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### FORMULATION AND EVALUATION OF MUCOADHESIVE TABLET OF METFORMIN HCL USING JACK FRUIT LATEX (*ARTOCARPUS HETEROPHYLLUS*)

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#### ABSTRACT

The concept of mucoadhesion is one that has the potential efficiency to improve the highly variable residence times experienced by drugs and dosage forms at various sites in the gastrointestinal tract, and consequently, to reduce variability and improve efficacy. Intimate contact of the drug with the mucosa should enhance absorption. *Artocarpus heterophyllus* (Jack fruit) is one of the most evergreen trees in tropical areas and widely grown in Asia including India. The latex contains 71.8% resins consisting of 63.3% yellow fluavilles and 8.5% white albanes. The dried latex yields Artostenone, convertible to Artosterone, a compound with androgenic action. The work accomplished so far reveals that jackfruit latex possesses the desirable properties required for a polymer to be used as mucoadhesive agent/binder. The flow properties of the latex as well as that of granules depicted by its compressibility index, Hausner's ratio, Kawatika factors, angle of repose etc. are found to be within the desired range. Moreover FTIR spectroscopy, Differential Scanning Calorimetric study has shown that there was no chemical interactions between the drug and latex neither there is prominent endothermic decrease of melting point of the drug due to presence of latex in the powder mixture. Investigation in terms of *in-vitro* dissolution study, comparative mucoadhesion study, compatibility study with the selected formulation, stability study etc reveals that Jackfruit latex has potential to act as natural binder in mucoadhesive solid dosage form (tablet) and can also be suitably used for formulating tablets.

**Keywords:** Mucoadhesion, *Artocarpus heterophyllus*, Metformin hydrochloride, Jack fruit latex, *in-vitro* dissolution study.

#### INTRODUCTION

Bioadhesion can be defined as the process by which a natural or a synthetic polymer can adhere to a biological substrate. When the biological substrate is a mucosal layer then the phenomenon is known as mucoadhesion. Mucoadhesion is the attachment of the drug along with suitable carrier to the mucous membrane. It is complex phenomenon which involves wetting, adsorption and interpenetration of polymer chains. Mucoadhesive drug delivery system includes the following delivery systems namely Buccal/Oral, Nasal, Ocular, Vaginal, Rectal and Gastrointestinal. These system remain in close contact with the absorption tissue, the mucous

membrane releasing the drug at the action site leading to increase in bioavailability for local/systemic effects.<sup>1</sup>

#### Natural Mucoadhesive Polymers

Mucoadhesive polymers that bind to the gastric mucin or epithelial cell surface are useful in drug delivery for the purpose of increasing the intimacy and duration of contact of drug with the absorbing membrane. Natural gums and mucilage have been extensively explored as pharmaceutical excipients. Several synthetic polymers are in use for mucoadhesive. Since the biodegradability of the synthetic polymers are questionable, study of mucoadhesive obtained from natural sources are

gaining interest among research scientists<sup>2</sup> however, research on mucoadhesive is still in budding stage. Therefore there is need of further advances for successful conversion of theoretical concept into practical application in controlled drug delivery by promoting dosage form residence time and contact time with the mucous membrane.

### Jack Fruit

Botanical name: *Artocarpus heterophyllus*

Family: Moraceae

#### Description

*Artocarpus heterophyllus* is one of the most evergreen trees in tropical areas and widely grown in Asia including India. It is a medium sized tree typically reaching 28-80 ft in height.<sup>3</sup> The average weight of the fruit is between 3.5 to 10 kg and sometimes the fruit may reach up to 35 kg. Jackfruit has a multiple fruit with a green to yellow brown outer peel that is composed of hexagonal, bluntly conical thorns. It is medium-size tree typically reaching 28-80ft in height that is easily accessible by its fruit, the ripe fruit contains well succulent, aromatic and flavorful yellow sweet bulbs and seeds make up around 8 to 15% of the total fruit weight. The fruit is held together by a central fibrous core. The interior consists of large bulbs along with whitish yellow aril. Each bulb encloses a smooth, oval shaped, brown spermoderm covered by a thin white cotyledon. The seed is 2-3 cm long and 1-2 cm in diameter. Up to 500 seeds can be found in a single fruit. Jackfruit is eaten raw or used in curries, soups, chips, jams, jellies, juice and stews and also a common ingredient in fruit salads. The leaves used for animal feeds and white latex are used as adhesives. The seeds are roasted and eaten like chestnuts, seeds are used in cooking and its flour used for backing. Jackfruit seeds are fairly rich in starch. *Artocarpus heterophyllus* is an important source of compounds like morin, dihydromorin, cynomacurin, artocarpin, isoartocarpin, cyloartocarpin, artocarpesin, oxydihydroartocarpesin, artocarpetin, norartocarpetin, cycloartinone, betulinic acid, artocarpanone and heterophyllol which are useful in fever, boils, wounds, skin diseases,

convulsions, diuretic, constipation, ophthalmic disorders and snake bite etc.<sup>4</sup>

### Chemical Constituents

The latex contains 71.8% resins consisting of 63.3% yellow fluavilles and 8.5% white albanes. The dried latex yields Artostenone, convertible to Artosterone, a compound with androgenic action.

## MATERIALS AND METHODS

Metformin hydrochloride was obtained as a gift from Psychotropic India Limited, Haridwar 249403, Uttarakhand, Dicalcium phosphate; Magnesium stearate; Microcrystalline cellulose etc from Merck Specialities Pvt Ltd, Mumbai-400018. All chemical and reagent used in this study were of analytical grade.

### Isolation of Jack Fruit Latex

The latex was collected from bark and the peduncle of the slightly under ripe jackfruit. The latex was collected in a beaker containing demineralised water. The diluted latex started coagulating. The coagulated mass was washed several times with demineralised water to free it from the extraneous water soluble plant materials. The washed rubbery latex was dried under vacuum. This was then stored in desiccators. At the beginning the latex appears white which changes to off white on storage. The dried latex was powdered with the help of mortar & pestle. Than this latex powder were dissolved in acetone. Then this solution was filtered to remove all insoluble organic and inorganic matters. The filtered solution was then spread on a glass petri dish for solvent evaporation and allowed to dry completely under vacuum to get yellowish white powdery but slightly sticky mass. This was then spread on a watch glass and maintained at a temperature of 120 °C in a hot air oven for 2 hours. The residue was then cooled and allowed to dry completely under vacuum to get a yellowish white solid mass. The solid mass was powdered and transferred into a tightly closed container.

### Determination of % Yield

A known quantity of crude material was weighed. After the latex was precipitated using acetone, the dried latex solid mass was

determined. The yield was expressed as percentage of the mass of the dry precipitate against the mass of the whole fresh crude materials.

#### **Preformulation Study of Jackfruit Latex**

The isolated, dried and powdered latex was tested for flow properties (bulk density, Tapped density, Carr's Index, Hausner's ratio, Angle of repose, Kawatika factors), elemental analysis (Euro EA) and NMR of the powdered extract for chemical characterization of latex was observed with Varian, Inc. Inova and MercuryPlus NMR Systems.

#### **Preformulation Study of Metformin Hydrochloride**

The drug was subjected to the following preformulation test.

##### *Organoleptic Properties*

The Organoleptic properties such as Colours, Odours and Taste were examined manually.

##### *Determination of Solubility*

On the basis of polarity different solvent system were selected and the solubility was observed. A minute quantity of the drug sample was taken in a test tube and solubility of the drug was determined by dissolving the drug in 10 ml various solvent like water, 0.1 N HCL, Ethanol, Acetone, Phosphate buffer etc.

##### *Melting Point Determination*

Melting point of metformin hydrochloride was determined using a capillary tube by Melting Point Instrument (Macro scientific works10A/UA).

##### *UV Scanning*

The various concentration of drug sample was prepared. The spectrum of this solution was run in 200 to 400 nm range in UV-visible spectrophotometer and the maximum absorption frequency was detected from the spectrum.

##### *Preparation of Standard Calibration Curve in Phosphate Buffer pH 6.8:*

100 mg of drug was weighed accurately and dissolved in 100ml of phosphate buffer (pH 6.8) to prepare a stock solution in a volumetric flask. Then further dilutions were made to get

concentrations of 2, 4, 6, 8, 10 µg/ml. The absorbance of each samples were measured by using UV-visible spectrophotometer at 230 nm.

##### *FTIR Spectra*

FTIR study was carried out for the pure drug. About 10mg of drug powder was taken for the pellet formulation and observed under FTIR instrument (Bruker; ALPHA; Model No-10059736). The pellet was kept onto the sample holder and scanned from 400 cm<sup>-1</sup> to 4000 cm<sup>-1</sup> in Broker FTIR spectrophotometer. The observed FTIR Spectra was than compared with a standard.

#### **Formulation of Mucoadhesive Tablet**

##### *Preparation of Granules*

A formula for a trial batch of mucoadhesive tablet was developed and accordingly granules were prepared using various excipients like Dicalcium phosphate, Magnesium stearate, Talc, Microcrystalline cellulose along with Metformin hydrochloride and latex as mucoadhesive binder. Conventional wet granulation technique was used to prepare granules. The powder mixture was granulated with latex (4%) in acetone solution. The damp dough was passed through sieve 22 and the granules were dried at 60 °C for 1 hrs in a hot air oven. The dried granules were passed through sieve 22 and lubricated with magnesium stearate and talc.

##### *Evaluation of granules*

Precompression study of prepared granules was carried out for Bulk density ( $D_b$ ), Tapped density ( $D_t$ ), Carr's Index (C.I.), Hausner's ratio, Angle of repose ( $\theta$ ), Kawatika factors 'a' and '1/b'.

##### *Compression*

The prepared granules were compressed in a tablet compression machine to produce 200mg tablets using 8mm flat punches (Tablet Compression Machine, Shakti, 9001:2000 Co.). The formula for trial batch of tablet is shown in Table 8.

##### *Evaluation of Tablet*

Hardness test, Friability loss, Weight variation tests were carried out for the trial batch of tablet. The results are shown in Table 9.

##### *Mucoadhesion Test of Tablet*

The mucoadhesion strength was determined by measuring the maximal force required to separate the test material from the mucosal surface. Mucoadhesion test was performed with using Texture Analyzer (TA.XT EXPRESS, FD/I-077). A fresh part of goat intestine was collected from a local meat shop at Chandmari and was incised to expose the inner mucous surface. The incised part was washed properly and dipped into a freshly prepared phosphate buffer solution of pH 6.8 during the preparation time. The upper probe of Texture Analyser was fitted with a rounded shaped adhesive tape to which the prepared tablet was fixed with application of pressure. The collected and cleaned goat intestine was fixed into the lower probe of Texture Analyser by the help of a lid and secured with screws in such a way that inner mucous side is exposed for tablets to adhere while testing. Then a drop of buffer solution was placed over the rounded exposed surface of intestine and the instrument was switch on. The results were recorded for tablets using different surface of intestine for each of the tablet and compared.

#### *Dissolution*

Drug release studies of tablets were done in Phosphate buffer pH 6.8 by using USP Type II Dissolution Apparatus. The assembly was kept in a jacket vessel of water maintained at  $37 \pm 0.5^\circ\text{C}$

and 50 rpm speed. The dissolution studies were carried out for 24 hours. The samples were collected at fixed time intervals (at 0.25,0.5,1,2,3,4,5,6,8,12,24 hrs in phosphate buffer of pH 6.8) filtered and their absorbance were determined at a wavelength of 230 nm. Corresponding % drug release was determined. Results of the above test are shown in Table 10.

#### *Release Kinetics*

The in vitro release data of selected formulations were fitted to various kinetic equations such as Zero order, First order, Higuchi, Koresmeyer-Peppas.

## RESULT AND DISCUSSION

### *Isolation of Artocarpus heterophyllus Latex*

The Jackfruit latex was isolated, dried, sieved and stored in well closed container.

### *Characterization of Latex Powder*

#### *Determination of % Yield*

The % yield found was to be 27.33w/w. During the process of latex isolation several washing required which causes appreciable loss of mucoadhesive agent.

### Preformulation Data for Latex

**Table 1:** Organoleptic Properties of latex

Sample	Colour	Odour	Taste
Latex Powder	Yellowish White	Odourless	Tasteless

**Table 2:** Solubility of latex in different solvents

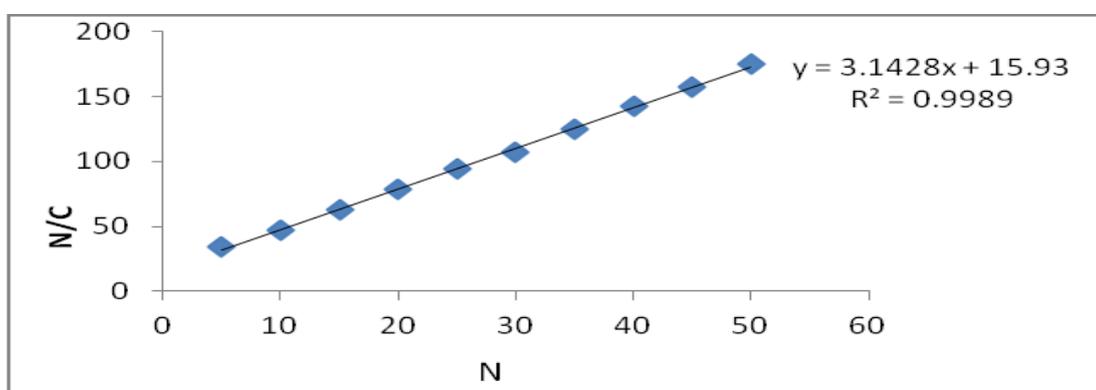
Solvent System	Observation
0.1M HCL (pH 1.2)	Insoluble
Buffer (pH 6.8)	Viscous Solution
Acetone	Soluble
Ethanol	Soluble
Methanol	Soluble

**Table 3: Flow Properties of Latex Powder**

Sample	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (% CI)	Hausner's Ratio (HR)	Kawatika	Factors	Angle of Repose (θ)
					'a'	'1/b'	
Latex Powder	0.484	0.597	18.92	1.23	0.318	5.066	$\tan^{-1}(1.3/2.3) = 29.4^{\circ}$

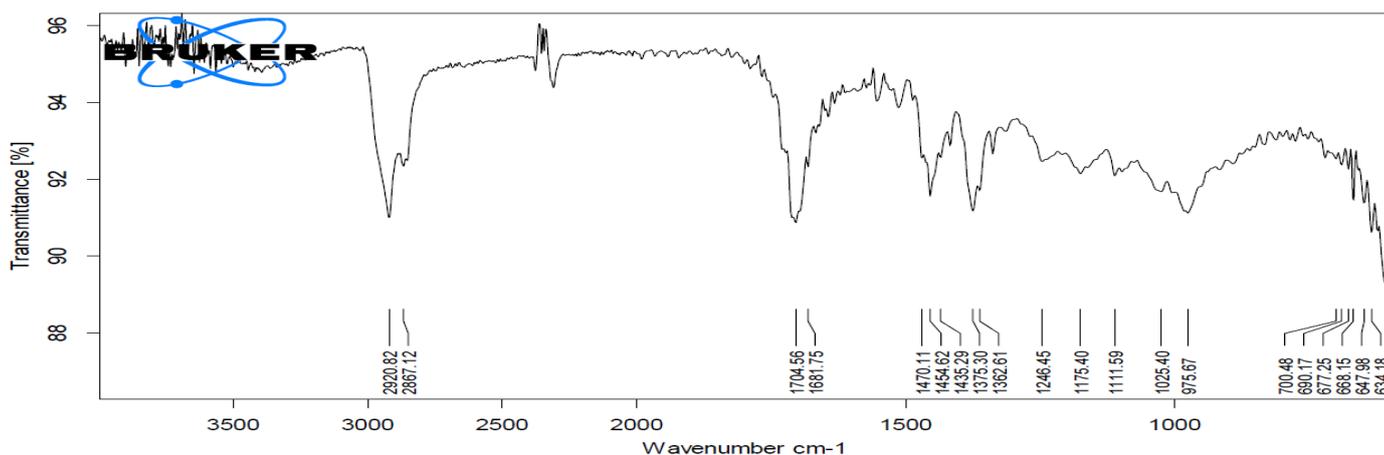
**Table 4: Data of latex powder Bulk volume  $V_0 = 7.5$  ml; Weight = 3.632 g; Degree of compression  $C = (1 - V/V_0)$**

N	5	10	15	20	25	30	35	40	45	50
Vol.(ml)	6.4	5.9	5.7	5.6	5.5	5.4	5.4	5.4	5.35	5.35
C	0.1466	0.2133	0.240	0.2533	0.266	0.280	0.280	0.280	0.286	0.286
N/C	34.106	46.88	62.50	78.95	93.98	107.14	125.0	142.86	157.34	174.83



**Figure 1: Kawatika plot for jackfruit latex**

Based on above the Kawatika constants 'a' and 'b' are determined  $1/3.142 = 'a' = 0.318$ ;  $1/ab = \text{intercept} = 15.93$ , putting the value of 'a' from above we get  $1/0.318b = 15.93$ ,  $1/b = 5.066$



D:\FTIR\JACK FRUIT LATEX.0	JACK FRUIT LATEX	Instrument type and / or accessory	11/23/2015
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**Figure 2: FTIR spectrum of Jackfruit Latex**

**Table 5:** Structural assignment of latex powder

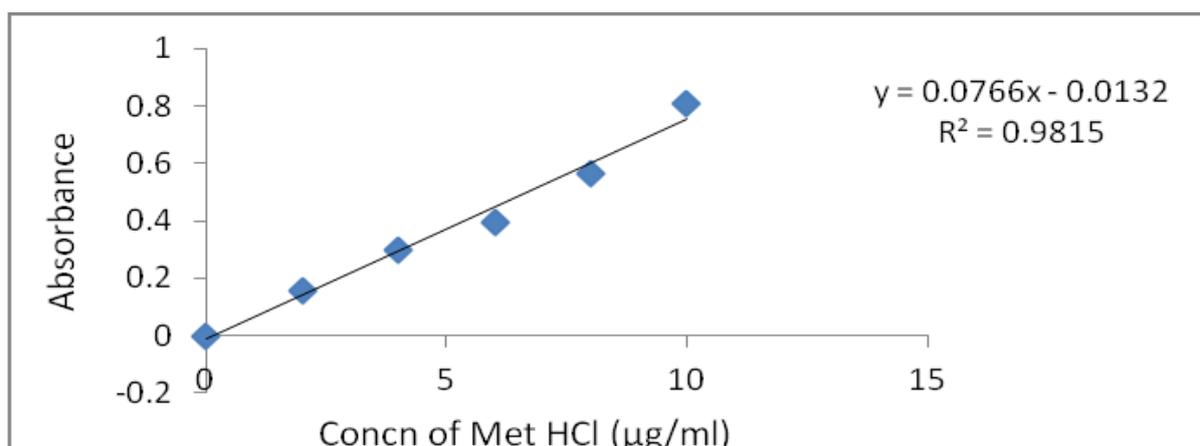
Wave number( $\text{cm}^{-1}$ )	Structural Assignment
2928	C-H stretching
1732	Amides
1448	C=C
1372	C-O

### Preparation of Standard Calibration Curve

Standard calibration curve of Metformin HCl was done in Phosphate buffer pH 6.8. A Standard curve was obtained by putting concentration and absorbance respectively. The  $R^2$  value in Phosphate buffer of pH 6.8 was found to be 0.981 (Figure 3).

**Table 6:** Solubility of drug in different solvents

Solvent System	Observation
Water	Freely soluble
Acetone	Practically insoluble
Ethanol 95%	Slightly soluble
0.1M HCl	Soluble
Phosphate buffer( pH 6.8)	Soluble

**Figure 3:** Standard curve of Metformin HCl in phosphate buffer pH 6.8 at 230 nm

### Mucoadhesive Strength of Formulation

The mucoadhesive strength determination was performed using Texture analyzer. The mucoadhesive strength all formulation were varied from 10.2 to 36.7g. The Formulation F1 has lowest Mucoadhesive strength and the formulation F6 has highest Mucoadhesive Strength. From this we conclude that the mucoadhesive strength increases with the increase in latex concentration, and decreases with decrease in Latex concentration. This may be due to increase in availability of adhesive sites of natural polymer with mucin that tends to increase in bond strength. The results are shown in Table 12 and Figure 4.

**Table 7:** Precompression parameters of granules

Sample	Angle of Repose ( $\theta$ )	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (% CI)	Hausner's Ratio (HR)	Kawatika constants	
						'a'	'1/b'
Granules	$\tan^{-1}(1.9/3.55) = 28.2^\circ$	0.487	0.584	16.61	1.19	0.297	17.576

**Table 8:** Formula for trial batch of tablet

S. No.	Ingredients	% Content
1	Metformin hydrochloride	25.0%
2	Latex	4.0%
3	Dicalcium phosphate	40.5%
4	Microcrystalline cellulose	27.5%
5	Talc	1.0%
6	Magnesium stearate	2.0%

Weight of each tablet = 200 mg

**Table 9:** Post Compression parameters of Metformin HCl tablet

Batch code	Parameter				
	Hardness (kg/cm <sup>2</sup> )	Friability (%)	Thickness (mm)	% Weight variation	t 90% (hr)
F1	3.0	0.379	4.4	1.101 x 10 <sup>-2</sup>	3
F2	4.0	0.381	4.5	3.75 x 10 <sup>-2</sup>	3
F3	3.0	0.365	4.5	3.75 x 10 <sup>-2</sup>	3
F4	5.0	0.401	4.4	3.75 x 10 <sup>-2</sup>	3
F5	5.0	0.403	4.5	1.647 x 10 <sup>-2</sup>	3
F6	5.0	0.391	4.5	1.796 x 10 <sup>-2</sup>	5
F7	4.0	0.373	4.5	4.975 x 10 <sup>-3</sup>	5
F8	3.0	0.385	4.5	3.75 x 10 <sup>-2</sup>	5
F9	4.0	0.383	4.5	3.75 x 10 <sup>-2</sup>	3

**Table 10:** In Vitro Drug release

Time (hr)	% Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.25	61.51	60.44	60.44	60.44	59.87	47.53	48.1	48.1	59.87
0.5	76.66	79.2	79.2	79.2	70.51	73.35	76.78	76.78	70.51
0.75	82.20	80.74	80.74	80.74	81.54	82.96	80.62	80.62	81.54
1	83.29	85.16	85.16	85.16	83.81	83.51	83.20	83.20	83.81
2	86.66	87.42	87.42	87.42	84.03	83.65	83.88	83.88	84.03
3	89.31	89.97	89.97	89.97	90.26	85.52	85.92	85.92	90.26
4	90.63	91.01	91.01	91.01	90.59	89.59	86.94	86.94	90.59
5	91.20	91.84	91.84	91.84	90.99	90.07	89.95	89.95	90.99
6	92.20	92.65	92.65	92.65	92.51	91.23	90.73	90.73	92.51
8	93.41	93.41	93.41	93.41	94.12	91.35	92.53	92.53	94.12
12	95.47	95.37	95.37	95.37	95.77	92.86	93.62	93.62	95.77
24	96.42	97.48	97.48	97.48	97.53	93.17	94.66	94.66	97.53

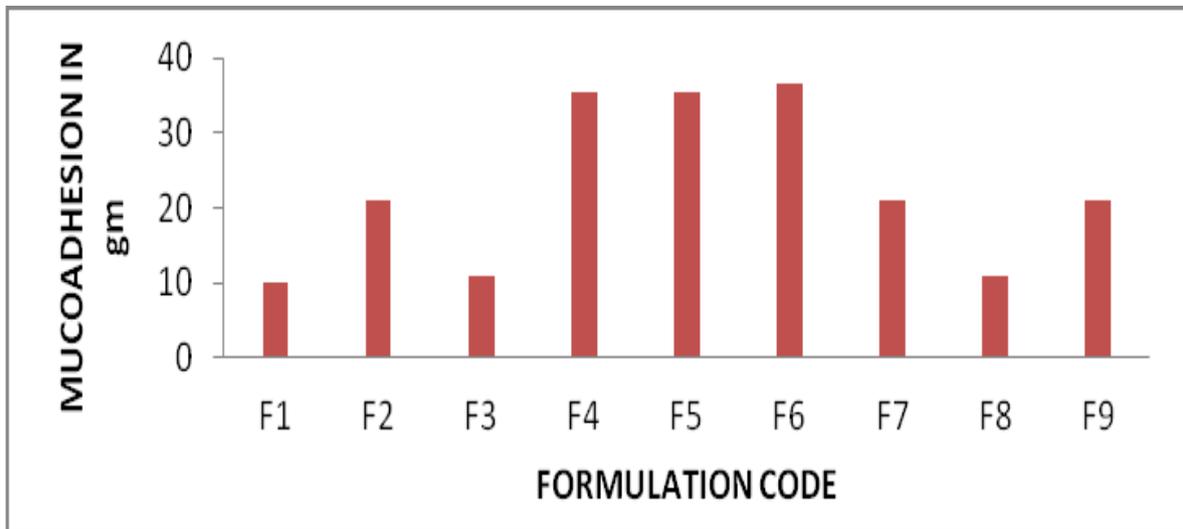


Figure 4: Mucoadhesive Strength of various formulations optimization in-vitro drug release kinetic curves:

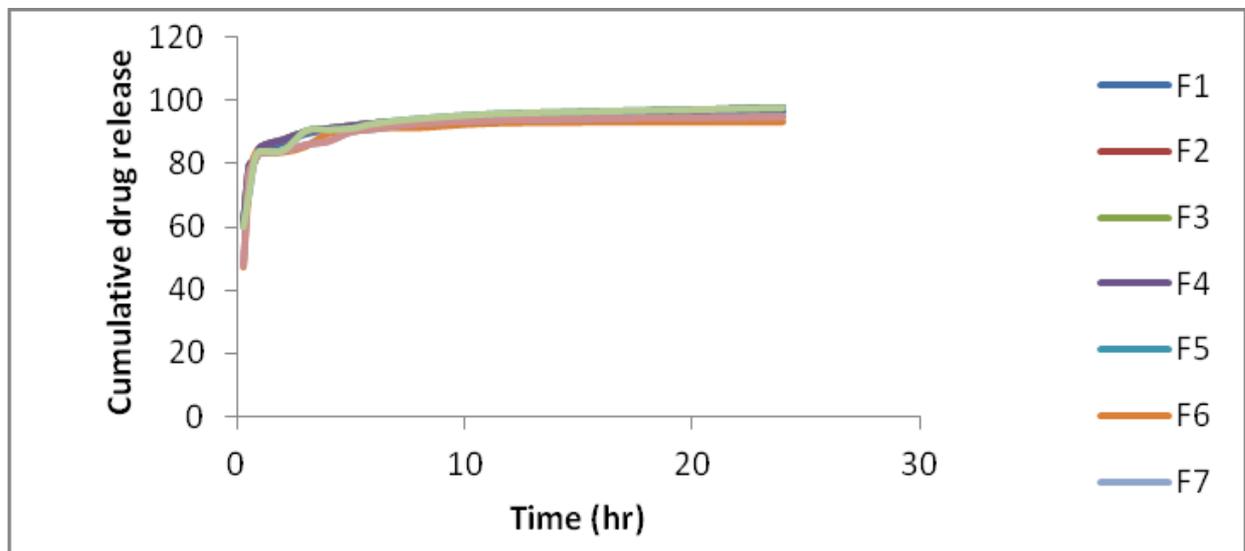


Figure 5 (a): Plot showing Zero Order Release Curve

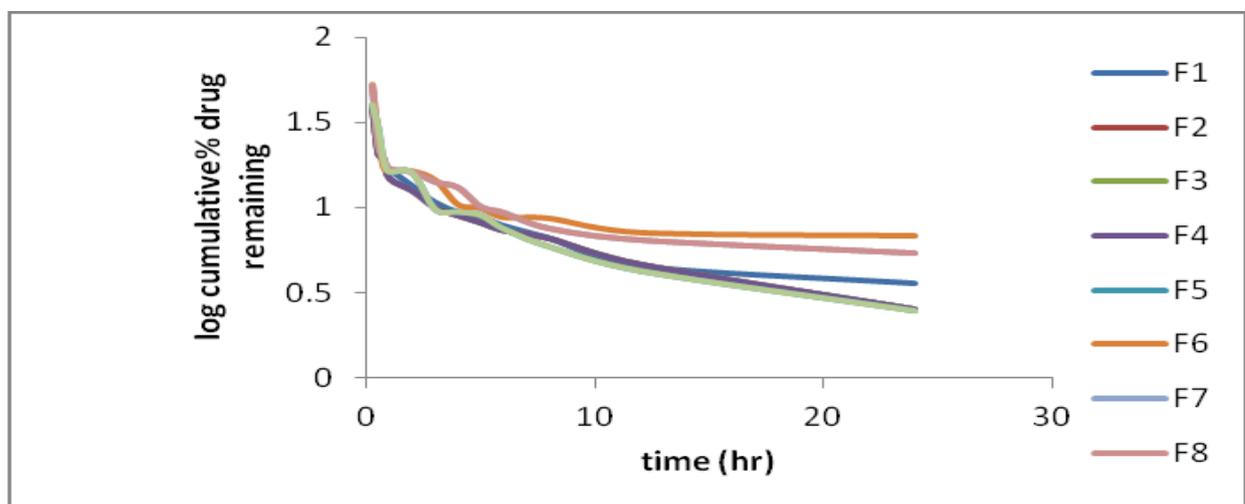


Figure 5 (b): Plot Showing First Order Release Curve

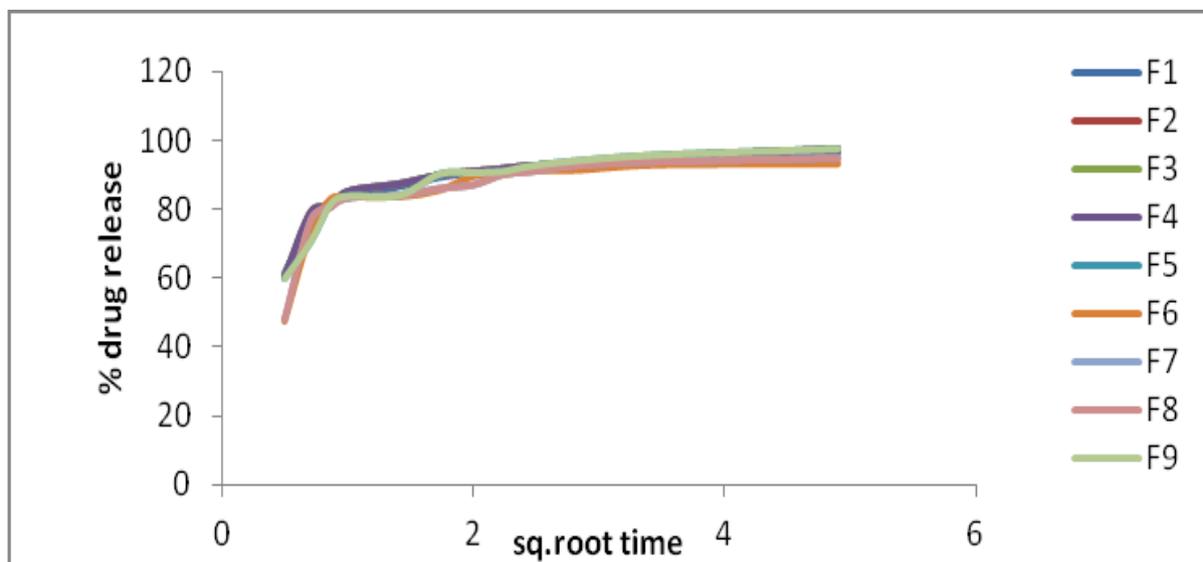


Figure 5 (c): Plot showing Higuchi Model

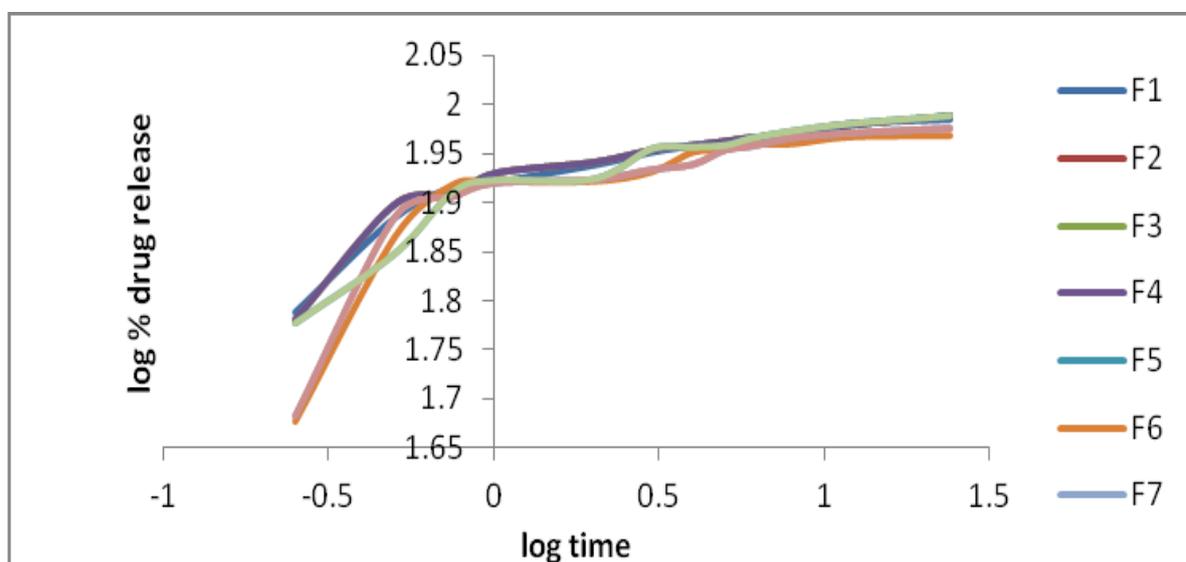


Figure 5 (d): Plot showing korsmeyer-peppas model

Table 11: In-Vitro Release Kinetics of Metformin HCl Tablet

Model	Parameters	Formulation Code								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
Zero Order	R <sup>2</sup>	0.396	0.385	0.385	0.385	0.414	0.262	0.305	0.305	0.414
	K <sub>o</sub>	0.908	0.918	0.918	0.918	1.050	0.960	1.018	1.018	1.050
First Order	R <sup>2</sup>	0.704	0.773	0.773	0.773	0.771	0.488	0.615	0.615	0.771
	K <sub>1</sub>	-0.036	-0.041	-0.041	-0.041	-0.044	-0.026	-0.031	-0.031	-0.044
Higuchi	R <sup>2</sup>	0.617	0.595	0.595	0.595	0.638	0.448	0.491	0.491	0.638
	KH	6.002	6.042	6.042	6.042	6.903	6.641	6.838	6.838	6.903
Korsmeyer–Peppas	R <sup>2</sup>	0.807	0.772	0.772	0.772	0.829	0.619	0.635	0.635	0.829
	Release Exponent (n)	0.082	0.083	0.083	0.083	0.094	0.107	0.106	0.106	0.094

**Table 12:** Data for mucoadhesion

Samples	Conc. Of binder %	Target Force(g)	Approaching Speed(mm/sec)	Returning Speed(mm/sec)	Holding Time (sec)	Detachment Force (g)
F1	1.1715	500	0.5	0.1	10	10.2
F2	4	500	0.5	0.1	10	21.0
F3	2	500	0.5	0.1	10	11.0
F4	6	500	0.5	0.1	10	35.5
F5	6	500	0.5	0.1	10	35.5
F6	6.82843	500	0.5	0.1	10	36.7
F7	4	500	0.5	0.1	10	21.0
F8	2	500	0.5	0.1	10	11.0
F9	4	500	0.5	0.1	10	21.0

### Optimization

The design expert gives an one optimized batch formulation. According to the software the prediction value of percentage drug release, mucoadhesive strength hardness and time to release 90% were found to be 97.48%, 22.9903gm, 4.99kg/cm<sup>2</sup>, 4.31 hr respectively. From the investigation the observed value of percentage drug release, mucoadhesive strength, hardness, t<sub>90%</sub> were found to be 96.25%, 22.8 gm, 4.6 kg/cm<sup>2</sup>, 4 hr respectively. Hence, the percentage error of % drug release was found to be 1.26, the percentage error of mucoadhesive strength was found to be 0.82.

**Table 13:** Optimized formulation

Batch Code	Concentration of latex	Hardness	Mucoadhesive strength (gm)	t 90% (hr)
F4	4.5131%	4.99998	22.9903	4.3145

**Table 14:** Comparison of experimentally observed responses of the optimized formulation with predicted responses

Response Parameter	Predicted Value	Observed Value	% Error
Mucoadhesive Strength(gm)	22.9903	22.8	0.82
t 90% (hr)	4.3145	4	7.28%

### CONCLUSION

The work accomplished so far reveals that jackfruit latex possesses the desirable properties required for a polymer to be used as mucoadhesive agent/binder. The flow properties of the latex as well as that of granules depicted by its compressibility index, Hausner's ratio, Kawatika factors, angle of repose etc. are found to be within the desired range. Moreover FTIR spectroscopy, Differential Scanning Calorimetric study has shown that there was no chemical interactions between the drug and latex neither there is prominent endothermic decrease of melting point of the drug due to presence of latex in the powder mixture. Investigation in terms of in-vitro dissolution study, comparative

mucoadhesion study, compatibility study with the selected formulation, in-vivo study, stability study etc reveals that Jackfruit latex has potential to act as natural binder in mucoadhesive solid dosage form (tablet) and can also be suitably used for formulating tablets.

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