ORIGINAL ARTICLE

Study on Binding Effect of Extracted Mucilage from *Bombax ceiba* Plant Flower Petals for Tablet Formulation

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Abstract

Aim: The objective of the present investigation was to extract the mucilage from flower petals of *Bombax ceiba* and explore its use as a promising excipient for Pharmaceutical preparation. The natural polymers have constantly a remarkable property which makes them particular from synthetic polymer and *B. ceiba* flower mucilage is one such model that shows increasingly important properties making it a helpful excipient for a wide scope of utilizations. **Materials and Methods:** The flowers of *B. ceiba* were collected from the Regional Ayurveda Research Institute for Drug Development, Gwalior region of India and were authenticated at the Botanical Survey of India, Central Regional Centre, Allahabad, U.P (Authentication voucher No. B.S.I/C.R.C/TECH./2018-19/559 with Accession No. 103976). *B. ceiba* flower petals mucilage is isolated by the microwave-assisted method and tablet prepared by experimental runs was designed by Design Expert 10.0.1 (Stat Ease. Inc.) software following full factorial method. 3^2 full factorial designs were applied for examining two variables (factors) at three levels with a minimum of nine runs. The tablets containing paracetamol as main active constituent were prepared with by a wet granulation method using isolated mucilage in different composition (F1-F9) or starch (F10) or PVP K 30 (F11) as internal binder. **Results:** The flow properties of the drug excipients mixture were studied in term of bulk density; tapped density; car's index; and angle of repose to establish the flow property reflect the appropriateness of formulation. All tablet formulations batch evaluated for post-compression parameters have shown acceptable and within the Pharmacopoeial limits of results. The release characteristics of formulations were studied using tablet dissolution test apparatus is paddle type (USP type II) at 50 rpm. The cumulative percent drug release of formulations, i.e., F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, and F11 was 91.31%, 92.67%, 94.22%, 88.83%, 90.36%, 91.11%, 90.54%, 92.11%, 93.98%, 78.66%, and 80.36%, respectively, in 60 min. The result justified that the effect of optimized formulation F3 is significantly more effective than starch and similar effect as synthetic polymer. **Conclusions:** The results suggest that *B. ceiba* mucilage could be useful as an alternative binding agent in tablets with better mechanical properties and release profile.

Key words: 3^2 Full factorial designs, *Bombax ceiba* flower, eco-friendly, natural excipient, paracetamol, polymer

INTRODUCTION

Formulation of functioning pharmaceutical content into wanted measurement structures is once in a while conceivable without the expansion of excipients. They are a crucial piece of the restorative compound, which may likewise be a significant segment of the therapeutic product. These are dormant atoms that assume a significant job in the planning of measurements form.[1] Today, we have various plant-based pharmaceutical excipients, which might be chosen and upgraded dependent on the properties of the medication, necessities of the dosage form, and its site of activity. Aside from its regular capacities like filling in as an inert vehicle for the organization of the correct volume of dynamic pharmaceutical fixing with consistency in weight, excipients likewise satisfy multifunctional jobs, for example, discharge retardants, solvency enhancers, thickness modifiers, and so on. What is more, they offer huge favorable circumstances in

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Received: 02-05-2020
Revised: 02-06-2020
Accepted: 08-06-2020

the simplicity of assembling, upgrade of patient compliance, improved bioavailability, reproducibility, targeted delivery, etc.[2] Mucilage's are the most frequently utilized adjuvant in pharmaceutical preparations. Plant mucilage's are pharmaceutically significant polysaccharides with a wide scope of utilizations, for example, stabilizing, thickening gelling operators, binding, disintegrating, suspending, emulsifying, balancing out, and gelling specialists. They have been likewise utilized as lattices for continued and controlled release drugs.[3] Aside from its utilization in completed medicines, fresher uses have been found in the preparation of beautifying agents, textiles, and paint paper. Thus, the interest for these substances is expanding and new sources are getting tapped.[4,5] Tremendous utilization of plant mucilage and gums in different enterprises is a direct result of minimal cost, prepared accessibility, and significant properties that they present on products. The interest for these substances is expanding and new sources are being created. India, in view of its geological and environmental position, has customarily been a decent hotspot for such items among the Asian nations. Naturally accessible mucilage's are wanted to synthetic materials due to their non-harmfulness, minimal cost, simplicity of accessibility, emollient and non-disturbing nature, and less administrative issues.[6]

The different species of *Bombax* are accounted for to have different medicinal properties, namely, cholera, fractures, smallpox, coughs, urinary problems, and influenza. The *Bombax ceiba* is broadly developed as an elaborate plant all through the tropical and subtropical regions.[7]

In the current research work, an exertion was made to extract the mucilage from *B. ceiba* flower petals by the microwave-assisted method. It was then evaluated to check the chance of utilizing this mucilage as authoritative/crushing specialists in tablet formulation. The fasteners are the pharmaceutical excipient that is usually utilized in a tablet formulation to improve the stream properties of the granules. The proposed work investigates the binding property of plant oriented mucilage material from petals of *B. ceiba* flower in oral drug delivery system. There are various example of binding agent of plant and synthetic adapt for oral drug delivery system. The proposed methodology provides information of effective concentration of plant mucilage and its collection methodology, which act as binding agent. The formulations were evaluated for post-compression parameters such as tablet thickness testing, uniformity of weight of tablet, hardness determination of tablet, friability of tablets, disintegration test for uncoated core tablets, determination of drug content, and *in vitro* drug release study.

MATERIALS AND METHODS

Materials

The flowers of *B. ceiba* were collected from the Regional Ayurveda Research Institute for Drug Development, Gwalior region of India and were authenticated at the Botanical Survey of India, Central Regional Centre, Allahabad, U.P (Authentication voucher No. B.S.I/C.R.C/TECH./2018-19/559 with Accession No. 103976). Paracetamol was obtained as gift sample from Meghmani LLP, Bharuch, Gujarat. Sodium starch glycolate was obtained as gift sample from Maple Biotech Pvt. Ltd. (Pune, India). All other chemicals used were of analytical grade, and distilled water was used throughout the experiments.

Isolation of mucilage from *B. ceiba* flower petals

The fresh petals of *B. ceiba* flower were gathered, washed with water to expel soil and flotsam and jetsam. The petals of flowers (150 g) were squashed and absorbed refined water (500 ml) for 24 h. The splashed flowers were kept in a microwave alongside a glass tube inside to forestall knocking and the procedure of microwave illumination was begun at 420 W intensity for 7 min. The measuring utensil was confined from the oven and warded off for 2 h for the release of mucilage into water. The material was separated through a muslin pack and hot refined water (25 ml) was added through the sides of the marc and pressed well so as to obliterate the mucilage totally. An equivalent volume of ethanol was added to the filtrate, in this manner hasten of mucilage was appeared and it was kept inside a cooler for approximately 24 h for successful settling. It was separated and dried absolutely in an incubator at 37 ± 2°C, powdered, and gauged. The amount of mucilage acquired from the microwave was calculated.[8]

Physical analysis of mucilage powder

Fourier transforms infrared (FTIR) analysis

FTIR analysis spectra of mucilage were recorded on a FT-IR spectrometer (RF-6000, SHIMADZU, Japan). The dry powder was mixed with KBr and pressed into pellets under mechanical pressure. The FT-IR spectra were obtained by scanning between 4000 and 400/cm [Figure 1].

Differential scanning calorimetry (DSC)

Weighed amount of sample was placed in hermitically sealed aluminum pans and was heated at a speed of 20°C/min over a temperature range of 50°C–450°C in a differential scanning calorimetry (DSC60PLUS, SHIMADZU, Japan) at a chart speed of 10 mm/min [Figure 2].

Factorial designing for optimizing the combinational study of isolated mucilage and drug

Experimental runs were designed by Design Expert 10.0.1 (Stat Ease. Inc.) Software following full factorial method. 3^2 full factorial designs were applied for examining two variables (factors) at three levels with a minimum of nine runs. The actual and coded experimental levels based on

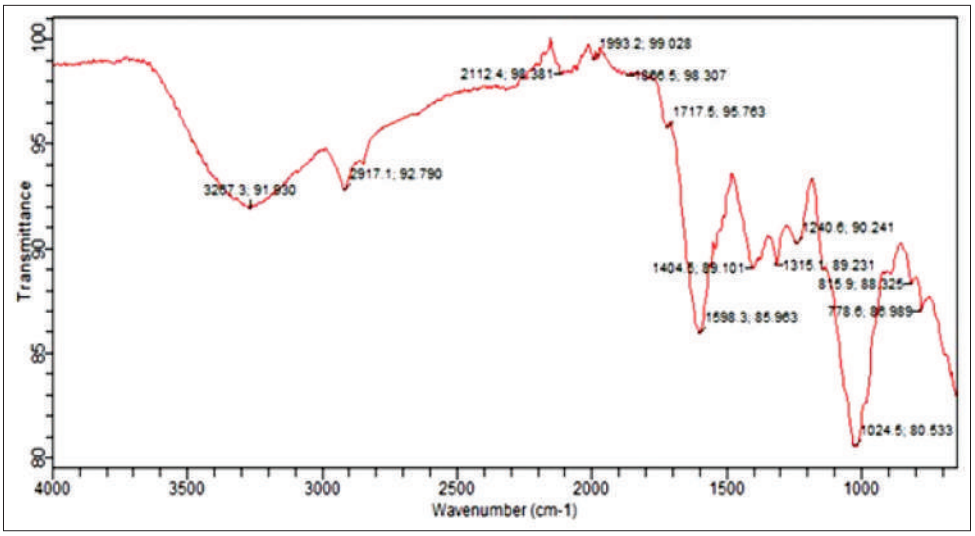

Figure 1: Fourier transforms infrared spectra of plant mucilage of *Bombax ceiba* flower

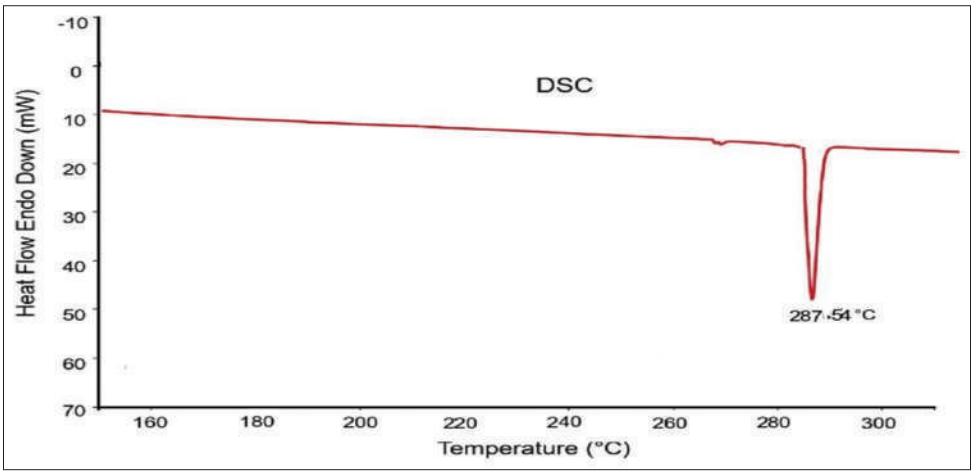

Figure 2: Differential scanning calorimetry thermogram of plant mucilage of *Bombax ceiba* flower

3^2 full factorial designs three-level approach are given in Tables 1 and 2.

Drug-excipient compatibility studies

The compatibility, i.e., drug-excipient interaction studies is useful for dosage form design. In general, solid-state reactions are slower and more difficult to interpret than reaction in solution, because of a reduced number of molecular constants between drug substances and excipients molecules and the occurrence of multiple-phase reactions. This performed by FTIR spectrophotometer, and DSC study of pure drug and formulation.

Preparation of uncoated tablet

The tablets containing 500 mg of paracetamol as main active constituent were prepared with by a wet granulation method using isolated mucilage in different composition (F1-F9) or starch (F10) or PVP K 30 (F11) as internal binder. The microcrystalline cellulose was used as diluents or filler and sodium starch glycolate is used as disintegrant at granulation process of proposed work. The wet granulated mass was passed through a mesh #10 and dried at 60°C for 1 h in a hot air oven. The dried granules were sized by passing through a sieve #14. The complete batch of dried granules was collected and mixed with 5% magnesium stearate and 4% talc and 0.1% sucrose in glass Petri dish. These lubricated granules were compressed into tablets on single-station punch machine (Anant Electricals Pvt. Ltd.) using 4 mm deep concave and 1.2 mm round, flat and plain punches[9,10] [Table 3].

Characterization of uncoated tablets

Pre-compression parameters

Flow properties of granules

The flow properties of granules were characterized in terms of bulk density (BD), tapped density (TD), compressibility

index, angle of repose, and Hausner's ratio. The tapping method was used to determine the BD, TD, percent compressibility index, and Hausner's ratio.

Determination of BD and TD

An accurately weighed quantity of the powder (W) was carefully poured into the graduated cylinder and volume (V_0) was measured. Then, the graduated cylinder was closed with lid and set into the tap density tester. The density apparatus was set for 100 tabs and after that the tapped volume (V_f) was measured and continued operation till the three consecutive readings were equal.[11] The bulk density (BD) and the tapped density (TD) were calculated using the following formulae,

Bulk density = W/V_0, and Tapped density = W/V_f

Where, W= Weight of the powder V_0 = Initial volume, V_f = final volume.

Table 1: 3^2 factorial designs and experimental condition

Factors	Low level (–)	Mid-level (0)	High level (+)
Plant mucilage (X1) (mg)	35	70	105
Sodium starch glycolate (X2) (mg)	7	14	21

Table 2: Formulation of tablets by implementing 3^2

Formulation code	X1 (Independent variable)		X2 (Independent variable)	
	Actual value	Code value	Actual value	Code value
F1	35	–1	7	–1
F2	70	0	7	–1
F3	105	1	7	–1
F4	35	–1	14	0
F5	70	0	14	0
F6	105	1	14	0
F7	35	–1	21	1
F8	70	0	21	1
F9	105	1	21	1

Compressibility index

Compressibility index of the powder of pure drug was determined by Carr's compressibility index.[12]

Carr's index (%) = [(TD-BD)×100]/TD.

Hausner's ratio

It is the ratio of TD and BD. Hausner's found that this ratio was related to inter particle friction and, as such, could be used to predict powder flow properties. In general, a value less than 1.25 indicates good flow properties, which is equivalent to 20% of Carr's index.

Angle of repose

Static angle of repose of the powder of drug sample was determined by the funnel method. It reflects the flow ability of a powder. The accurately weighed powders of drug sample were taken in the funnel. The height of the funnel was adjusted in such a way that the tip of funnel just touched the apex of the heap of the powders of drug sample. The powders of drug sample were allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation,

Table 3: Composition of paracetamol uncoated tablet formulations using *Bombax ceiba* flower petals extracted mucilage

Ingredients (mg)	Formulations										
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
Drug (Paracetamol)	500	500	500	500	500	500	500	500	500	500	500
Plant mucilage	35	70	105	35	70	105	35	70	105	-	-
Sodium starch glycolate	7	7	7	14	14	14	21	21	21	14	14
Potato starch	-	-	-	-	-	-	-	-	-	70	-
PVP K-30 (Solution in Isopropyl alcohol)	-	-	-	-	-	-	-	-	-	-	70
Microcrystalline cellulose	88	53	18	81	46	11	74	39	04	46	46
Magnesium stearate	35	35	35	35	35	35	35	35	35	35	35
Purified Talc	28	28	28	28	28	28	28	28	28	28	28
Sucrose	7	7	7	7	7	7	7	7	7	7	7
Total weight	700	700	700	700	700	700	700	700	700	700	700

Tan θ = h/r
Where, h= Height of pile and r= Radius of the pile.

Post-compression parameters

Thickness

The thickness of the tablets was determined using screw gauze.

Hardness

The hardness of tablets is indicates the tensile strength of a tablet. It is expressed in terms of load/pressure required to crush it when placed on its edge. The tablet hardness was evaluated using the Monsanto hardness tester. The tablet hardness is expressed in kg/cm^2.

Uniformity of weight

Uniformity of weight was determined by sampled 20 tablets from each batch and accurately weighed using an analytical balance and average weights were calculated for determination of weight variation.

Friability test

Ten tablets from each batch were accurately weighed and placed in the friability test apparatus (Roche friabilator). Apparatus was operated at 100 rpm for 4 min. The tablets were taken after 100 rotations, de-dusted, and reweighed. A maximum loss of weight (from a single test or from the mean of the three tests) was not >1.0%.

Disintegration test

The disintegration test was performed using disintegration test apparatus following the method specified in I.P., etc., using 900 ml of 0.1 N hydrochloric acid.

Drug content assay

Ten tablets were finely powdered, and a quantity of powder equivalent to 500 mg of paracetamol (F1-F11) was accurately weighed. The weighed sample transferred to 100 ml volumetric flasks containing approximately 50 ml of 0.1 N HCL solution. The flasks were shaken for solubilizing the drug and sonicated for 10 min. The volume was diluted made up to 100 ml by 0.1 N Hcl and mixed thoroughly. The drug samples were diluted with same solvent up to 10 µg/ml. The solutions were filtered through a 0.45 µm membrane filter and analyzed for the content of paracetamol at 257 nm using double beam UV spectrophotometer (UV-1800, SHIMADZU, Japan).

In vitro drug release study

An USP paddle apparatus has been used to study *in vitro* drug release from uncoated tablet. In the present study, drug release was studied using a USP dissolution rate test apparatus (apparatus type II) at 100 rpm in 0.1 N HCL as dissolution fluid (900 ml) maintained at 37 ± 0.5°C. Withdrawn samples (1 ml) were filtered, analyzed by UV-visible spectrophotometer at 257 nm. The volume was replaced with the same amount of fresh dissolution fluid each time to maintain the sink condition.

Characterization of release profiles

The characterization of release profile of the entrapped drug from coated formulations was evaluated. Release profile of tablets was characterized for release lag time (T_{lag}) and release rate k. Release data within the linear range were selected and fitted to a zero-order mathematical model:
$Q = C + kt$

Where Q is the release percentage at time t; k is the slope of the fitted linear equation and here represents release rate; and C is the intercept of the linear equation. $T_{lag}$is defined as the time of the start of ciprofloxacin release and calculated here from the fitted equation, setting Q = 0:
$T_{lag} = -C/k$.

The linear equation is based on regression of at least three release data, and only correlation coefficient of over 0.99 is acceptable for T_{lag} and k calculation.

Stability studies

A established drug delivery system should retain its reliability, morphology, and occasionally should save various character is quality and quantity of entrapped drug, etc. The major emphasis has been directed toward the stability testing. A study of stability of pharmaceutical invention is crucial for three important reasons, i.e., protection of patients, authorized needs apprehensive with the distinctiveness, potency, transparency, and features of the drug. The superiority of the drug material or products varies with time of storage and its conditions such as temperature, humidity, and light. Hence, there is a need to establish a shelf life for the drug product and recommended storage conditions.

RESULTS AND DISCUSSION

Physical analysis of mucilage powder

Fourier transforms analysis

Fourier Transform Analysis (FTIR) spectra of mucilage were recorded on a FT-IR spectrometer (RF-6000, SHIMADZU, Japan). The mucilage showed the presence of spectrum lines at 1018, 1247, 1455, 1574, 1734, 2923 and 3280 cm-1. The result showed the presence of lactone ring with -OH, -COOH, -CH3 stretching, -C-O stretching in functional group structure.

DSC

The melting point of plant isolated mucilage particles was obtained by DSC thermal analysis and it was 287.54°C.

Drug-excipient compatibility studies

To study the interaction between drug and excipients, the samples were studied for FTIR and DSC. The FTIR spectra of pure drug

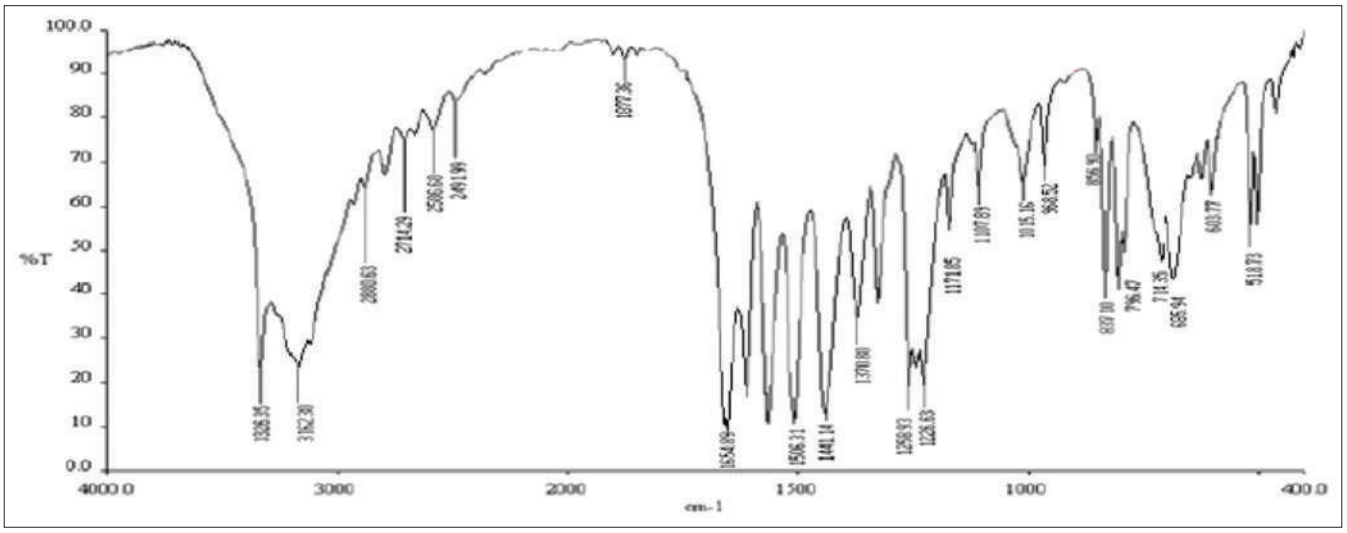

Figure 3: Fourier transforms infrared spectrum of sample of pure paracetamol

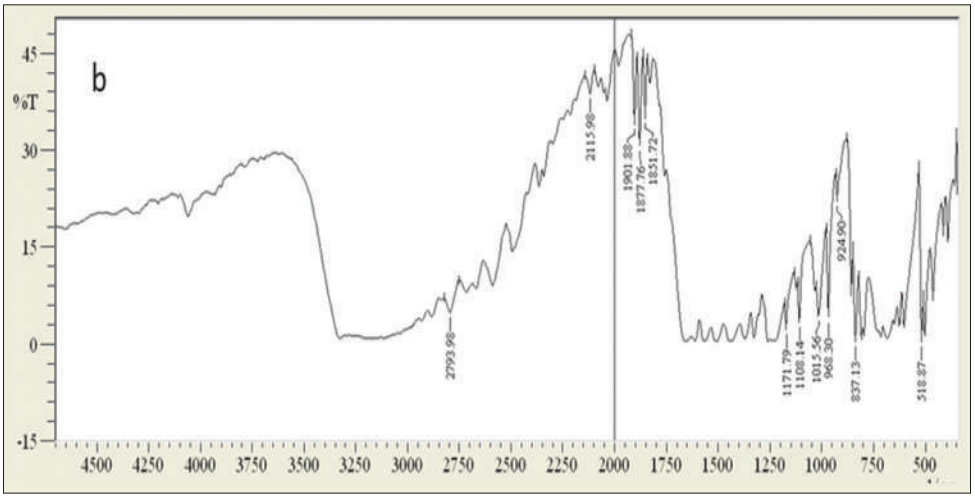

Figure 4: Fourier transforms infrared spectra of paracetamol and plant mucilage of *Bombax ceiba* flower

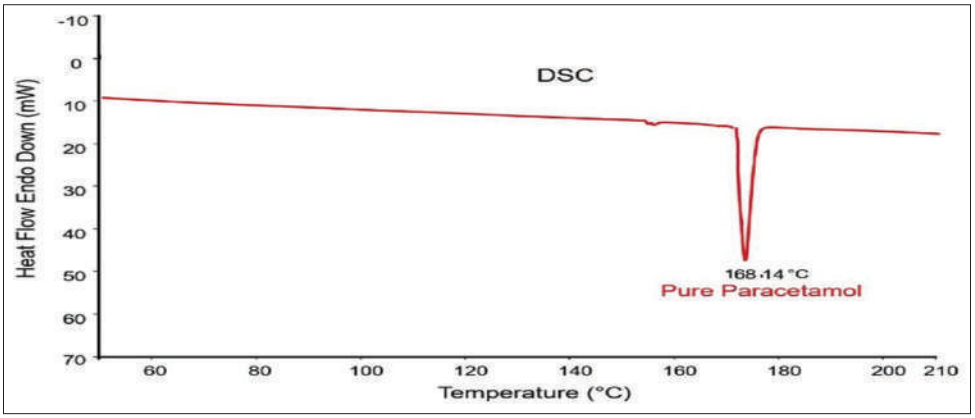

Figure 5: Differential scanning calorimetry thermogram of sample of paracetamol

show characteristic peaks correlated with formulation peak indicated compatibility of drug with formulation components and show no chemical interaction between isolated mucilage from *Bombax ceiba* flower petals and paracetamol [Figures 3-6].

Characterization of uncoated tablets

Pre-compression parameters

Flow properties of powder reflect the appropriateness of formulation. Hence, flow properties of the drug excipients mixture were studied in term of BD, TD, car's index, and angle of repose to establish the flow property. The BD of formulations was found from 0.521 g/ml (F7) to 0.546 g/ml (F9) range while their TD ranged between 0.621 g/ml (F4) and 0.659 g/ml (F11). The Carr's index (%), Hausner's ratio, and angle of repose were found 13.76 (F3) to 17.90 (F11), 1.15 (F3) to 1.21 (F7), and 23.1° (F3) to 28.2° (F10), respectively. The observation showed that as the Carr's index (%), Hausner's ratio, and angle of repose (ɵ) were within in the range of standard value of good flowability. The result of flow properties of powder mixtures of all formulations is given in Table 4.

Post-compression parameters

The formulations were evaluated for post-compression parameters such as tablet thickness testing, uniformity of weight of tablet, hardness determination of tablet, friability of tablets, and disintegration test for uncoated core tablets, determination of drug content, *in vitro* drug release study, and characterization of release profiles of were studied.

Thickness

All the prepared tablets are characterized by their size and shape, which found round shape and uniform thickness in the range of 5.35 (F8)–5.49 (F10) mm. The thickness of the formulations (in mm) is graphically represented in Figure 7.

Hardness

Tablets require certain hardness to withstand the mechanical shocks in handling, packaging, and in transportation. The hardness of formulations was within the range of 3.18 (F1)–4.13 (F10) kg/cm^2. The hardness of the formulations (in kg/cm^2) is graphically represented in Figure 7.

Table 4: Flow properties of granules of paracetamol

Batch	Bulk density	Tapped density	Carr's index (%)	Hausner's ratio	Angle of repose (θ°)
F1	0.540±0.026	0.631±0.032	14.42±0.318	1.16±0.002	27.5±0.516
F2	0.545±0.010	0.640±0.019	14.84±0.534	1.17±0.004	26.2±0.430
F3	0.539±0.015	0.625±0.008	13.76±0.673	1.15±0.001	23.1±0.611
F4	0.532±0.024	0.621±0.023	14.33±0.752	1.16±0.002	23.9±0.803
F5	0.543±0.019	0.649±0.022	16.33±0.416	1.19±0.002	24.5±0.211
F6	0.540±0.007	0.645±0.006	14.72±0.362	1.19±0.003	28.1±0.411
F7	0.521±0.004	0.634±0.032	17.82±0.528	1.21±0.001	28.2±0.510
F8	0.535±0.022	0.639±0.025	16.27±0.632	1.19±0.002	27.3±0.912
F9	0.546±0.021	0.645±0.034	15.34±0.217	1.18±0.001	28.1±0.721
F10	0.543±0.014	0.645±0.011	15.81±0.732	1.18±0.003	28.2±0.311
F11	0.541±0.022	0.659±0.021	17.90±0.632	1.21±0.005	21.1±0.610

Values are expressed as mean±SD, n=3. SD: Standard deviation

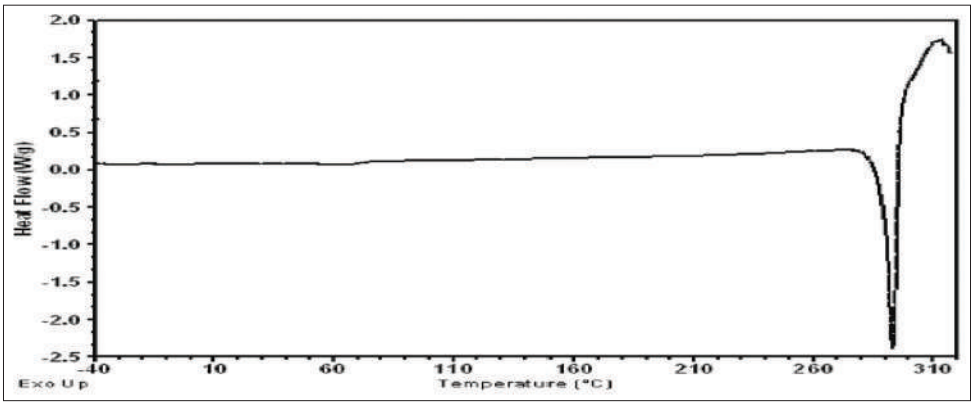

Figure 6: Differential scanning calorimetry thermogram of paracetamol and plant mucilage of *Bombax ceiba* flower

Uniformity of weight

The weight variation of tablets was determined according to the specification in USP and all the tablets were found to comply with specification. All formulated tablets have weight variation limit of 5 %, shows the uniformity of weight. (United State Pharmacopoeia, 2007). Average weight of the all formulations is graphically represented in Figure 8.

Friability test

The friability of all formulations was found to be <1%. This is in the acceptable limit. The result shows resistance to loss of weight indicated the tablet ability to withstand abrasion in handling, packaging, and shipment. All the tablets formulations found friability from 0.24% (F3) to 0.88% (F7). The % friability of all formulations is graphically represented in Figure 9.

Disintegration test

Disintegration time was varies from 3.59 (F1) to 5.23 (F10) min. Disintegration time for all formulations is graphically represented in Figure 10.

Drug content assay

Percentage drug content for various formulations, i.e., F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, and F11 was found to be 95.42%, 92.95%, 94.63%, 91.67%, 93.02%, 94.46%, 90.56%, 92.09%, 89.01%, 90.89%, and 93.09%, respectively. The % drug content of all formulations is graphically represented in Figure 11.

In vitro drug release study

The release characteristics of formulations was studied using tablet dissolution test apparatus is paddle type (USP

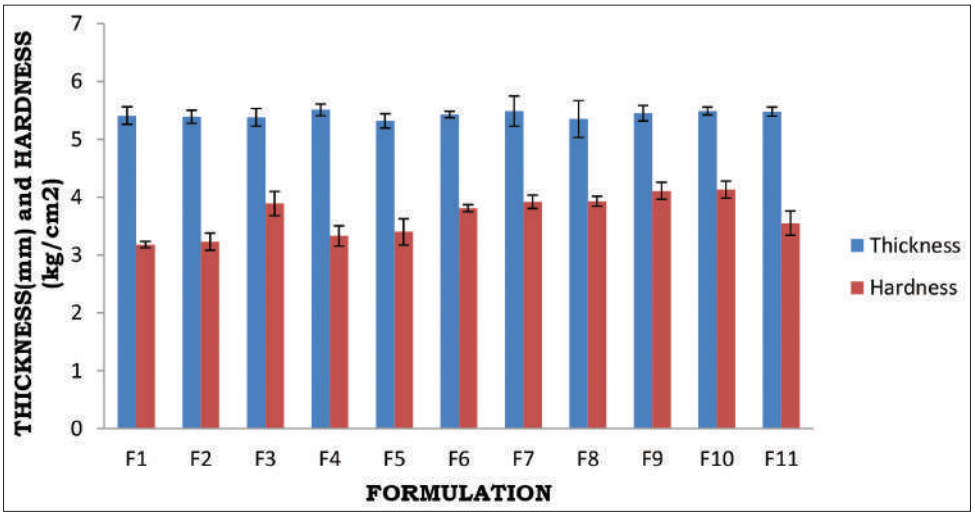

Figure 7: Thickness and hardness of various formulations

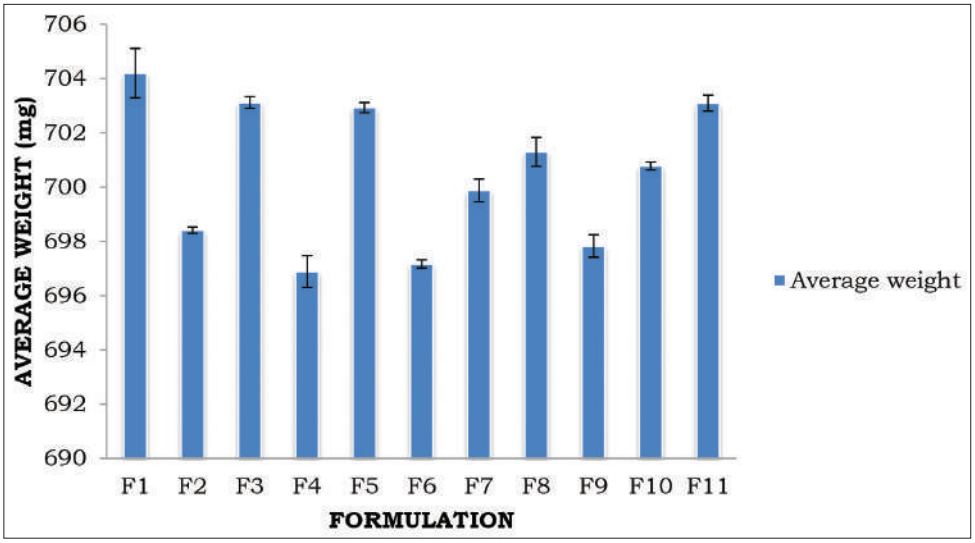

Figure 8: Average weights of various formulations

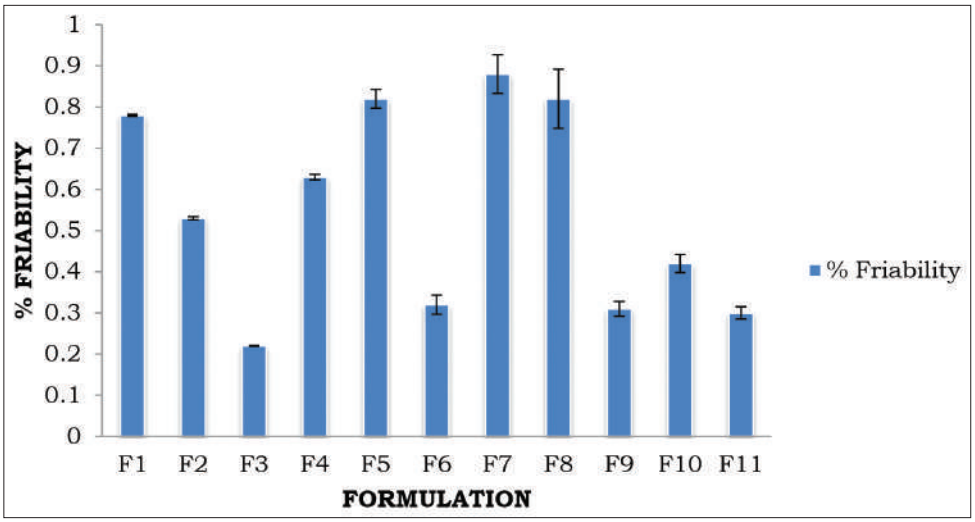

Figure 9: % Friability of various formulations

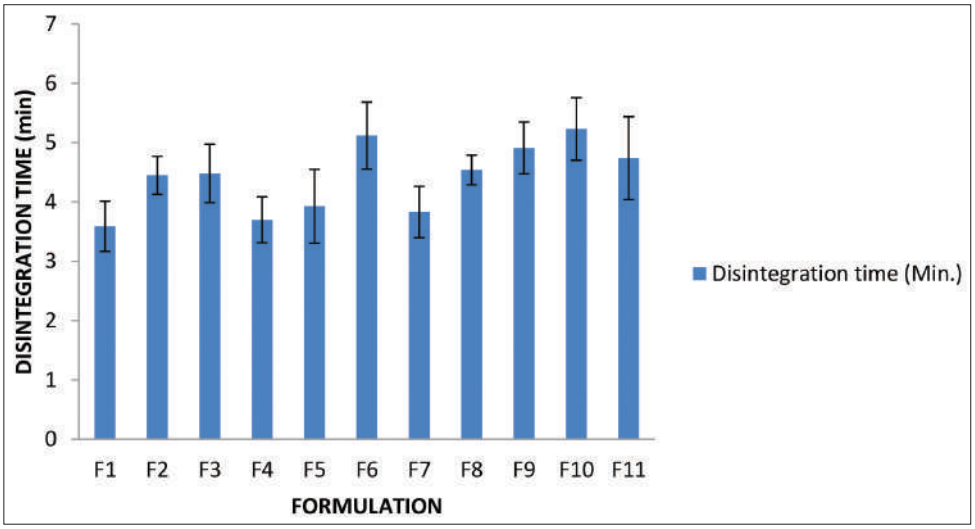

Figure 10: Disintegration time of various formulations

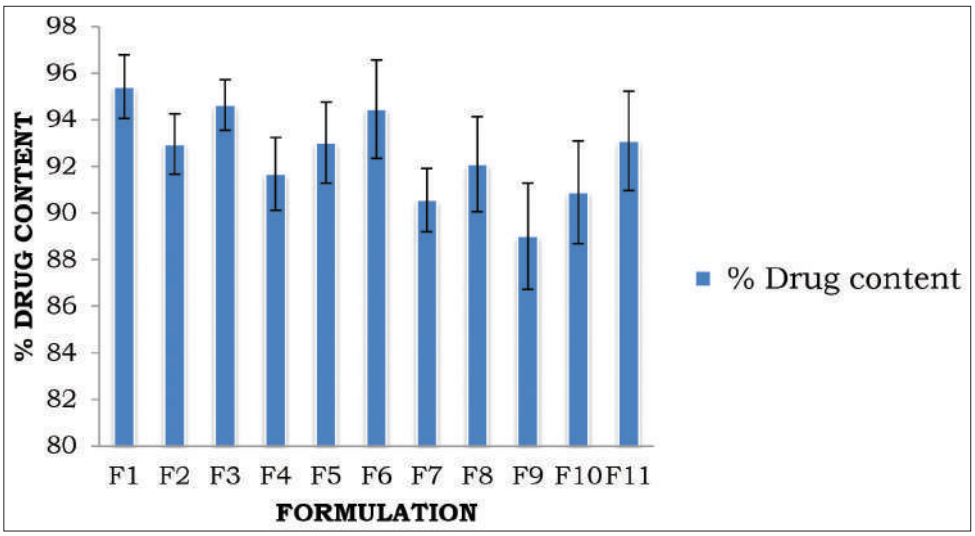

Figure 11: % Drug content of various formulations

type II) at 50 rpm. 0.1N HCL solution 900 ml was used as the dissolution media with temperature maintained at 37.0±0.5°C. The cumulative percent drug release of formulations, i.e., F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, and F11 was 91.31%, 92.67%, 94.22%, 88.83%, 90.36%, 91.11%, 90.54%, 92.11%, 93.98%, 78.66%, and 80.36%, respectively, in 60 min. All the results of cumulative percent drug release of all formulations are graphically represented in Figure 12.

Characterization of release profiles

Kinetic study of drug release from dosage forms is useful as they influence the dosage interval, bioavailability, overall patient adherence, and the occurrence of toxic and untoward effects. In addition, kinetic parameters can be used to study the influence of formulation factors on the drug release for optimization as well as control of release. The criterion for selecting the most appropriate model was on the basis of goodness of best fit which was determined by the highest correlation coefficient. The kinetic parameters and correlation coefficient (r^2) derived from the equations are presented in Tables 5 and 6.

Table 5: Fit of various kinetic models for uncoated tablets of paracetamol (F1-F11)

Formulation code	Zero-order kinetics		First-order kinetics	
	r^2	k	r^2	K
F1	0.876	−0.031	0.978	1.714
F2	0.833	−0.030	0.989	1.784
F3	0.710	−0.027	0.995	1.691
F4	0.894	−0.0.033	0.969	1.717
F5	0.849	−0.033	0.988	1.734
F6	0.744	−0.027	0.995	1.691
F7	0.912	−0.036	0.929	1.657
F8	0.877	−0.034	0.968	1.695
F9	0.725	−0.027	0.994	1.681
F10	0.788	−0.028	0.994	1.731
F11	0.749	−0.028	0.995	1.724

A number of mathematical models have been developed by a number of researchers, i.e.

- Zero order (Cumulative % drug release vs. time)
- First order (Log cumulative % drug remaining vs. time)
- Korsmeyer–Peppas model (Log cumulative % drug release vs. log time)
- Higuchi plot (Cumulative % drug release vs. square root of time).

The results of performed study showed that the first-order (r^2 = 0.995–0.929) gave the best fit for the formulations made through isolated mucilage while the drug release for tablets prepared by starch and PVP-K30 also fitted the first order model with r^2 ranging between 0.994 and 0.995. This indicates that the release of the drug from the tablet is dependent on the concentration of drug in the formulation. This is consistent with the previous reports on release kinetics of paracetamol formulations. To confirm the diffusion mechanism, the data were fitted into Korsmeyer–Peppas model equation which gave a release exponent (n) values ranging from 1.691 to 1.711 which indicates that the drug release mechanism from the formulations was by

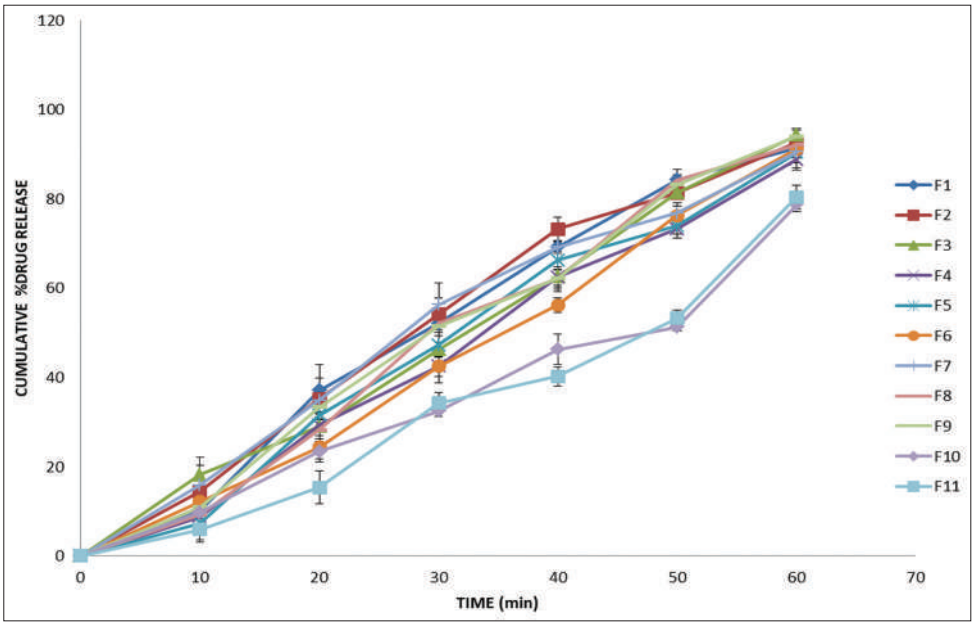

Figure 12: Cumulative % drug releases of different formulations

super case II transport, in which a pronounced acceleration in drug release from the formulation occurred towards the latter stages of release, resulting in a more rapid relaxation-controlled transport.

Table 6: Fit of various kinetic models for uncoated tablets of paracetamol (F1-F11)

Formulation code	Higuchi's plot		Korsmeyer-Peppas plot	
	r^2	K	r^2	N
F1	0.953	13.75	0.945	1.692
F2	0.911	13.80	0.972	1.708
F3	0.776	12.89	0.986	1.702
F4	0.961	13.90	0.940	1.695
F5	0.935	13.71	0.955	1.696
F6	0.905	13.10	0.976	1.701
F7	0.984	13.86	0.919	1.693
F8	0.965	13.75	0.932	1.691
F9	0.896	12.97	0.979	1.701
F10	0.916	13.44	0.772	1.703
F11	0.887	13.29	0.985	1.711

Stability studies

The uncoated tablet (F3) is the oral drug delivery system that was prepared with combination of plant oriented mucilage as binding agent and paracetamol as API. The formulation was used for stability study at temperature 4°C, 25°C and 60% RH and 40°C and 75% RH, 50°C and 75% RH, and 60°C and 75% RH for a period of 180 days. The stability of a formulation is known as the power of the materials to stay on inside definite restrictions over a fixed phase of time and known as shelf life of the product. The data of stability studies are presented graphically in Figures 13 and 14. The data identified that the F3 stored at temperature 25°C and 60% RH, informed, it was <5% degradation at the end of 6 months. It may indicate that the formulations could provide a minimum shelf life of 2 years [Table 7].

Table 7: Stability study of uncoated tablet (F3)

Temperature (°C)	RH (%)	Residual drug content (%)				
		Time in days				
		0	30	60	90	180
4	-	99.92±0.081	99.91±0.673	99.87±0.811	99.82±0.826	99.78±0.383
25	60	99.92±0.068	99.81±0.342	98.87±0.295	98.11±0.918	97.2±0.446
40	75	99.92±0.749	99.11±0.675	98.02±0.566	97.36±0.357	97.02±0.887
50	75	99.92±0.828	99.10±0.923	98.01±0.922	97.01±0.612	96.98±0.134
60	75	99.92±0.437	99.01±0.738	97.98±0.313	96.87±0.118	96.43±0.457

Values are expressed as mean±S.D, n=3. SD: Standard deviation, RH: Relative humidity

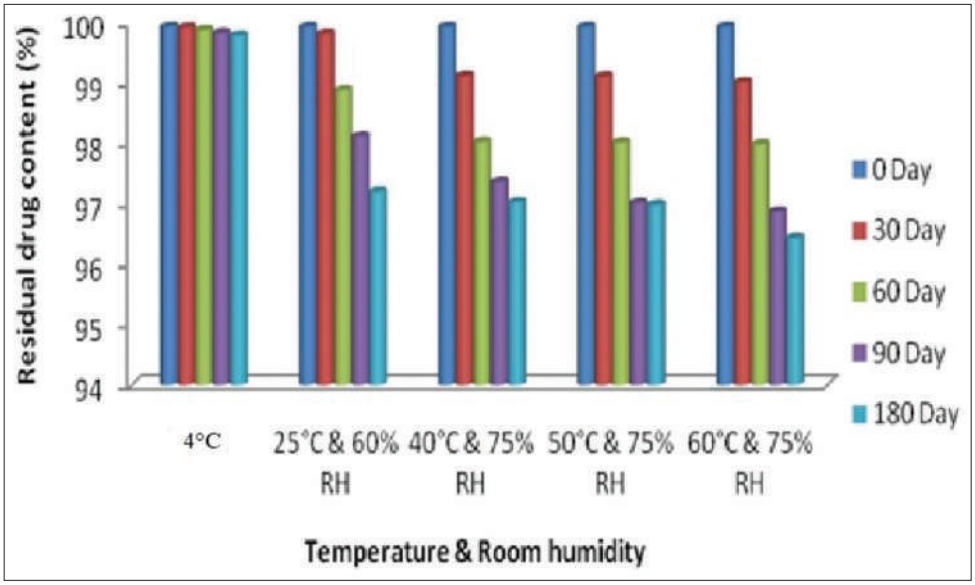

Figure 13: Bar graph showing residual drug content of uncoated tablet (F3) at temperature 4°C, 25°C and 60% RH and 40°C and 75% RH, 50°C and 75% RH, 60°C and 75% RH

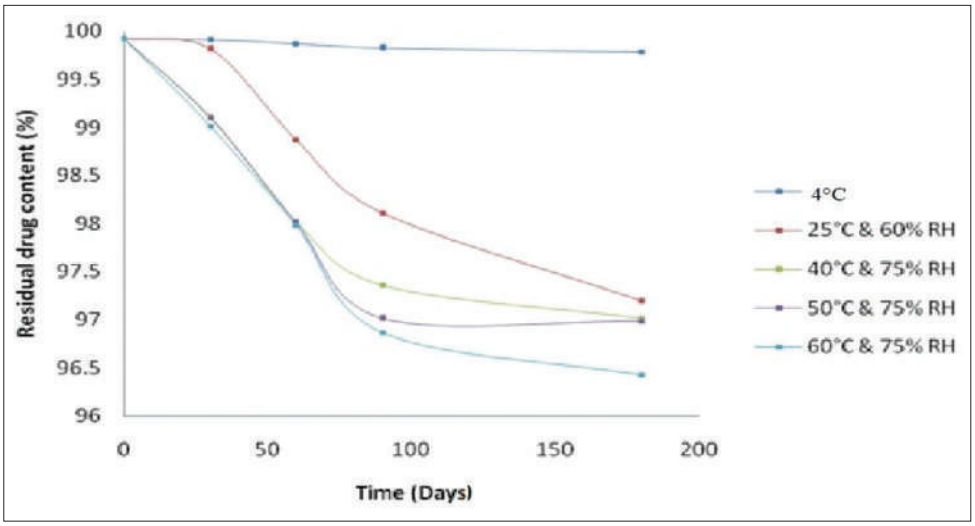

Figure 14: Degradation curves for stability studies of uncoated tablet (F3) at temperature 4°C, 25°C and 60% RH and 40°C and 75% RH, 50°C and 75% RH, 60°C and 75% RH

CONCLUSIONS

Based on all available classical and contemporary references, we may conclude that all medicinal values of *B. ceiba* are true. The work demonstrates the successful development and optimization of the flower mucilage loaded paracetamol tablets. It can be found that the yield obtained from microwave method for extraction of mucilage is much better as compared to the conventional method because microwave method works on the cellular level for extraction of the mucilage whereas conventional method is less efficient. After all, it only uses heat externally for the extraction of mucilage. Hence, we can conclude that microwave-assisted method is more suitable, fast economic, and simple for the extraction of mucilage as compared to the conventional method.

The current study shows the effect of *B. ceiba* mucilage as a binder in the development of paracetamol tablets in comparison with other standard binders. From the results, it is concluded that *B. ceiba* mucilage has a better binding property in comparison with starch and almost equal to PVP K-30. The results of hardness significantly affect the result of friability and disintegration time of uncoated formulations. The friability of Formulation F3 is more effective than the formulation F10 and F11. The result justified that mucilage of *B. ceiba* flower obtained by microwave-assisted method in 15% concentration is more promising binding agents as compared to starch and PVP K30. Drug release properties of the tablets were assessed using disintegration time and dissolution time as assessment parameters. The crushing strength, disintegration, and dissolution times of the tablets increased with increased binder concentration while their friability decreased. *B. ceiba* mucilage produced tablets with better mechanical properties and shorter disintegration and dissolution times than those containing starch and PVP K-30. The results suggest that *B. ceiba* mucilage could be useful as an alternative binding agent in tablets with better mechanical properties and release profile.

ACKNOWLEDGMENT

The authors wish to thanks Dr. Suman Jain, Director and Dr. Mukul Tailing, Professor, School of studies in Pharmaceutical sciences, for their skillful technical assistance.

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Source of Support: Nil. **Conflicts of Interest:** None declared.