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"PREPARATION AND CHARACTERIZATION OF HERBAL SOLID DOSAGE FORM FOR ANTI DIABETIC ACTIVITY"

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ABSTRACT

The present work aims to investigate the anti-diabetic effects of *Mimosa pudica linn* and *Curcuma longa*. The ethanolic extract of dried leaves of *Mimosa pudica* was evaluated for its antidiabetic activity. Phytochemical screening including qualitative chemical examinations was also carried out. Herbal sublingual tablets of extract of *Mimosa leaves, curcuma longa* and both in combination were formulated and evaluated for anti-diabetic activity. The tablets were prepared by direct compression method and comparative study was performed. The results of physicochemical parameters and pre-compression studies revealed that all the values were within the acceptable limit. The formulated tablets were evaluated for weight variation, friability, hardness, disintegration time as well as studied for drug release. Batch 'C' was optimized because it has exhibited good wetting time, water absorption ratio, faster disintegration time and in-vitro dispersion time when compared to other formulations. Results of all the evaluated parameters of the formulated tablets were found to be within the pharmacopoeial limits. The stability studies of optimized batch (Batches 'C') tablets were conducted for 90 days as per ICH guidelines and were found to be stable.

KEYWORDS: *Mimosa pudica linn, Curcuma longa.*

1. INTRODUCTION

Treatment of illness and maintenance of health using herbal medicines is the oldest and most popular form of health care practice known to humanity that has been practiced by all cultures in all ages throughout the history of civilization. Herbal medicines have long earned reputation as "*the people's medicines*" because of their easy accessibility, safety, and the ease with which they can be prepared. In some

Asian and African countries, 80 per cent of the population depends on traditional herbal medicines for primary health care. In many developed countries, 70 to 80 per cent of the population have used some form of complementary or alternative medicines [CAM) composed primarily of herbal medicines.[1,2]

Diabetes mellitus is one of the most common chronic metabolic diseases, which determine a dramatic progression of the disease over the past decades. Diabetes meaning 'run through' characterized by excretion of large amount of urine (polyuria) and mellitus and its meaning 'sweet taste' because glucose is excreted in the urine. In India, the term 'Madhumeham' is used with etymological sense of the word 'passing sweet urine'.[3]

It is estimated that this number will increase in 2030 to 100 million. More than 80% of diabetes deaths occur in low and middle-income countries.[4] WHO projects that diabetes deaths will increase by two thirds between 2008 and 2030.[5] Ten list of countries with the highest diabetes figures led by India with 40.9 million diabetics, followed by China with 39.8 million. High prevalence is located especially in the fast developing industrial countries expected - such as India and China.[6]

Mimosa Pudica which is also called as lajjalu or Chuimui, family Leguminosae. It is widely available in South America. Within India, it has naturalized nearly throughout the tropical and sub-tropical parts. It is found in mostly marshy and open waste area. The main chemical constituents present in it are Stigmasterol, Leucoantho cyanidin, Phenolic ketone, Mimosine, D-xyloe, Palmitic, and Stearic. Pharmacologically it has Diuretic, Spasmogenic, Antiviral and Antidiabetic activity. It is therapeutically used as Blood purifier, treatment of Sexual disorders and Sperm weakness.[7,8]

Curcuma longa also known as turmeric, haldi or Indian saffron, it consists of dried as well as fresh rhizomes of Curcuma longa, family Zingiberaceae. It is native of Southern Asia. Now cultivated in India, China, Java, Pakistan and other tropical countries. The main chemical constituents present are Curcuminoids (5%)-curcumin, dicaffeoyl methane and dihydrocurumin, Volatile Oil (5%), sesquiterpenese methane (25%), turmerone and arturmerone, borneol are other constituent present in plant. Pharmacologically it has antiseptic, stimulant, carminative, stomachic and blood purifier activity. It is also used as Antidiabetic, Antiparasitic,Anti inflammation etc.[7,8]

Mimosa pudica and Curcuma longa is an anti-diabetic in the herbal class of drug.

2. MATERIAL AND METHOD

The plant materials of *Mimosa pudica were* collected from the plants grown in the Konkan region (Sawarde, Chiplun of Ratnagiri district, Maharashtra). The plant was collected, dried and authenticated in the month of December, 2015. The plant identification was done by Dr.M.Y.Cholekar-Bachulkar, M.Sc., Ph.D, Plant Taxonomist, Principal, Shri Vijaysinha Yadav Arts & Science College, Peth-Vadgaon – 416 112. The leaves of the plant were washed, dried, coarsely powdered and stored in an air tight container until further use. The curcumin was directly purchased from reputed supplier.

Preparation of the Sample: The leaves were air-dried after collection for 2 to 3 weeks in the laboratory condition for easy powdering. The dried leaves were ground into coarse powder using hand grinding mill and was passed through 40-mesh sieve to get uniform particle size and then used for extraction.

Extraction of the Sample: Powdered leaves were charged into soxhlet apparatus and successive hot extraction was carried out using ethanol as a solvent (70%) at a temp. of 50^{o}-60^{o}C for 6 hours. In each extraction, the material (gm) to solvent (ml) ratio was 1:20.[9] Further filtered through whatmann filter paper and was then defatted by using petroleum ether, for twice or thrice to remove the fat present. Then these semisolid extract was concentrated by placing in desiccator. The extract obtained was stored in air tight container for future use.

3.CHARACTERIZATION OF COMPOUND

Mimosa leaves extract and curcumin were studied as follows

Identification of pure drug: Identification of drug was carried out by Infrared absorption spectroscopy (FTIR).

Solubility Analysis: 50 mg of Mimosa leaves extract was weighed and solubility was checked in water, methanol, ethanol, chloroform, glacial acetic acid, conc. HCl.

Melting Point determination: The melting point was determined by melting point apparatus using capillary fusion method.

UV Spectra- λ_{max}determination: Mimoa pudica leaves extract and curcumin were scanned in UV range from 200-800nm, which could be utilized for analysis and spectrum was recorded, using ethanol as blank.

Preparation of Calibration Curve of Eth. extract of Mimosa pudica linn. and Curcumin

The calibration curve of ethanolic extract of Mimosa pudica linn and Curcumin was determined in Phosphate buffer (pH 6.8) using U.V. Spectrophotometer at 232 nm and 432 nm respectively.

Compatibility studies: Compatibility of the Mimosa leaves extract, Curcumin, Physical mixture with excipients respectively used to formulate Sublingual tablet was established by Infrared absorption spectral analysis (FTIR). I.R. Spectral analysis of pure drug Mimosa leaves extract and curcumin and combination of the drug was carried out to investigate any changes in chemical composition of the drug after combining it with the excipients.

PHARMACOLOGICAL INVESTIGATION

Inhibition assay for α-amylase activity (DNSA)

Separately prepare four concentrations of plant extracts were prepared by dissolving in double distilled water. These were 25mg/ml, 50mg/ml, 75mg/ml and 100mg/ml. A total of 500µl of plant extract and 500 µl of 0.02M sodium phosphate buffer (pH 6.9 with 0.006M sodium chloride) containing α-amylase solution (0.5mg/ml) were incubated for 10 minutes at 25°C.After pre-incubation,500 µl of 1% starch solution in 0.02M sodium phosphate buffer (pH6.9 with 0.006M sodium chloride)was added to each tube at 5s intervals. This reaction mixture was then incubated for 10 minutes at 25°C.1ml of DNSA colour reagent was added to stop the reaction. These test tubes were then incubated in a boiling water bath for 5 minutes and cooled to room temperature. Finally this reaction mixture was again diluted by adding 10ml distilled water following which absorbance was measured at 540nm.[10]

$$\% \text{ Inhibition} = \frac{\text{A540control} - \text{A540extract}}{\text{A540control}} \text{X10}$$

4. FORMULATION DESIGN

The formula for preparation of sublingual tablets by direct compression method

Table No.1. The composition of various formulations

Ingredients (mg)	Curcumin			Mimosa Extract			Combination		
	A1	A2	A3	B1	B2	B3	C1	C2	C3
Drug	120	120	120	120	120	120	60	60	60
							60	60	60
Avicel pH 101	20	30	40	20	30	40	20	30	40
Mannitol	22	22	22	22	22	22	22	22	22
Lactose DCL	75	65	55	75	65	55	75	65	55
Magnesium Stearate	2	2	2	2	2	2	2	2	2

Talc	2	2	2	2	2	2	2	2	2
Saccharine Sodium	3	3	3	3	3	3	3	3	3
Aerosil	1	1	1	1	1	1	1	1	1
Citric acid	1	1	1	1	1	1	1	1	1
Croscarmellose sodium	2	2	2	2	2	2	2	2	2
Sodium starch glycollate	2	2	2	2	2	2	2	2	2
Total	250	250	250	250	250	250	250	250	250

5. PRE-COMPRESSION PARAMETERS

Micromeritic Properties

1. Angle of repose: Angle of repose was determined by using fixed funnel method.[11]

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

Here **h** = Height of pile

r = Radius of pile

θ = Angle of repose

Table No.2.Angle of repose as an indication of powder flow properties.

Sr. No.	Angle of Repose (^{0})	Type of flow
1.	< 20	Excellent
2.	20 – 30	Good
3.	30 – 34	Passable
4.	> 34	Very poor

2. Bulk density: Bulk density was determined by pouring a weighed quantity of tablet blend into graduated cylinder and measuring the height. Bulk density is the ratio of mass of tablet blend to bulk volume.[11,12]

Bulk Density = $\frac{m}{v} = \frac{m}{\pi r^2 h}$

Here; **m** = weight of powder or granules (gm.)

v = Bulk Volume (cm^3)

π = 22/7 = 3.14

r = Radius of Cylinder (cm.)

h = Height reached by powder in cylinder (cm.)

3. Tapped Density: Tapped density is ratio of mass of tablet blend to tapped volume of tablet blend. Accurately weighed amount of tablet blend poured in graduated cylinder and height is measured. Then cylinder was allowed to 100 tap under its own weight onto a hard surface. The tapping was continued until no further change in height was noted.[11,12]

Tapped Density = $\frac{m}{v} = \frac{m}{\pi r^2 h}$

Here; **m** = weight of powder or granules (gm.)

v = Tapped Volume (cm^3)

π = 22/7 = 3.14

r = Radius of Cylinder (cm.)

h = Height reached by powder in cylinder after tapping (cm.)

4. Hausner's Ratio: Hausner's ratio indicates the flow properties of powder and measured by the ratio of tapped density to bulk density. Hausner's ratio was determined by the given formula.[11,12]

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

5. Carr's Index (Compressibility Index): Compressibility is the ability of powder to decrease in volume under pressure using bulk density and tapped density the percentage compressibility of powder were determined, which is given as carr's compressibility index. It is indirectly related to the relative flow rate. Carr's compressibility index was determined by the given formula.[11,12]

Carr's Index = $\left(1 - \frac{\text{Tapped density}}{\text{Bulk density}}\right) \times 100$

Table No. 3. Relationship between % compressibility index, flow ability and Hausner's Ratio.

Sr. No.	% Compressibility index	Type of Flow	Hausner's Ratio
1.	≤ 10	Excellent	1.00 – 1.11
2.	11-15	Good	1.12 - 1.18
3.	16-20	Fair	1.19 - 1.25
4.	21-25	Passable	1.26 -1.34
5.	26-31	Poor	1.35 – 1.45
6.	32-37	Very poor.	1.46 – 1.59
7.	>38	Very, very Poor.	>1.60

6. POST-COMPRESSION PARAMETERS

The tablet formulated was evaluated.

1. Appearance: Tablets were evaluated for organoleptic properties.

2. Thickness: The thickness of three randomly selected tablets from each formulation was determined in mm using a vernier caliper .The average values were calculated.[11]

3. Hardness: The test was done as per the standard methods. The hardness of three randomly selected tablets from each formulation was determined by placing each tablet diagonally between the two plungers of monsanto hardness tester and applying pressure until the tablet broke down into two parts completely and the reading on the scale was noted down in Kg/cm^2.[11,12]

4. Weight variation: Ten tablets were selected randomly and weighed individually. The average weight was noted and standard deviation was calculated. The tablet passes the test if not more than two tablets fall outside the percentage limit and none of the tablet differs by more than double the percentage limit.[12]

Table No.4.I.P. Standards for uniformity in weight.

Sr. No.	Average Weight of Tablet	% Deviation
1.	80 mg or less	±10
2.	More than 80 mg but less than 250 mg	±7.5
3.	250 mg or more	±5

5. Friability

Friability indicates the ability of a tablet to withstand mechanical shocks while handling. Friability of tablets were determined using Roche Friabilator and is expressed in percentage (%). Ten tablets were initially weighed ($W_{initial}$) placed into the friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions and then the tablets were weight again (W_{final}). The loss in tablet weight due to abrasion or fracture was the measure of tablet friability. Percent friability (f) was calculated by using the following formula.[11,12]

$$\% f = \frac{(W\,initial) - (W\,final)}{W\,initial} \times 100$$

% friability of less than 1 % is considered acceptable.

6. Disintegration

The USP device to rest disintegration was six glass tubes that are "3 long, open at the top, and held against 10" screen at the bottom end of the basket rack assembly. One tablet is placed in each tube and the basket rack is positioned in 1 liter beaker of distilled water at 37± 2^0C, such that the tablets remain below the surface of the liquid on their upward movement and descend not closer than 2.5cm from the bottom of the beaker.[11,12]

7. *In- vitro* Dispersion time

In- vitro Disintegration Time was measured by dropping a tablet in a 10 ml measuring cylinder containing 6ml of buffer solution simulating saliva fluid (pH 6.8).The results are presented in table no.16.

8. Wetting Time

The tablet's wetting time was measured by using a simple procedure. A piece of tissue paper was cut circularly (10 cm diameter) and placed on a petridish containing 10 mL of water at room temperature. A tablet is placed on the surface of the tissue paper and the time required for the complete wetting of the tablet was noted.

9. Water absorption ratio

A piece of tissue paper folded twice was placed in a small Petri dish Containing 6 ml of water. A tablet was put on the tissue paper and allowed to completely wet. The wetted tablet was then weighted.Water absorption ratio, R was determined using following equation.

R = 100 × Wa –Wb/Wa

Where,

Wa = Weight of tablet after water absorption

Wb = Weight of tablet before water absorption.[13]

10. *In vitro* Drug Release Study

The *in vitro* dissolution studies of sublingual tablets were carried out in USP- type II dissolution test apparatus. The drug release study was carried out in 900ml phosphate buffer (pH 6.8) as the dissolution medium with agitation speed 50 rpm, maintained at37±0.5 ^{0}C. At predetermined time intervals 5ml of samples were drawn and filtered through Whattmann filter paper. The volume withdrawn at each interval was substituted with same quantity of fresh dissolution medium. The samples were analyzed for drug release by measuring the absorbance at 432 and 232nm in UV- spectrophotometer respectively. The percentage drug release was calculated using an equation obtained from the calibration curve.[14,15]

11. Stability studies: The stability of optimized formulation was determined by storing the formulation at accelerated temperature 40±2°C and 75±5% RH in a humidity chamber for 3 months.

Sample were withdrawn after one-month interval and evaluated for change in in-vitro drug

release pattern, physical appearance thickness, and hardness and disintegration time.[16,17]

7. RESULT AND DISCUSSION

PHYTOCHEMICAL INVESTIGATION

Qualitative preliminary phytochemical screening of Ethanolic extracts of leaves of *Mimosa Pudica linn and curcumin*.

Table No.5. Phytochemical constituents of Eth. extracts of Mimosa pudica linn and Curcumin.

Phytoconstituents	Extract of Mimosa pudica linn / Curcumin.	Extract of curcumin
Carbohydrates		
Molish	+	-
Barfoed	+	-
Benedict's	+	-
Fehling	+	-
Alkaloids		
Mayers	+	-
Hagers	+	+
Dragendorff	+	+
Wagners	+	+
Protein		
Million	+	-
Biuret	-	-
Xanthoprotic	+	+
Amino acid		
Ninhydrin	+	+
Phenol		
Ferric chloride test	+	+
Tannins		
Gelatin	-	-
Ferric chloride test	-	-
Saponins		
Foam	-	+
Haemolysis	-	-
Glycoside		
Fehling	+	-
Legal's test	+	-
Flavonoids		
Alkaline reagent	+	+
Zinc test	+	+
Steroid	+	-
+ Positive	- Negative	

CHARACTERIZATION OF DRUGS

Identification of pure drug

A**. Curcumin:** The drug in powdered form was scanned from a wavelength of 4000cm^{-1}to 650 cm^{-1}. The resultant spectrum obtained has been shown in Fig.1.

The major peaks of the spectrum were then interpreted so as to determine the respective functional groups present. The results are shown in Table 6.

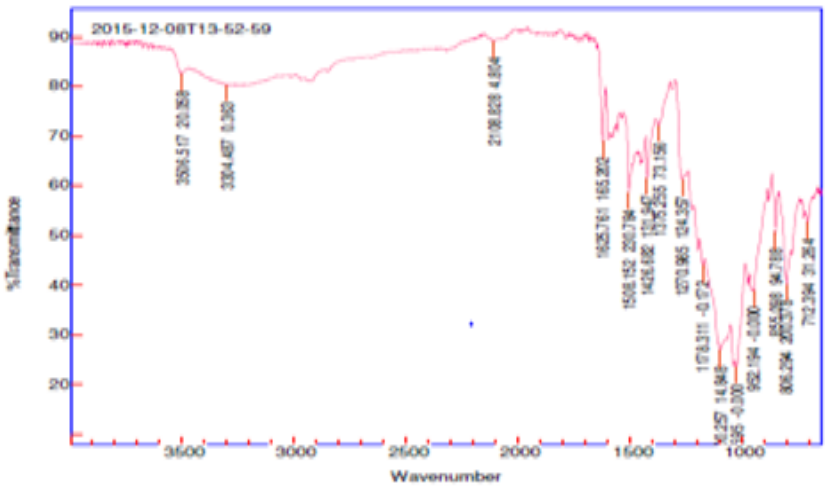

Fig. No.1. Interpretation of the FTIR spectrum of the curcumin.

Table No.6. Interpretation of the FTIR spectrum of the curcumin.

Observed	Functional Group Determination
3506.517cm^{-1}	Phenolic OH (Stretching)
1625.761cm^{-1}	Ketone C=O (Stretching)
1270.985 cm^{-1}	C-O

B. Mimosa pudica linn.(Mimosine)

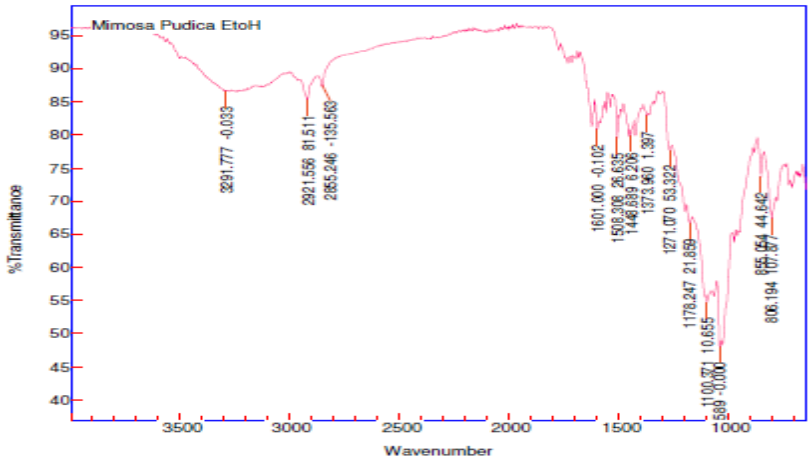

Fig. No. 2. Interpretation of the FTIR spectrum of the Mimosa pudica linn

Table No.7.Interpretation of the FTIR spectrum of the mimosa pudica linn.

Observed	Functional Group Determination
3291.77 cm^{-1}	N-H (Stretching)
2921.556cm^{-1}	C-H (Stretching)
1601.000cm^{-1}	C=C (Stretching)
1448.689cm^{-1}	CH Bending
1271cm^{-1}	C-N aliphatic amine stretching

Solubility Analysis: Solubility study of curcumin and Mimosine was performed .Table 8.shows solubility profile of curcumin and mimosa pudica in different solvents.

Table No.8. Solubility profile of curcumin and mimosa pudica in different solvents.

Solubility	Curcumin	Mimosa pudica
Very soluble	Ethanol, acetic acid.	Ethanol
Soluble	Alcohol, glacial acetic acid	Dil.acetone, dil.alkali.
Slightly soluble	Hot water	Water
Insoluble	Ether.	Acetone, dioxane, acetic acid.

Melting Point determination: The melting point of the drugs was observed by capillary fusion method. The results are shown in the table 9.

Table No.9.Melting point determination

Drug	Observed value	Reference value
Curcumin	180^0C	179-183^0C
Ethanolic extract of mimosa	226^0 C	228-230^0C

UV Spectra- λ_{max} determination: UV spectra of curcumin and ethanolic extract of mimosa pudica linn are shown in fig. 3 and 4. The spectra are deconvoluted with absorption at 432 nm for curcumin, at 232 nm for Mimosa pudica extract.

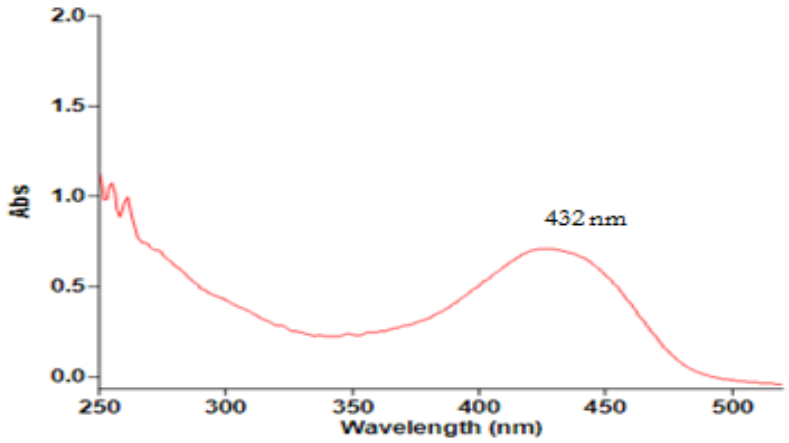

Fig.No.3.U.V Spectra of Curcumin.

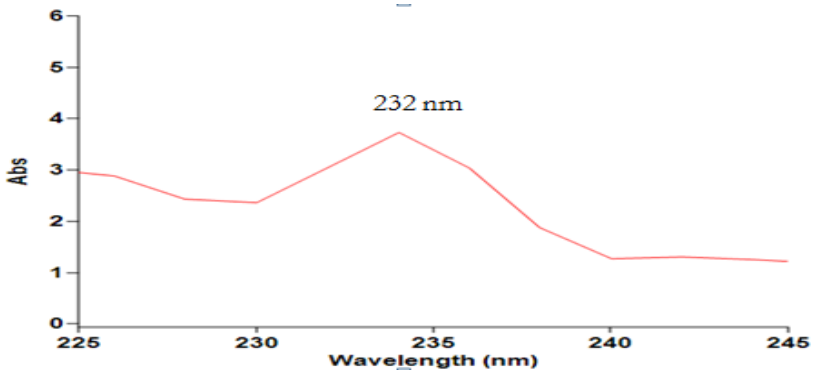

Fig.No.4.U.V Spectra of Ethanolic extract of Mimosa pudica linn.

Calibration curve of Curcumin in

Phosphate buffer (pH-6.8)

Table No.10.Caliberation curve of Curcumin in Phosphate buffer (pH-6.8)

Conc. in µg/ml	Absorbance
0	0
5	0.069
10	0.145
15	0.205
20	0.265
25	0.337
30	0.398

Caliberation curve of Ethanolic extract of Mimosa in Phosphate buffer (pH-6.8)

Table No.11.Caliberation curve of Eth. Ext. of Mimosine Phosphate buffer (pH-6.8)

Conc. in µg/ml	Absorbance
0	0
5	0.059
10	0.116
15	0.19
20	0.25
25	0.315
30	0.376

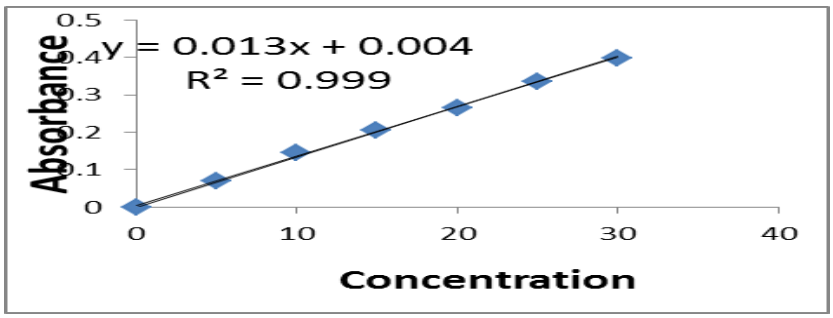

Fig.No.5.Caliberation curve of Curcumin in Phosphate buffer (pH-6.8)

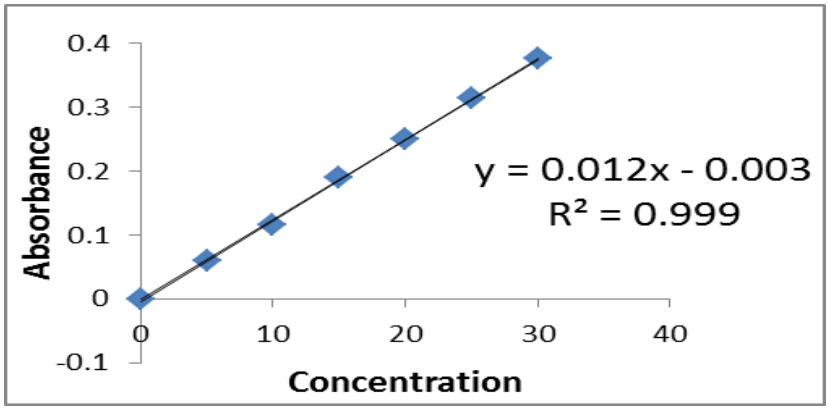

Fig.No.6.Caliberation curve of Ethanolic extract of Mimosine in Phosphate buffer

Compatibility studies: The Compatibility studies were carried out to ensure that there is no interaction occurred in between drug and excipient. For confirmation of stability of drug in the prepared formulations by taking IR spectra of mixture of drug and excipient, compared with that of pure drug. The result of these studies revealed that there were no definite changes obtained in the bands of drug with respect to pure drug.

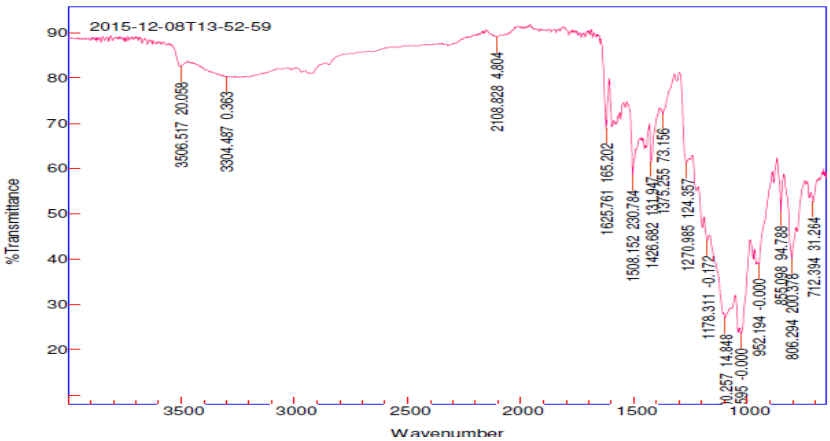

Fig.No.7.IR spectrum of Curcumin

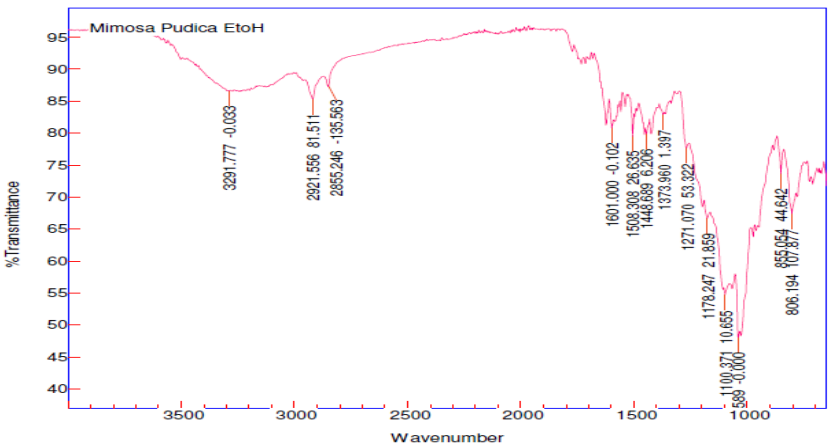

Fig.No.8.IR spectrum of Ethanolic extract of Mimosa pudica linn.

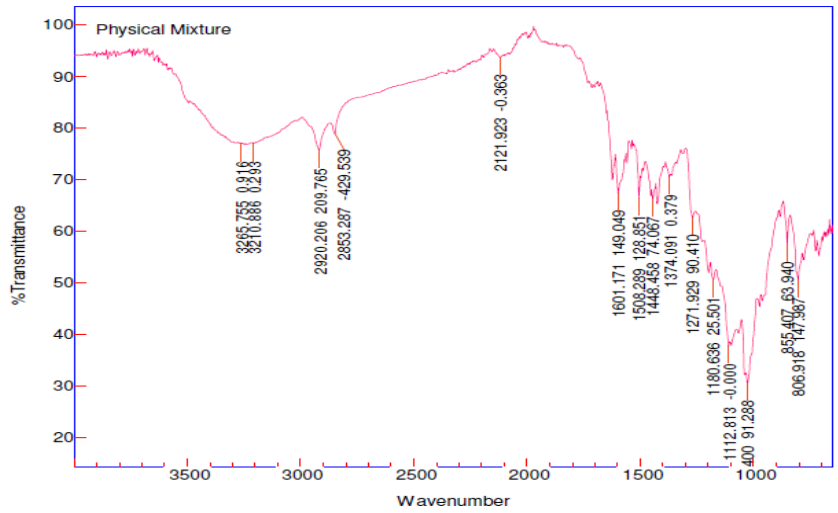

Fig.No.9.IR spectrum of physical Mixture (Curcumin + Mimosa pudica linn)

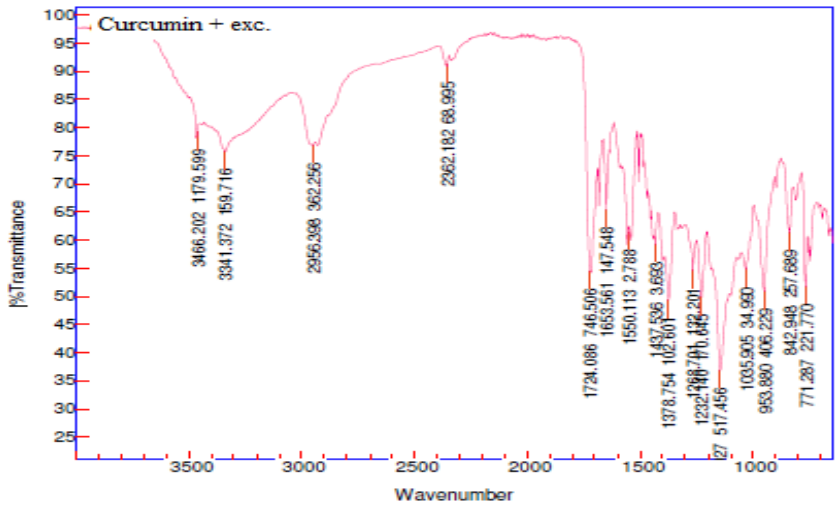

Fig.No.10.IR spectrum of Curcumin + Excipients

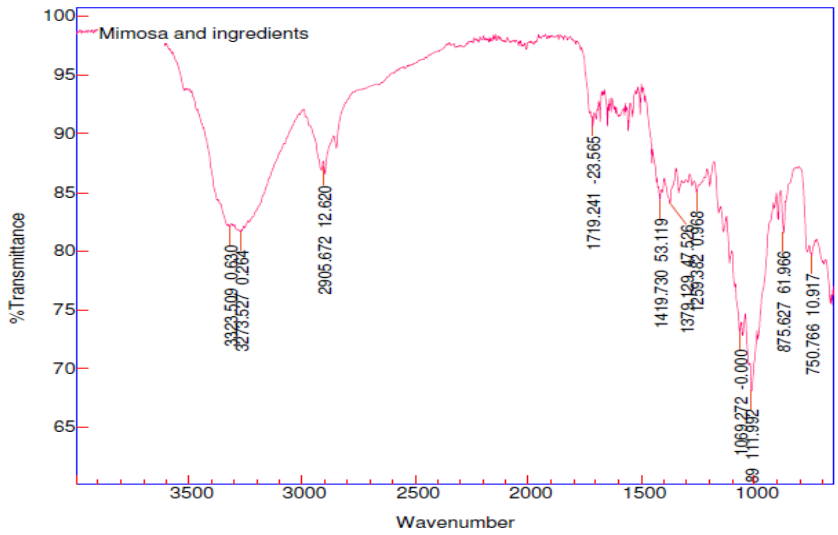

Fig.No.11.IR spectrum of Ethanolic extract of Mimosa pudica linn. + Excipients

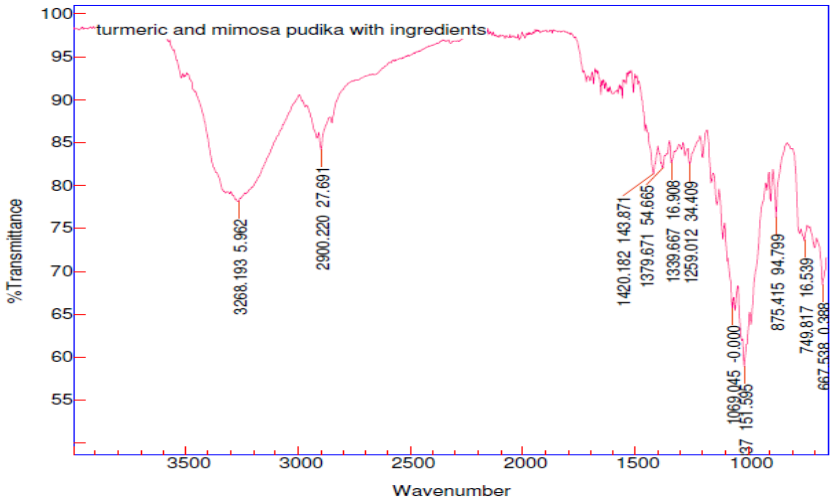

Fig.No.12. IR spectrum of physical Mixture+ Excipients (Curcumin + Mimosa pudica linn+ Excipients)

Table No.12.IR Spectrum of Drugs and Combination.

Sr.no	IR Spectrum	Functional Group Determination	Observed spectrum of drug	Observed spectrum of formulation (drug+ excipient)
1	Curcumin	Phenolic OH (Stretching)	3506.517cm^{-1}	3466.202cm^{-1}
		Ketone C=O (Stretching)	1625.761cm^{-1}	1653.561 cm^{-1}
		C-O	1270.985 cm^{-1}	1268.701 cm^{-1}
		Aromatic	806.918 cm^{-1}	771.287 cm^{-1}
2.	Ethanolic Extract of Mimosa Pudica Linn (Mimosine)	N-H (Stretching)	3291.77 cm^{-1}	3273.527 cm^{-1}
		C-H (Stretching)	2921.556cm^{-1}	2905.672 cm^{-1}
		C=C (Stretching)	1601.000cm^{-1}	
		CH Bending	1448.689cm^{-1}	1419.730 cm^{-1}
		C-N aliphatic amine stretching.	1271 cm^{-1}	1259.382 cm^{-1}
3.	Physical Mixture	N-H (Stretching)	3265.755 cm^{-1}	3268.193 cm^{-1}
		C-H (Stretching)	2920.206 cm^{-1}	2900.220 cm^{-1}
		OH (Stretching)	2853.287cm^{-1}	
		C=C (Stretching)	1601.171 cm^{-1}	
		CH Bending	1448.458 cm^{-1}	1420.182cm^{-1}
		C-N aliphatic amine stretching.	1271.929 cm^{-1}	
		C-O	1271.929cm^{-1}	1259.012 cm^{-1}
		C=O (Stretching)	1601.171 cm^{-1}	
		Aromatic	806.918 cm^{-1}	749.817 cm^{-1}

Fig.No.13.IR Spectrum for drug interaction.

The interaction study were carried out to ensure that there is no any interaction between both the drugs. However the above fig.13 illustrates that there was no drug-drug interaction between Curcumin and Mimosine pudica linn.

Inhibition assay for α-amylase activity (DNSA)

Table No.13. % Inhibition of α-amylase activity of varying concentrations of extract of Mimosa pudica linn and curcumin.

Concentration (mg/ml)	Control %*	*Mimosa pudica* %*	*Curcumin* %*
25	0	60.62	40.01
50	0	66.52	60.78
75	0	69.15	77.66
100	0	74.85	92

*p<0.05

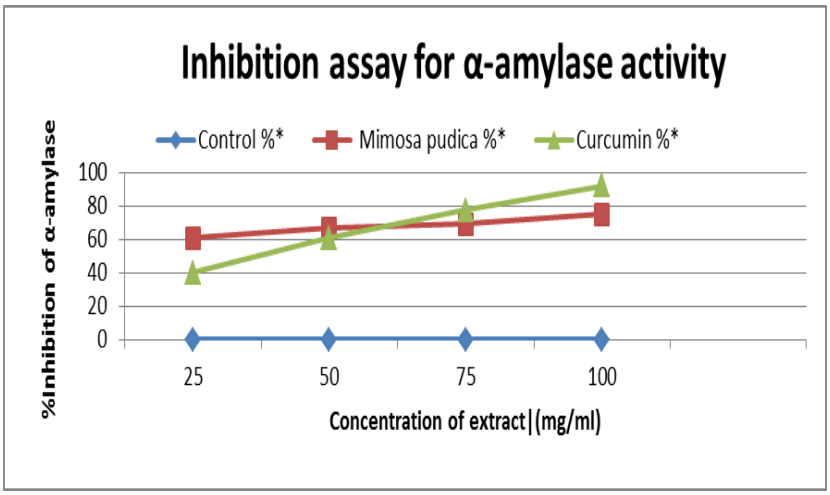

Fig.No.14: Effects of extracts of Mimosa pudica linn and curcumin at varying concentration on α-amylase activity as compared to an aq.extract

The results of the DNSA study are summarized in Fig. 14. Both the above plants showed varying effect on glucose utilization. Initially *curcumin* showed minimum inhibition of enzyme, and later showed maximum inhibitions of the enzyme with the highest value of 92 % seen at 100 mg/ml concentration. The another plant leaf powder extract of *Mimosa pudica linn.* showed next highest value of 74.85% seen at 100 mg/ml concentration.

PRE-COMPRESSION PARAMETERS

Evaluation of blend ready for compression: The powder ready for compression was evaluated for following pre compression parameters

Table No.14.Results of evaluated physical blend for pre-formulation codes

Formuation	Angle of repose (^{0})	Bulk Density (gm/ml)	Tap Density (gm/ml)	Hausner's Ratio	Carr's Index (%)
A1	27^0	0.58	0.64	1.10	9.37
A2	28^0	0.59	0.64	1.08	7.81
A3	28^0	0.56	0.62	1.10	9.67
B1	22^0	0.52	0.62	1.19	16.12
B2	20^0	0.55	0.64	1.16	14.06
B3	22^0	0.56	0.62	1.10	9.67
C1	25^0	0.52	0.57	1.09	8.77
C2	27^0	0.50	0.55	1.1	9.09
C3	26^0	0.48	0.54	1.12	11.11

The bulk densities and tapped densities of all batches of tablet blend ready for compression were found to be in the range of 0.48 –0.58 gm/ml and 0.54–0.64 gm/ml respectively. This value of bulk density indicates good packing character of the final blend. The value of Hausner ratio is less than 1.6 which indicates good flow properties. The compressibility index for all these formulation blends were found to be below 25% indicating fair to good flow properties. The values of angle of repose for all these formulationblends were found to be between 20^0 to 28^0.

From these observations,values of angle of repose were found between good passable ranges.

POST-COMPRESSION PARAMETERS

Evaluation of tablets

Appearance: Tablets prepared were randomly picked up from each batch examined under lens for shape and in presence of light for color. The tablet showed circular shape and were yellow and dark green and yellowish green of curcumin, Mimosa pudica extract and combination respectively.

Thickness, average weight, hardness, friability, disintegration time, wetting time and water absorption ratio are depicted in below table

Table No.15.Post compression parameters of all formulation code

Formulation	Thickness (mm)	Average weight (mg)	Hardness Kg/ cm^2	Friability (%)
A1	2.1±0.01	251± 0.8	2.8±0.06	0.74±0.18
A2	2 ±0.13	250±0.5	3±0.07	0.40±.0.12
A3	2.1±0.14	248±1.2	3.1±0.09	0.33±0.04
B1	2±0.2	255±1.3	3±0.06	0.40±0.05
B2	2±0.31	250±1.3	3.2±0.08	0.3±0.19
B3	2±0.21	244±2.1	3 ±0.07	0.42±0.12
C1	2±0.12	246±0.6	2.8±0.08	0.36±0.05
C2	2.1±0.20	250±1.8	2.8±0.08	0.54±0.06
C3	2.1±0.22	252±1.3	3±0.06	0.33±0.19

The results of hardness, friability and weight variation are within the Pharmacopoeial limits.

Table No.16.Post compression parameters of all formulation code

Formuation	Water absorption ratio	Invitro dispersion time (sec)	Wetting time (sec)	Disintegration Time (sec)
A1	36.66±1.6	200±0.02	76±1.3	180±0.9
A2	38.03±1.7	192±0.02	73 ±1.8	176 ±0.6
A3	37.21±1.6	190±0.03	70 ±1.5	178 ±1.4
B1	32.08±1.5	188±0.03	72 ±0.8	186 ±0.9
B2	36.66±0.6	188±0.04	81 ±1.5	170 ±1.6
B3	35.58±0.5	186±0.02	73 ±1.2	172 ±0.8
C1	33.86±0.2	186±0.06	74 ±1.3	180 ±0.6
C2	34.83±0.7	190±0.02	78 ±1.8	176 ±0.4
C3	32.03±0.6	184±0.04	70 ±0.6	174 ±0.8

In vitro drug release of Sublingual tablet

Table No.17.In-vitro drug release of sublingual tablets

Ingredients (mg) / Time	Curcumin			Mimosa Extract			Combination		
	A1	A2	A3	B1	B2	B3	C1	C2	C3
0	0	0	0	0	0	0	0	0	0
5	60.83	64.4	67.1	53.52	57.3	59.8	75.2	78.12	78.12
10	72.9	74.4	75.4	72.8	73.1	74.4	82.5	85.1	86.81
15	76.8	77.8	80.4	76.8	78.6	79.4	86.7	88.5	90.2
20	80.1	82.3	85.5	78.9	80.6	84.3	88.6	89.6	94.6

Percentage cumulative drug release comparisons

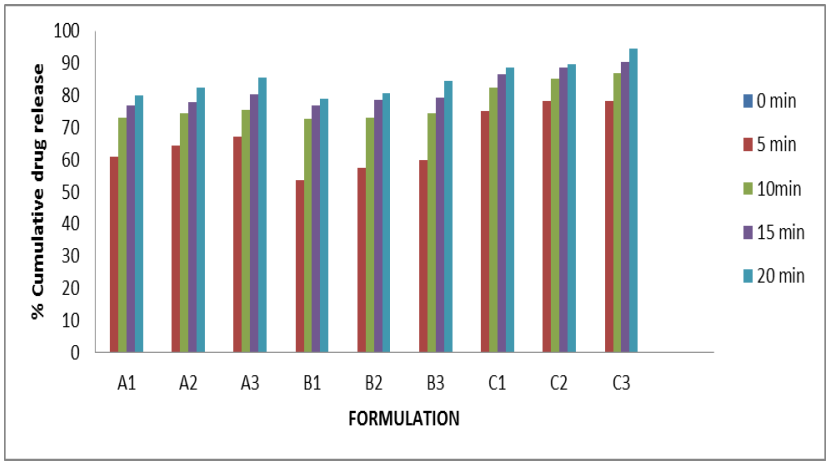

Fig.No.15.Percentage cumulative drug release comparisons

Percentage cumulative drug release of Combination (C- Batches) of Curcumin and Ethanolic extract of Mimosa pudica linn. from sublingual tablet was found to be best as compare to other batches.

The formulation C3 was found to be best among all other formulations because it has exhibited good *in-vitro dispersion time when compared* to other formulations having drug release 94.6%.

7.8. Stability studies

After one month of Accelerated stability study (40ºC ± 2ºC and 75% RH ± 5%) of optimized batch i.e. C3, all evaluation parameters and dissolution test were performed. Results showed no drastically changes in in-vitro drug release profile. Results of the Accelerated stability study had shown no remarkable change in the release profile.

Table No.18: Evaluation of optimized batch C3

(After Accelerated stability study 40 ^{0}C ± 2 ^{0} C and 75%RH ± 5%)

Evaluation parameters	0 day	30 days
Appearanse	No change	
Disintegration time	174	178
Hardness	3±0.06	2.9±0.02
Wetting time(sec)	70	76
Water absorption ratio	32.03	35.80
Friability	0.33±0.19	0.33

% Cumulative Drug release after 30 days

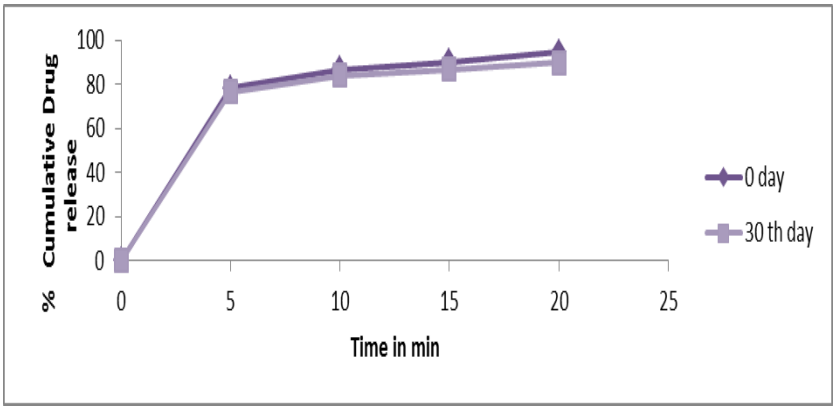

Fig.No.16.Drug release study after 1 month

8. CONCLUSION

The present study, confirms the antidiabetic activity of Curcumin and Mimosa pudicalinn. by inhibition assay for α-amylase activity (DNSA).

Preformulation studies were performed; the infrared spectral analysis revealed that the drug and excipients used were compatible.

Sublingual tablets of Curcumin, Ethanolic extract of Mimosa pudicalinn. and Combination of both was formulated with varying concentration of binding agent and diluents as per the formulation table.

Evaluation parameters like hardness, friability, indicated good mechanical resistance of the tablets for all the formulations.

Percentage weight variation and drug content uniformity were found to be within the approved range (Indian Pharmacopoeial Standards) for all the formulations.

Invitro dissolution studies shows that the formulation of Combination of Curcumin and Ethanolic extract of Mimosa pudica linn. shows good release behavior by sublingual route (94.6 %). Besides Formulated tablets of Combination gave good results for various physical tablet evaluation parameters like tablet thickness, hardness, friability, weight variation, wetting time, water absorption ratio.

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