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Formulation and Evaluation of *in situ* topical herbal gel of Flowers of *Tecoma stans* (L.) Juss. Ex Kunth

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Abstract

In the present study, an attempt was made to develop and evaluate topical gel formulations of ethanolic and aqueous flower extract of *Tecoma stans* (L.) Juss. Ex Kunth having controlled release for direct application in the site of fungal infection. In this study, PLX 407 & 188 has been used as the thermoreversible polymer while HPMC K100M has been used to improve the mucoadhesive and mechanical properties of formulation and to prolong the residence time. TG-1 to TG-6 was formulated using different concentration (0.5, 1.0, 1.5, 2.0, 2.5 & 3.0) of aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth, while TG-7 to TG-12 was formulated using different concentration (0.5, 1.0, 1.5, 2.0, 2.5 & 3.0) of ethanolic extract of *Tecoma stans* (L.) Juss. Ex Kunth. In above mentioned both the extract different proportion (5 to 30 g) of PLX 407 & 188 was added along with three different concentrations (0.25, 0.50 & 0.75) of HPMC K 100 M. The formulated herbal gel was evaluated for various parameters viz., physical appearance, pH, gelling capacity, gelation temperature, viscosity, Syringeability study, Extrudability, Spreadability and drug content.

Key words: Topical gel, Herbal, *Tecoma stans* (L.) Juss. Ex Kunth

Introduction

Tecoma stans (L.) Juss. Ex Kunth. Family. Bignoniaceae present in wild throughout India is an ornamental medicinal plant commonly known as Piliya (H), Yellow trumpetbusy, Yello bell (E). Traditionally all parts of the plant is used as medicine for the cure of the treatment of various diseases. Leaves, barks and roots have been used for a variety of purposes in the field of herbal medicine. Bark shows smooth muscle relaxant, mild cardio tonic and chlorotic activity. Applications include the experimental treatment of diabetes, digestive problems, control of yeast infections and other medicinal applications. It contains several compounds that are known for their catnip like effects on felines. The root of the plant is reported to be a powerful diuretic, vermifuge and tonic. A grinding of the root of *Tecoma stans* and lemon juice is reportedly used as an external application and also taken internally in small quantities as a remedy for snake and rat bites. [1-2]

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The present work was undertaken to formulate and evaluate in situ herbal gel containing extract *of Tecoma stans* (L.) Juss. Ex Kunth

Material and Methods

Collection of herbs and their authentication

The plant parts viz., TSF: *Tecoma stans* (Flowers), was collected in the months of September-December 2018 from the various local sites of Malwa region of Madhya Pradesh and identified & authenticated by Dr. S. N. Dwivedi, Prof. and Head, Department of Botany, Janata PG College, A.P.S. University, Rewa, (M.P.) and was deposited in our Laboratory. Voucher specimen No. P/TS-F/1210 was allotted.

Successive extraction of selected herb

Sample were shattered and screened with 40 mesh. The shade dried coarsely powdered plant material (250 gms) were loaded in Soxhlet apparatus and was extracted with petroleum ether (60-62°C), Chloroform, ethanol and water until the extraction was completed. After completion of extraction, the solvent was removed by distillation. The extracts were dried using rotator evaporator. The residue was then stored in dessicator and percentage yield were determined. [3-4]

Formulation topical *in situ* herbal gel

Poloxamer (PLX) 407 & 188 was dissolved slowly with stirring in 60 mL of demineralized water for 1 h to avoid agglomeration Then disodium edetate and triethanolamine were dissolved in 10 mL of demineralized water separately and stirred for 10 min. Mixed HPMC K 100M in 12 mL of demineralized water with stirring for 10 min. Disodium edetate and triethanolamine solution were added to PLX solution and the pH was then adjusted to 7.4 by stirring the solution for 10 min. Then HPMC K 100 M solutions were added with stirring for 10 min until a clear consistent gel base was obtained. At last weighed quantity of extract was added with continuous stirring and volume was adjusted with DM water. Twelve topical gel formulations were prepared using EETSF and AETSF of *Tecoma stans* (L.) Juss. Ex Kunth Flowers as per drug formulation mentioned were formulated [5] as per standard procedures as mentioned in Table 1.

Table 1: Formulation of *in-situ* herbal gel containing EETSF and AETSF

Formulation Code	EETSF (g)	AETSF (g)	PLX 407 (g)	PLX 188 (g)	Triethanol amine (g)	Disodium EDTA (g)	HPMC K100M (g)	D.M. water (100 g)
ISG-1	0.5	-	5	30	1.5	0.005	0.25	100
ISG-2	1.0	-	10	25	1.5	0.005	0.25	100
ISG-3	1.5	-	15	20	1.5	0.005	0.50	100
ISG-4	2.0	-	20	5	1.5	0.005	0.50	100
ISG-5	2.5	-	25	10	1.5	0.005	0.75	100
ISG-6	3.0	-	30	5	1.5	0.005	0.75	100
ISG-7	-	0.5	30	5	1.5	0.005	0.25	100
ISG-8	-	1.0	25	10	1.5	0.005	0.25	100
ISG-9	-	1.5	20	15	1.5	0.005	0.50	100
ISG-10	-	2.0	5	20	1.5	0.005	0.50	100
ISG-11	-	2.5	10	25	1.5	0.005	0.75	100
ISG-12	-	3.0	5	30	1.5	0.005	0.75	100

Abbr.: EETSF: Ethanolic Extract *Tecoma stans* (L.) Juss. Ex Kunth Flowers; AETSF: Aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers: Poloxamer (PLX); HPMC: Hydoxyl prpyl methyl cellulose; DM: De-mineralized water

Evaluation of topical *in situ* herbal gel [5-7]

Physical evaluation

The appearance of the formulation was observed which included clarity and transparency was determined visually.

Determination of pH

The pH of the gel was determined using a calibrated pH meter at 4 °C. The readings were taken for an average of 3 samples.

Gelling capacity

The gelling capacity was measured by visual method. 100µl sample was placed in a vial

containing 2 ml of artificial tear fluid freshly prepared and equilibrated at 35^0C and then visually assessing the gel formation and noting the time taken for gel formation.

Gelation temperature

The gelation temperature was determined using the test-tube-inverting method. A volume of 2 ml of the *in-situ* gel was placed in a test tube, which was then immersed in a water bath at 15 °C. The temperature of the water bath was then gradually increased, samples were examined every 2 minutes, and the gelation temperature was recorded when the gel stops fowing upon test tube inversion at 90°. The readings were taken for an average of 3 samples.

Viscosity

Viscosity of sols was measured using Brookfield viscometer (model DVII, Engineering Laboratories, Middleboro, MA) spindle no 01 at 20 r.p.m. at temperature 4 °C and 37 °C. The experiment was carried out in triplicate.

Syringeability study

The ability of the prepared formulations to fow easily through a syringe of 21 gauge needle was assessed using the method employed by Maheshwari. One ml of the cold gel was filled in 21 gauge needle syringe and the ability of the gel to flow under normal handling pressure was assessed.

Extrudability

A closed collapsible tube containing about 20 g of gel was pressed firmly at the crimped end and a clamp was applied to prevent any roll back. The cap was removed and the gel was extruded. The amount of the extruded gel was collected and weighed. The percentage of the extruded gel was calculated.

Spreadability

Two sets of glass slides of standard dimensions were taken. The herbal gel formulation was placed over one of the slides. The other slide was placed on the top of the gel, such that the gel was sandwiched between the two slides in an area occupied by a distance of 7.5 cm along the slides. Hundred g weight of gel was placed on the upper slides so that the gel was between the two slides was pressed uniformly to form a thin layer. The weight was removed and the excess of gel adhering to the slides was scrapped off. The two slides in position were fixed to a stand without slightest disturbance and in such a way that only upper slides to slip off freely by the force of weight tied on it. A 20 g weight was tied to the upper slide carefully. The time taken for the upper slide to travel the distance of 7.5 cm and separated away from the lower slide under the influence of the weight was noted. The experiment was repeated for three times and the mean time was taken for calculation.

Spreadability was calculated by using the following formula:

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

where, S= spreadability, m-weight tied to upper slides (20 g), l- length of the glass slide (7.5 cm), t- time taken in sec.

Drug content

Each formulation (1 g) was taken in a 50 mL volumetric flask and made up to volume with methanol and shaken well to dissolve the active constituents in methanol. The solution was filtered through Whatman filter paper and 0.1 mL of the filtrate was pipetted out and diluted to 10 mL with methanol. The content of active constituents was estimated spectro photometrically by using standard curve plotted at 280 nm.

***In-Vitro* release studies**

A sample of 1 ml of gel was placed into a dialysis membrane 7 cm long. Bags were then suspended in 50 ml of (ethanol: water 1:1) preheated at 37± 0.5 °C in shaking water bath at 37 °C and 25 strokes per min. At predetermined time intervals, one milliliter sample was withdrawn and replaced with an equal volume of fresh medium. The whole release media were changed and replaced with fresh media every day (24 h) during the release studies duration (up to one week). Samples were diluted and analyzed using an UV spectrophotometer for tannins concentration at λ 280 nm. The cumulative amount of drug released was calculated based on a calibration curve. All experiments were done in triplicate.

Results and Discussion

In general, gel formulation is more preferred, among the other topical semisolid preparations, since it has long residence time on the skin, high viscosity, moisturizing effect on flaky skin due to their occlusive properties, more bio adhesiveness, less irritation, independent of water solubility of active ingredient, ease of application and better release characters. Many studies have indicated

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that tannins such as gallic acid, ellagic acid in herbs possess anti-inflammatory and anti-fungal activity. Further, these polyphenolic compounds, reported that they can penetrate the human skin and hence a topical herbal gel formulation was designed containing these tannins for the treatment of fungal infections.

In the present study, an attempt was made to develop and evaluate topical gel formulations of ethanolic and aqueous flower extract of *Tecoma stans* (L.) Juss. Ex Kunth having controlled release for direct application in the site of fungal indection. In this study, PLX 407 & 188 has been used as the thermoreversible polymer while HPMC K100M has been used to improve the mucoadhesive and mechanical properties of formulation and to prolong the residence time in vaginal cavity.

TG-1 to TG-6 was formulated using different concentration (0.5, 1.0, 1.5, 2.0, 2.5 & 3.0) of aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth, while TG-7 to TG-12 was formulated using different concentration (0.5, 1.0, 1.5, 2.0, 2.5 & 3.0) of ethanolic extract of *Tecoma stans* (L.) Juss. Ex Kunth. In above mentioned both the extract different proportion (5 to 30 g) of PLX 407 & 188 was added along with three different concentrations (0.25, 0.50 & 0.75) of HPMC K 100 M.

The formulated herbal gel was evaluated for various parameters viz., physical appearance, pH, gelling capacity, gelation temperature, viscosity, Syringeability study, Extrudability, Spreadability and drug content. The result of evaluation parameters of formulated herbal gel was mentioned in table 2 & 2. *In-vitro* drug release profile was studied for all the formulated batches (Table 3 & 4).

Table 1: Evaluation parameters of topical gel containing ethanolic extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

Evaluation Parameters	Formulation Code					
	ISG-1	ISG -2	ISG -3	ISG -4	ISG -5	ISG -6
Clarity	C	C	C	C	C	C
Transparency	T	T	T	T	T	T
pH	7.38	7.48	7.32	7.33	7.15	7.42
Gelling capacity	++++	+++	+	+++	-	-
Gelation temperature	35.1	27.7	34.1	37.4	30.9	24.1
Viscosity (Poise)	0.3912	0.3782	0.3821	0.3610	0.3514	0.3441
Syringeability study	E	E	E	E	E	E
Extrudability (%)	99.29	98.41	97.08	97.28	95.75	95.40
Spreadability (gcm/sec)	72.44	67.28	71.31	62.41	59.13	58.37
Drug content (%)	99.23	98.32	97.12	97.20	95.21	94.28

Abbr: - : No gelation, + : Gel forms after some time, ++ : Gel forms immediately, +++: Immediate gelation remains for 8 hrs, ++++ : Immediate gelation remains for more than 10hrs. T : Translucent, C: Clear, E: Easily easily syringeable through 21-gauge needle at cold temperature.

Table 2: Evaluation parameters of topical gel containing aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

Evaluation Parameters	Formulation Code					
	ISG -7	ISG -8	ISG -9	ISG -10	ISG -11	ISG -12
Clarity	C	C	C	C	C	C
Transparency	T	T	T	T	T	T
pH	7.61	7.48	7.22	7.51	7.18	7.52
Gelling capacity	++++	+	+++	++	-	+
Gelation temperature	34.5	33.32	30.25	38.20	29.45	34.20
Viscosity (Poise)	0.3942	0.3761	0.3419	0.3415	0.3207	0.3140

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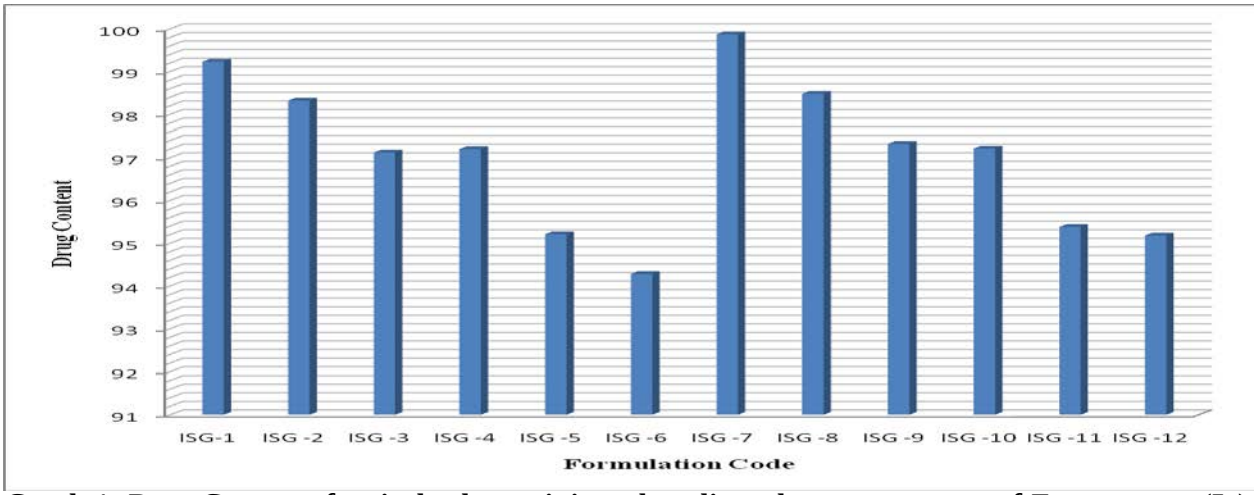
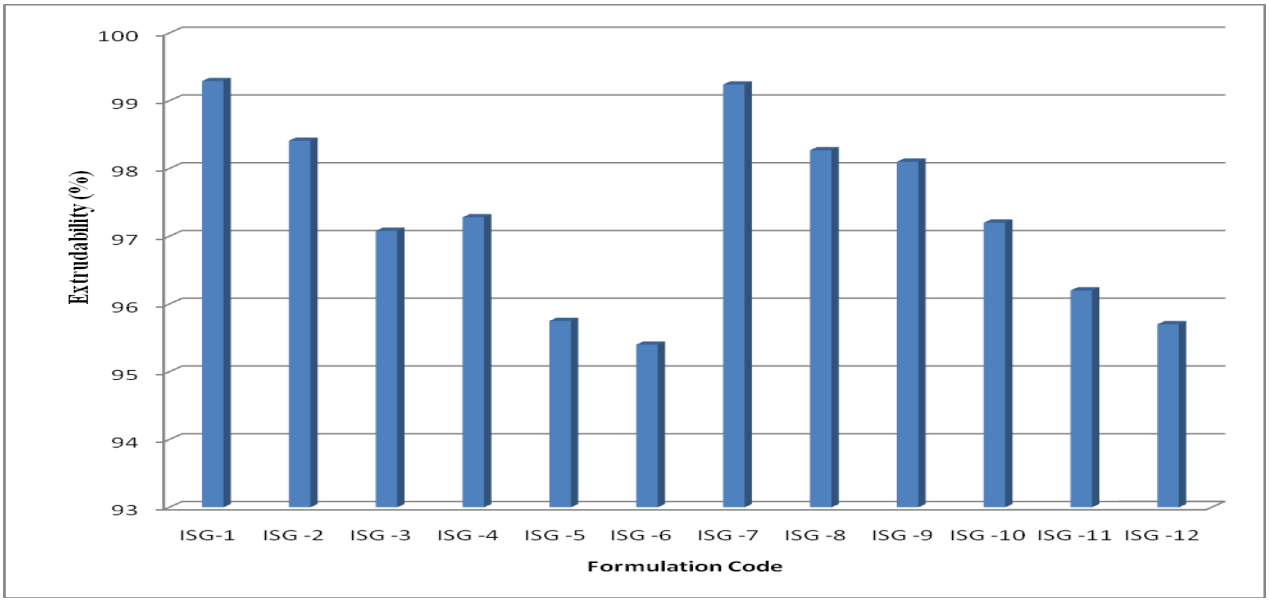
Syringeability study	E	E	E	E	E	E
Extrudability (%)	99.24	98.27	98.10	97.20	96.20	95.70
Spreadability (gcm/sec)	70.48	69.37	66.02	65.18	55.37	58.12
Drug content (%)	99.87	98.48	97.32	97.21	95.38	95.18

Abbr: - : No gelation, + : Gel forms after some time, ++ : Gel forms immediately, +++: Immediate gelation remains for 8 hrs, ++++ : Immediate gelation remains for more than 10hrs. T : Translucent, C: Clear, E: Easily easily syringeable through 21-gauge needle at cold temperature.



Graph 1: Drug Content of topical gel containing ethanolic and aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers



Graph 2: Extrudability of topical gel containing ethanolic and aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

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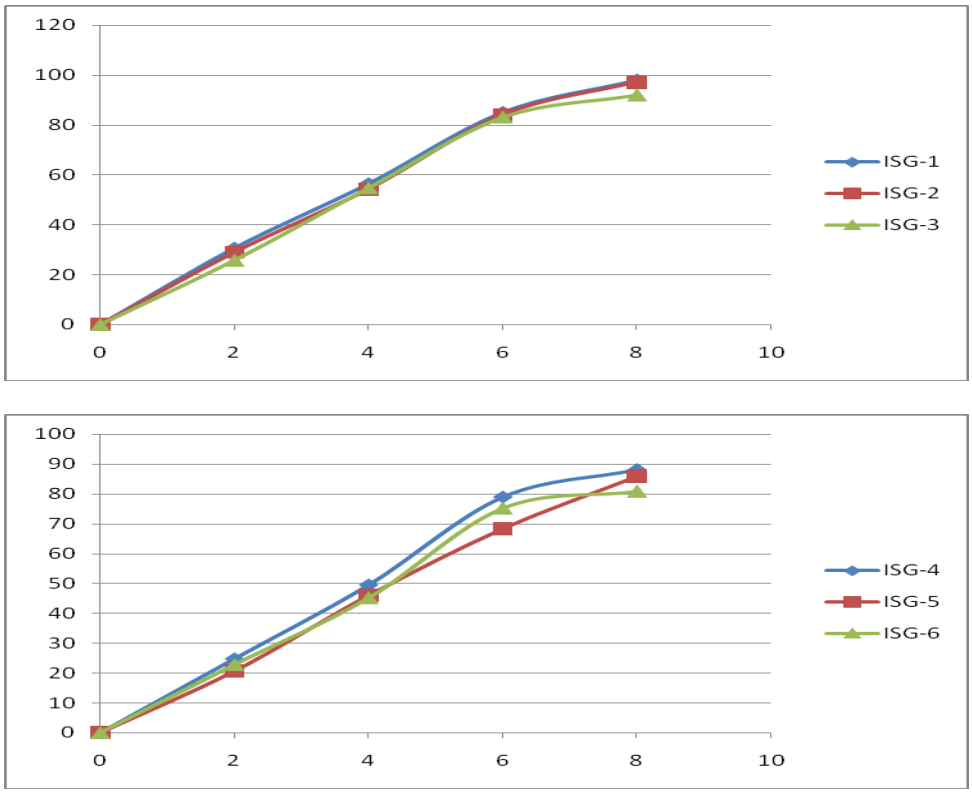
Table 3: *In-vitro* drug release of *in-situ* herbal gel containing ethanolic extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

Time (hrs)	Formulation Code					
	ISG-1	ISG-2	ISG-3	ISG-4	ISG-5	ISG-6
0	0	0	0	0	0	0
2	30.64	28.99	25.81	24.78	20.62	22.82
4	56.44	54.29	54.80	49.53	45.94	45.16
6	85.03	84.11	83.18	78.97	68.26	75.20
8	97.98	97.22	92.09	88.15	85.81	80.83

Table 4: *In-vitro* drug release of *in-situ* herbal gel containing aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

Time (hrs)	Formulation Code					
	ISG-7	ISG-8	ISG-9	ISG-10	ISG-11	ISG-12
0	0	0	0	0	0	0
2	32.18	30.27	27.34	25.46	24.14	23.49
4	58.29	56.19	55.19	51.27	46.09	47.28
6	88.49	86.27	84.94	81.90	77.46	79.82
8	98.11	97.43	94.15	90.16	89.10	88.38



Graph 3: *In-vitro* drug release of *in-situ* herbal gel containing ethanolic extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

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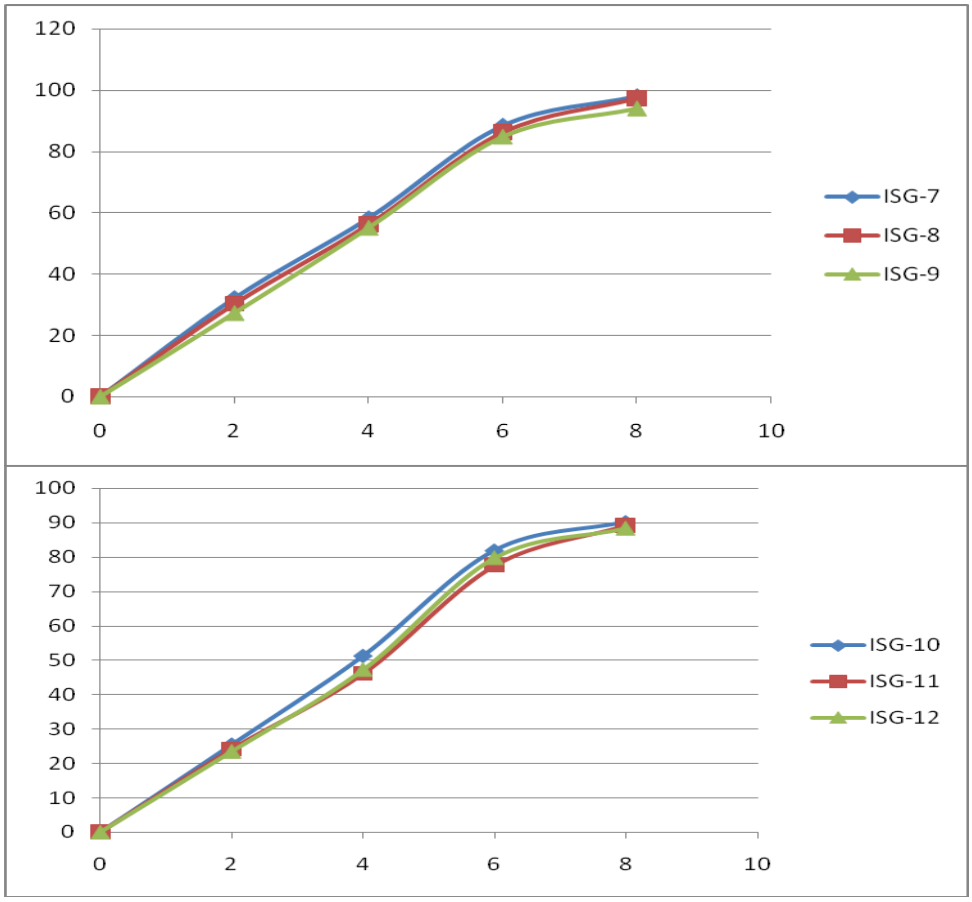

Graph 4: *In-vitro* drug release of *in-situ* herbal gel containing aqueous extract of *Tecoma stans* (L.) Juss. Ex Kunth Flowers

Conclusion

Different batches for conventional dosage form i.e., topical gel were prepared as per the standard procedure. In general, gel formulation is more preferred, among the other topical semisolid preparations, since it has long residence time on the skin, high viscosity, moisturizing effect on flaky skin due to their occlusive properties, more bio adhesiveness, less irritation, independent of water solubility of active ingredient, ease of application and better release characters. Many studies have indicated that tannins such as gallic acid, ellagic acid in herbs possess anti-inflammatory and anti-fungal activity. Further, these polyphenolic compounds, reported that they can penetrate the human skin and hence a topical herbal gel formulation was designed for the treatment of fungal infections.

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