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STUDY OF THE BINDING PROPERTIES OF GUM OBTAINED FROM *CURCUMA AMADA* ON MODEL DRUG PARACETAMOL

Nishant Thakur [*1], Payal Mittal [1], Manish Goswami [1], Rajwinder Kaur [1], Raman Bansal [2], Monika Bansal[2], and Vikas Gupta [3]

Chandigarh University [1], Gharuan, Mohali, Punjab, India
Akal college of Pharmacy and Technical Education [2] Mastuana Sahib, Punjab, India
University Centre of Excellence [3], BFUHS, Faridkot, Punjab, India

Key words:

Curcuma amada gum, Tablet binder, Paracetamol

Correspondence to Author:
Nishant Thakur

Chandigarh University, Gharuan, Mohali, Punjab.

E-mail: nishant.thakur33@rediffmail.com

ABSTRACT: The aim of the present study is to evaluate the gum of *Curcuma amada* (mango ginger) as a tablet binder employing paracetamol as a model drug. Natural gums are economic, easily available and found useful as tablet binder. The physicochemical properties of a gum obtained from the rhizomes of *Curcuma amada* were characterized by Fourier transmittance infra red (FTIR) and Differential scanning colorimetry (DSC). Amada gum has a glass transition (Tg) temperature and melting peak at 94.3°C. Paracetamol tablets were prepared by wet granulation technique using amada gum as a tablet binder in the concentrations of 1%, 3%, 5%, 7% & 9% w/w and compared with standard binders. The prepared tablets were evaluated for tablet characteristics. The values of granules showed angle of repose good flow property. The hardness of the prepared tablets varies with binder concentration. The prepared tablets showed friability decrease with increases concentration and disintegration time increase with increase the binder concentration. *In vitro* drug release was also depending on binder concentration. Tablets with 1%and 5% w/w binder concentration showed optimum results than standard binders, thus conclusion was drawn that amada gum was found to be useful for the preparation of uncoated tablet dosage form.

INTRODUCTION: The present investigation is an effort to study the suitability of gum obtained from *Curcuma amada* as tablet binder. The binder properties of the gum was evaluated and compared with gum & PVP K30. All the chemicals and reagents used in the present study were of analytical grade. Paracetamol was purchased from yarrow chem. Mumbai.

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Curcuma amada was purchased from Sri Venketeswra University. Lactose and PVP K30 were obtained from Helios Pharmaceuticals Baddi Himachal Pradesh. Acetone, ammonia, choloroform, Glacial acetic acid, ethanol, ethyl acetate, acetic acid, toulene and dicholoromethane were obtained from S.D. Fine chemicals. *Curcuma amada*, family Zingiberaceae rhizome was authenticated by DR. K. madhava Chetty in department of Botany from Sri Venkateshwara University, Tirupati-517502, (A.P.) India. The rhizomes *Curcuma amada* were dried and powdered. The powder of rhizomes was Soaked in demineralized water for one day. Boiled for 30 minute and put to cool at room temperature for 1 hour for complete release of gum into water.

The material was squeezed within eight fold muslin cloth. The filtrate was precipitated from solution using absolute acetone. The precipitates were separated and dried on hot air oven. The dried gum was stored in dessicator to prevent from moisture.

Physiochemical characterization of gum:

(1)Solubility test:

The separated gum was evaluated for solubility in water, acetone, chloroform and ethanol in accordance with the British pharmacopoeia specifications.

(2) Loss on drying [1]:

The method adopted was that specified in the B.P 2004 for acacia. 1.0 g of the sample was transferred 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.

(3)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 obtained 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. Filtrate was washed with hot water and ignited and the subsequent weight was determined. The percent acid insoluble ash was calculated.

(4) pH determination:

This was done by shaking a 1%w/v dispersion of the sample in water for 5 min and the pH was determined using a digital pH meter.

(5) Swelling index[1]:

Swelling index of polysaccharide was determined by using modified method reported. One gram of gum powder was accurately weighed and transferred to a 25mL Stoppard measuring cylinder. The initial volume of the powder in the measuring cylinder was noted.

The volume was made up to 25 ml mark with distilled water. The cylinder was Stoppard, shaken gently and set aside for 24 h. The volume occupied by the gum sediment was noted after 24 h.

Swelling index (SI) is expressed as a percentage and calculated according to the following equation.

$$\text{Swelling index} = \frac{Wt - Wo}{Wo}$$

Where Wo is the initial height of the powder in graduated cylinder and W_t denotes the height occupied by swollen gum after 24 h.

(6)Angle of repose [2]:

The static angle of repose 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 placed 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 calculated using the equation:

$$\text{Angle of repose } (\theta) = \tan^{-1} (h/r)$$

Where;
(θ) = angle of repose
h = height of the cone
r = radius of the cone base

Scale of flow ability:

TABLE 1:

Flow property	Angle of repose
Excellent	25-30
Good	31-35
Fair- (aid not added)	36-40
Passable- may hang up	41-45
Poor- must agitate, vibrate	46-55

(7) Bulk and Tapped densities [3]:

2.0 g quantity powder sample was placed in a 10ml measuring cylinder and the volume, V_0, occupied by each of the samples without tapping was noted. After 100 taps on the table, the occupied volume V_{100} was read. The bulk and tap densities were calculated as the ratio of weight to volume (V_0 and V_{100} respectively).

Bulk Density = W/ Vo
Tapped density = W/ V_{100}

W= weight of the powder
Vo = Initial volume of the powder
V_{100}= Final volume of the powder

(8) Hausners index:
Hausner ratio is an indirect index of ease of measuring the powder flow. This was calculated as the ratio of tapped density to bulk density of the samples.

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

(9) Carr's index (%) [4]:
The Carr's index (Percent compressibility) of the granules was calculated from the difference between the tapped and bulk densities divided by the tapped density and the ratio expressed as a percentage

This was calculated using the equation:

$$\text{Compressibility index} = \frac{\text{Tapped density - Bulk density}}{\text{Tapped density}} \times 100$$

Scale of flowability:

TABLE 2:

Compressibility index	Flow character	Hausner ratio
10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very poor	1.46-1.59

Formulation of paracetamol tablets:
The granules after blending with lubricants and were compressed by using hydraulic press with flat faced punches. The tablets were developed for 400mg weight.

TABLE 3: PARACETAMOL FORMULATION CONTAINING GUM AND PVP K30 AS A BINDER.

Ingredient	F1	F2	F3	F4	F5	F6	F7
Paracetamol	200	200	200	200	200	200	200
Gum	4	12	20	28	36	-	-
PVP K30	-	-	-	-	-	4	20
Lactose	88	80	72	64	56	88	72
MCC	100	100	100	100	100	100	100
Talc	8	8	8	8	8	8	8
Total	400	400	400	400	400	400	400

Post-compression evaluation of paracetamol tablets:

(1)Thickness:
The thickness of the tablets was determined by using digital vernier calipers. Five tablets were used, and average values were calculated.

(2) Weight variation test [5]:
To study weight variation twenty tablets of the formulation were weighed using an Essae electronic balance and the test was performed according to the official method. Twenty tablets were selected randomly from each batch and weighed individually to check for weight variation.

TABLE 4: SPECIFICATION FOR WEIGHT VARIATION OF TABLETS

Average weight of tablets (mg)	Percent difference
130 or less	10
From 130 through 324	7.5
More than 324	5

(3) Hardness (crushing strength) [6]:
Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. Three tablets were randomly picked and hardness of the tablets was determined.

(4) Friability test [7]:

The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed (=F) and transferred into friabilator. The friabilator was operated at 25rpm for 4 minutes i.e.100 revolutions. The tablets were weighed again (W). The % friability was then calculated by

$$\% \text{ Friability} = \frac{\text{Initial wt. of tablets} - \text{Final wt. of tablets}}{\text{Initial wt. of tablets}} \times 100$$

% Friability of tablets less than 1% are considered acceptable.

(5) Drug content:

Five tablets were weighed individually and powdered. The powder equivalent to average weight of tablets was weighed and drug was extracted in acetone, the drug content was determined measuring the absorbance at 244.4 nm after suitable dilution using a Shimadzu 1800 UV-Vis double beam spectrophotometer.

(6) Disintegration test:

DT test was carried out according to USP specification. 6 tablets were placed in a disintegration tester (type USP- Electro lab USP-ED-2AL) filled with 7.8 pH at 37±0.20C. The tablets were considered completely disintegrated when all the particles passed through the wire mesh. Disintegration times recorded are the mean of two determinations.

(7) *In vitro* dissolution studies [8]:

The release rate of paracetamol from tablets was determined using the dissolution test. Test was performed using 900 ml of 7.8 phosphate buffer, at 37 ± 0.5°C at 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus, and the replaced with fresh dissolution medium. The samples diluted to a suitable concentration with 7.8 pH phosphate buffer. Absorbance of this solution was measured at 244.4 nm using a Shimadzu UV-Vis double beam spectrophotometer 1800. Cumulative percentage of drug release was calculated using the equation obtained from a standard curve.

RESULTS AND DISCUSSION:

(1) Selection of plant and authentication of plant: Selected plant was authenticated by Dr.R Madhava Chetty at Dept of Botany from Sri Venkateshwra University ,Tirupati-517502 A.P. and it was found to be Curcuma amada ,Family Zingiberaceae.

(2) Extraction of gum:

Rhizomes of plant are selected for extraction of gum. The yield of extracted gum was 0.26%/1kg.

TABLE 5:

Parameters	Results
Solubility	Soluble in water. Practically insoluble in ethanol, acetone and chloroform.
Loss on drying	5.5%
Total ash	9%
Acid insoluble ash	2.5%
Density of powder	
Bulk density (g/cc)	0.74
Tapped density (g/cc)	0.92
Compressibility index	19.56%
Hausners quotient	1.24
Angle of repose	25.75^0
pH	7.6-8.2
Swelling index	0.26

(3)Physicochemical characterization of gum:

Gum extracted from rhizomes of water soluble and found to be insoluble in acetone, ethanol and chloroform. Moisture content was low, suggestion its stability in formations containing moisture sensitive drugs. Low the value of total ash and insoluble ash obtained in this study of indicate low level of contamination.

From the flow property studies of gum show true density of gum 1.6811 while as bulk density and tapped density was found 0.74 and 0.92 respectively. The cars index and angle of repose of gum was 19.56% and 25.75° respectively, concluded from the flow properties that the gum has good flow.

A 1% w/v solution of gum in water gave a pH of 7.6-8.2. The near neutral pH of gum implies that when used in uncoated tablets.

IR Spectrum of *Curcuma amada* gum:

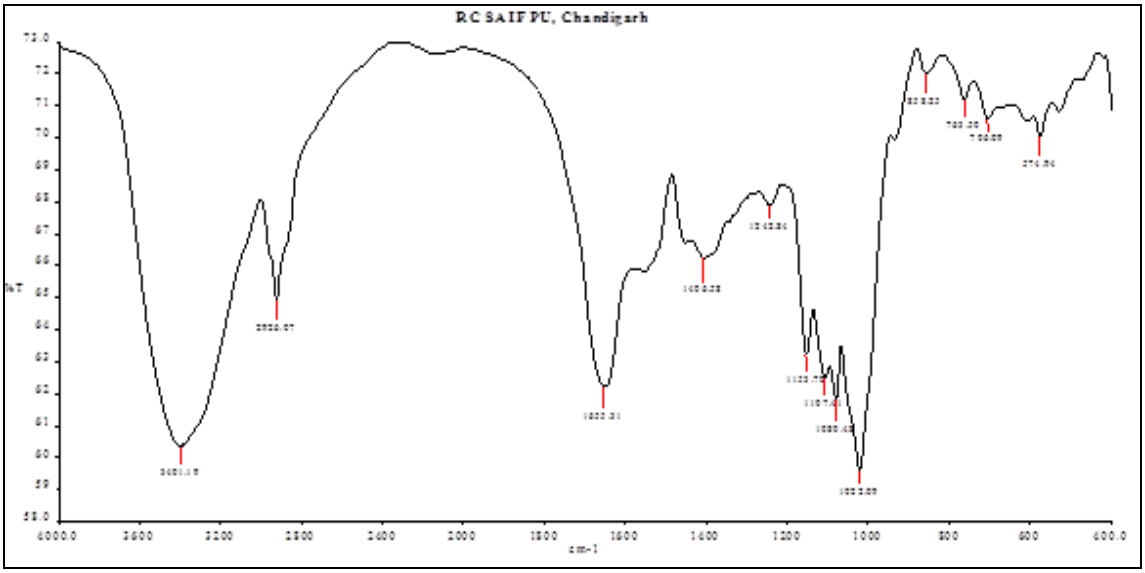

FIG.1: IR SPECTRUM OF GUM

TABLE 6: IR SPECTRUM INTERPRETATION OF GUM

IR spectrum	Wave number (cm^{-1})	Assignment	Comments
Amada gum	3401.19	O-H stretch	Very board due to strong hydrogen binding
	2926.07	C-H stretching	methyl C-H stretching associated with aromatic rings
	1655.31	C-C Stretch	assigned to the C-C strech of water

The peaks observed in **Fig. 2** the given spectrum were mainly of carbohydrates or glucose. It showed the O-H stretch, C-H stretching and C-C Stretch occurred in given sample.

Differential scaning calorimetery (DSC) of gum:

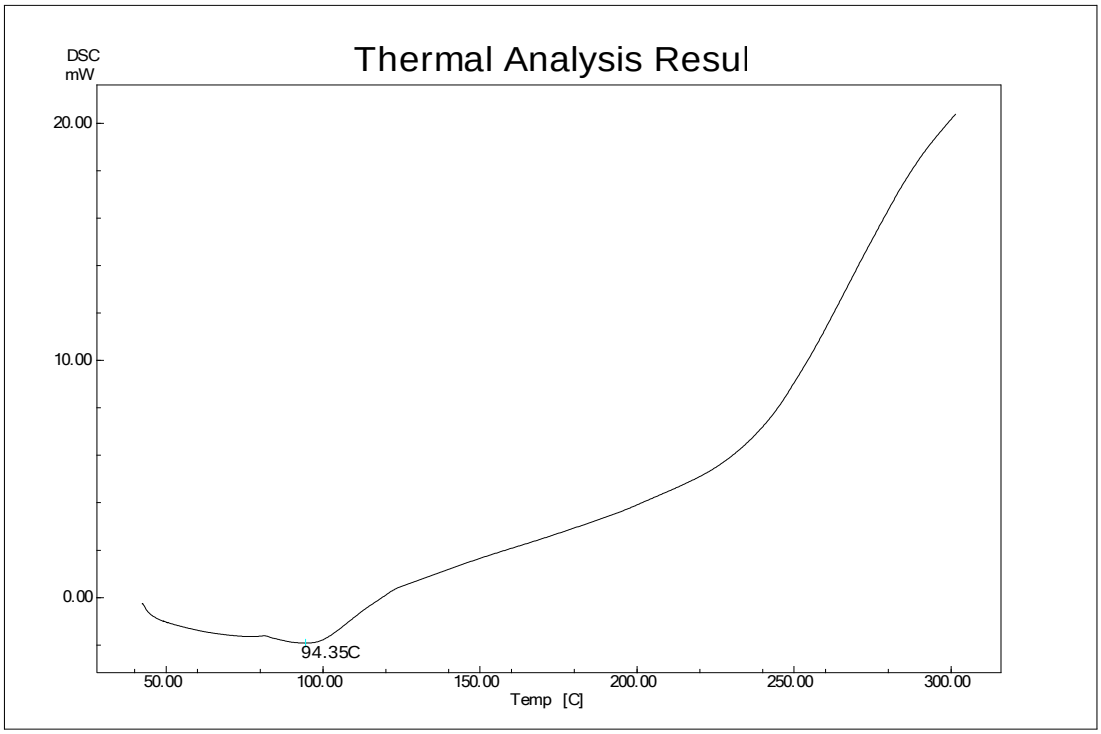

FIG.2: DSC PATTERN OF *CURCUMA AMADA* GUM

Differential scanning calorimetry (DSC) was used to measure the occurrence of exothermal or endothermal changes with increase in temperature. DSC, because of its sensitivity and accuracy, has been extensively used to study the phase transitions of polymers.

The thermogram for *Curcuma amada* gum is shown in **Fig. 3**, showed that the gum has amorphous. Glass transition (Tg) temperature occurred at 94.35°C.

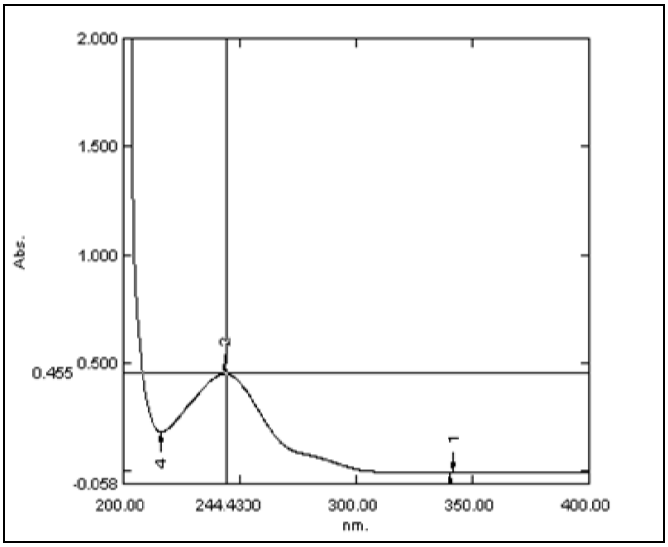

FIG. 3: UV ABSORPTION SPECTRUM OF PARACETAMOL IN 7.8 pH PHOSPHATE BUFFER

Preformulation of paracetamol:

Preformulation studies of Paracetamol:

TABLE 7: VALIDATION PARAMETERS OF CALIBRATION CURVE

Validation Parameter	In phosphate buffer(pH7.8)
Linearity equation	0.0531x-0.0263
Linearity range	1-10µg/ml
Slope(m)	0.0531
Intercept(C)	0.0263
R^2	0.998
LOD(n=3)	0.952µg/ml
LOQ(n=3)	0.28868µg/ml
Accuracy	97.89±0.34*
Precision	98.46±0.136*

Validation parameters
* = ±RSD

The Preformulation study of drug was carried out by conducting various parameters viz. solubility, melting point and pH determination, and spectral analyses.

Solubility:
The solubility of pure drug in solvent was carried out and found to be soluble in, acetone, and ethanol, insoluble in water.

Melting point:
Melting point of paracetamol was found to be 169°C. From this we concluded that the drug sample is pure.

Estimation of paracetamol by UV spectroscopy:
The absorption spectrum of pure drug was scanned between 200 -400 nm with 10 µg/ml concentration in 7.8 pH phosphate buffer solutions using UV Spectrophotometer. The maximum peak was obtained at 243 nm that was taken as λ max.

Calibration curve:
Absorbance data for the calibration curve of Paracetamol at 244.4 nm.

The absorbances of paracetamol standard solutions containing 1-10µg /ml of drug in 7.8 pH phosphate solution were obtained. **Fig.4** showed the standard calibration curve with regression value of 0.9981. The curve was found to be linear in the range of 1-10 µg /ml at max 244.4 nm.

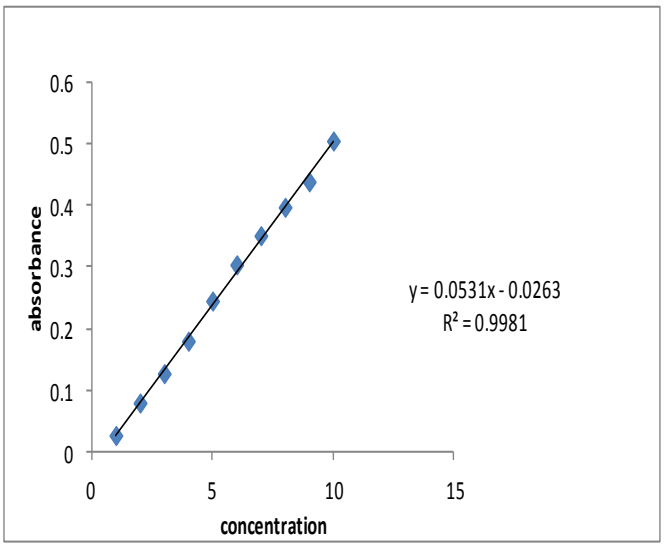

FIG. 4: STANDARD CALIBRATION CURVE OF PARACETAMOL (7.8 pH)

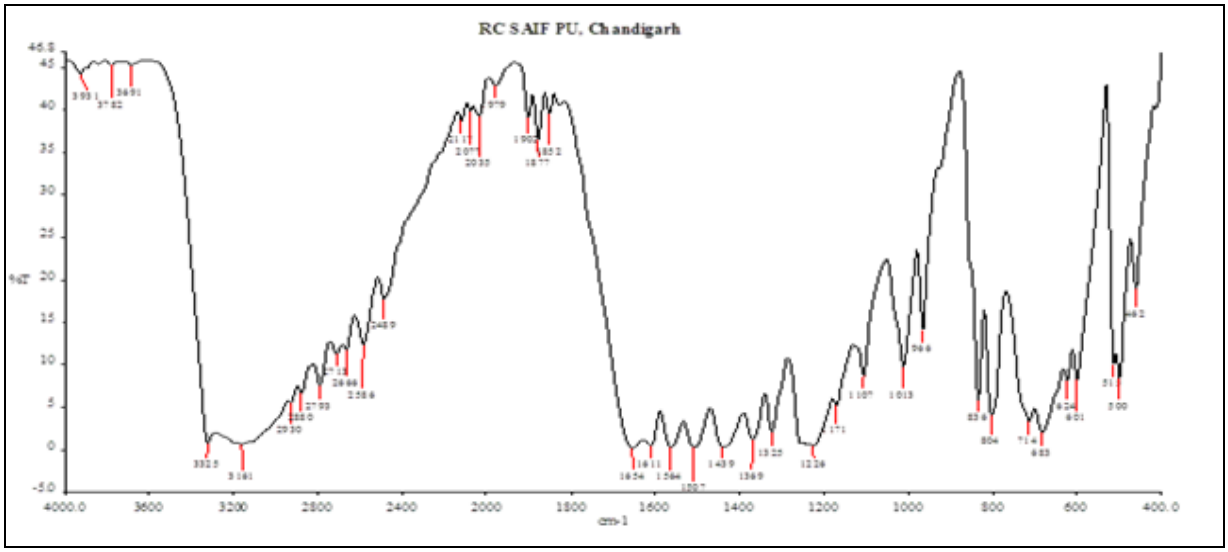

FIG.5: IR SPECTRUM OF PARACETAMOL

TABLE 8:

IR spectrum	Wave number cm-1	Assignment	Comments
Paracetamol	3325	N-H amide stretch	This band can be seen quite clearly although it is on top of the broad OH stretch
	3161	Phenolic OH stretch	Very board due to strong hydrogen binding
	2880	C-H stretching	Not clear due to underlying OH absorption
	1654	C=O amide stretch	Stretching in amides occurs at a low wave number
	1611	Aromatic C=C Stretch	This band is strong since the aromatic ring has polar substituent's which increase the dipole moment of the C=C bonds in the ring
	1507	AromaticC=C Stretch	Evidence of a doublet due to interaction with ring substituent's

IR spectrum in **Fig. 6** shows that the given sample of drug is Paracetamole. The major peaks of given spectrum showed all major function groups present of paracetamole.

Compatible study:
Paracetamol and gum:

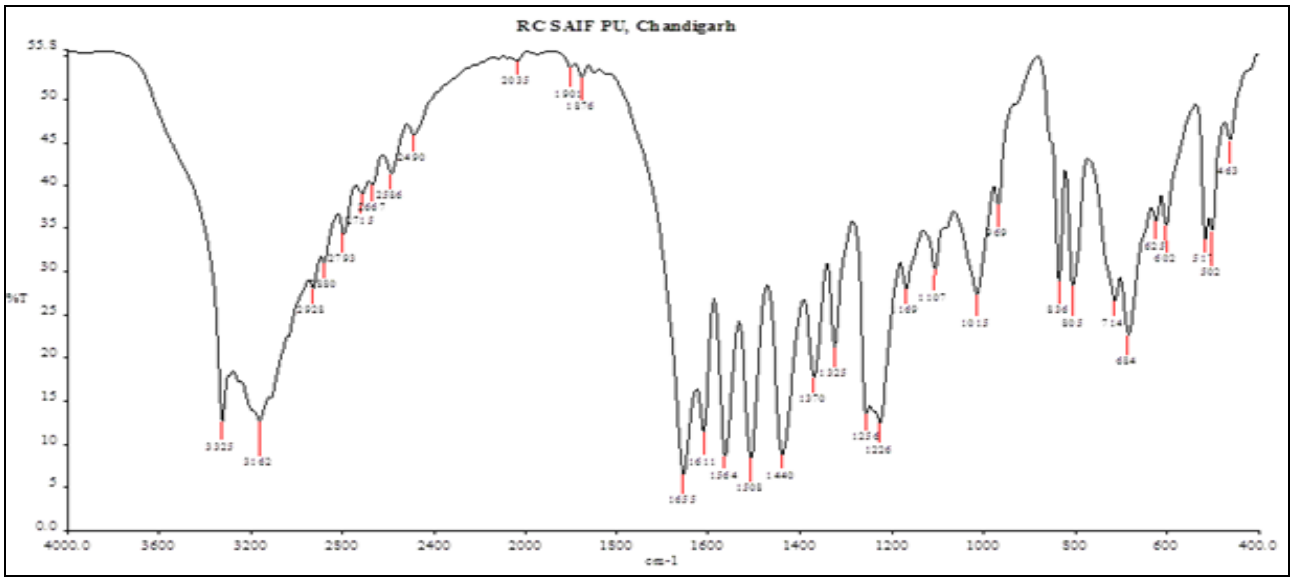

FIG.6: IR SPECTRUM OF PARACETAMOL AND GUM

TABLE 9:

IR spectrum	Wave number (cm^{-1})	Assignment	Comments
Paracetamol and gum	3162	Phenolic OH Stretch	Very board due to strong hydrogen binding
	2880	C-H stretching	Not clear due to underlying OH absorption
	1655	C=O amide stretch	Stretching in amides occurs at a low wave number compared to other unconjugated C=O groups

All the characteristic peaks of Paracetamol were present in this spectrum. It indicates compatibility between drug and polymer (*Curcuma amada* gum). The IR Spectrum values of Paracetamol and amada gum combination. It shows that there was no significant change in the chemical integrity of the drug.

Paracetamol and PVP k30:

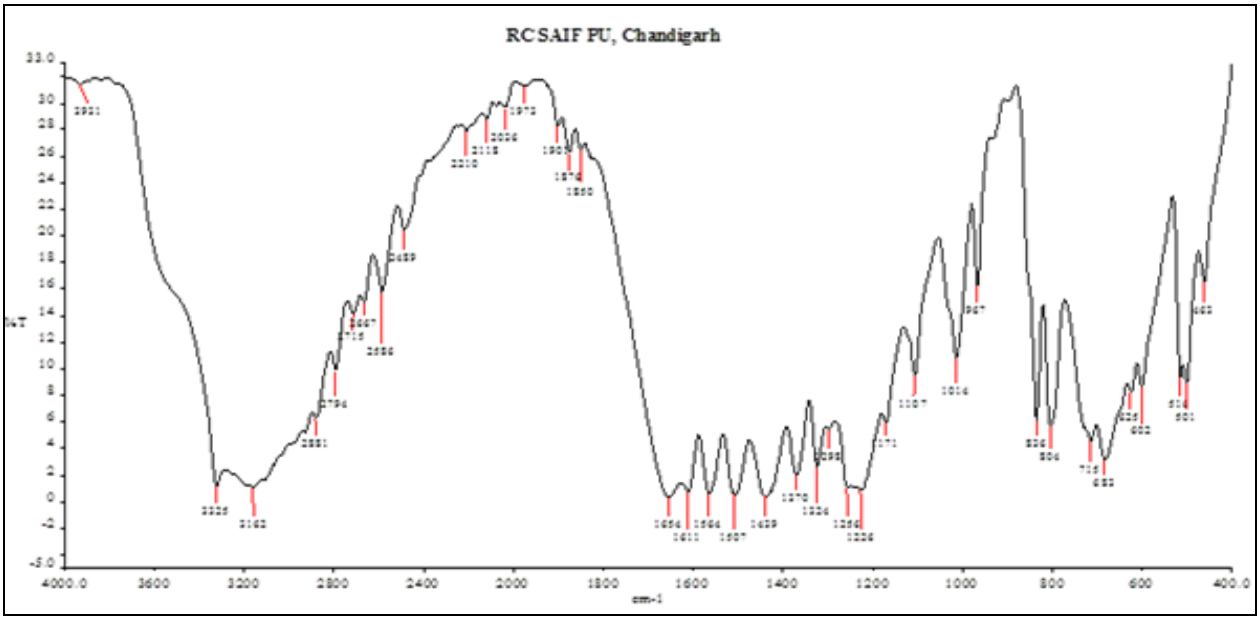

FIG.7: IR SPECTRUM OF PARACETAMOL AND PVP K30

Interpetation IR of Paracetamol and PVP K30

TABLE 10:

IR Spectrum	Wave number (cm-1)	Assignment	Comments
Parcetamol and PVP k30	3325	N-H amide stretch	This band can be seen quite clearly although it is on top of the broad OH stretch
	3162	Phenolic OH Stretch	Very board due to strong hydrogen binding
	2881	C-H stretching	Not clear due to underlying OH absorption
	1654	C=O amide stretch	Stretching in amides occurs at a low wave number compared to other unconjugated C=O groups

The major peaks of Paracetamol were present in this spectrum **Fig. 8**. It shows that there was no significant change in the chemical integrity of the drug. Paracetamol and PVP K30 show compatibility.

Differential scanning calorimeter (DSC) of gum:

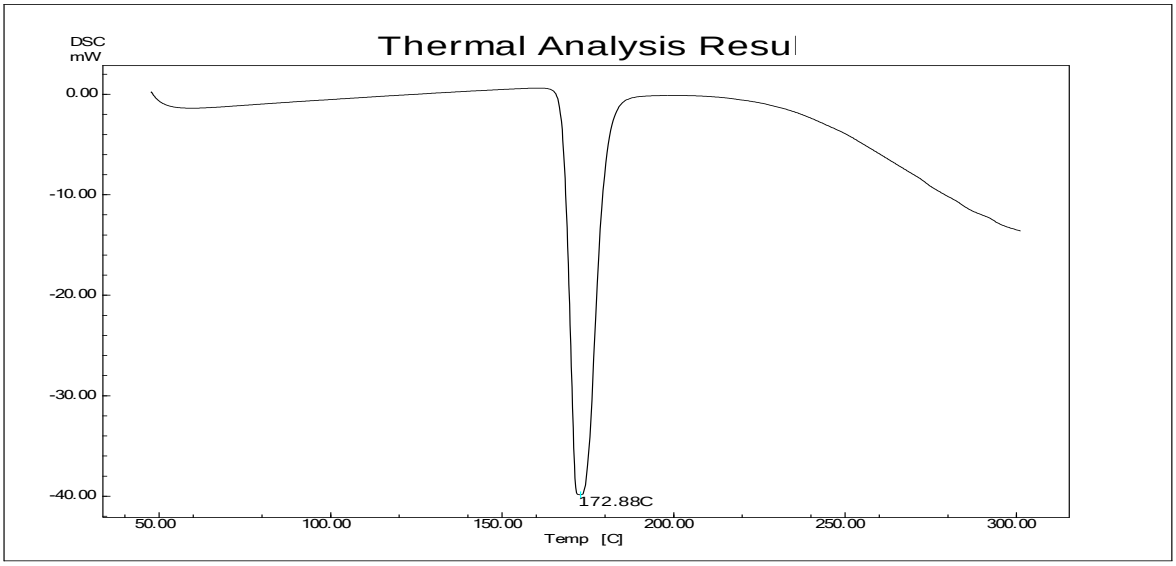

FIG.8: DSC OF PARACETAMOL

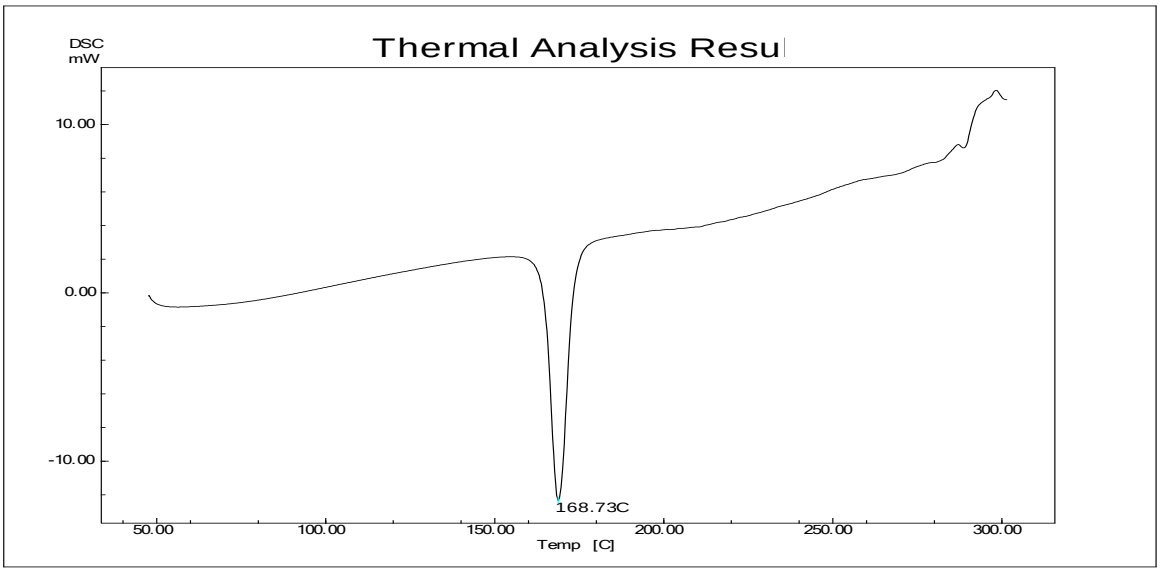

FIG.9: DSC OF PARCETAMOL AND GUM

The thermo gram of pure drug showed endothermic peak at 172.88^{o}C. The mixture of pure drug and polymer showed endothermic peak at 168.73^{o}C indicating decrease the melting point due to amorphous nature of gum.

Determination of flow properties of granules

TABLE 11:

Formulation	Bulk density	Tapped density	Hausner ratio	Carr's index	Angle of repose
F1	0.307 ±0.004	0.371±0.006	1.209 ±0.045	17.724±1.21	28.166±0.152
F2	0.379±0.0055	0.450±0.002	1.187 ±0.050	17.256±1.20	27.366±0.152
F3	0.435±0.0030	0.476±0.005	1.094±0.028	7.643±1.082	26.566±0.208
F4	0.473 ±0.003	0.526 ±0.007	1.111±0.037	9.404±1.103	26.1±0.1
F5	0.513 ±0.006	0.550 ±0.006	1.070 ±0.025	5.444±1.057	25.766±0.057
F6	0.332 ±0.006	0.376 ±0.013	1.133 ±0.031	13.77±1.159	26.233±0.152
F7	0.551±0.007	0.581 ±0.006	1.053 ±0.02	7.495±1.081	25.433±0.251

Bulk density of a granulation is primarily dependent on particle size, particle size distribution and particle shape. It is an indirect measure of granule flow and determines the die fill volume. The bulk and tapped density of the granules decreases with increasing concentration of binders.

The granules occupied larger volume making the bulk density value lower than smaller granules occupying smaller bulk volume. It also show that the granules of paracetamol have Carr's compressibility index, less than 18% implying the granules have good flow property. The Hausner ratio was also observed to be less than 1.25, which also confirmed that the granules have good flow property. The amada gum and PVP K30 yielded granules with good flow properties as can be seen from angle of repose of the granules. There was no significant difference in the angle of repose of the granules.

Post compression evolution of PCM tablets:

TABLE 12:

Formulation	Weigh variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Drug content	Disintegration (min.)
F1	400±3	5.6	3.6±0.04	0.686±0.15	99.60%	4.75±0.22
F2	399.6±3.9	5.6	4	0.645±0.12	98.40%	7.94±0.20
F3	397.5±3.5	5.5	4.3±0.04	0.464±0.23	98.59%	13.49±.014
F4	400.3±4.8	5.9	4.7±0.04	0.297±0.73	98.65%	18.61±0.2
F5	397.6±4.6	5.6	5.1	0.208±0.05	99.15%	28.05±0.4
F6	397.8±3.7	5.4	3.8±0.04	0.696±0.02	99.23%	5.23±0.21
F7	400.2±3.7	5.3	4.4±0.04	0.3±0.03	97.15%	14.5±0.46

***In vitro* Dissolution of different binder:**

In-vitro drug release data of paracetamol tablet formulations containing different binder concentration.

TABLE 13:

Time (min.)	F1	F2	F3	F4	F5	F6	F7
15	35.424±4.2	16.810±0.5	21.461±0.2	14.654±0.6	13.173±1.7	25.307±1.8	18.197±0.04
30	53.009±3	25.741±0.8	41.655±3.7	23.202±0.8	18.954±0.7	38.90±2.1	28.701±0.6
45	68.683±2.5	38.963±1.0	51.556±2	32.466±2.1	24.790±0.5	56.295±6.3	37.094±1
60	88.965±5.2	61.055±1.6	62.038±2.5	37.916±1.1	30.053±0.9	70.057±4.3	46.325±1.4
75	94.279±4.9	71.730±0.4	66.824±2.3	47.948±0.5	36.953±0.8	83.886±2.7	61.318±4.6
90	99.735±3.5	80.522±8.	73.847±3.6	64.335±1.2	45.457±3.3	96.620±2.3	70.816±1.7
105	100.7±.1.5	87.981±4.5	79.013±5.6	70.832±1.9	58.548±5.0	100.2±.2.5	78.150±2.3
120	100.9±.2.2	95.636±1.3	84.618±0.5	75.734±2.4	67.469±2.0	100.7±.2.4	85.913±1.1

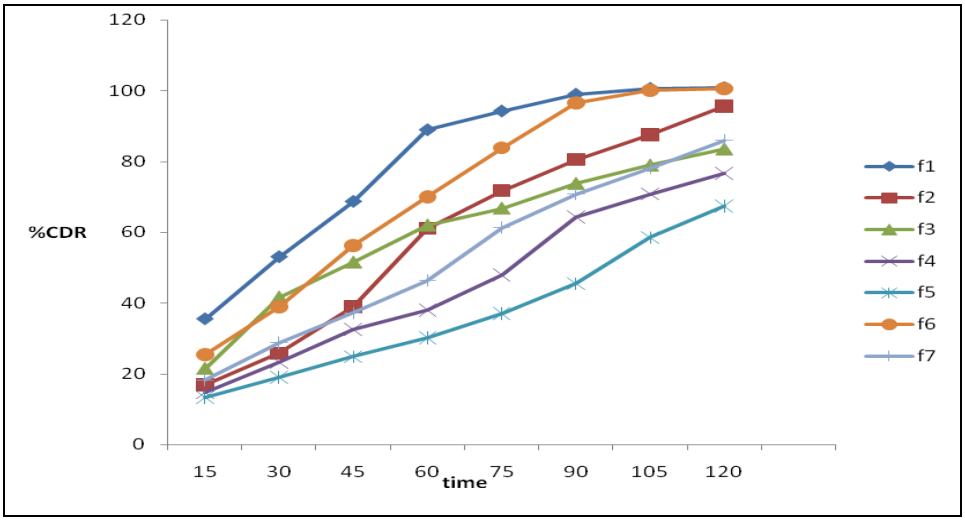

FIG.10: DISSOLUTION OF DIFFERENT FORMULATIONS

Comparative dissolution of amada gum and PVP K-30 gum. The release was almost complete with in 105 min. in the case of tablet containing 1% binder (PVP K30and amada gum). Apart of this tablet, contained 9% show delayed release.

CONCLUSION: The present study shows the effect of amada gum as binder in the formulation development of paracetamol tablets in comparison with the standard binders. From the results, it is concluded that, amada gum has a better binding capacity in comparison with standard binder. Even the novel gum used is having high binding capacity. Compressional properties were analyzed using density measurement and the compression the mechanical properties of the tablets were assessed using the hardness and friability of the tablet. Drug release properties of the tablets were assessed using disintegration time and dissolution time as assessment parameters.

Formulations containing amada gum as a binding agent show a faster onset and higher amount of plastic deformation under compression pressure than those containing PVP K30.The weight variation, disintegration and dissolution times of the tablets increased with increased binder concentration while their friability decreased. Amada gum produced tablets with better mechanical properties and shorter disintegration and dissolution times than those containing PVP K-30.

The results suggest that amada gum could be useful as an alternative binding agent to produce tablets with a particular mechanical properties and release profile.

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