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Research Article

Tinospora cordifolia Transdermal Patches Novel Approach

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ABSTRACT

This research provides knowledge about a novel herbal transdermal patch preparation (transdermal patch) useful in treatment of arthritis. Formulation comprises of plant extract as anti-artheritic with synthetic polymers. The main aim of the study is to evaluate, optimize and evaluate transdermal patch of *Tinospora cardifolia* extract (Tce) by the combination of different synthetic polymers and to release the drug in a controlled manner. Transdermal patches were often formulations was developed by solvent evaporation technique by the combination of Eudragit L-100 and HPMC as rate controlling (release retardants) polymer with different concentrations. Formulation F9 showed maximum bioavailability and maximum release *i.e.*, 100.19% ± 0.34% within 6 h and it is said to be ideal combination for controlling the release. It has been surprisingly found that a transdermal delivery patch comprising this composition, or matrix layer, can effectively delivers biologically active compounds.

Keywords: *Tinospora cardifolia*; HPMC; Eudragit L-100; Tansdermal patch; Anti-arithritis

INTRODUCTION

Transdermal delivery provides controlled, constant administration of the drug, and allows the continuous input of drugs with short biological half-lives through skin, which acts as a barrier for entry of drug and eliminates pulsed entry of an active moiety into systemic circulation. Transdermal patches deliver therapeutically effective (very small concentration) amount of drug across the skin when it placed on skin. Once they apply on unbroken skin they deliver active ingredients into systemic circulation passing *via* skin barriers. It contains high dose of drug inside which is retained on the skin for prolonged period of time, which get enters into blood flow *via* diffusion process.

The present research relates to a composition suitable for use in a transdermal delivery patch for administration of a biologically active compound Tce for treatment of arthritis, because Tce contains required concentrations of sesquiterpenoids, which required for the treatment of the disease. As Tc extract contains sesquiterpenoids, which inhibits the important pro-inflammatory cytokines, and chemokines along with mediators of bone remodeling, and matrix degradation, and provides anti-arthritis activity. The compositions of patch comprising extract of Tc, and release retardants HPMC and Eudragit L-100 [1-8].

MATERIALS AND METHODS

Tc leaves were collected from medicinal garden of St. Pauls college of pharmacy, Hyderabad. The polymers HPMC, and Eudragit L-100 were of analytical grade purchased from Rasula pharmaceuticals and fine chemicals, Hyderabad. Poly ethylene glycol 400, and propylene glycol, methanol, and acetone were purchased from Hi media chemicals. Eukalyptus oil and glycerin were purchased from J and J dechane laboratories Pvt Ltd. All the excipients used in the study were of analytical and pharmaceutical grade.

Preparation of Tce

From Tc plants, the leaves were collected dried under shade for about 10 days, and extracted with methanol by using soxhlet apparatus for 48 hrs methanolic extract was evaporated by flash evaporation technique using rotary flash evaporator, and the residue *i.e.*, Tce was used for further studies for preparation of transdermal patches (Figure 1).

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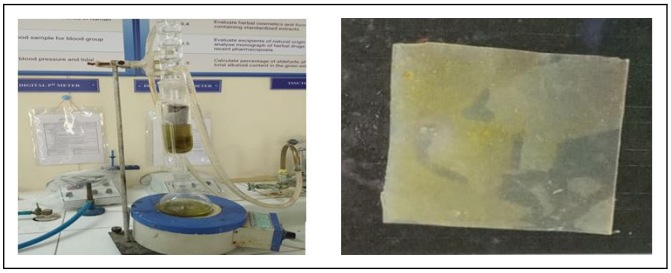

Figure 1: Preparation of Tc extract and prepared Tc transdermal patch.

Determination of wavelength of Tce

1 ml of Tce was dissolved in 100 ml of pH 4.8 acetate buffer in 100 ml volumetric flask (1000 mcg/ml solution) and it was scanned with UV-spectrophotometer (Electro lab) at 200 nm-400 nm for determination of wavelength of Tce (Figures 2 and 3).

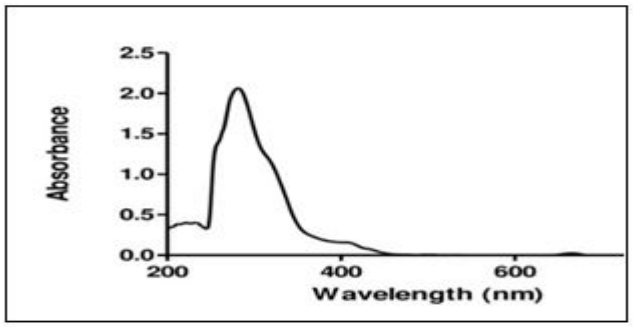

Figure 2: Determination of wavelength of Tce.

Compatibility study

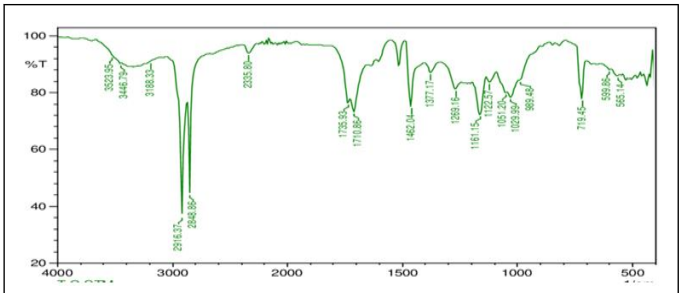

Figure 3: FTIR spectrum of Tce.

Development of transdermal patches

The patches were prepared by solvent evaporation technique. The required quantities of polymers weighed according to the formula. The required amounts of polymers were dissolved in combination of 20 ml of solvents methanol and acetone, Polyethylene glycol 400 (0.5 ml) and permeation enhancer (0.5 ml). Then 10 mg of Tce was added to the above polymeric solution and solvent mixture and dispersed completely with magnetic stirrer for 10 mins to get a homogenous dispersion. The dispersion was poured into petridish impregnated with glycerin and covered with glass funnel, kept for 24 hrs for drying. Next day, the patches were collected and folded in aluminum foil, kept in desiccators for further evaluation studies. The retardants combinations were changed based on the results obtained for the *in vitro* studies (Table 1).

Table 1: Design of Tce transdermal patches.

Formulation	Tce (mg)	Retarding polymers		Solvent		Plasticizer (PEG 400) %	Permeation enhancer % (Eukalyptus oil)
		HPMC	EudragitL-100	Methanol	Acetone		
F1	10	-	100	10	10	0.5	0.5
F2	10	100	-	10	10	0.5	0.5
F3	10	200	-	10	10	0.5	0.5
F4	10	-	200	10	10	0.5	0.5
F5	10	100	100	10	10	0.5	0.5
F6	10	250	150	10	10	0.5	0.5
F7	10	200	200	10	10	0.5	0.5
F8	10	150	250	10	10	0.5	0.5
F9	10	100	300	10	10	0.5	0.5

Evaluation of Tce transdermal patches

The Tce was analyzed (scanned) after making solution (1000 mcg/ml) with UV-spectrophotometer, to measure the wavelength at 200 nm-400 nm. The wavelength of Tce was found at 296 nm. Then the standard graph of Tce was made in pH 4.8 acetate buffers (Table 2 and Figure 4).

Table 2: Standard graph values.

Concentration (mcg/ml)	Absorbance
0	0
5	0.093
10	0.265
15	0.396
20	0.548
25	0.724
30	0.875

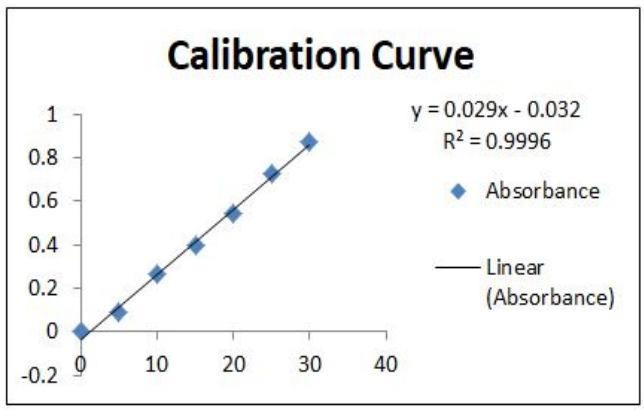

Figure 4: Standard graph of Tce.

The prepared Tce patches were evaluated for following tests.

Folding endurance: The patch was folded repeatedly till it broke. The point at which it was stable without breaking was considered as folding endurance. The folding endurance was determined for 4 patches from each formulation.

Thickness: Vernier caliperse was used to determine the thickness of patch. Selected 4 patches randomly from each formulation and determined the thickness.

Uniformity of weight: Selected 4 patches from each formulation and measured the weights by weighing balance (contech).

Moisture content: The patches were weighed and kept in desiccators containing calcium chloride for 24 hrs and measured the weights again to calculate the moisture present in the patches.

Moisture uptake: The patches were weighed and kept in desiccators containing potassium chloride for maintaining humidity for 24 hrs and measured the weights again to calculate the moisture absorbed by the patches [9-13].

***In-vitro* permeation study:** Franz diffusion cell was used and the selected rat abdominal skin of rat was placed between the donor and receptor compartments, receptor compartment was filled with 18 ml of pH 5.4 acetate buffer and a magnetic bead. The apparatus was placed on magnetic stirrer, maintained the temperature of 32°C ± 0.5°C for 8 hrs. At different time intervals 1 ml of sample was removed and replaced with fresh acetate buffer. The collected samples were analyzed by spectrophotometer (Electro lab) at 296 nm.

RESULTS AND DISCUSSION

The prepared Tce was subjected for wavelength measurement for further evaluation studies using UV-spectrophotometer (electrolab) and the λ_{max} of the Tce was found to be at 296 nm. *Tinospora cardifolia* transdermal patches were prepared by the method mentioned above.

The prepared patches were evaluated for physico chemical parameters and *in vitro* drug release behaviour. The determination of the average weight of patch, having 15.21 cm^2 surface area showed a significant change between the patches prepared with different polymer ratios. The Tce patches were evaluated for quality control tests and the results are discussed below.

Folding endurance: The results concluded that patches would not break, maintain integrity and adheres to skin after application. All the prepared formulation provided good folding ability without formation of any cracks.

Thickness: with the help of vernier caliperse, the thickness of patches was determined and average of selected 4 patches was taken as the thickness. The thickness of patches was varied from 0.268 mm ± 0.23 mm to 0.314 mm ± 0.18 mm for F1 to F5 formulations.

Uniformity of weight: Selected 4 patches from each formulation and measured the weights by weighing balance

(contech) and the average was taken and it was in between 168.24 ± 0.39 to 219 ± 0.28.

Moisture content: The patches moisture content was within the range of 2.96 ± 0.012 to 4.32 ± 0.08 (Table 3).

Table 3: Physico-chemical properties of prepared transdermal patches.

Formulation	Weight variation (gm)	Thickness (mm)	Moisture content	Moisture uptake	Drug content (mg/cm^2)
F1	0.592 ± 0.028	0.1	3.31	5.68	0.412
F2	0.523 ± 0.12	0.2	2.22	4.79	0.378
F3	0.596 ± 0.059	0.2	2.65	5.12	0.644
F4	0.421 ± 0.856	0.2	3.84	4.98	0.608
F5	0.126 ± 0.265	0.1	2.97	4.24	0.514

Moisture uptake: The patches moisture absorbed by the patches was within the range of 2.34 ± 0.012 to 4.81 ± 0.08.

***In-vitro* permeation study:** The formulations like F1, F2 and F3 shown incomplete and immediate release in 6 hrs, which contains different concentrations of retardants like HPMC and Eudragit L-100 without combination. The formulations F4 and to F10 showed 90.32% and 99.32% in 6 hrs. The study revealed that, by increasing the polymer concentrations the release rate was retarded. All the results were reported in table 4 [14-17].

Table 4: Results of *in-vitro* drug permeation study.

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
0.5	4.43	5.34	15.65	11.86	5.25	9.18	12.65	4.99	9.34
1	50.09	55.75	65.66	25.74	13.43	26.24	27.85	7.32	21.73
2	69.32	81.76	88.74	39.82	28.65	32.98	42.37	19.66	42.17
3	98.45	97.36	-	50.27	42.11	49.19	53.92	37.75	63.01
4	-	-	-	69.69	61.32	60.7	68.37	51.33	73.43
5	-	-	-	78.49	75.45	89.35	81.582	76.32	86.19
6	-	-	-	-	94.86	96.24	98.09	99.32	-

CONCLUSION

The *Tinospora cardifolia* transdermal patches were suitable drug candidates for treatment of allergy and arthritis and it delivers the medicament for 6 hrs and also drug release can be retarded by further increasing polymer concentrations. It can be considered as best option for allergy and arthritis. The composition, or matrix layer, may form part of a transdermal delivery matrix patch. It has been surprisingly found that a transdermal delivery patch comprising this composition, or matrix layer, can effectively delivers biologically active compounds. Their efficacy in clinical levels must be studied in future.

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