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Assessment of various pharmaceutical excipient properties of natural *Moringa oleifera* gum [Mucoadhesion, disintegration, binder]

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Abstract

Plant gums and mucilages are being used due to their abundance in nature, safety and economy. So in The present investigation was an effort to study the suitability of gum obtained from *Moringa oleifera* as tablet mucoadhesive polymer, disintegrant and binder. This property of the gum was evaluated and compared with standard polymers like Chitosan, HPMC for mucoadhesion. Sodium starch glycolate (SSG), crospovidone for disintegration. Xanthan gum, and Starch for binder study. In this study gum isolated from trunk of *Moringa oleifera* was studied at different concentrations and conditions. The properties of *Moringa oleifera* gum were evaluated for solubility, loss on drying, total ash and acid in soluble ash, pH, angle of repose, bulk density, tapped density, carr's compressibility index and Hausner's ratio. The physicochemical properties of gum were characterized, by FTIR, DSC, and SEM. The gum disks were prepared for mucoadhesive study and evaluated for mucoadhesive strength, surface pH, swelling index. For disintegration study tablets were prepared by direct compression and wet granulation method with different concentration of gum and evaluated for disintegration time, wetting time. And for binding property the tablets were prepared with different concentration of gum as binder by wet granulation method, and evaluated for hardness, friability, and in vitro release profiles. Studies show that increasing concentration of *Moringa oleifera* gum decrease disintegration time in disintegration property study, and decrease % cumulative release in binder property study. Results obtained indicated that Moringa oleifera gum performed as good mucoadhesive polymer, disintegrating agent and binder.

Key-Words: *Moringa oleifera*, Gum, Mucoadhesion, Disintegration, Binder

Introduction

Researchers are trying to introduce new excipients for drug formulations to exhibit varied functions. The popularity of new excipient research is growing tremendously over the last few decades due to increasing demand for safe, economical and functionally reliable substitutes for the existing synthetic ones. Almost all therapeutic formulations used for humans and others include excipients. Pharmaceutical excipients can be regarded as totally inert or inactive substance within the formulation, but are used to convert Active Pharmaceutical Ingredients into dosage forms suitable for administration to patients.[1-4]

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A sticky, colloidal carbohydrate found in certain trees and plants, which dries into an uncrystallized, brittle mass that dissolves or swells in water, is known as Gums. Gum are amorphous, translucent solids, insoluble in alcohol and most organic solvent; they are however soluble in water to yield viscous, adhesive solutions and are swollen by absorption of water to get a jelly like mass. The word "*Gum"* 'sticky material' (14th c.) comes ultimately from Egyptian *kemai*, which passed into English via Greek *kómmi*, Latin *cummi* or *gummi*, Vulgar Latin *gumma*, and Old French *gomme*. And *gum* in the exclamation *by gum* (19th c.).[5]

Chemically, the natural gums are acidic complex polysaccharides composed of salts of sugars other than glucose: L-arabinose, D-galactose, L-rhamnose and D-glucuronic acid combined with certain metallic cations such as sodium, potassium, calcium and magnesium. For the most part, these gum have highly branched structures containing the different sugar units with many possible variations as regard to degree of branching, length of branches and type of linkages.

Therefore, an almost infinite number of structures are possible. Forces act between molecules, between different parts of the same molecules and between polymer and solvent. These forces include hydrogen bonding, ionic charges, dipole and induced dipole interactions and Vander Waals forces. All these forces affect properties as gel forming tendency, viscosity and adhesiveness.[6]

Material and Methods

Paracetamol pure drug was obtained as a gift sample from sun pharmaceutical LTD., Halol. *Moringa oleifera* gum was collected from village Surasamal, Vadodara. All other ingredients were obtained from Loba chem.

Isolation and purification of gum

The gum was collected from trees (injured site). It was dried, ground, and passed through sieve no 80.dried gum (10 g) was stirred in distilled water (250 ml) for 6-8 h at room temperature. The supernatant was obtained by centrifugation. The residue was washed with water and the washings were added to separate supernatant. The procedure was repeated four more times. Finally the supernatant was made up to 500 ml and treated with twice the volume of acetone by continuous stirring. The precipitated material was washed with distilled water and dried at 50-60° under vacuum.

Physicochemical characterization of the gum

Loss on drying

The method adopted was that specified in the B.P 2004 for acacia. 1.0 g of the sample was transfer into each of several Petri dishes and then dried in an oven at 105°C until a constant weight was obtained. The moisture content was then determined as the ratio of weight of moisture loss to weight of sample expressed as a percentage.

Total ash and acid insoluble ash determination

Ash content was estimated by the measurement of the residue left after combustion in a furnace at 450°C. The ash obtain from the determination of the ash was boiled with 25 ml of 2M hydrochloric acid solution for 5 minutes and the insoluble matter was filtered and washed with hot water and ignited and the subsequent weight was determined. The percent acid insoluble ash was calculated.

pH determination

pH was determined by shaking a 1%w/v solution of the sample in water for 5 min and the reading were noted by digital pH meter.

Angle of repose

The static angle of repose "θ" was measured according to the fixed funnel and free standing cone method. A funnel was clamped with its tip 2 cm above a graph paper place on a flat horizontal surface. The powders were carefully poured through the funnel until the apex of the cone thus formed just reached the tip of the funnel. The mean diameters of the base of the powder cones were determined and the tangent of the angle of repose calculate using the equation,

Where, θ = Angle of repose

$\theta = \tan^{-1} h/r$ h= Height of granules, r= Radius of granules

Bulk and tap densities

A quantity of 2gm from each of the powder sample was placed in a 10ml measuring cylinder and the volume, Vb, occupied by each of the samples without tapping was noted. After 100 taps on the table, the occupied volume Vt was read. The bulk and tap densities were calculated as the ratio of weight to volume (Vb and Vt respectively) by the following equations

Bulk densities: $(\rho b) = M/V_b$

Tapped densities: $(\rho t) = M/V_t$ M = Weight of powder

Vb = Volume occupied by powder without tapping

Vt = Volume occupied by powder after tapping

Hausner's ratio

This was calculated as the ratio of tapped density to bulk density of the samples

Hausner's ratio = Tapped density / Bulk density

Carr's compressibility index

This was calculated by equation:

Carr's index = [Tapped density - Bulk density/Tapped density] X 100

Viscosity

The viscosity was carried out using preparing 1% solution of gum in distilled water. The viscosity was measured using Brookfield viscosity meter.

Preparation of tablets

For mucoadhesive property

Disks were prepared by direct compression technique. The Moringa gum powder was passing through sieve #80 meshes and disks were made on single punch rotary machine. 50mg gum powder was compressed on flat faced punch, 5mm in diameter. Similar procedure is employed for preparation of disks using chitosan and HPMC K4M.

For disintegration property

Tablets were prepared by direct compression and wet granulation method.

Direct compression method

Tablets were prepared by direct compression method using moringa oleifera gum, SSG, crospovidone as super disintegrants, Dibasic calcium phosphate as diluent, PVP K30 as binder, purified talc and mg. stearate as lubricant and glidant. The model drug (paracetamol) and other ingredients passed through the sieve no. 60. Paracetamol, excipient and super

disintegrant are mixed in polyethylene bag, to the above mixture talc was added, mix it well. The tablets were prepared by direct compression on rotary tablet machine. (Table 1)

Wet granulation method

Wet granulation method was used to prepare granules of drug. The formulation was developed by using paracetamol as model drug. The different concentration of super disintegrant were used and adjusted by lowering the level of lactose in the formula. All ingredients were mixed in mortar and granulated with 5% PVP K30 as granulating fluid. The wet mass was passed through sieve # 30 meshes. The granules were dried at 50ºC for 20min. in oven. The dry granules were passed through sieve # 60, lubricated with lubricants and were compressed. Similar procedure employed for preparation of tablets using SSG and crospovidone. (Table 2)

For binding property study

Wet granulation method was used to prepare granules of drug. The formulation was developed by paracetamol as model drug. The different binder concentrations were used and binder level was adjusted by lowering the level of lactose in the formula. All ingredients were dry & mixed manually in mortar and granulated with water as granulating fluid. The wet mass was passed through sieve # 30 meshes. The granules were dried at 50ºC for 20min. in oven. The dry granules were passed through sieve # 60, lubricated with lubricants and were compressed. Similar procedure employed for preparation of tablets using xanthan gum and starch. (Table 3)

Post-compression evaluation of paracetamol tablets

Common tests for disintegration and binder property study.

Weight variation

Twenty tablets from each formulation were weighed using electronic weighing balance and the average weight was calculated.

Hardness

The hardness of the tablets was determined using Monsanto hardness tester. It was expressed in Kg/cm^2. Three tablets were randomly picked from each formulation and mean & standard deviation values were calculated.

Friability

Roche type friabilator was used for testing friability. Six tablets were weighed accurately and placed in the tumbling apparatus that revolves at 25 rpm dropping the tablets through a distance of six inches with each revolution. After 4 min, the tablets were weighed and the percentage loss was determined.

% loss = [initial wt. - final wt. / initial wt.] × 100

Thickness

The thickness of the tablets was determined by using vernier calipers. Five tablets were used, and average values were calculated.

Tests for mucoadhesive study

a) Surface pH

It was determined in order to investigate the possibility of any side effects *in vivo*. A combined glass electrode was used for this purpose. The disk was allowed to swell by keeping it in contact with 5 ml of pH 6.8 phosphate buffer for 1 hr. the pH was measured by bringing the electrode in contact with the surface of the tablets and allowing it to equilibrate for 1 min.

b) Swelling index

Six disks of each polymer were individually weighed (W_1) and placed separately in petri dishes with 5 ml of phosphate buffer of pH 6.8. At the time interval of 1,2,3,4, and 6 h, disk was removed from the petri dish and excess water was removed carefully using the filter paper. Then the swollen disk was reweighed (W_2) and the percentage hydration was calculated using the following formula.

Swelling index = $[(W_2-W_1)/W_1] \times 100$

c) Bio-adhesion study

Mucoadhesive strength of the formulation was determined by two methods.

Time-based

In this method time require to detach the disk from mucosa was measured. Fresh porcine chicken intestinal mucosa was obtained from a local slaughterhouse and used within 2 hours after collection. The collected membrane was treated for removing underlying fat and loose tissues using scalpel. The membrane was washed with distilled water and then with phosphate buffer pH 6.8 at 37°C.The intestinal mucosa was cut into pieces and washed with phosphate buffer pH 6.8.In this method the intestinal mucosa was adhered to the paddle of the dissolution apparatus with cyanoacrylate adhesive. Then at one side of each disk of plain polymer was wetted with 50µl simulated saliva and pressed over intestinal mucosa for 30 sec. Then paddle was immersed in a basket of the dissolution apparatus containing 500 ml of 6.8 pH phosphate buffer, at 37^0C. The paddle was rotated at 50 rpm. Time required to detach the disk from the intestinal mucosa was measured.

Force-based

In this method the mucoadhesive strength of the polymer study was determined by measuring the force required to detach the disk from the mucosal tissue. Here also primary treatment of porcine intestinal mucosa was carried out as above mention procedure. Modified physical balance was used for this procedure.

At one side of balance, a piece of intestinal mucosa was tied to the Teflon tap coated anvil by cyanoacrylate adhesive. The disk was adhered on another anvil. Then both the anvils were made in contact for 30 sec. of contact time. In another pan of the balance consequently addition of the weight was done until the disk dose not detach from the mucosa. Force require to detach was measured.

$$\text{Force of adhesion (N)} = \frac{\text{Mucoadhesive strength} \times 9.81}{100}$$

Test for super disintegration study

a) Disintegration time (DT)

DT test was carried out according to USP specification. Tablets were placed in a disintegration tester (type USP- Electro lab USP- ED-2AL) filled with distilled water at 37±0.2ºC. The tablets were considered completely disintegrated when all the particles passed through the wire mesh. Disintegration times recorded was mean of two determinations.

b) Wetting time

A piece of tissue paper folded twice was placed in a petri dish containing 6ml of water. A tablet was placed on the paper and the time taken for complete wetting of tablet was noted. Three tablets from each formulation were randomly selected and the average wetting time was noted.

c) Dissolution studies

In vitro drug release studies of all the formulations were carried out using tablet dissolution test apparatus at 50rpm. Phosphate buffer pH1.2 was used as the dissolution media with temperature maintained at 37±2°C. Sample were withdrawn at different time intervals, diluted suitably and analyzed at 257nm for percentage drug release using shimadzu UV-Visible spectrophotometer. The sample after each withdrawal was replaced with same volume of fresh media.

Test for binding study

In Vitro dissolution studies

The release rate of paracetamol from tablets was determined using The United States Pharmacopoeia (USP) XXIV dissolution testing apparatus II (paddle method). The dissolution test was performed using 900 ml of 0.1 N HCl, at 37 ± 0.5°C and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus, and was replaced with fresh dissolution medium. The samples diluted to a suitable concentration with 0.1N HCl. Absorbance of these solutions was measured at 257 nm using a UV-Vis double beam spectrophotometer.

Results and Discussion

From the results, it can be concluded that, *Moringa oleifera* gum has a better Mucoadhesion, Disintegration, and binding capacity. The gum used having high Mucoadhesive property, its disintegration property time falls within the standard limits, the mechanical properties of the tablets were assessed using the crushing strength and friability of the tablet. Drug release properties of the tablets were assessed using dissolution time as assessment parameters.

Isolation & purification of *Moringa oleifera* gum were yielded 47% w/w of purified gum. This could be due to the nature of gum as it formed two phase: the supernatant and the residue which may not be readily soluble after soaking in the extraction medium. (Figure 1 - 6)

The Preformulation studies like solubility, loss on drying, total ash, acid insoluble ash, viscosity and pH of gum were evaluated results are shown in Table 4.

The FTIR Spectra revealed that, there was no interaction between polymer and drug. Polymers used were compatible with Paracetamol. (Figure 7 - 9)

Surface smoothness of the Paracetamol was decrease by increases in the gum concentration. (Figure 10 - 12)

The DSC data indicates that the PCM is still present in pure form because the melting point is not shifted from its original peak. (Figure 13 - 15)

Through the time based technique (Figure 16) which was used for mucoadhesive strength determination, it was found that *Moringa oleifera* gum had greater mucoadhesive strength than that of chitosan and HPMC K4M. This may be due to the greater swelling rate of *Moringa oleifera* gum as well as of swelling property, which results in larger surface of polymer that is exposed to the mucosal layer, resulting in the increase in number of hydrogen bonding between the polymer and mucosal layer and thus increase in the mucoadhesive strength of the polymer. Here chitosan having very less mucoadhesive strength this may be due to disintegration property of chitosan. Results are shown in Table 5

The result shows that disintegration time of natural gum was found to be less when compared to synthetic one. As increasing the concentration of gum there was decrease in disintegration time. The tablet prepared by wet granulation method takes more time to disintegrate when compare to tablet prepared by direct compression method results are shown in Table 6-9. All batches shows a faster and maximum of drug release from all the formulations proving the disintegration property of isolated gum of Moringa oleifera. (Figure 17&18) For binding property study it can be concluded that Moringa oleifera gum may be used as a binding agent

in the tablet formulation when high mechanical strength is more essential. Studies shows that Paracetamol tablets prepared with 4% - 16% binding concentrations of *Moringa oleifera* gum shows delayed drug release (Figure 19-20). Hence this gum may be used to formulate Sustained release/Controlled release tablets by increasing the binding concentration of the same. Results are shown in Table 10.

So, it was concluded from the results that *Moringa oleifera* gum can be an alternative polymer for the pharmaceutical formulations. The gum was found to be affective as mucoadhesive polymer, disintegrant, and binder. Abundant availability, food grade status, economical feasibility, commercial suitability and reliability make the gum as an alternative for the existing toxic, synthetic and ineffective excipients.

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Fig. 1: Dried Crude MOG

Fig. 2: Trituration of Crude MOG

Fig. 3: Cloudy Mass of Isolated MOG

Fig. 4: Isolated MOG

Fig. 5: Dried Isolated MOG

Fig. 6: Powder Isolated MOG

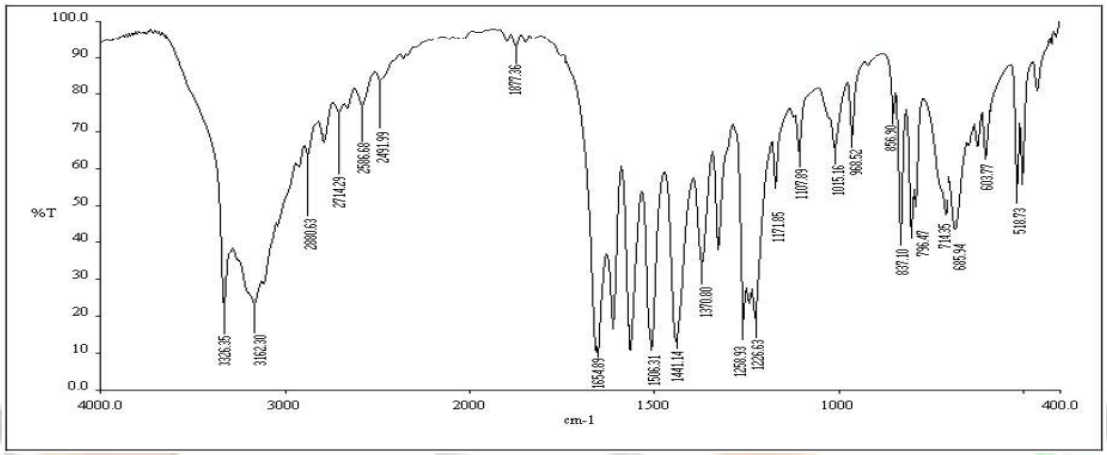

Fig. 7:IR Spectrum of Paracetamol

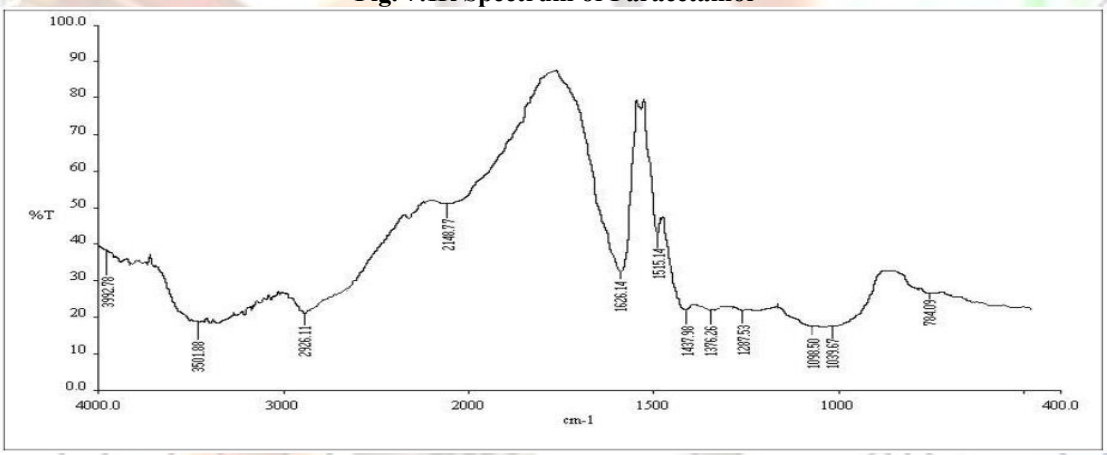

Fig. 8; IR Spectrum of Moringa oleifera gum

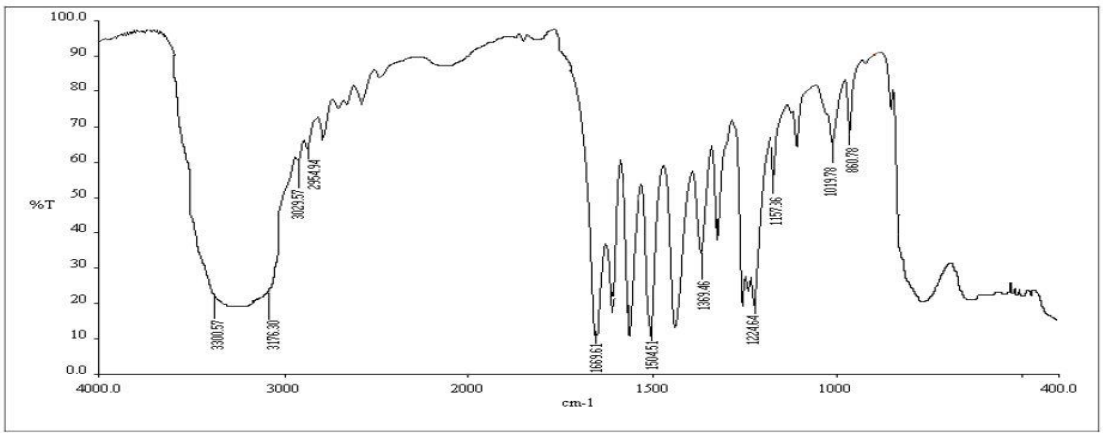

Fig. 9: IR Spectrum of Combination of Moringa oleifera gum and Paracetamol

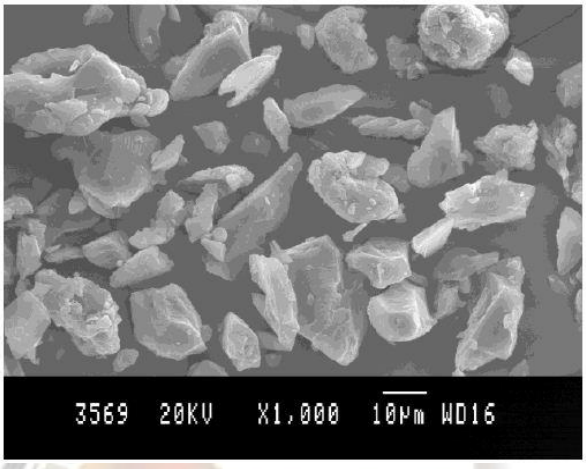

Fig. 10: SEM of Moringa oleifera gum

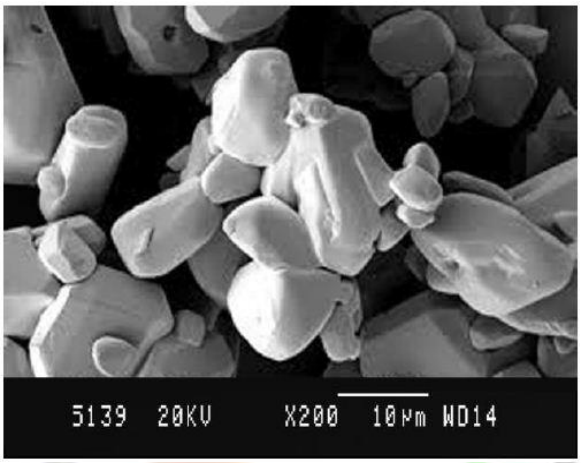

Fig. 11: SEM of Paracetamol

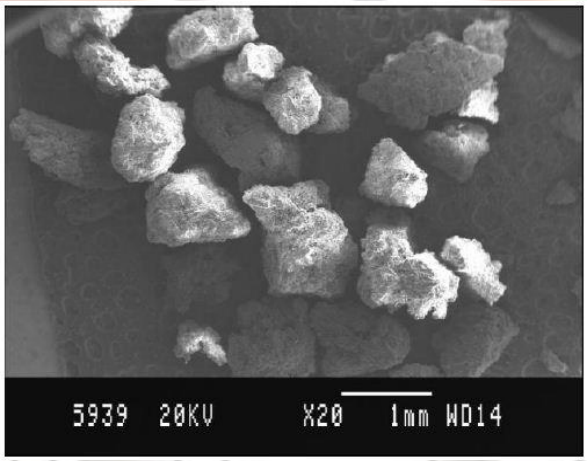

Fig. 12: SEM of granules (Paracetamol + Moringa oleifera gum)

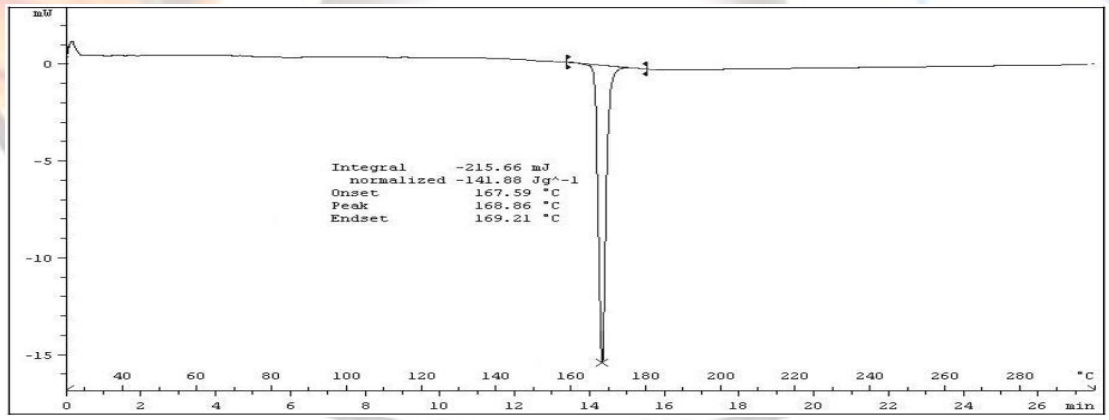

Fig. 13: DSC pattern of Paracetamol Pure Drug

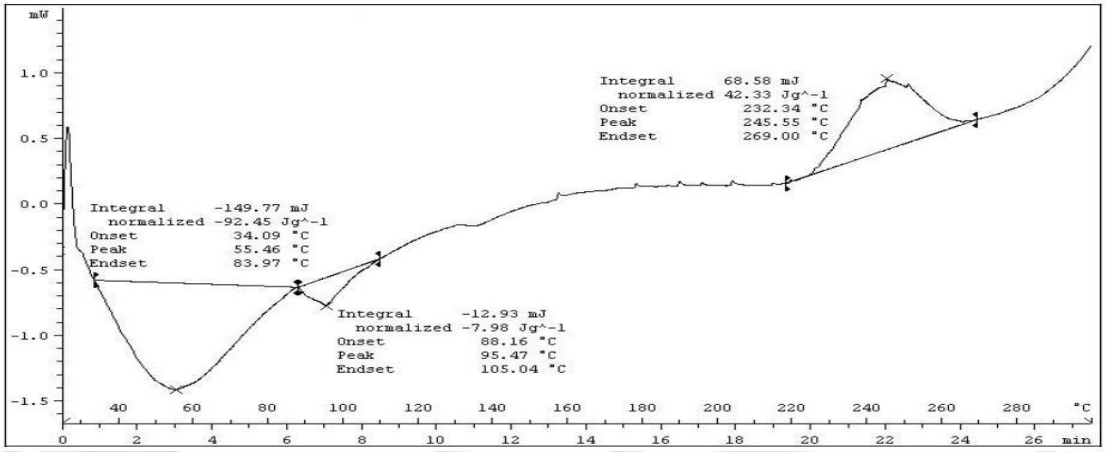

Fig. 14: DSC pattern of Moringa oleifera Gum

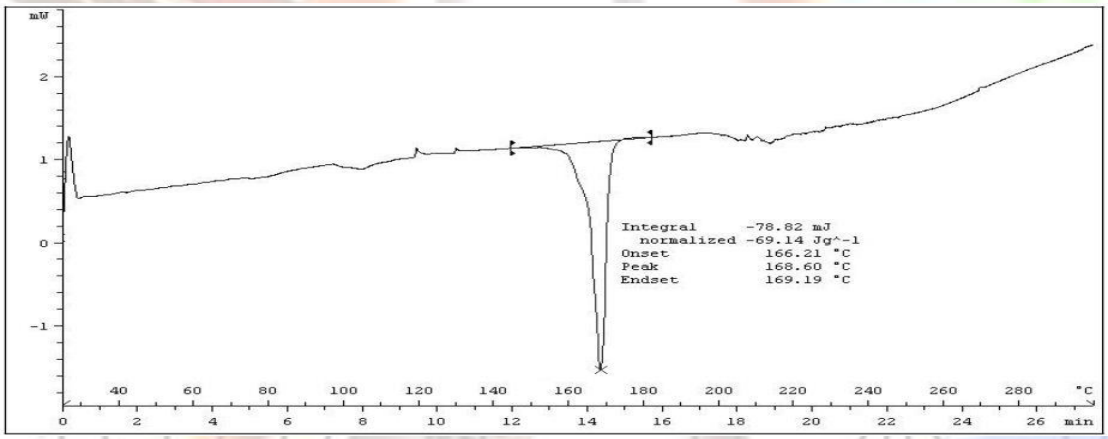

Fig. 15: DSC patterns of Combination of Paracetamol and Moringa oleifera gum

Fig. 16: Modified physical balance

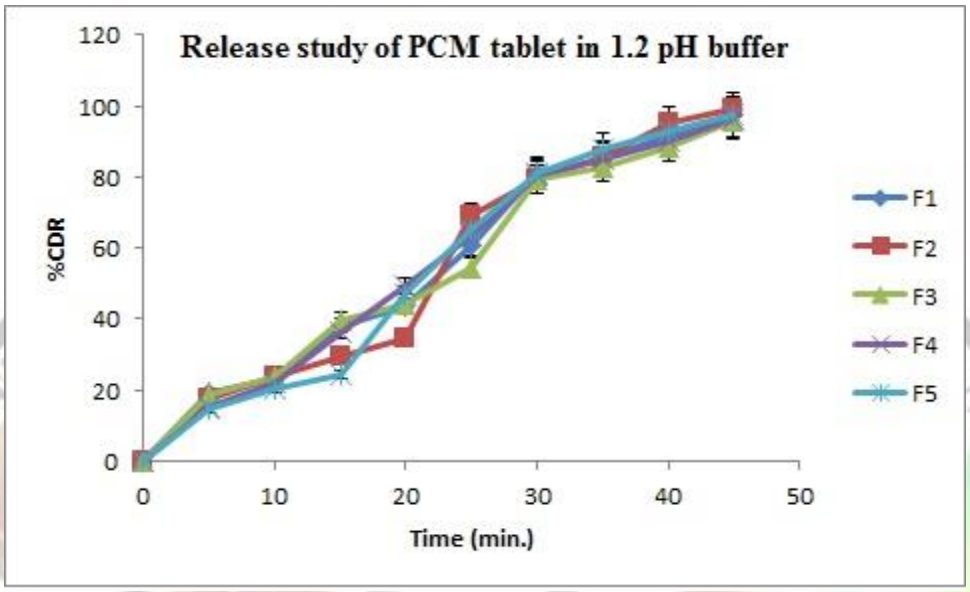

Fig. 17: *In vitro* release profile disintegrating tablet prepared by direct compression method

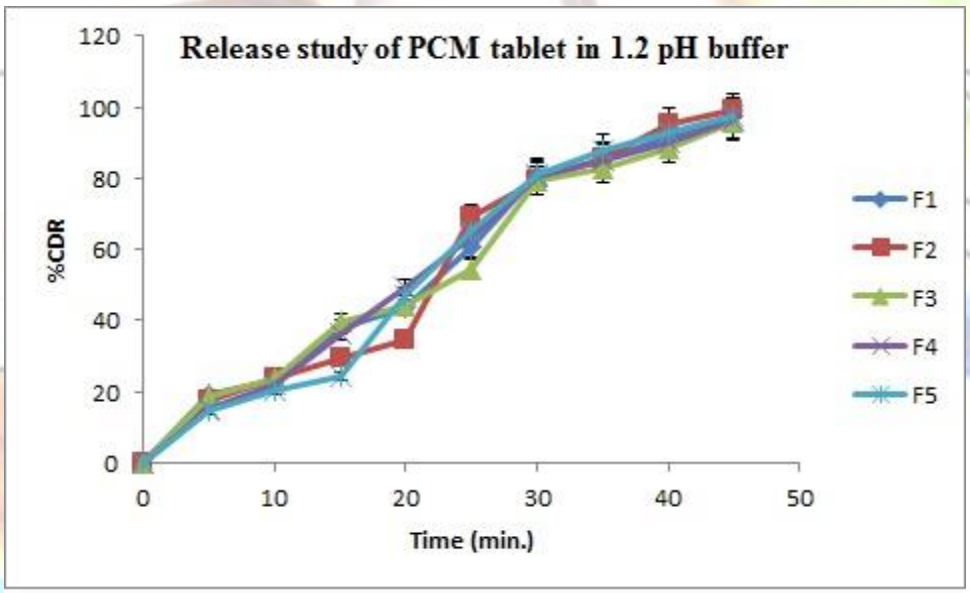

Fig. 18: *In vitro* release profile of disintegrating tablet prepared by wet granulation method

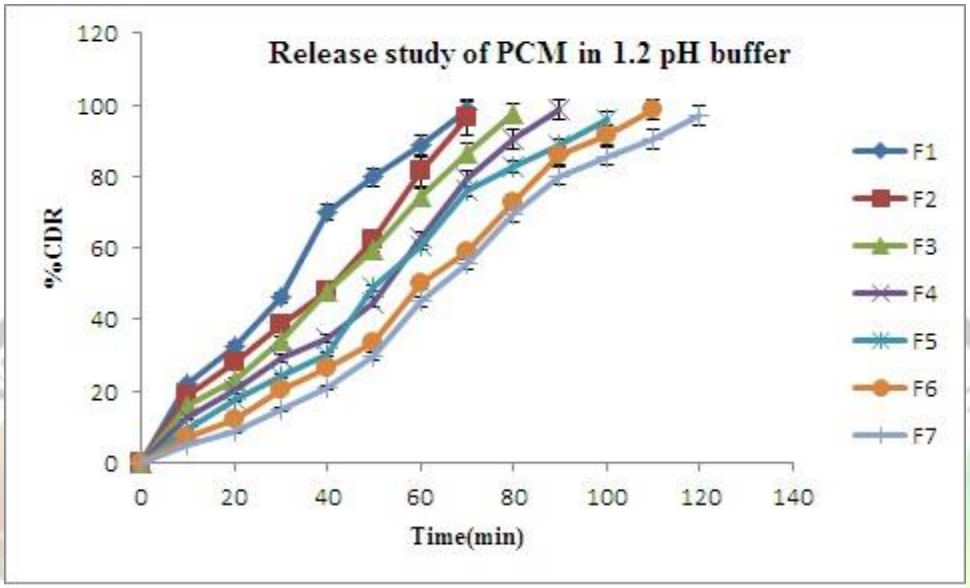

Fig. 19: In vitro release study data of F1-F7 for binding study

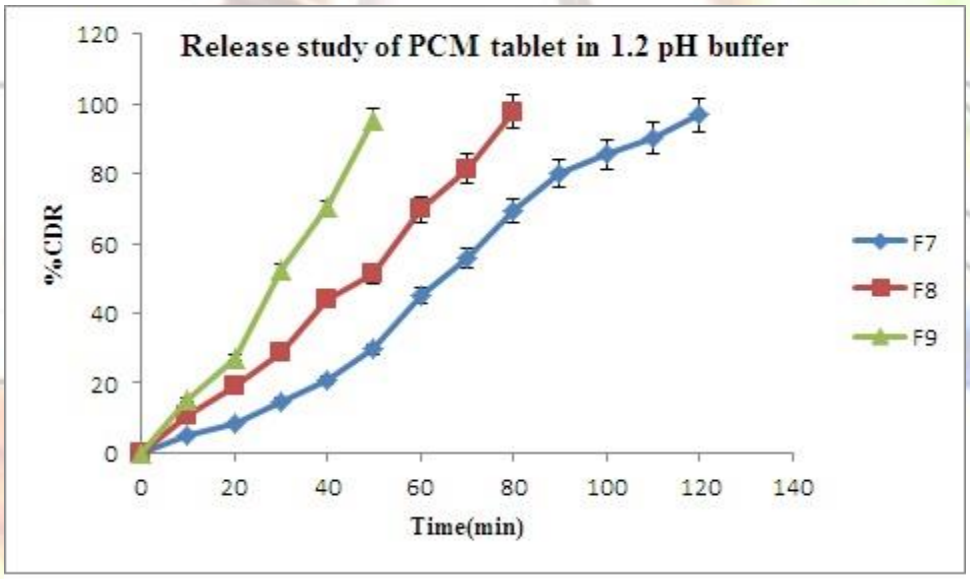

Fig. 20: Comparative in vitro release study data of Moringa gum (F7), Xanthan gum (F8), and Starch paste (F9)

Table 1: Disintegrating tablet prepared by direct compression method

Ingredients	F1 (2%)	F2 (3%)	F3 (4%)	F4 (2%)	F5 (2%)
Paracetamol	250	250	250	250	250
Moringa gum powder	10	15	20	--	--
Sodium starch glycolate	--	--	--	10	--
Crospovidone	--	--	--	--	10
Dibasic calcium phosphate	200	195	190	200	200
PVP K30	25	25	25	25	25
Mg.stearate	10	10	10	10	10
Talc	5	5	5	5	5
Total	500	500	500	500	500

***All weights in mg**

Table 2: Disintegrating tablet prepared by wet granulation method

Ingredients	F1 (2%)	F2 (3%)	F3 (4%)	F4 (2%)	F5 (2%)
Paracetamol	250	250	250	250	250
Moringa gum powder	10	15	20	--	--
Sodium starch glycolate	--	--	--	10	--
Crospovidone	--	--	--	--	10
Lactose	225	220	215	225	225
PVP in IPA	5% solution of PVP K30 in IPA				
Mg.stearate	10	10	10	10	10
Talc	5	5	5	5	5
Total (mg)	500	500	500	500	500

***All weights in mg**

Table 3: Formulation table (binding study)

Ingredients (mg)	F1 (4%)	F2 (6%)	F3 (8%)	F4 (10%)	F5 (12%)	F6 (14%)	F7 (16%)	F8 (16%)	F9 (16%)
Paracetamol	250	250	250	250	250	250	250	250	250
Moringa gum powder	20	30	40	50	60	70	80	--	--
Starch paste	--	--	--	--	--	--	--	80	--
Xanthan gum	--	--	--	--	--	--	--	--	80
Lactose	175	165	155	145	135	125	115	115	115
Starch	40	40	40	40	40	40	40	40	40
Mg.stearate	10	10	10	10	10	10	10	10	10
Talc	5	5	5	5	5	5	5	5	5
Total (mg)	500	500	500	500	500	500	500	500	500

***All weights in mg**

Table 4: Physicochemical characterization of gum

Some physicochemical properties of *Moringa oleifera gum*	
Parameters	Result
Solubility	Soluble in water. Practically in soluble in ethanol, acetone and chloroform
Loss on Drying	12.02%
Total ash	12%
Acid insoluble Ash	3%
Bulk Density (g/cm^3)	0.65±0.05
Tapped Density (g/cm^3)	0.84±0.04
Carr's Index (%)	22.34±0.76
Hausner's ratio	1.28±0.07
Angle of Repose (θ°)	42.76°±1.05°
pH	6.8-6.9
Viscosity	900 cps.

Table 5: Time-based study, Force-based study, Surface pH, swelling index

Formulation Code	Time-based (hrs.)	Force-based (N)	Surface pH	% Swelling index (Up to 5hrs.)
F1	>24	2.50	6.8±0.3	90.2 ± 0.3
F2	6.15±0.45	1.51	6.4±0.4	31.9 ± 0.5
F3	15.25±0.35	1.96	6.6±0.4	73.7 ± 0.3

Table 6: Weight variations, Thickness, Hardness, and Friability of Directly compressed disintegrating tablet

Formulation code	Weight variation (%S.D ≤ 5%)	Tablet thickness (mm)	Hardness (kg/cm^2)	Friability (%)
F1	Pass (≤ 3.14)	5.1±0.2	4.2±0.3	0.68
F2	Pass (≤ 3.17)	5.2±0.1	4.1±0.2	0.64
F3	Pass (≤ 2.56)	5.3±0.2	4.2±0.2	0.72
F4	Pass (≤ 3.23)	5.2±0.2	4.0±0.4	0.76
F5	Pass (≤ 3.05)	5.3±0.1	4.1±0.3	0.81

Table 7: Disintegration time, wetting time of directly compressed disintegrating tablet

Formulation code	Disintegration time (sec.) mean ± S.D (n=3)	Wetting time (sec.) mean ± S.D (n=3)
F1	72±3.0	81±2.0
F2	64±2.0	78±3.0
F3	59±3.0	68±2.0
F4	127±4.0	142±4.0
F5	92±3.0	103±3.0

Table 8: Weight variations, Thickness, Hardness, and Friability of disintegrating tablet prepared by wet granulation

Formulation code	Weight variation (%S.D ≤ 5%)	Tablet thickness (mm)	Hardness (kg/cm^2)	Friability (%)	
F1	Pass (≤3.67)	5±0.2	4.2±0.3	0.57	
F2	Pass (≤2.93)	5.1±0.1	4.1±0.2	0.48	
F3	Pass (≤2.24)	4.9±0.2	4.3±0.2	0.56	
F4	Pass (≤3.11)	5.1±0.1	4.0±0.4	0.62	
F5	Pass (≤3.52)	5±0.2	4.2±0.1	0.67	

Table 9: Disintegration time, wetting time of tablet prepared by wet granulation method

Formulation code	Disintegration time (sec.) mean ± S.D (n=3)	Wetting time (sec.) mean ± S.D (n=3)
F1	132±2.0	146±4.0
F2	121±3.0	134±3.0
F3	113±3.0	128±2.0
F4	195±2.0	209±3.0
F5	173±3.0	188±3.0

Table 10 Weight variations, Thickness, Hardness, and Friability of tablets for binding study

Formula binder weight (%w/w)	Weight variation (%S.D $\leq$ 5%)	Tablet thickness (mm)	Hardness (kg/cm^2)	Friability (%)
F1 (4%)	Pass (≤2.89)	3.8±0.2	6.5 ± 0.2	0.76
F2 (6%)	Pass (≤2.81)	3.6±0.1	6.5 ± 0.3	0.62
F3 (8%)	Pass (≤2.87)	3.7±0.2	6.9 ± 0.2	0.51
F4 (10%)	Pass (≤2.59)	3.5±0.2	7.1 ± 0.3	0.42
F5 (12%)	Pass (≤2.42)	3.4±0.1	7.9 ± 0.1	0.41
F6 (14%)	Pass (≤2.44)	3.5±0.1	8.0 ± 0.2	0.35
F7 (16%)	Pass (≤2.36)	3.4±0.1	8.5 ± 0.2	0.25
F8 (16%)	Pass (≤2.51)	3.6±0.1	7.5 ± 0.2	0.37
F9 (16%)	Pass (≤2.65)	3.7±0.2	7.2 ± 0.4	0.39