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Research Article

**FORMULATION AND CHARACTERIZATION OF A HERBAL
TRANSDERMAL PATCH****Gorentala Shruthi¹, Bantu Kavya², Burgula Soumya², Kothi Varshitha²,
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Bheemaram, Ramaram, Hanumakonda. Telangana, India 506015.²Department of Pharmacy, SVS Group of Institutions (Autonomous), Bheemaram, Ramaram,
Hanumakonda. Telangana, India 506015.**Abstract:**

The present study aimed to develop and characterize a herbal transdermal patch as a novel approach for effective muscle pain relief. Curcuma longa, well known for its anti-inflammatory and analgesic properties, was incorporated into the transdermal patch formulation to enhance its therapeutic potential in the management of muscle pain. Herbal transdermal patches were prepared using different combinations of Hydroxypropyl Methylcellulose (HPMC) and Eudragit polymers by the solvent evaporation method. FT-IR studies confirmed the compatibility between the herbal drug and selected polymers, indicating the absence of significant chemical interactions. All formulations exhibited satisfactory physicochemical characteristics, indicating successful patch formation with uniform drug distribution. Among the developed formulations, F2 demonstrated superior performance with optimum drug content (89.47%), satisfactory folding endurance (162), and acceptable moisture characteristics. In vitro drug release studies using phosphate buffer pH 7.4 containing 0.5% SLS demonstrated that the polymer composition significantly influenced the release profile of the active constituents. The optimized formulation (F2) exhibited the highest cumulative drug release of 98.98% within 8 hours, indicating its ability to provide effective and sustained delivery of herbal actives through the skin. Accelerated stability studies performed under ICH conditions (40 ± 2°C and 75 ± 5% RH) for three months revealed minimal changes in drug content, folding endurance, physical appearance, and drug release profile, confirming the stability of the optimized formulation.

Keywords: Herbal transdermal patch, Curcuma longa, Muscle pain relief, HPMC, Eudragit, Solvent evaporation method, In vitro drug release, Stability studies.

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INTRODUCTION:**Traditional and Herbal Medicine**

The use of plants as medicine goes back to the period of early humans. Fossil records human use of plants as medicines at least to the Middle Paleolithic age. Evidences of this early association have been found in the grave of a Neanderthal man buried 60,000 years ago. The earliest known medical document is a 4000-year-old Sumerian clay tablet that recorded plant remedies for various illnesses. By the time of the ancient Egyptian civilization, a great wealth of information already existed on medicinal plants. This information, along with the hundreds of other remedies, has been preserved in the Ebers papyrus for nearly 3500 years. The development of systematic pharmacopoeias dates back to 3000 BC, when the Chinese were already using more than 350 herbal remedies. China has demonstrated the best use of traditional medicine in providing health care. Ayurveda, a system of herbal medicines widely practiced in India, Sri Lanka, and Southeast Asia has more than 8000 plant remedies and uses nearly 35,000 to 70,000 plant species. Among the ancient civilizations, India have been known to be the richest repository of medicinal plants. About 8000 herbal remedies have been codified in Ayurveda. The Rigveda (5000 BC) has recorded 67 medicinal plants, the Yajurveda 81 species, the Atharvaveda (4500-2500 BC) 290 species, and the Charak Samhita (700 BC) and Sushrut Samhita (200 BC) have described properties and uses of 1100 and 1270 species, respectively, to compound the drugs and use. It is a well known fact that Traditional Systems of medicines always played important role in meeting the global health care needs. They are continuing to do so at present and shall play major role in future also. The system of medicines which are considered to be Indian in origin or the systems of medicine, which have come to India from outside and got assimilated in to Indian culture are known as Indian Systems of Medicine. India has the unique distinction of having six recognized systems of medicine in this category. They are: Ayurveda, Siddha, Unani and Yoga, Naturopathy and Homoeopathy.

Current Status of Herbal Medicine

Currently more than 80% of the world population depends on traditional and plant derived medicine because, plants are important sources of medicines and presently about 25% of pharmaceutical prescriptions in the United States contain at least one plant-derived ingredient. In the last century, roughly 121 pharmaceutical products were formulated based on the traditional knowledge obtained from various sources.

Future importance of Herbal Medicine

It is estimated that there are about 350,000 species of existing plants (including seed plants, bryophytes, and ferns), among which 287,655 species have been

identified as of 2004. Relatively small percentages (1 to 10%) of these are used as foods by both humans and other animal species. It is possible that even more are used for medicinal purpose. The strategy has four main objectives, in line with those of WHO's medicines strategy:

Objectives

- To integrate relevant aspects of traditional medicine within national health care systems by framing national traditional medicine Policies and implementing programmes
- To Promote the safety, efficacy and quality of Traditional Medicine Practices by providing guidance on regulatory and quality assurance standards
- To increase access to, and affordability of, traditional medicine

MATERIALS

Curcuma longa was procured from Synpharma Research Labs, Hyd, HPMC K5M, Eudragit RLPO, Poly ethylene glycol and Methanol were obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

METHODOLOGY:**Compatibility studies of Curcuma longa extract and polymers:**

In the formulation of Curcuma longa patch formation, API and Excipient may interact as they are in close communication with each other, which could lead to the instability of drug. FT-IR spectroscopy was employed to ascertain the compatibility between Curcuma longa extract and the selected polymers. The pure drug and drug with excipients were scanned separately.

Preparation of Calibration curve of Curcuma longa

Extract Accurately weighed quantity (100mg) of Curcuma longa was transferred into a 100ml volumetric flask and dissolved in small amount of methanol and made up to the volume to make the standard stock solution of 1 mg/ml. From the stock, 1ml was taken in 10ml volumetric flask and made up the volume with the buffer; from this solution 0.5ml to 3ml solution was transferred to 10ml volumetric flask and made up to required volume with more methanol and the resulting concentration ranges from 5 to 50 µg/ml. The absorbance of these solutions was determined at 425 nm using UV spectrophotometer. The calibration curve was constructed between the absorbance and concentration.

Preparation of Curcuma longa Extract

During this stage, we applied the extraction technique. Prior to the extract preparation, fresh

rhizomes of *Curcuma longa* were collected and washed thoroughly with water to remove dirt and impurities. The cleaned rhizomes were shade dried for several days until complete removal of moisture. The dried rhizomes were powdered using a grinder and passed through sieve to obtain uniform powder. Accurately weighed quantity of turmeric powder (50 g) was taken in a clean conical flask. Ethanol was added to the powder in sufficient quantity (200mL). The mixture was kept for 24–48 hours with occasional shaking to ensure proper extraction of phytoconstituents (Maceration Process). After maceration, the extract was filtered using muslin cloth followed by Whatman filter paper. The filtrate was concentrated by evaporating the solvent by using Rotary evaporator. The concentrated extract was dried completely to obtain semisolid or dry extract. The prepared extract was stored in airtight container and kept in refrigerator until further use.

Formulation design

Preparation of transdermal patches:

Transdermal patches containing *Curcuma longa* were prepared by the solvent casting evaporation technique. The drug *Curcuma longa* extract was dissolved in suitable solvent. Polymers HPMC were taken in a boiling tube, to this add *Curcuma longa* drug which was previously dissolved in methanol. PEG was taken as a plasticizer, and added to the mixture and mixed well. It was set aside for 2 hours to exclude any entrapped air and was then transferred into a previously cleaned petri plate (40cm²), drying of patches was carried out in vacuum oven at room temperature. Dried patches were packed in aluminium foil and stored in a desiccator for further evaluation.

Table-: 1 Formulation Design of *Curcuma longa* Transdermal Patches

F.Code	Extract(mg)	HMPC(mg)	Edragit RLPO(mg)	PEG	DMSO
F1	50	100	-	1ml	0.1ml
F2	50	200	-	1ml	0.1ml
F3	50	-	100	1ml	0.1ml
F4	50	-	200	1ml	0.1ml

Evaluation of transdermal formulation:

Physico- chemical evaluation:

Physical appearance:

All the prepared transdermal films were observed for color, clarity, flexibility, and smoothness.

Folding endurance:

Folding endurance of the patches was determined by repeatedly folding at the same place till it broke. The number of times the patch could be folded at the same place without breaking is the folding endurance. This was repeated on all the patches for three times and the mean values plus standard deviation was calculated.

Thickness of the film :

The thickness of each film was measured by using screw gauge. The thickness was measured at three different places on each film and the average thickness of the film was taken as the thickness of the film.

Weight uniformity :

The prepared patches are to be dried at 60°C for 4hrs before testing. A specified area of 4.52 cm² of patch is to be cut in different parts of the patch and weigh in digital balance. The average weight and standard deviation values are to be calculated from the individual weight.

Drug content:

The formulated transdermal films were assayed for drug content in each case. Three patches from each formulation were assayed for content of drug. Each formulation was casted in triplicate and one film from each was taken and assayed for content of drug.

Moisture absorption studies:

The films were weighed accurately and placed in a desiccators containing aluminium chloride to maintain 79.50% RH. After 3 days, the films were taken out and weighed. The percentage of moisture uptake was calculated using the following formula.

$$\text{Percentage moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

Moisture loss studies :

Three films were weighed individually and kept in a desiccator containing calcium chloride at 37°C for 24 hrs. Then the final weight was noted when there was no further change in the weight of the patch. The percentage of moisture loss was calculated using the following formula.

$$\text{Percentage moisture loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Final weight}} \times 100$$

In-vitro Drug release studies:

The in-vitro study of drug permeation through the Dialysis membrane was performed using a modified Franz type glass diffusion cell. The modified cell having higher capacity is (10 ml) is used to maintain sink condition. The samples were analyzed for drug content spectrophotometrically. The receptor phase was replenished with an equal volume of phosphate buffer at each sample withdrawal. Percentage of drug release was determined using the following formula.

$$\text{Percentage drug release} = \frac{D_a}{D_t} \times 100$$

Where, D_t = Total amount of the drug in the patch
 D_a = The amount of drug released

Conditions:

Medium: Phosphate buffer pH 7.4

RPM: 200

Temperature: $37 \pm 0.5^\circ\text{C}$

Time intervals: 1, 2, 3, 4, 5, 6, 7, 8 hours

Stability studies:

Optimized medicated films were subjected to short term stability testing. The transdermal films were sealed in aluminium foils and kept in a humidity chamber maintained at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ RH for 1 month as per ICH guidelines. Changes in the appearance and drug content of the stored films were investigated after storage at the end of every week.

RESULTS & DISCUSSION:**FT-IR Spectrum of Curcuma longa**

FT-IR Spectra of Curcuma longa and polymers were recorded. All these peaks have appeared in formulation and physical mixture, indicating no chemical interaction between Curcuma longa and polymers. It also confirmed that the stability of drug during process.

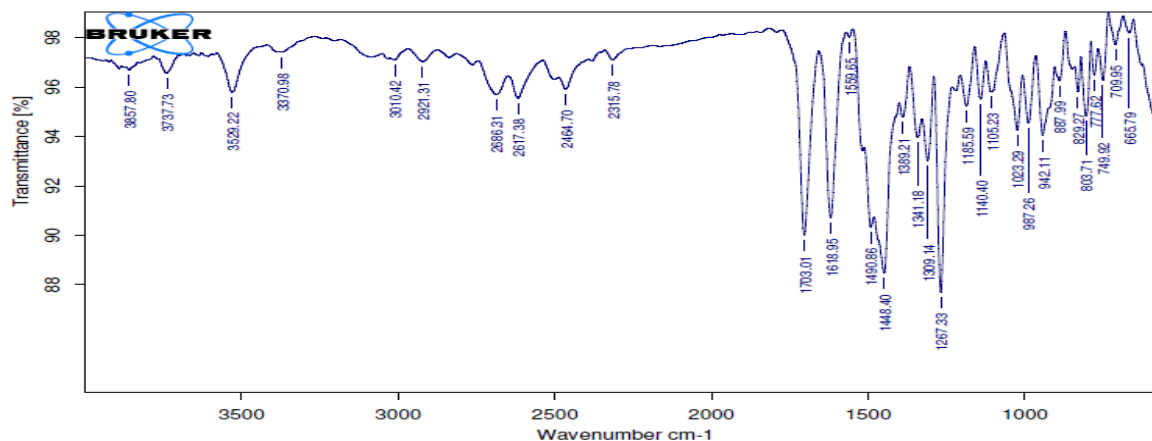


Fig:- 1 FT-IR Sample for Curcuma longa

Table:- 2 Characteristic Peaks and frequency of Curcuma longa

S. No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3887-3737	3500
2	OH Bending	2342-2421	2100
3	C-H stretching	2464-2315	2500
4	C-N stretching	1750-1653	1650

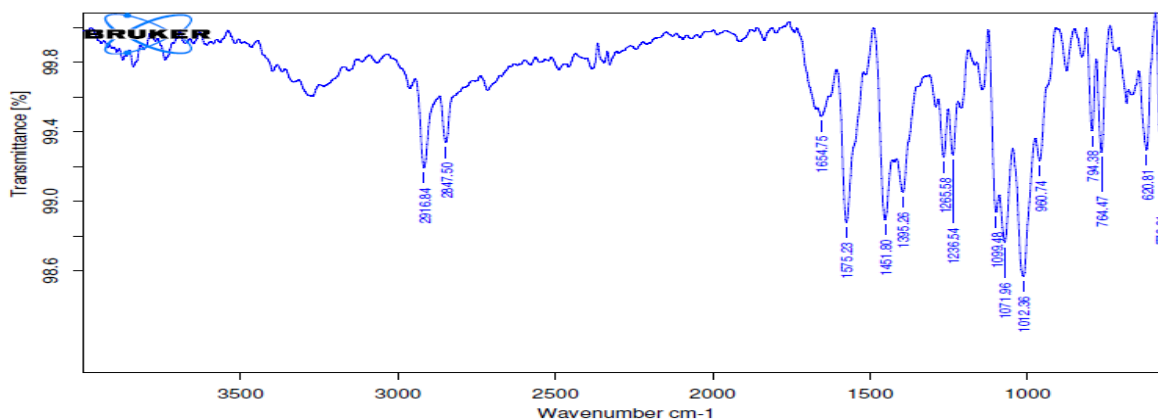


Fig-: 2 FT-IR Sample for Optimised Formulation

Table: 3 Characteristic Peaks and Frequency of Optimised Formulation

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	2916-2847	3000
2	OH Bending	1575-1421	1500
3	C-N stretching	1395-1236	1600

Evaluation of Transdermal formulation

Physical appearance:

The prepared patches were found to be uniform, smooth, flexible and homogenous.

Folding endurance:

The folding endurance numbers of all the Curcuma longa patches are 186.8 -192.4 . The folding endurance number gives the mechanical property of the patches, high folding endurance number indicate that has high mechanical property. The folding endurance number was increased with increasing the sodium alginate content. These results indicated that the patches would not break and maintain their integrity with general skin folding when applied.

Thickness of the film:

Thickness was changed from batch to batch in individual strips of medicated patch carry uniform

thickness, which indicates that total medicated patch carry uniform thickness.

Weight uniformity:

The mean weights of all the prepared patches are shown in table . The weights are in the range of 186.8-192.4. The F2 formulation patches showed maximum weight.

Drug content:

The drug content analysis of the prepared formulations have shown that the process employed to prepare the patches was capable of giving uniform drug content with minimum batch variability. All the patches were found to have drug content in the range of 82.35 – 90%. So the method employed i.e. solvent evaporation method is satisfactory for the preparation of transdermal patches.

Table: 4 Physicochemical evaluation of Curcuma longa patches

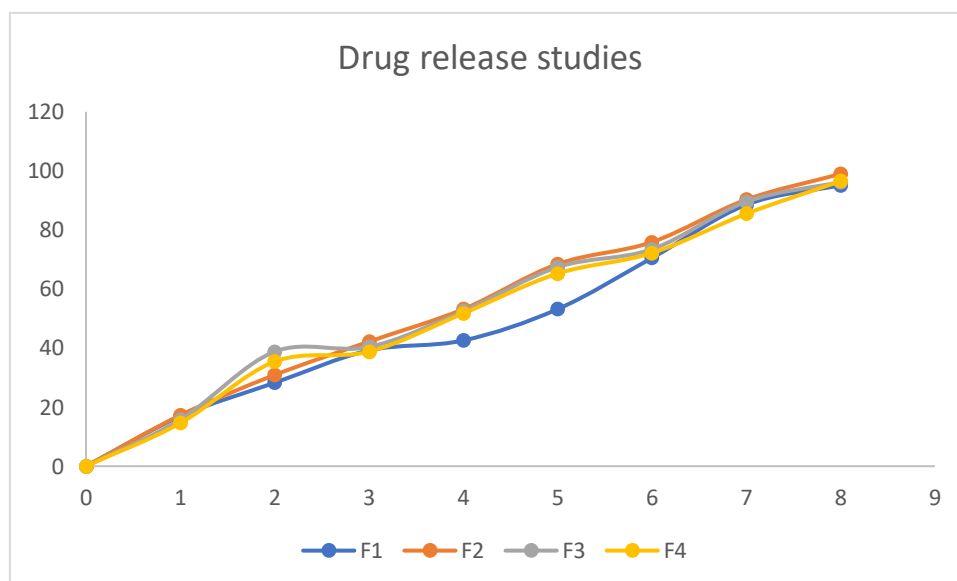
Formulation code	Weight (mg)	Thickness (mm)	Folding endurance	Drug content (%)	% moisture loss	% moisture absorption
F1	191.2	0.86	158	86.39	6.79	7.85
F2	192.4	0.89	162	89.47	5.37	6.89
F3	190.1	0.76	170	82.35	7.58	7.99
F4	186.8	0.82	168	83.56	7.88	8.12

In vitro release study:

Phosphate buffer pH 7.4 containing 0.5% SLS was used as medium for the release studies and good linearity was observed in the plotted standard graph with a correlation coefficient of 0.999. The drug release profiles of curcuma longa patches containing different ratios of polymers HPMC and Eudragit . It was cleared from the release profiles of formulations, that the drug release was governed by polymer nature and content.

Table :5 In vitro drug release profiles of Curcuma longa transdermal patch (F1-F4)

Time	F1	F2	F3	F4
0	0	0	0	0
1	16.89	17.25	15.79	14.58
2	28.25	30.89	38.79	35.42
3	39.20	42.18	40.38	38.79
4	42.58	53.17	52.49	51.74
5	53.19	68.46	67.42	65.24
6	70.52	75.89	73.48	72.19
7	88.54	90.27	89.54	85.49
8	95.15	98.98	96.25	96.52

**Fig: 3 Drug release for all formulations****Stability studies:**

Optimized formulations F2 was selected for accelerated stability studies as per ICH guidelines. The patches were observed for color, appearance and flexibility for a period of three months. The folding endurance, weight, drug content, % cumulative drug release of the formulation was found to be decreasing. This decrease may be attributed to the harsh environment (40°C) maintained during the studies.

Table: 6 Stability studies of optimised formulations at $40 \pm 2^{\circ}\text{C}$ and $75 \pm 5\%$ RH for 3 months

Time in days	Drug content (%)	Folding endurance	Physical appearance	% Cumulative drug release
0	89.47	162	No change in color	98.98
90	88.99	161	Slight yellowish color	98.52

CONCLUSION:

The present study successfully developed and evaluated Curcuma longa-loaded transdermal patches using different polymer combinations of HPMC and Eudragit by the solvent evaporation method. Preformulation studies confirmed the suitability of Curcuma longa for transdermal delivery. The drug exhibited characteristic organoleptic properties, a melting point of 186°C , and good solubility in organic solvents such as ethanol, DMSO, and methanol. UV

spectrophotometric analysis showed a λ_{max} at 425 nm in phosphate buffer pH 7.4 containing 0.5% SLS, with an excellent linearity ($R^2 = 0.999$), indicating the reliability of the analytical method. FT-IR studies demonstrated the compatibility between Curcuma longa and the selected polymers, as the characteristic peaks of the drug were retained in the optimized formulation without significant shifts, indicating the absence of any chemical interaction and confirming drug stability during formulation.

The prepared transdermal patches were found to be smooth, uniform, flexible, and homogeneous. Physicochemical evaluation showed acceptable weight variation, thickness, folding endurance, moisture content, and drug content for all formulations. Among the developed formulations, F2 exhibited superior characteristics with optimum drug content (89.47%), satisfactory folding endurance (162), lower moisture loss and absorption, and excellent physical properties. In vitro drug release studies revealed that polymer composition significantly influenced the release profile of Curcuma longa from the transdermal patches.

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