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Fabrication and Characterization of Fast Dissolving Herbal Buccal Film Containing Mimosa Pudica Leaf Extract

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ABSTRACT: Buccal films has distinct advantages over conventional dosage forms. Drugs can be delivered through buccal route, by avoiding first pass metabolism to produce local and systemic action. Rapid absorption of the drug is achieved because buccal mucosa is highly permeable with rich blood supply. Only few dosage forms are designed to deliver the drug through this route. Leaf extract of Mimosa pudica has number of pharmacological actions. Buccal film of leaf extract of mimosa pudica is prepared by solvent casting method and evaluated for its characteristics. Six formulations were prepared, out of which F3 formulation was found promising formulation, releases 96.13% of drug in 10 minutes.

KEY WORDS: Buccal mucosa, folding endurance, mimosa pudica, permeable.

INTRODUCTION

Buccal drug delivery system is one of the drug delivery system in which drug is administered to the buccal mucosa to produce local as well as systemic action. In buccal drug delivery system, mucus or a mucous membrane is held together for extended period of time.[1] Drug administration by this route is suitable for group of patients who can't swallow tablets, pharmacological action of drugs can be achieved by avoiding first pass metabolism, enzymatic drug degradation.[2] Buccal mucosa offers many advantages like relatively large surface area for absorption, easy accessibility. Buccal films are simple delivery devices, with small size and thickness, they have improved patient compliance, compared to other drug delivery systems.[3] The mucosa is relatively permeable with a rich blood supply. Hence rate of drug absorption will be rapid.[4]

Mimosa pudica also known as touch me not, live and die, shame plant, curiosity plant and it is a diffuse prickly undershrub belonging to family Mimosaceae. The plant is a native of tropical America and naturalized nearly all through the tropical and subtropical parts of India. The herb has been used traditionally for ages in the treatment of urogenital diseases, piles, sinus, dysentery and also helps in wound healing. The whole plant appears to be a promising herbal candidate, The ethanol extract of the plant consists of alkaloids , flavonoids , steroids , saponins , phenols , tannins , cyanogenic glycosides and anthocyanins. [5] Ethanolic extract of mimosa leaves contain alkaloids, flavonoids, saponins and triterpenes,and evident for number of pharmacological activities.[6] Mimosa pudica leaves has high pharmacological profile, and produces Analgesic and anti-inflammatory activity, Anticonvulsant, Antidiarrhoeal activity, Anti-hepatotoxic activity, Antimalarial activity,Antihyperglycemic activity, Antiulcer activity.[7] In present study buccal film of ethanolic leaf extract of mimosa pudica is fabricated ,may help to deliver the drug to produce number of pharmacological actions.

MATERIALS AND METHOD

Materials:

Extract of Mimosa pudica, Carbopol-940, Hydroxy Propyl Methyl Cellulose(HPMC 15),Poly vinyl alcohol(PVA) as polymers from Yarrow chemicals, Mumbai. Citric acid is used as saliva stimulating agent, Propylene glycol as plasticizer, honey as sweetening agent and vanillin as flavouring agent from SD Fine Chem Limited. All the reagents are of analytical grade.

Preparation of Plant Extract:

Leaves of Mimosa pudica were collected from local area of Tumkur washed well, dried and powdered. Extraction is done by using 95% ethanol by cold maceration method for 7 days.After the extraction process the solution was filtered and the filtrate is evaporated. Calculate the percentage yield.Various chemical tests are performed to identify the phytochemical constituents.[8]

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Preparation of Buccal film:

Films are prepared by solvent casting method. Polymers, Plasticizer were dissolved in distilled water by stirring for one hour using magnetic stirrer. Drug is dissolved in distilled water add citric acid ,sweetening agent and flavouring agent stirred well for one hour using magnetic stirrer. Mix the drug solution to the polymeric mixture by stirring. Solution is then casted on petri dish and kept in hot air oven at 40^0c,for 72 hours. After solvent evaporation, thin film is trimmed to required size. Packed in aluminium foil in card board box at room temperature.[9]

Table no 1: Composition of different formulations of buccal film.

Formulations	Drug (mg)	Carbopol - 940(mg)	HPMC E-5(mg)	PVA (mg)	Propylene glycol(ml)	Citric acid (mg)	Honey (ml)	Vanillin (mg)	Distilled water (ml)
F1	10	25	-	-	0.1	60	2	2	10
F2	10	50	-	-	0.1	60	2	2	10
F3	10	75	300	100	0.1	60	2	2	10
F4	10	100	350	150	0.1	60	2	2	10
F5	10	-	400	200	0.1	60	2	2	10
F6	10	-	450	250	0.1	60	2	2	10

Evaluation of Buccal Films:

Physical appearance and surface texture of films:

Physical appearance was evaluated by visual inspection and surface texture is tested by feel or touch.

Thickness of films:

Thickness of the films is measured at three different spots of the film using screw gauge and average is calculated.[10]

Folding endurance of films:

Flexibility of films is measured here. Films of 2X2cm is taken and repeatedly folded at same place for 300 times or until it breaks ,number of times films could be folded at the same place, without breaking gives the value of folding endurance.[11]

Uniformity of drug content:

Films of 2X2cm is taken and dissolved in 100 ml of simulated saliva of pH 6.8 in volumetric flask, 2ml of this solution is diluted with water up to 10ml.The percentage drug content is determined by using UV Spectrophotometer by measuring the absorbance at 251nm.[12]

***In vitro* drug release:**

By dissolving the prepared films in 100 ml of simulated saliva of pH 6.8 ,the mixture is stirred in magnetic stirrer at 50 rpm at 37^0c.2 ml of the sample solution is withdrawn at different time intervals. Samples are filtered using whatman filter paper, absorbance was read at 251 nm using double beam UV- Visible spectrophotometer.

Caliberation curve of Mimosa pudica leaf extract:

Ethanolic leaf extract of mimosa pudica in phosphate buffer 6.8 shows maximum absorbance at 251 nm in UV Spectrophotometer**.**

Table no 2: Absorbance of Ethanolic leaf extract of mimosa pudica in phosphate buffer

Sl No	Concentration µg/ml	Absorbance at 251nm
1	0	0
2	5	0.57
3	10	0.11
4	15	0.18
5	20	0.26
6	25	0.32
7	30	0.38

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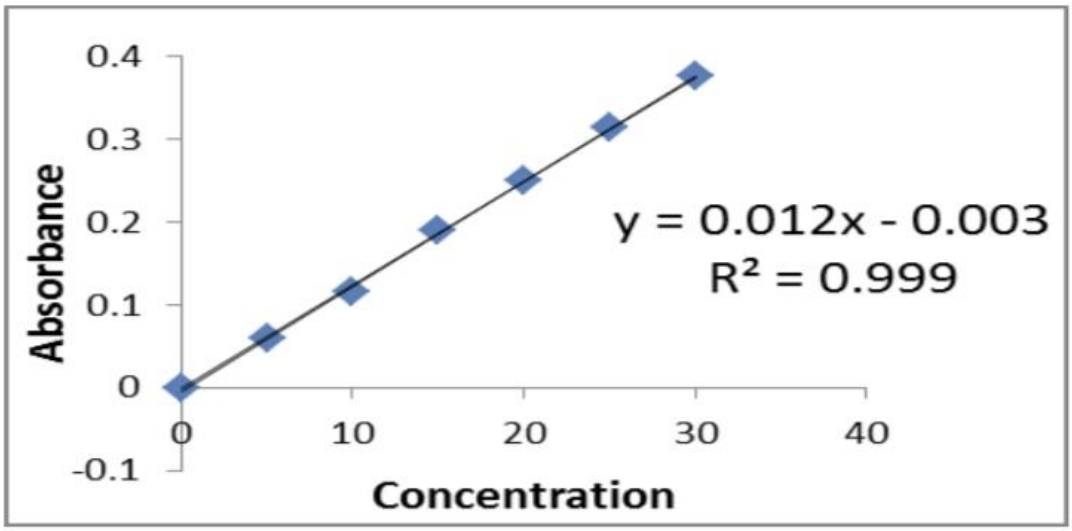

Fig no 1: Calibration curve of Ethanolic leaf extract of mimosa pudica in phosphate buffer

RESULTS AND DISCUSSION

Drug polymer interaction by FT-IR Spectrophotometer:

The compatibility studies were carried out to ensure that there is no interaction between drug and polymers.

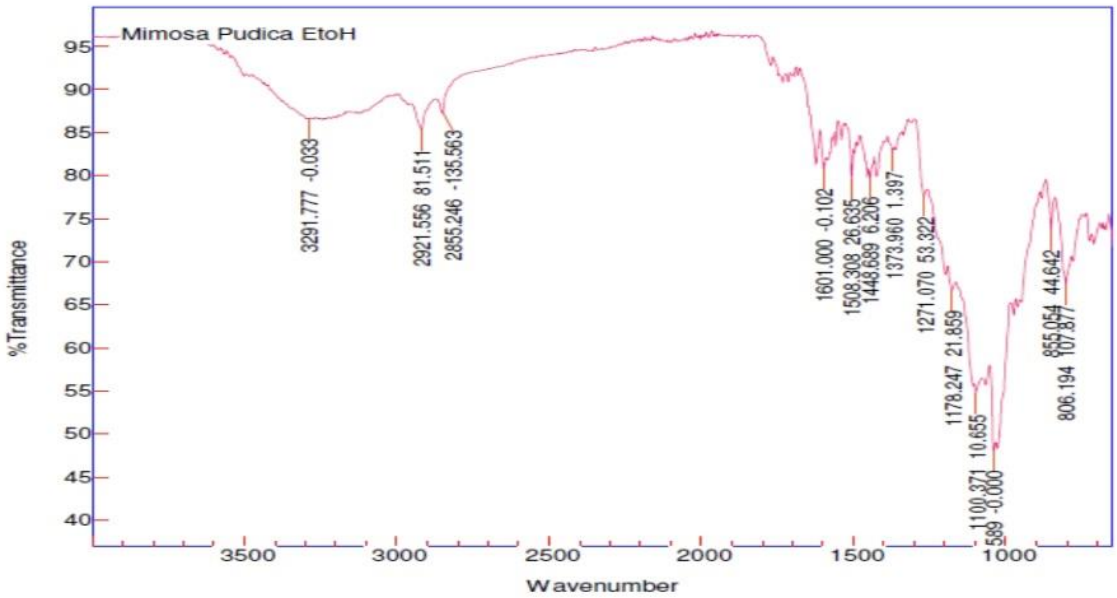

Fig no 2: FT-IR Spectrum of mimosa pudica leaf extract

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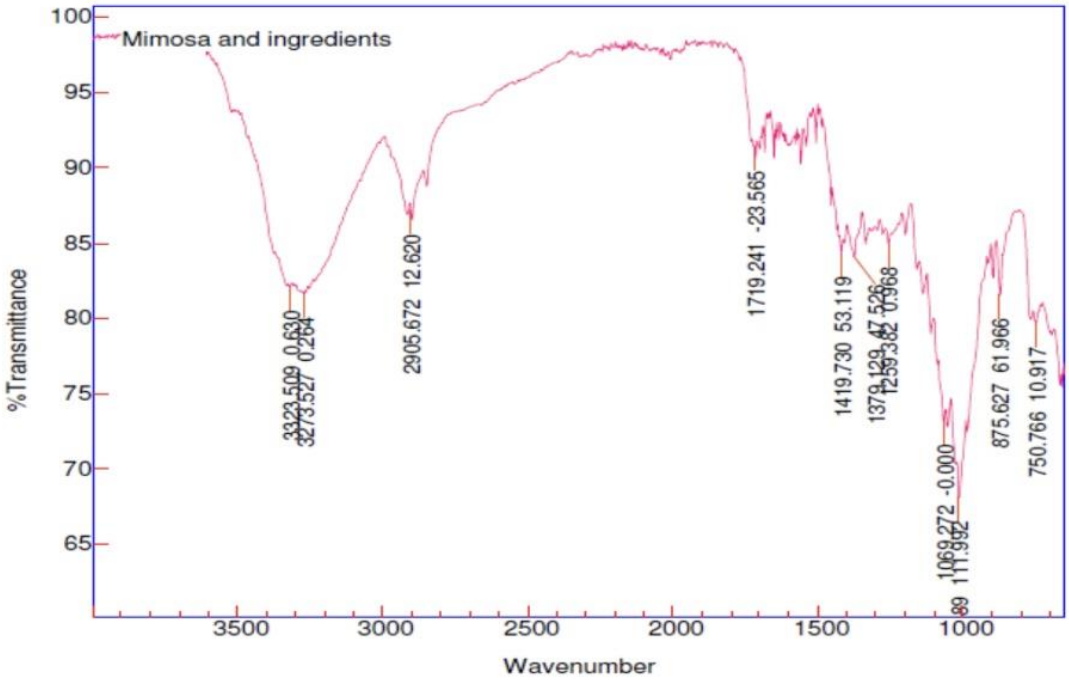

Fig no 3: FT-IR Spectrum of mimosa pudica leaf extract with polymers

Weight uniformity of prepared films:

Table no 3: Weight uniformity of prepared films

Formulations	Weight of strips (mg)			Average weight (mg)
	I	II	III	
F1	42.7	43.1	43.7	43.16
F2	43.6	44.0	42.8	43.46
F3	46.1	45.8	46.3	46.06
F4	47.6	46.5	46.9	47.00
F5	45.4	45.7	43.9	45.00
F6	46.1	45.8	47.6	46.50

Thickness uniformity of prepared films:

Table no 4: Thickness uniformity of prepared films

Formulations	Thickness of strips (mm)			Average thickness (mm)
	I	II	III	
F1	0.13	0.18	0.22	0.17
F2	0.15	0.14	0.19	0.16
F3	0.19	0.20	0.18	0.22
F4	0.24	0.31	0.26	0.27
F5	0.21	0.28	0.24	0.24
F6	0.28	0.23	0.27	0.26

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Folding endurance of prepared films:

Table no 4: Folding endurance of prepared films

Formulations	Folding endurance of strips			Average Folding endurance
	I	II	III	
F1	345	346	343	344
F2	346	350	348	348
F3	351	355	346	350
F4	313	324	336	324
F5	338	345	321	334
F6	341	335	340	338

Disintegration study of prepared films:

Table no 5: Disintegration study of prepared films

Formulations	Disintegration time (sec)			Average Disintegration time (sec)
	I	II	III	
F1	38	36	37	37
F2	39	41	43	41
F3	48	50	50	49
F4	52	54	49	51
F5	48	51	53	50
F6	38	37	39	38

Drug content uniformity of prepared films:

Table no 6: Drug content uniformity of prepared films

Formulations	% Drug content
F1	91.4
F2	93.6
F3	97.2
F4	89.2
F5	92.5
F6	90.0

***In vitro* drug release of prepared films:**

Table no 7: *In vitro* drug release of prepared films

Time(min)	% Cumulative Drug release					
	F1	F2	F3	F4	F5	F6
2	19.08	31.65	23.58	27.30	12.86	14.20
4	32.02	42.20	58.14	39.32	20.07	22.37
6	46.98	58.91	73.56	51.21	32.50	35.21
10	59.62	70.32	96.13	68.97	43.84	48.01
12	68.21	81.21	-	79.54	56.10	59.30
14	79.60	94.10	-	85.21	67.21	70.91
16	91.32	-	-	93.40	79.53	76.27
18	-	-	-	-	88.61	81.23
20	-	-	-	-	-	88.20

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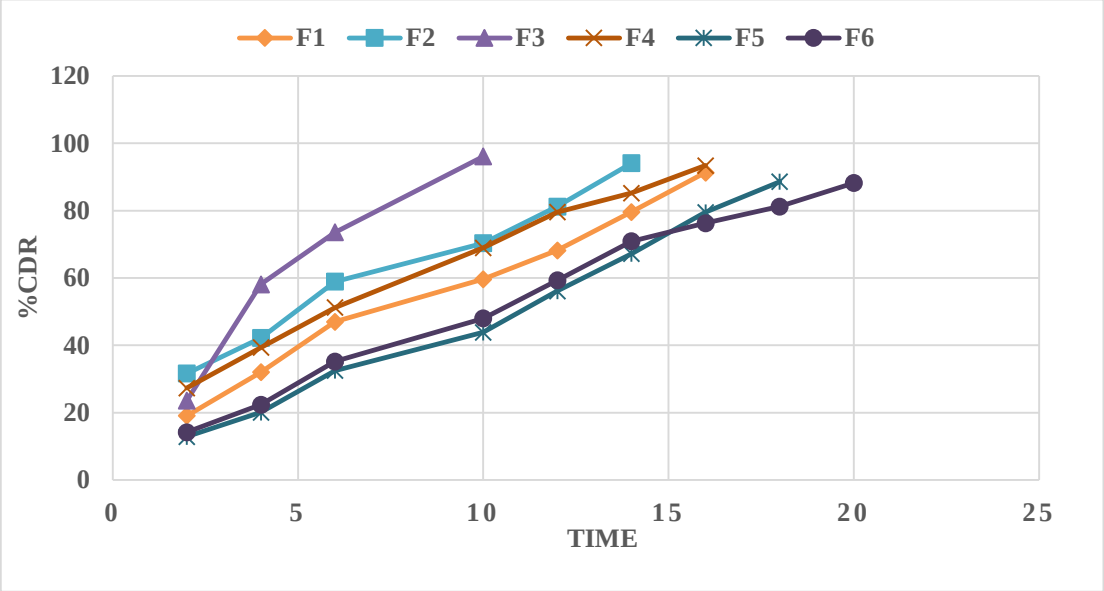

Fig 4: *In vitro* drug release of prepared films

Stability studies:

Based on weight uniformity, thickness uniformity, folding endurance, disintegration time, drug content uniformity, *In vitro* drug release F3 formulation found as best formulation hence for F3 formulation stability studies were carried out.

The prepared buccal film(F3) is packed in aluminium foil and stored at a temperature of 45 ± 0.5ºC for 12 weeks in hot air oven, and then tested for drug content.[13]

Table no 8: Stability studies of prepared films

Sl No	Trial no	1st day	After 4 weeks	After 8 weeks	After 12 weeks
1	I	95.23	95.85	95.21	95.86
2	II	95.68	95.73	95.32	95.75
3	III	95.32	95.86	95.14	95.11
4	Mean	95.41	95.81	95.22	95.57

CONCLUSION

In present study buccal film of leaf extract of Mimosa pudica is fabricated using different polymers like carbopal-940, HPMC-E, PVA.Six formulations are prepared by solvent casting method. The prepared strips were evaluated for following parameters like physical appearance and surface texture, weight uniformity, thickness of strips, folding endurance and drug content uniformity, disintegration, permeation study, drug excipients interaction studies, in vitro drug release and stability studies. All the formulations showed acceptable quality control properties.F3 formulation gave better drug release of 96.13% in 10 minutes. Stability studies conducted for F3 formulations for period of 3 months which revealed that the formulation was stable.

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