RESEARCH PAPER

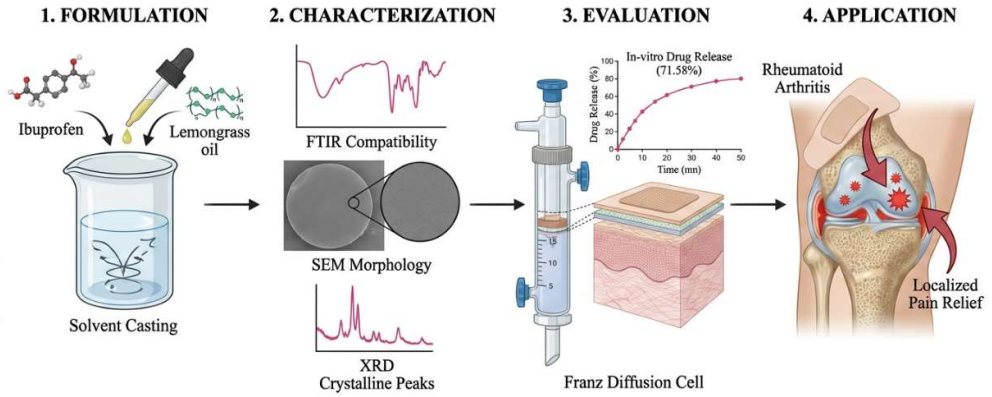
Formulation and *In Vitro* Evaluation of An Herbal Essential Oil-Infused Ibuprofen Transdermal Patch for Rheumatoid Arthritis

Rajendran Akash[1], Sathiyamoorthy Rajesh[1], Sarkgunan Sedhu Raagavan[1], Jeganathan Benjamin[2], Sundaresan Nandhini[4], Mohammed Wasiq Rahman M.[3], D. Yogashri[3], S. Neha[3], R. Prathiksha[3], Bhuvaragavan Devi Shree[5]*

[1] Ph.D. Full-Time Research Scholar, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600116, Tamil Nadu, India.
[2] Master of Pharmacy, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600116, Tamil Nadu, India.
[3] Bachelor of Pharmacy, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600116, Tamil Nadu, India.
[4] Assistant Professor, Department of Pharmacognosy, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600116, Tamil Nadu, India.
[5] Assistant Professor, Department of Pharmaceutics, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600116, Tamil Nadu, India.
Corresponding Author:
Mrs. Bhuvaragavan Devi Shree, M.Pharm.
Assistant Professor, Department of Pharmaceutics, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education and Research (Deemed to be University), Porur, Chennai – 600116, Tamil Nadu, India.
Email: devishree16@sriramachandra.edu.in
Received: 24-06-2026 Revised: 15-07-2026 Accepted: 04-08-2026

ABSTRACT
Objective: "A variety of ailments are treated with volatile oils derived from lemon grass (*Cymbopogon citratus*) in conventional medicine." The objective of the study is to prepare and evaluate topical formulation of Ibuprofen in combination with Lemon grass oil for the treatment of Rheumatoid Arthritis. **Materials and Methods:** The transdermal patch was formulated by using ethyl cellulose (EC) and Hydroxypropyl methyl cellulose (HPMC) as basic polymers with dibutyl phthalate as plasticizer. The chemical compatibility of each ingredient was investigated using Fourier Transform Infra-Red (FTIR) spectroscopy, quantitative analysis using scanning electron microscopy (SEM), and X-ray diffraction (XRD) studies to assess the nature of the drug both in formulation and in pure form. The patches were further subjected into various physical evaluation along with *In- vitro* drug release studies. **Results:** FTIR confirmed the compatibility between the nature of the drug and polymers, indicating no drug-excipient interaction. SEM analysis revealed the homogenous mixing of the components in the patches, ensuring uniform drug distribution. In-vitro drug diffusion studies using Franz diffusion cells demonstrated gradual and sustained drug release over a period of 180 minutes. The formulation exhibited a crystalline structure, as evidenced by X-ray diffraction (XRD) studies. **Conclusion:** The transdermal patch with ibuprofen and lemongrass oil enhances promising research for the treatment of rheumatoid arthritis. Hence the novel drug delivery system provides localized pain relief and reduce systemic side effects associated with oral NSAID administration.

GRAPHICAL ABSTRACT



*Author for Correspondence: devishree16@sriramachandra.edu.in

Keywords: Controlled Drug Delivery, Healthcare, Ibuprofen, Lemongrass, Rheumatoid arthritis, Transdermal patches.
How to cite this article: Akash R, Rajesh S, Raagavan SS, Benjamin J, Nandhini S, Rahman MWM, Yogashri D, Neha S, Prathiksha R, Shree BD. Formulation and in vitro evaluation of an herbal essential oil-infused ibuprofen transdermal patch for rheumatoid arthritis. Int J Drug Deliv Technol. 2026;16(75s): 780-788. DOI: 10.25258/ijddt.16.75s.93
Source of support: Nil.
Conflict of interest: Nil.

INTRODUCTION

The utilization of transdermal drug delivery systems (TDDS) represents a controlled method of delivering non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen. Such systems involve the use of transdermal patches through which the systematic delivery of medications can be achieved [1]. The key principle of TDDS involves the delivery of drugs for systemic effects; therefore, there will be no need for repeated dosing, and long-term therapeutic effects will be achieved. Main components of TDDS involve polymer matrix or drug reservoir, rate-controlling membrane, the drug itself, permeation enhancers, pressure sensitive adhesives (PSA), backing laminate, release liners, plasticizers and solvents. Stratum corneum that is rich in lipids serves as the main barrier that hinders the transdermal penetration of drugs [2]. All these components work in a synergic way to enable the drug release, skin permeation and desired therapeutic effect. Several advantages are associated with TDDS compared to other systemic delivery systems including the prolonged effect, reduced dosing frequency and improved patient compliance [3]. Moreover, TDDS involves less gastrointestinal adverse effects and first pass effect. Patients can even apply the drug by themselves while being able to cease drug input by removing the patch. Nevertheless, some disadvantages of TDDS include the possibility of developing allergic reaction at the application area (e.g. rash, itching and edema). Physical and chemical properties of the drug, particularly its size and hydrophilicity can limit the absorption of the drug [4].

Lemongrass (*Cymbopogon citratus*) essential oil is commonly used in traditional medicine and represents a substance that possesses anti-inflammatory, analgesic, antioxidant and antimicrobial activities. Citral, a major bioactive component of lemongrass oil, can inhibit COX-2 expression and activate PPARα and PPARγ; therefore, this substance is effective in treating inflammatory diseases including rheumatoid arthritis. Review of *Cymbopogon citratus* essential oil demonstrates the potential anti-inflammatory activity of this substance and suggests its use in skin-associated inflammatory conditions. In regard to the transdermal patch, the relevance of lemongrass oil lies not only in its pharmacological properties but also in its ability to complement the action of ibuprofen on pain and inflammation at the local level. Despite the fact that ibuprofen is a well-known NSAID, the oral intake of this medication is frequently associated with gastrointestinal side effects and first-pass effect; thus, TDDS can be considered as an alternative to oral ibuprofen [5,6].

Additional research on topical and dermatological properties of lemongrass oil has proved its anti-inflammatory properties. The use of lemongrass oil demonstrated its anti-inflammatory activity on pre-inflammatory human dermal fibroblasts, and it was shown to possess benefits in decreasing erythema, edema, and barrier damage through topical application in clinical studies. Altogether, these data validate the scientific rationale for using lemongrass oil as an herbal supplement in a transdermal ibuprofen system for rheumatic pain management [7].

MATERTIALS AND METHODS [8]

Solvent casting method:

Chloroform and ethanol were used as a solvent in 1:5 ratio and the drug (ibuprofen) were dissolved in it. To the above mixture HPMC, Ethyl cellulose, Di butyl phthalate was added and kept in a magnetic stirrer for 5-7 minutes. Accurately measured lemon grass oil gets infused to the above mixture and kept until a homogenous mixture is obtained without the formation of bubbles and the homogenous mixture was poured into a petri plate, allowed to dry for 24 hours and later the patch was carefully removed from the petri plate. The composition is mentioned in the table 1.

Composition of ibuprofen transdermal patch:

S.NO.	INGREDIENTS	QUANTITY
01.	Ibuprofen	1.1g
02.	HPMC	0.9g
03.	Ethyl cellulose	0.1g
04.	Lemongrass oil	0.5mL
05.	Dibutyl phthalate	0.001mL

PREFORMULATION STUDIES:

Construction of calibration curve:

About 10 mg of the drug (Ibuprofen) was precisely weighed and dissolved in a small amount of water and then sonicated for 10 minutes. The volume was made up to 100 mL by using pH 7.4 Buffer. This was taken as the stock solution. This solution was scanned using UV Spectrophotometer from 400-200m and the λmax was found to be 248 nm. From the stock solution, suitable dilutions were made to get

the concentration ranging from 2 to 10 µg/mL. After that, a calibration curve was plotted with the absorbance (nm) on the Y-axis and the concentration (µg/mL) on the X-axis. This solution was scanned using a UV Spectrophotometer from 248nm.

Compatibility Studies

Fourier Transform Infrared Spectroscopy (FTIR):

The chemical mixture of sample and excipients was analysed by attenuated total reflectance - FTIR (Bruker Alpha 2 FTIR) in the spectral region 4000 to 500 cm^{-1} wavelength with 4cm^{-1} resolution at a total scan of 64 scans per sample. It records spectral data with great resolution over a wide range of frequencies.

X-Ray Diffraction Studies (XRD):

The HPMC, Ethyl Cellulose, Ibuprofen, and their combination were characterized at 25°C using an XPERT-PRO diffractometer operating at 45 kV and 40 mA, featuring Cu-K (λ=1.54060 Å). Using a continuous scan mode with a step size of 0.0170 °2θ value and a scan speed of 1.0 min-1, data were gathered with a specimen length of 10 mm spanning an angular range of 10° to 90° at 2θ.

EVALUATION STUDIES FOR TRANSDERMAL PATCH:

Scanning Electron Microscopy (SEM):

The particle size of the formulation Lemongrass oil infused ibuprofen patch (With drug and Without drug) was viewed and photographed using scanning electron microscope (QUANTA 3D FE-SEM). It was moved to a cover slip that had a 20 x 20 mm diameter cut out of it, and it was fixed to an aluminium stub with carbon tape. The solution was gradually evaporated at room temperature. The image was captured using the SEM mode at appropriate magnification.

Thickness Test for Patch:

Transdermal patches are measured for thickness at three different points along the patch using a traveling microscope, dial gauge, screw gauge, micrometre, and calliper scale. Vernier calliper scale is used to measure the thickness of the patch and the measurement was done by choosing three different areas. The patch's thickness was determined by calculating the average of three values. The variation of thickness within the patch can be calculated.

Folding Endurance Test:

Folding endurance is calculated by repeatedly folding a patch in the same point until it breaks or folds up to 300 times. The durability of the patch during folding is determined by the number of times it can be folded without breaking. The flexibility of the patch is determined by folding endurance. After the study was completed, its results were reported.

Disintegration Test for Patches:

Prepared transdermal patch was cut into 2*2 cm^2 area. This was then soaked in the deionized water continuously by placing the patch on the wire gauze in a petri dish. The time required for disintegrate completely in water was recorded and reported.

***In-vitro* Drug Release:**

The Franz diffusion method was used to measure drug diffusion and permeability. The cellulose membrane was previously soaked in glycerol for 6-7 hours before being inserted between the Franz apparatus. Buffer pH 7.4 was filled with a bead and placed in a magnetic stirrer. A few pieces of the transdermal patch were cut and applied above the membrane. The drug release was monitored every 15 minutes using a UV spectrophotometer at 222nm.

RESULTS AND DISCUSSION:

Construction of calibration curve:

The concentration range of 0-100µg/mL with a slope value of **0.0713** and the correlation coefficient was found to be **R^2= 0.9988** Obey's *Beer's law* and Concentration *vs* absorbance Graph were plotted as mentioned in Fig 1.

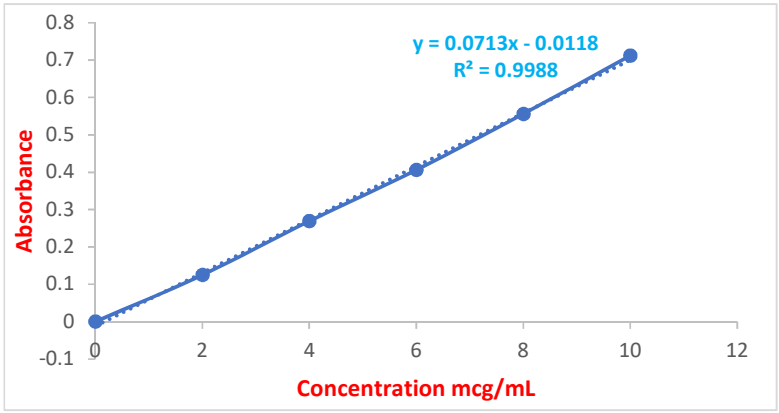


Fig 1: Calibration curve of Ibuprofen

Fourier Transform-Infrared Spectroscopy (FTIR):

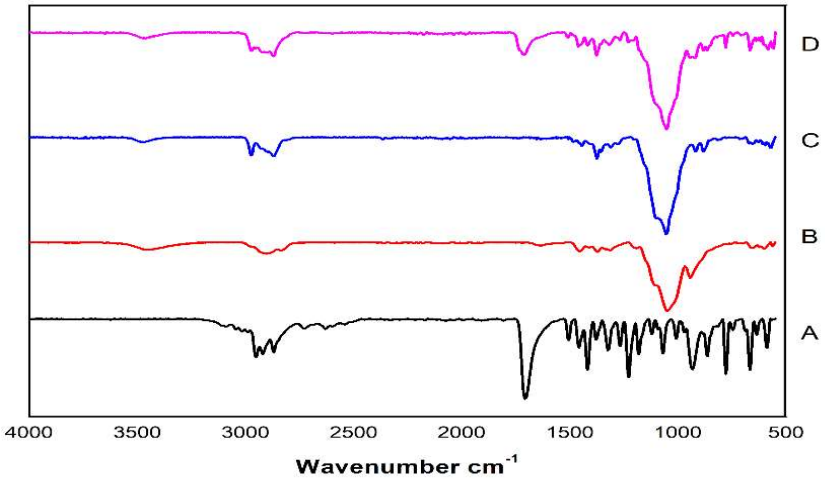


Fig 2: FTIR-spectrum

Fig 2 represents the FTIR spectrum of drug and polymer. A-Drug, B-HPMC, C-Ethyl cellulose, D-mixture
The FTIR spectra analysis suggests that the drug and the excipients (HPMC and Ethyl Cellulose) are compatible. The lack of chemical interactions, as evidenced by the absence of new peaks or significant shifts, indicates that the drug remains chemically stable in the formulation. Drug-infused transdermal patch showed there was no overlap of peaks between HPMC, EC, and Drug. It shows all major peaks corresponding to HPMC, EC, and Drug.

Scanning Electron Microscopy (SEM):
The SEM morphology of the Lemongrass oil-infused ibuprofen patch were shown in the figure 3 and 4.

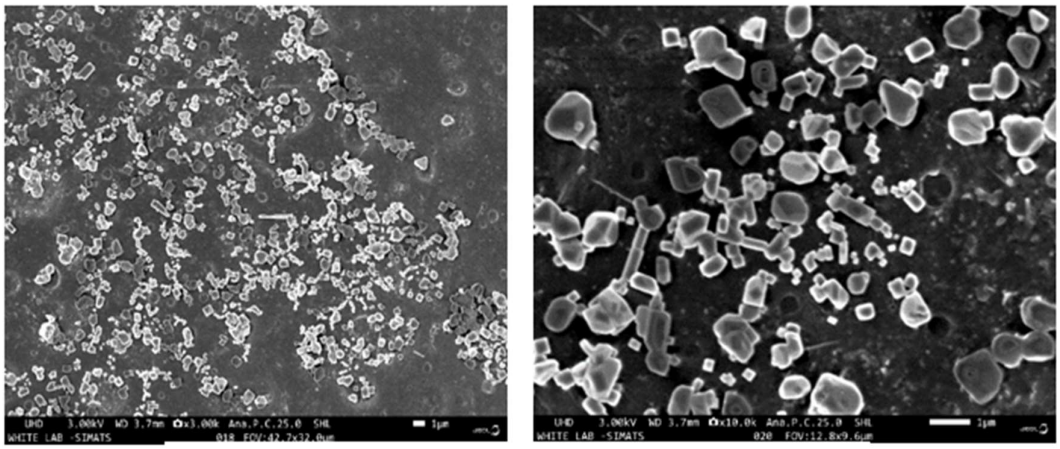


Fig 3: Transdermal placebo patch (without drug)

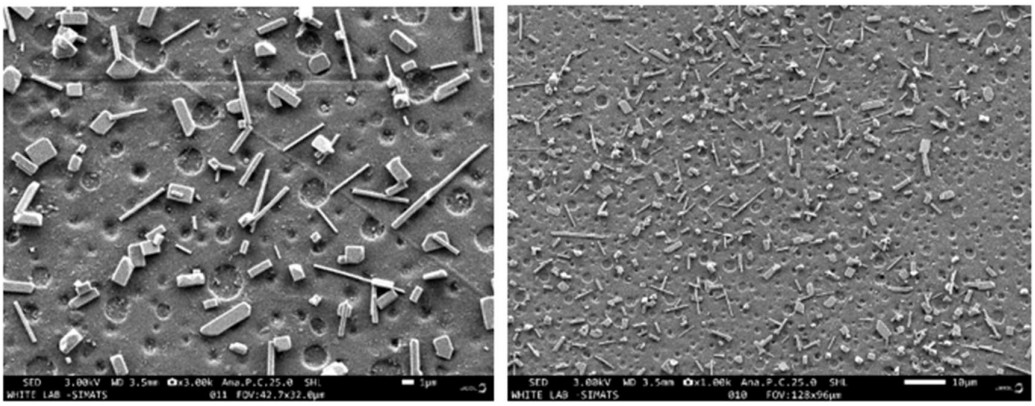


Fig 4: Transdermal patch with lemongrass oil infused drug

X-Ray Diffraction Studies (XRD):
X-ray diffraction studies of HPMC, Ethyl Cellulose, Ibuprofen and their combination were shown in Fig 5.

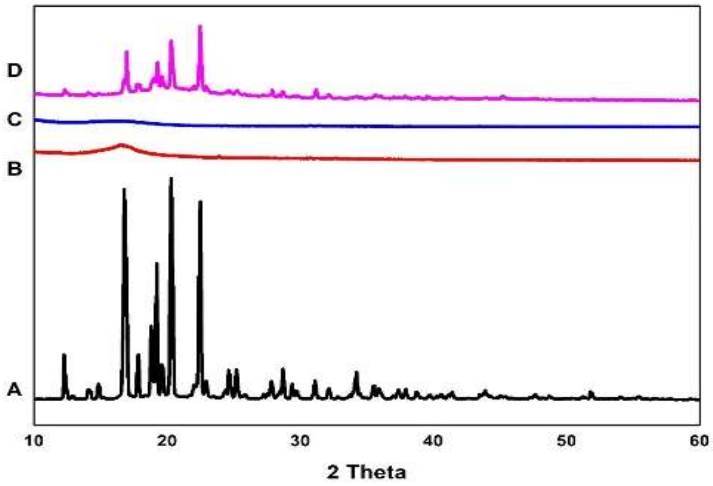


Fig 5: XRD Combined Graph

Here 4 peaks were noticed where the 1st one is the peak of A. Ibuprofen B. HPMC C. Ethyl cellulose and D. Mixture. No peaks due to impurity were observed, which proves the patch is highly pure and found to exhibit a crystalline structure. From all the above results, the formulated transdermal patch was found to exhibit a crystalline structure.

Patch Thickness:
The measured thickness values of the transdermal patches for each batch are as follows in table 2:

Table No.2: Thickness of the transdermal patches

Batch No.	Thickness (mm)
01.	0.20
02.	0.32
03.	0.41

The Thickness of the patch ranges from 0.20 mm to 0.45mm and fulfils the standard patchthickness limits 0.230 to 0.834 mm.

Folding Endurance:
The folding endurance of the transdermal patches was tested by folding repeatedly the patches at the same point until they broke or developed visible cracks. The results were mentioned in table 3.

Table No.3: Folding Endurance of the transdermal patches

Batch No.	No. of times folded
01.	20
02.	22
03	23

The Folding endurance value of patch ranges from 20-23 times. Overall, the results indicate that the transdermal patches have adequate mechanical properties, with sufficient flexibility.

Disintegration Test of the Patch:
The disintegration times of the transdermal patches from three batches are as follows in table 4.

Table No.4: Disintegration of the transdermal patches

Batch No.	Disintegration time
01.	12
02.	14
03.	12

The disintegration time of the patch was found to be 12 minutes suggests that the formulation process is consistent and reliable across different batches.

***In-vitro* Drug Release:**
The drug release from transdermal patch may be significantly, underestimated in non-sink environments since release experiments were carried out under sink conditions.
The drug release of transdermal patch formulation was performed it had a drug release of about 71.58% on 180 minutes. The release characteristics of the prepared formulation were studied and the respective graph was depicted in figure 6 and the release data was mentioned in table 5.

Table No.5: *In-vitro* Drug release

S. No.	Time (min)	Cumulative % drug diffused
1	5	3.571
2	10	6.895
3	15	9.476
4	30	16.56
5	45	25.34
6	60	31.23
7	90	42.31

8	120	53.25
9	180	71.58

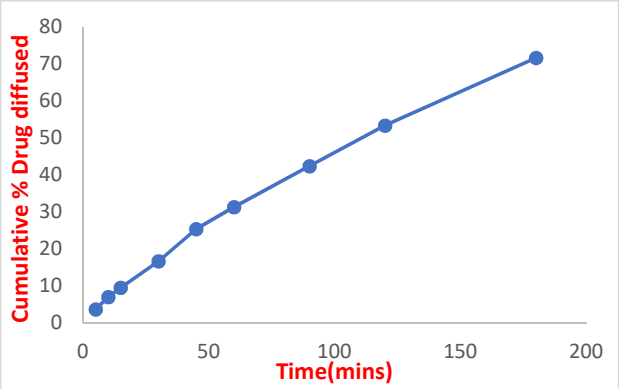


Fig 6: *In-vitro* Drug release graph

DISCUSSION

The present research describes the successful development of a transdermal ibuprofen patch containing lemongrass oil prepared using HPMC, ethyl cellulose, and dibutyl phthalate as key components. The compatibility tests confirmed that there were no chemical interactions of ibuprofen with the excipients. It is consistent with previous investigations on ibuprofen transdermal patches where compatibility was found to be an important property of polymer matrixes for drug preservation during patch preparation [9].

The results obtained with respect to the patch thickness, flexibility, and mechanical characteristics allow concluding that the formulation under consideration is suitable for transdermal administration. In previous studies, the effect of the choice of polymer matrix on the coating uniformity, adhesion, and handling characteristics of ibuprofen patches were examined; a favourable effect of cellulose-based matrixes on patch physical characteristics was also noted. In this regard, the obtained values of the patch thickness varying from 0.20 to 0.45 mm and folding endurance being 20–23 folds can be regarded as adequate for patch preparation. However, the flexibility of the present patch is rather low compared with those of optimized PSA systems [10].

In vitro release profile was characterized by a gradual diffusion of the drug within 180 min with the cumulative drug release being 71.58%. The *in vitro* release characteristics were indicative of a controlled release from the drug matrix. It is consistent with the *in vitro* drug release observed with the previously studied ibuprofen transdermal systems, where there was progressive release of the drug from either adhesive or polymeric matrixes, and permeation was more readily regulated by formulation technique rather than the drug itself. In contrast to highly developed adhesive formulations, with higher permeation rate of the drug in 24 hours, owing to their use of pressure-sensitive adhesives and permeation enhancers, this study seems to favor a shorter *in vitro* release window, which may be sufficient for topical application and requires optimization for the purpose of extended therapeutic effect [11].

A distinguishing feature of the current formulation is the inclusion of lemongrass oil. Essential oil of lemongrass was shown to have anti-inflammatory properties, and specifically, citral-containing lemongrass oil inhibits inflammatory processes mediated by COX-2. Additionally, previous cell culture experiments had shown anti-inflammatory properties of lemongrass oil in human dermal fibroblasts. Therefore, it is reasonable to combine lemongrass oil with ibuprofen in a transdermal system to be used for the treatment of local inflammation and pain. Thus, it provides a synergistic effect due to ibuprofen inhibition of prostaglandins and lemongrass oil anti-inflammatory properties [12].

Compared to previous studies with respect to topical ibuprofen delivery, the current patch demonstrates a more straightforward formulation but shows less optimization for maximum permeation compared to the previous work. The solvent-free ibuprofen patch, which was developed using pressure-sensitive adhesive, had great ibuprofen loading, stability, and enhancement of ibuprofen permeation through human skin, with permeation enhancers greatly increasing the permeation flux. On another study concerning ibuprofen modifications in a drug-in-adhesive type of formulation, permeation could be increased several times due to the changes in ibuprofen modifications. The chemistry of the formulation is very crucial in the process of skin permeation. In this context, the current patch loaded with herbal essential oil is an example of a formulation using an anti-inflammatory natural product; however, optimization of polymer ratios and permeation enhancer system will be needed to match the permeation of other adhesive formulations [13].

In summary, the findings suggest that the synthesized patch holds promise as a topical drug delivery device for the management of pain and inflammation in rheumatoid arthritis. The outcomes are consistent with the general

transdermal research body of knowledge, which shows that ibuprofen makes an ideal candidate for dermal delivery because of its physicochemical characteristics and anti-inflammatory effect, while lemongrass oil acts as a natural anti-inflammatory agent. Nevertheless, in view of past research on transdermal delivery of ibuprofen, it is necessary to conduct further in vivo testing, skin irritation tests, and adhesion/permeation optimization studies.

CONCLUSION

From the above discussion, it can be concluded that the developed transdermal patch with lemongrass oil incorporated into ibuprofen was developed by using hydroxypropyl methylcellulose (HPMC) as polymer, ethyl cellulose as polymer, dibutyl phthalate as plasticizer, and ethanol and chloroform as solvents. The evaluation of the transdermal patch included organoleptic testing, FTIR analysis, thickness measurement, SEM, folding endurance, disintegration time, and *in vitro* diffusion of the drug. FTIR analysis confirmed the presence of HPMC, Ethyl Cellulose, Ibuprofen, and the mixture. *In-vitro* diffusion utilizing Franz diffusion cells in phosphate buffer pH 7.4 medium for 180 minutes revealed 71.58% achieves Sustained drug release - Enhanced skin permeation and bioavailability- Reduced side effects and improved patient compliance- Significant anti-inflammatory and analgesic effects- Enhanced therapeutic efficacy with lemon grass oil infusion. These findings suggest that our transdermal patch is a promising alternative for rheumatoid arthritis treatment. Further studies can explore its long-term efficacy and potential applications in treating other inflammatory conditions. With adequate design and testing protocols in place, these drug delivery systems can provide a more convenient alternative to standard oral drugs.

SUMMARY

The present study successfully developed a transdermal ibuprofen patch incorporating lemongrass oil using HPMC, ethyl cellulose, and dibutyl phthalate as the principal formulation components. Compatibility studies confirmed the absence of significant interactions between ibuprofen and the selected excipients, indicating satisfactory formulation compatibility. The prepared patches exhibited acceptable physical and mechanical characteristics, with a thickness ranging from 0.20–0.45 mm and folding endurance of 20–23 folds, demonstrating adequate flexibility and handling properties for transdermal application. The *in vitro* drug-release study showed a gradual and controlled release of ibuprofen over 180 min, achieving 71.58% cumulative drug release. The incorporation of lemongrass oil provides an additional therapeutic advantage due to its reported anti-inflammatory activity, potentially complementing the cyclooxygenase-inhibitory action of ibuprofen. Overall, the findings demonstrate the feasibility of combining ibuprofen with a natural anti-inflammatory essential oil in a polymeric transdermal system for localized management of pain and inflammation.

DECLARATION

Ethics approval and consent to participate: Not applicable

Consent for publication: Not applicable

Availability of data and material:

All data generated or analyzed during this study are included in this manuscript.

Competing interests:

The authors declare that they have no competing interests

Declaration of generative AI scientific writing:

The author declares that they have not drafted the manuscript using AI.

Funding:

No funding was received from any Governmental or non-Governmental agencies for carrying out this work

Acknowledgements:

The authors thank the management of Sri Ramachandra Institute of Higher Education and Research, Chennai, India and Department of Pharmaceutics (DST-FIST Sponsored Department) for infrastructural facilities to carry out the research work and the Principal, Sri Ramachandra Faculty of Pharmacy, SRIHER (DU) for the constant motivation and encouragement.

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