by using banana peel mucilage as tablet binder

S.NO	Parameters	Formulation code				
		F6	F7	F8	F9	F10 (PVP)
1	Weight variation	200±0.001	200 ± 0.015	200 ± 0.008	200±0.002	200 ± 0.001
2	Thickness(mm)	3.37±0.02	2.72 ± 0.02	2.52±0.02	2.17±0.02	2.32 ±0.02
3	Friability (%)	0.96±0.04	0.83±0.02	0.62±0.05	0.35±0.09	0.49±0.08
4	Hardness (kg/cm^2)	3.04±0.12	3.14±0.09	3.62±0.13	5.54±0.04	5.69±0.07
5	Drug content(%)	99.86±0.56	101.25±0.12	100.02±0.22	99.66±0.36	101.78±0.78
6	Disintegration time(min)	4 min, 3 sec	4min,30se	5min,21sec	5min,45se	6min,4sec

Table 23: *In-vitro* drug release from aceclofenac tablets prepared with different amounts of banana peel mucilage powder, synthetic binder PVP (7.5% w/w) and marketed product (Acenac)

Time in min	Average percent cumulative drug released (n=3)					
	F1	F2	F3	F4	F5 (PVP)	Marketed product
0	0	0	0	0	0	0
10	15.50±0.35	17.77±0.12	13.61±0.10	15.87±0.36	10.32±0.07	11.12±0.78
20	38.60±0.46	37.09±0.02	34.82±0.30	29.52±0.26	26.85±0.11	24.75±0.85
30	77.63±0.10	61.35±0.12	53.78±0.16	42.42±0.25	38.12±0.10	38.12±0.33
40	88.16±0.50	83.09±0.30	72.77±0.42	54.96±0.32	44.16±0.61	44.16±0.33
50	98.16±0.50	86.97±0.32	84.96±0.18	70.16±0.06	52.12±0.49	52.12±0.13
60	98.16±0.50	98.99±0.32	89.06±0.13	84.96±0.05	61.78±0.36	61.78±0.26
70	98.16±0.50	98.99±0.32	99.26±0.23	89.89±0.04	72.85±0.34	72.85±0.89
80	98.16±0.50	98.99±0.32	98.26±0.23	99.89±0.44	84.56±0.85	82.56±0.25
90	99.32±0.14	99.32±0.14	99.32±0.14	99.32±0.14	99.32±0.14	91.12±0.45
100	99.32±0.14	99.32±0.14	99.32±0.14	99.32±0.14	99.32±0.14	99.32±0.69

Table 24: *In-vitro* drug released from aceclofenac suspension prepared with different amounts of banana peel mucilage powder and synthetic suspending agent Sodium CMC (1.5% w/v)

Time in minutes	Average percent cumulative drug released (n=3)				
	F16	F17	F18	F19	F20
0	0	0	0	0	0
2	21.55±0.56	23.44±0.88	17.77±0.85	17.39±0.45	16.18±0.29
4	43.15±0.45	44.28±0.27	35.20±0.89	32.93±0.87	31.82±0.17
6	65.90±0.78	54.93±0.75	48.10±0.75	37.13±0.58	48.65±0.25
8	73.17±0.67	70.89±0.42	62.92±0.59	47.76±0.62	59.72±0.56
10	85.36±0.28	81.94±0.39	72.83±0.83	61.82±0.76	62.16±0.85
12	97.57±0.46	92.63±0.13	89.94±0.88	74.38±0.84	78.82±0.79
14	97.67±0.46	97.52±0.46	93.45±0.87	82.41±0.57	82.12±0.76
16	97.71±0.46	97.67±0.49	99.13±0.85	93.10±0.52	91.34±0.48
18	97.79±0.46	97.97±0.51	99.23±0.89	99.64±0.54	99.62±0.64

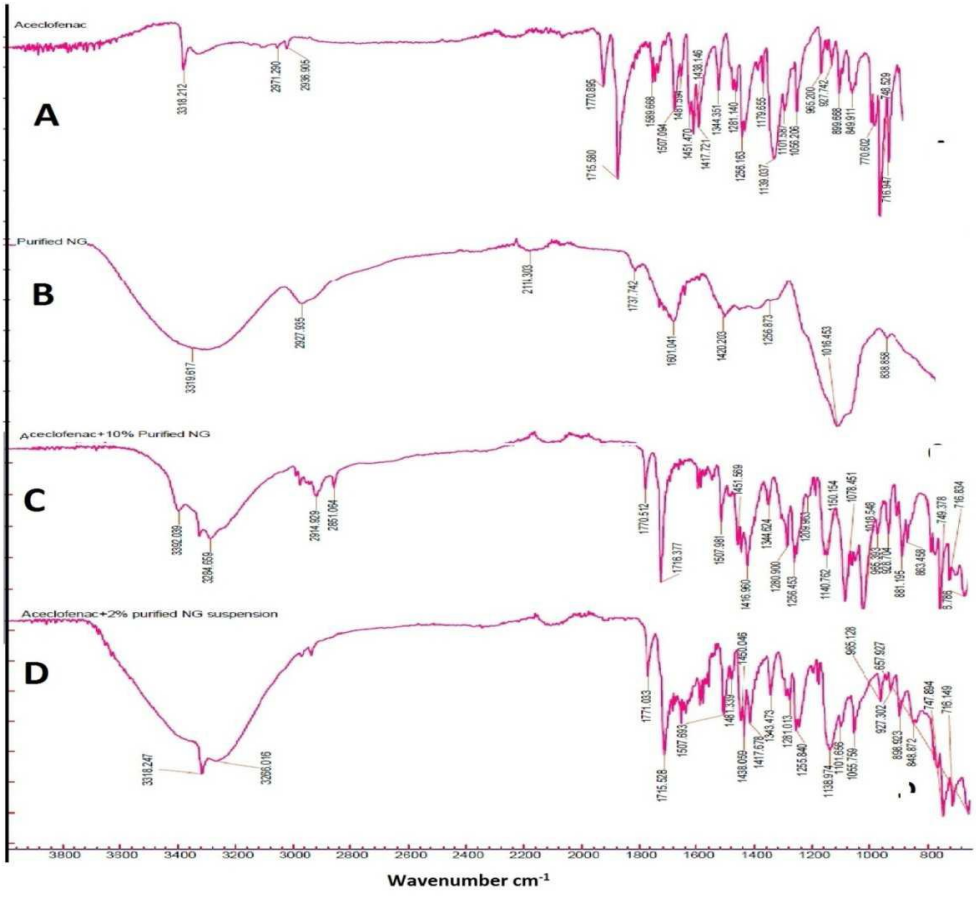

Fig. 1: FTIR spectra of aceclofenac, banana peel mucilage powder, Aceclofenac tablet Formulation F4 and Aceclofenac suspension Formulation F9

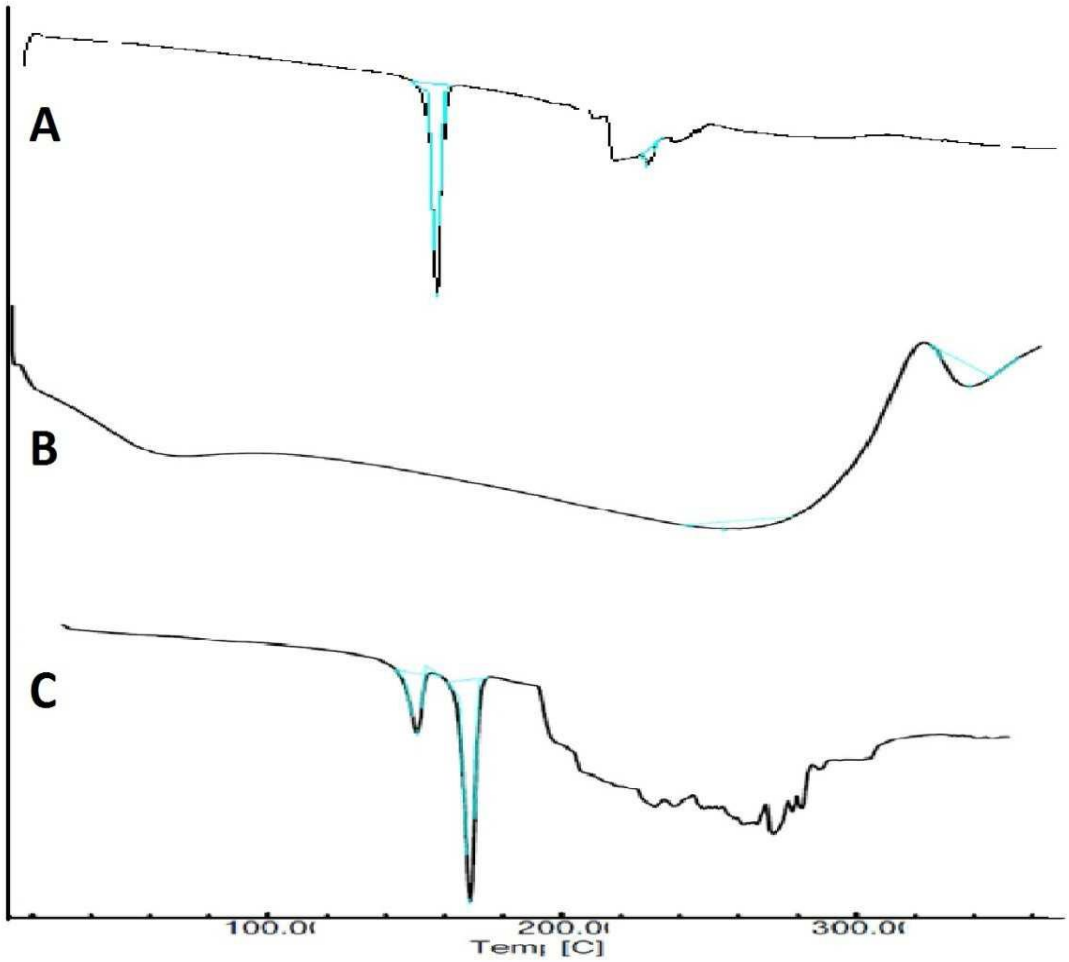

Fig. 2: DSC thermogram of aceclofenac, banana peel mucilage powder and Formulation F4

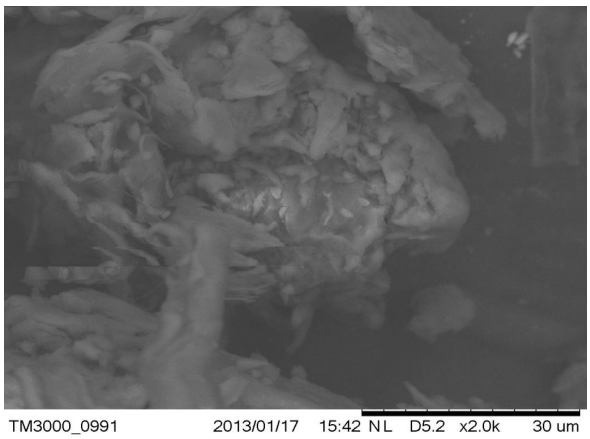

Fig. 3: SEM photograph of banana peel mucilage powder (2.0 k, Magnification)

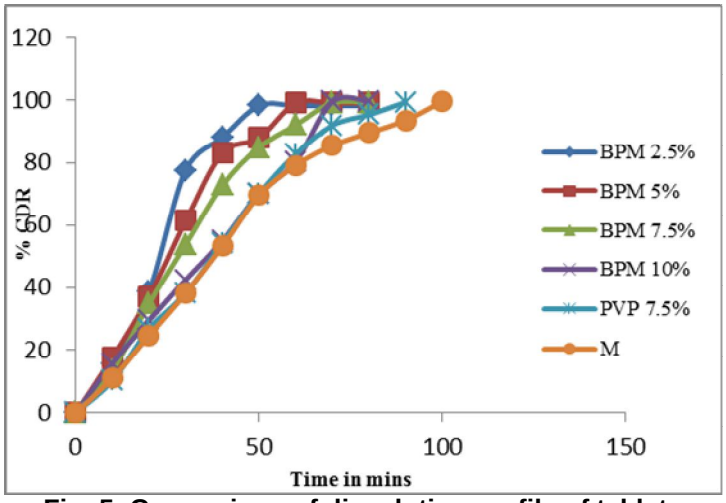

Fig. 5: Comparison of dissolution profile of tablets prepared with banana peel mucilage powder (BPM) as binder, synthetic binding agent PVP and marketed product

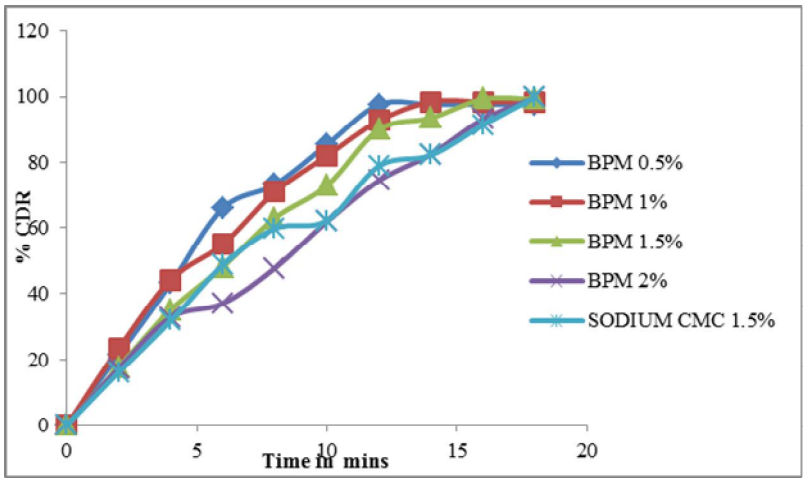

Fig. 6: Comparison of dissolution profile of suspension prepared with banana peel mucilage powder (BPM) as suspending agent and synthetic suspending agent (1.5 %w/v)

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