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Novel anti-Psoriatic topical herbal gel containing *cassia tora* seeds extract

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ABSTRACT

Herbal medicine has become an integral part of standard healthcare based on combination of traditional usage and on-going scientific research. Gel is a semisolid system consisting of dispersion made up of either small inorganic particles or large organic molecules enclosing an interpenetrated liquid. The inorganic particles form a three dimensional structure. The gel formulation was designed by using ethanolic extract of *Cassia tora* seeds and evaluated for various physiological measurements; preparation involved various concentration combinations of Carbopol 934 and Sodium CMC. Containing 1.55%of *Cassia tora* extract, Glycerin, Methyl paraben, Propyl paraben and required amount of distilled water and neutralized by drop wise addition of tri-ethanolamine to get gel like consistency. The results of physiochemical parameters of formulations were pH (6.8 to 6.89), viscosity, spreadability, extrudability, in-vitro release respectively. Concentration and combination effect of Carbopol 934 and Sodium CMC showed increased consistency and sustained action with increase in concentration.

Keywords: Herbal gel, *Cassia tora*, Carbopol 934, Sodium CMC

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INTRODUCTION

Semisolid Dosage Forms:

Semisolids constitute a significant proportion of pharmaceutical dosage forms. They serve as carriers for drugs that are topically delivered by way of the skin, cornea, rectal tissue, nasal mucosa, vagina, buccal tissue, urethral membrane, and external ear lining. Because of their peculiar rheological behavior, semisolids can adhere to the application surface for sufficiently long periods before they are washed off. This property helps prolong drug delivery at the application site. A semisolid dosage form is advantageous in terms of its easy application, rapid formulation, and ability to topically deliver a wide variety of drug molecules.[2]

Gels:

Gels are transparent to opaque semisolids containing gelling agent that merges or entangles to form a three-dimensional colloidal network structure. It is responsible for gel resistance to deformation and its visco-elastic properties. Gels have better potential as a vehicle to administer drug topically in comparison to ointment, because they are non-sticky, require low energy during formulation, are stable and have aesthetic value. Skininjuries (major and minor) or local infection can best be treated by application of product that form transparent water vapour andair permeable film over the skin surface from which the drug releases continuously from the application site.[3]

Cassiatora:

Cassia tora (*C. tora*) (sub-family: Caesalpinioideae; Family: Leguminosae/Fabaceae) is a small shrub which grows up in warm moist soil throughout the tropical parts of Asian and African countries. It is known by different names in different places like wise Foetid *Cassia tora*, Sickle Senna, Wild Senna, Sickle Pod,Coffee Pod, Tovara, Chakvad, Ring-worm Plant. Several compounds belonging to anthraquinone and naphthopyrone groups have been isolated from seeds of this plant. Three crystalline substances have been isolated from seeds of *C. tora* known as tora substance A, B and C. From properties of these substances and some typical derivatives, it appeared that tora substance C might be identical with rubro fusarin a metabolic product of the fungus, *Fusarium culmorum*and tora substance B with nor-rubrofusarin the demethylation product of rubrofusarin.[4, 5]

Psoriasis

Psoriasis is regarded as an autoimmune disease in which genetic and environmental factors have a significant role. The name of the disease is derived from Greek word “psora” which means

"itch". Psoriasis is a non-contagious, dry, inflammatory and ugly skin disorder, which can involve entire system of person. It is mostly inherited and mainly characterized by sharply emarginated scaly, erythematous plaques that develop in a relatively symmetrical distribution. The silvery-white plaques are caused by accelerated regeneration and accumulation of skin on sites of predilection due to rapid destruction process.[6]

MATERIALS AND METHODS

EXTRACTION PROCESS:[7]

The seeds were collected from Western Ghats and Low lands of Dakshina Kannada and Udupi Districts and the seeds were identified and authenticated by Dr. B.V. Shetty(Mangalore University) and Dr. K. Gopalkrishna Bhat (Dept. of Botany, Poorna Prajna College,Udupi). The seeds were then cleaned, dried under shade and powdered by a mechanical grinder. Hundred grams of the pulverized seeds were extracted with petroleum ether and ethanol successively in a Soxhletion apparatus. Pet. ether was used in initial step of extraction for defatting the plant materials. The successive extracts were separately filtered and concentrated at reduced temperature on a rotary evaporator. The chloroform and ethanol extracts furthermore kept in the desiccator to get dried powder extracts. The biologically potent ethanol extract was prepared for herbal gel formulation.

PREPARATION OF GEL:[8]

Different proportions of Carbopol 934 and Sodium CMC were dispersed in distilled water with continuous stirring. Then small quantity of distilled water was taken and required quantity of methyl paraben and propyl paraben were dissolved by heating on water bath. Cool the solution, then to that added glycerine and mixed it. Further required quantity of Cassia tora plant extract was mixed to the above mixture and volume made up to 20 ml by adding remaining distilled water. Finally full mixed ingredients were mixed properly to the gel with continuous stirring and triethanolamine was added drop wise to the formulation for adjustment of required skin pH (6.8-7) and to obtain the gel at required consistency.

Table 1.Formulation chart for herbal gel of *Cassia tora* extract

Ingredients	Formulation Code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cassia tora extract	0.31	0.31	0.31	0.31	0.31	0.31	0.31	0.31	0.31
Carbopol 934	0.1	0.2	0.4	0.2	0.1	0.2	0.1	0.4	0.4
Sod. CMC	0.8	1.2	0.8	0.4	0.4	0.8	1.2	1.2	0.4
Glycerine	4	4	4	4	4	4	4	4	4
Methyl Paraben	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Propyl Paraben	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06

Triethanolamine	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Dist. Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

EVALUATION OF GEL

Physical Observation: [9]

Transparency and Homogeneity were observed.

pH Measurement:[9]

pH of the gel was measured by using pH meter.

Spreadability: [10]

Two glass slides of standard dimensions were selected. The gel formulation whose spreadability had to be determined was placed over one of the slide. The other slide was placed on top of the gel in such a way that the gel was sandwiched between the two slides across the slide.

$$S = m\ l\ /t$$

S - Spreadability,

m - Weight tied to the upper slide (100g)

l - Length of the glass (cm)

t - Time taken in seconds

Viscosity:[11]

The measurement of viscosity of the prepared gel was done with a Brookfield Viscometer. The gels were rotated at 1.5 rotations per minute. At each speed, the corresponding dial reading was noted. The viscosity of the gel was obtained by multiplication of the dial reading with factor given in the Brookfield Viscometer catalogues.

Drug content:[12]

1g each formulation containing approximately 15.5 mg of drug was taken in a 50 ml volumetric flask and diluted with water and shaken to dissolve the drug in water. The solution was filtered through whatmann filter paper.1 ml of the filtrate was pipetted out and diluted to 10 ml with water. The content of the drug was estimated spectrophotometrically by using standard curve plotted at 276 nm.

***In-vitro* drug Diffusion studies:**[13]

The diffusion studies of the prepared gels can be carrying out in Franz diffusion cell for studying the dissolution release of gels through a cellophane membrane. Gel sample (0.5g) was taken in cellophane membrane and the diffusion studies were carried out at 37 ± 5°C using phosphate buffer (pH 6.8) as the dissolution medium. 5 ml of each sample was withdrawn periodically at 0.5, 1, 2, 3, 4, 5, 6, 7 and 8 hrs. and each sample was replaced with equal volume of fresh

dissolution medium. Then the samples were analyzed for the drug content by using phosphate buffer as blank at 276nm.

Stability study: [15]

The stability study was performed as per ICHQ1A(R) 2guidelines. The formulated gel were filled in the collapsible tubes and stored at different temperatures and humidity conditions, viz. 25ºC ± 2ºC / 60% ± 5% RH, 30ºC ± 2ºC/65% ± 5% RH, 40ºC ± 2ºC / 75% ± 5% RH for a period of six months and studied for appearance, pH, viscosity, spreadability, In-vitro diffusion study.

Extrudability: [16]

The gel formulations were filled in standard capped collapsible aluminum tubes and sealed by crimping to the end. The weights of the tubes were recorded. The tubes were placed between two glass slides and were clamped. 1500 gm. was placed over the slides and then the cap was removed. The amount of the extruded gel was collected and weighed. The percent of the extruded gel was calculated. (>90% extrudability: excellent, >80% extrudability: good, >70% extrudability: fair)

RESULTS AND DISCUSSION

Herbal gel was prepared and evaluated for their use with a view to obtain controlled drug delivery system using ethanolic extract of seeds of C*assia tora*.

In the present study, an attempt was made to develop herbal gel from the ethanolic extract of *Cassia tora* seeds. All the formulations were prepared by using combination of two polymers Carbopol 934 and Sodium CMC as gelling agent in various quantity considering the minimum and maximum concentration of respective polymer and with the assistance of software Design Expert 8.0.6.1 Stat Ease Inc. (Table 1 and Figure: 2)and the purpose is to see the possible combination of polymers at least concentration perform the desirable results compared to maximum concentrations and the evaluation of gel like physical observation, pH, Drug content, Spreadability, Viscosity, Extrudability(Table: 2) and *in-vitro* diffusion studies (Table:3, Figure :3,4,5) of the prepared gel was carried out. The procedure adopted to perform the above mentioned parameters were discussed in methodology section and the obtained data were shown in results section.

All the formulations were evaluated and it was found that the prepared gel was translucent brown in colour. The pH (6.80 to 6.89), viscosity (22617 – 36270m.Pas), spreadability (19.20-28.95gm.cm/sec), drug content uniformity (97.07% to 99.42%), In-vitro diffusion studies(80.94-99.99%), extrudability were depicted in Table: 3,4 and Figure 3,4,5.

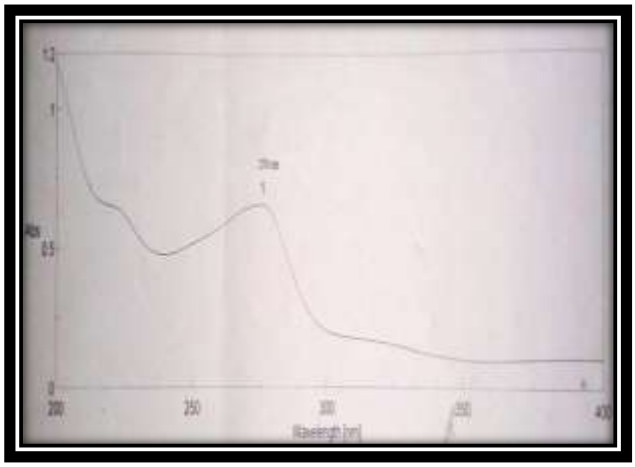

Figure 1: UV-Spectrum of Ethanolic Extract of Cassia tora

Figure 2: Prepared Herbal Gel

Table 2:Evaluation of Herbal gel of *Cassia tora* extract

	Appearance	pH ± SD n=3	Viscosity± SDn=3 (m.Pas)	Spreadability± SD, n=3 (gm.cm/sec)	Drug Content (%)	Extrudability (%)
F1	Translucent Brown	6.82 ± 0.032	27967 ± 2.00	26.52 ± 0.03	98.75	93.42
F2	Translucent Brown	6.84 ± 0.020	35450 ± 1.53	23.91 ± 0.02	98.29	96.52
F3	Translucent Brown	6.80 ± 0.021	30291± 1.52	24.76 ± 0.02	98.35	84.34
F4	Translucent Brown	6.88 ± 0.0259	24340 ± 1.00	28.89 ± 0.01	98.84	93.51
F5	Translucent Brown	6.87 ± 0.0124	22617 ± 2.51	28.95 ± 0.02	99.42	98.75
F6	Translucent Brown	6.87 ± 0.0263	29350 ± 1.53	24.78 ± 0.04	97.07	81.01
F7	Translucent Brown	6.87 ± 0.0125	33175 ± 2.51	24.17 ± 0.06	99.42	91.02
F8	Translucent Brown	6.89 ± 0.0169	36270 ± 2.52	19.20 ± 0.03	98.25	92.74
F9	Translucent Brown	6.87 ± 0.0125	25570 ± 2.08	26.67 ± 0.02	99.03	89.75

All values are expressed as mean ± SD, n=3

Table 3: *In-vitro* Diffusion studies of herbal gel formulation

Time (Hrs.)	% Cumulative Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	7.39	6.14	5.60	7.39	11.31	3.14	5.54	4.58	6.65
1	13.61	13.55	9.23	13.61	24.42	6.37	11.83	6.02	8.33
2	27.46	21.01	12.43	27.46	36.99	13.32	24.80	7.66	11.68
3	37.40	52.33	17.56	37.40	40.34	19.46	32.72	12.02	24.63
4	48.44	59.92	29.32	48.44	57.08	33.30	44.91	29.49	38.23

5	59.12	62.94	40.27	59.12	68.22	46.85	56.43	46.01	46.33
6	72.38	68.41	54.72	72.38	81.05	58.15	72.86	58.64	51.01
7	83.13	76.59	70.43	83.13	89.48	72.64	79.36	57.20	69.86
8	91.24	80.94	84.40	98.63	99.99	87.12	82.68	78.18	94.57

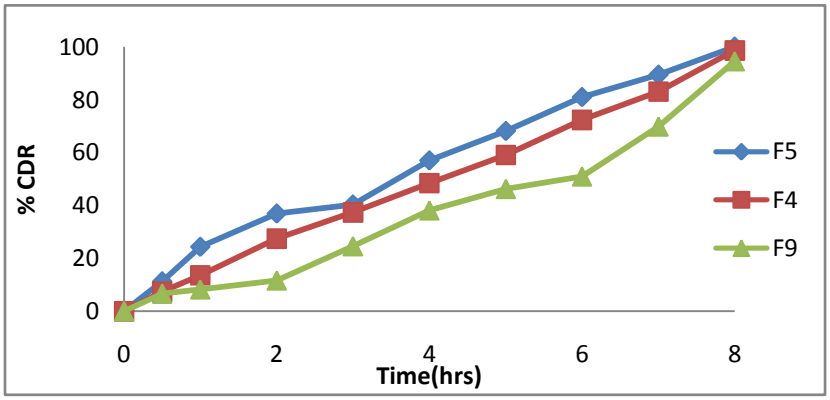

Figure 3:In vitro drug release of Formulation F5, F4 & F9 containing Carbopol 934 0.1%, 0.2%, 0.4 and Sodium CMC 0.4%

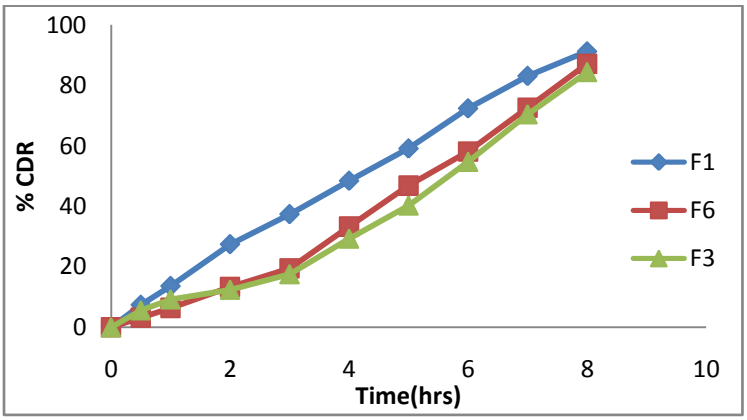

Figure 4: In vitro drug release of Formulation F1, F6 & F3 containing Carbopol 934 0.1%, 0.2%, 0.4 and Sodium CMC 0.8%

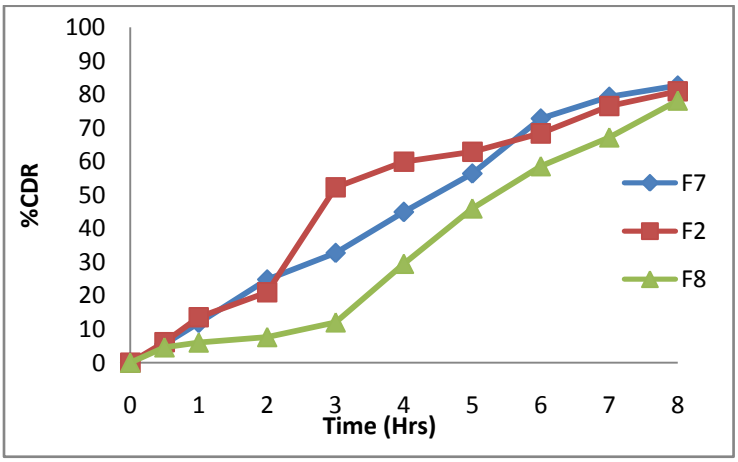

Figure 5:In vitro drug release of Formulation F7, F2 & F8 containing Carbopol 934 0.1%, 0.2%, 0.4 and Sodium CMC 1.2%

Various medicinal plants were known to possess anti-psoriatic activity, out of which *Cassia tora* was selected showing significant activity in the traditional system. Extraction was carried out using Petroleum ether and Ethanol. Various excipients were used to formulate a stable herbal gel. Carbopol 934 and Sodium CMC were used in different combinations to achieve the desired herbal gel which is required for controlled topical drug delivery system. The Characteristics properties of gel were identified by all the physicochemical parameters like pH, Viscosity, Spreadability, Drug content uniformity, Skin-irritation, Extrudability, in-vitro diffusion study and accelerated stability studies. Amongst different combination of polymers given by 32 factorial design batch F5 containing following ingredients i.e., Carbopol 934(0.1gm), Sodium CMC(0.4gm) was selected as best formulation in terms of all physicochemical properties. The designed formulation exhibited excellent physico-chemical properties ,diffusion profile and performance with adequate drug stability. Over all formulation F5 showed satisfactory results for the parameters evaluated. The viscosity of formulation F5 (Carbopol 0.1gm, Sodium CMC 0.4gm) was found to be 22617±2.51 m. Pas and spreadability was found to be 28.95±0.02gm.cm/sec. In-vitro drug release of Formulation F5 (Carbopol 0.1gm, Sod. CMC 0.4gm)was found to be 99.99 % at the end of 8hrs.During this study, it was noted that the conclusion was made that as the concentration of polymers decreases, viscosity also decreases with increased spreadability and extrudability. Hence the formulation shows faster drug release. The kinetics of drug release showed that it follows zero-order drug release. Stability studies showed that the formulations are stable at the conditions mentioned as per ICH guidelines.

CONCLUSION

The study has proved that *Cassia tora*seeds show significant anti-psoriasis and can be used as natural antioxidant. From the above results, it can be concluded that ethanolic seed extract showed marked anti-psoriatic activity.

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