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FORMULATION AND EVALUATION OF HERBAL TRANSDERMAL PATCH CONTAINING EXTRACT OF *OCIMUM TENUIFLORUM*

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ABSTRACT

The study on the formulation and evaluation of herbal transdermal patches containing *Ocimum tenuiflorum* extract highlights a significant advancement in the integration of natural remedies into modern drug delivery systems. Tulsi, a medicinal plant renowned for its anti-inflammatory, antimicrobial, and antioxidant properties, serves as the core therapeutic agent. In this study, a ethanolic extract of Tulsi leaves was prepared and incorporated the extract into a polymer matrix composed of suitable film forming agents such as HPMC and PVP along with plasticizers like glycerine or PEG to enhance flexibility and adhesion of the transdermal patch. The transdermal patches were developed using the solvent casting method and subjected to comprehensive physicochemical evaluations including thickness , weight variation , folding endurance , moisture content and weight uniformity .This study highlights the successful integration of a traditional herbal remedy into modern transdermal drug delivery system , paving the way for non-invasive, eco-friendly alternatives to conventional treatments which can be particularly beneficial for patients seeking holistic and sustainable approaches to health and wellness . The use of Tulsi in transdermal patches underscores its potential in enhancing holistic healthcare through innovative application. As a natural remedy with long history of use in traditional medicine Tulsi offers a promising avenue for developing novel therapeutic agents that are both effective and environmentally friendly

KEYWORDS: *Ocimum tenuiflorum*, Herbal transdermal patch, Modern drug delivery, Polymer matrix, Holistic healthcare, non-invasive treatment, Eco- friendly alternatives.

INTRODUCTION

Holy basil is an important symbol of the Hindu religious tradition. Although the word 'Tulsi' gives the connotation of the incomparable one, its other name, Vishnupriya means the one that pleases Lord Vishnu. Tulsi is found in most of the Indian homes and worshipped, its legend has permeated Indian ethos down the ages. in English Tulsi is known as Holy Basil, in Hindi we called Tulsi and botanically called Ocimum tenuiflorum, which belongs to family *Lamiaceae* Tulsi has given important contribution to the field of science from ancient times to modern research due to its large number of medicinal properties.[1]

Ocimum tenuiflorum L. (also known as Tulsi) has been used for millennium in Ayurveda for its diverse healing properties. Tulsi, the Queen of herbs, the legendary 'Incomparable one' of India, is one of the religious and most cherished of the many healing and healthy giving herbs of the orient. The holy basil, Tulsi, is renowned for its religious and spiritual sanctity, as well as for its important role in the traditional Ayurvedic and Unani system of holistic health and herbal medicine of the East. Charaka has mentioned this in the ayurvedic book named as Charaka Samhita. Tulsi is considered to be an adaptogen, balancing different processes in the body, and helpful for adapting to stress. Due to its strong aroma and astringent taste, it is regarded in Ayurveda as a kind of 'elixir of life' and believed to promote longevity. Extracts of Tulsi are used in Ayurvedic remedies for common colds, headaches, gastrointestinal diseases , inflammation, cardiovascular disease, and various forms of poisoning .Traditionally, *O. tenuiflorum* L. is taken in many forms, as herbal tea, dried power or fresh leaf. For centuries, the dried leaves of Tulsi have been mixed with stored grains to repel insects.[2]

From literature, it is known that Tulsi has been utilized therapeutically since 400-500 BC. Earliest references of Tulsi were found in Rigveda (3500-1600 BC). Therapeutically it is used in anticancer, anti-oxidant, anti-diabetic, radiations, infertility and for many other major and minor diseases. Being adaptogenic, Tulsi is used to improve health. Extract of Tulsi is used in ayurvedic treatments for common cold, heart diseases, and stomach disorders, poisoning cases, convulsions, epilepsy, malaria, fever, bronchitis and certain inflammatory problems. Therefore, extract of Tulsi is also known as "Extract of Life" and considered to grant longevity.[3]

Plant profile

Ocimum belongs to family Labiateae and O. tenuiflorum is very important for their therapeutic potentials. Ocimum tenuiflorum L. (Labiatae) is a strongly scented small annual herb, up to 18 inches tall, grows into a low bush and is commonly known as holy basil.[4]

Fig. 1: Tulsi leaves.

Fig. 2: Tulsi powder.

Varieties of Tulsi

Various types of Tulsi which cultivated in different parts of the World, they are categorized in 2 groups.[5]

A. Holy basil: It is known as Tulsi and is the most revered houseplant, in India it is associated with ayurveda and hindu religion as goddess of wealth, health and prosperity. This is further classified into 4 species

- O. sanctum (Rama-tulsi)
- O. tenuiflorum (Krishna-tulsi)
- O. tenuiflorum (Amrita-tulsi)
- O. gratissum (Vana-tulsi)

B. Mediterranean Basil : It is known as Sweet basil and is the most popular variety of basil which is found all over the world including Asia, Europe , America and Africa. It is most consumed herb worldwide and characterized in several further types**:**

- Sweet basil (O. basilicum)
- Thai basil (O. thyrsiflora)
- Purple basil (O. basilicum)
- Lemon basil (O. citriodorum)
- Vietnamese basil (O. cinnamon)
- American basil (O. americanum)
- African blue basil (O. kilimandscharicum)
- Italian genovese basil (O. basilicum**)**

Medicinal properties[5]

- Tulsi has antioxidant properties and reduces blood glucose levels, and blood pressure.
- It reduces lipid level. So, it is good for heart disorders
- It builds the stamina and it is essential ingredient of herbal tea .
- It also used to treat gastric disorders, cough, common colds, malaria, and headaches
- It's extracted water is used as mouth wash to reduce tooth ache.
- It is used in the manufacturing of many skin ointments and cosmetics because it contains anti-bacterial activities.
- A chemical present in tulsi known as beta-Ursolic acid, may used as a anti-fertility agent in future**.**

TRANSDERMAL PATCH

A transdermal patch is defined as adhesive medicated patch that is placed on to the above skin to deliver an exact dose of drug through the skin into the bloodstream with a predetermined rate of release to reach in the body. Today the most common transdermal system present in the market mainly based on semi permeable membranes which were called as patches. Transdermal drug delivery systems (TDDS), also known as "Transdermal patches" or "Skin patches" are dosage forms designed to deliver a therapeutically effective amount of drug across a patient's skin and in the bloodstream.[6]

ADVANTAGES OF TRANSDERMAL PATCHES [7]

1. It offers constant permeation of drugs through the skin giving constant serum drug level, the goal of therapy.
2. Like intravenous infusion, it also gives constant plasma level.
3. If toxicity develops from TDDS, patch can be removed easily.
4. It is very convenience as application of drug is very easy.
5. It eliminates first pass mechanism.

Mechanism of Action of Transdermal Patches

The function of the transdermal patch and the flow of the active drug ingredient from the patch to the circulatory system via skin transpire through different methods. For a systemically active drug to reach a target tissue, it has to take some physicochemical properties which make easy the sorption of the drug through the skin and enter the microcirculation.[8]

TYPES OF TRANSDERMAL PATHCES[9]

Single layer drug-in-Adhesive Patches: In this system, the drug is remains in contact with the adhesive layer which is attached to the skin. In the layer of adhesive helps to releasing the drug and also serve to adhere to the various layers together along with the skin.

Multi-layer drug-in-Adhesive Patches: The multi layer drug in adhesive is similar to the single layer drug in adhesive which involves the drug introduction directly into the adhesive layer. In this system one of the layers is immediate to release the drug from the reservoir. This patch also has a permanent backing and temporary liner layer.

Reservoir type patches: The reservoir transdermal system has a separate drug layer unlike the single layer drug-in-adhesive and multilayer-drug-in-adhesive system. In this system, it includes a compartment for liquid that contains a solution or suspension of drugs separated from the liner by a membrane and adhesive. This patch system is also backed by the backing layer. In the reservoir system the rate of release is zero order.

Matrix type patches: The matrix system consist a medicament layer of a semisolid matrix that contains a drug as a solution or suspension; that is direct contact with the liner layer. In this device the adhesive layer surrounds the drug layer partially overlaying it.

Vapour patches: In this type of patch system the adhesive layer not only serves to adhere the various layers together but also releases vapour. These patches are new to the market, and commonly used for releasing of essential oils for up to 6 hrs. These patches release of essential oils and are used in cases of decongestion mainly. Many types of vapour patches are available in the market which are used to improve the quantity of sleep and reduces the cigarette smoking condition

MATERIAL AND METHOD

Plant collection: The leaves of Tulsi were collected from the home garden. The fresh Tulsi leaves were selected from a mature plants. Leaves are harvested by hand. Tulsi leaves are than washed and shade drying method is used to dry the leaves.

Authentication of plant

Authentication no. 2552/Dis./2018/Syst. Bot./Rev.Gen.4-5

The plant sample is authenticated from systematic botany discipline, Forest botany division ICFRE-Forest Research Institute, Dehradun.

Extraction process by Soxhlet apparatus: 26.0g of the coarsely powder was placed inside a thimble already attached with the chromatographic paper. Add 350 ml ethanol for extraction and poured into the round bottom flask of Soxhlet apparatus. The temperature should be maintained at 70°C throughout the process. The complete process took

approximately 30 hours to finish till the clearance of colour extract. The residue of maceration extract and filtrate of maceration have been separated and being kept inside the cabinet to further screening. The 25ml of filtrate was poured into China dish which was further evaporator at 70°C on water bath and extract was dried on desiccator.[10]

Fig. 3: Extraction process by Soxhlet apparatus.

Phytochemical screening

Phytochemical screening of Ocimum sanctum (Tulsi) ethanolic extract for the presence of alkaloids, flavonoids, saponins, glycosides, phenolic compounds, tannins, and proteins was performed.[11]

Table 1: Test for phytochemical screening.

S.No	Test for	Methodology	Observation (For presence)
1.	Alkaloids	1ml extract +1ml Wagner's reagent	Reddish brown ppt formed
2.	Glycosides	1ml extract +picric acid	Yellow colour appears
3.	Phenols	1ml extract +4drops of ferric chloride	Blackish colour
4.	Saponins	5ml extract shaken vigorously	Foamy layer formed
5.	Tannins	5ml extract +few drops of ferric chloride (1%)	Green colour ppt formed
6.	Steroids	2ml extract +2ml chloroform +2ml sulphuric acid. Shake well	Chloroform layer appears red and acid layer appears green in colour.

Patch formulation

Solvent Evaporation method

Preparation of backing membrane

The 4 gm HPMC is dissolve in 100 ml of distilled water to put together 4% of polymeric solution with continuous stirring on magnetic stirring. After that 4% polymeric solution is pour in four open glass mould at equal quantity and switch in hot air oven at 60 C for six hrs Before pouring of polymeric solution in glass mould a few drops of glycerine is pour in glass mould.[12]

Preparation of casting solution

Casting solution is prepared by means of the using suitable solvent (ethanol), methyl cellulose, polymer (polyvinyl pyrrolidone) and plasticizer (polyethylene glycol) is introduced slowly-slowly with continuous stirring. The selected drug is also introduced slowly with non-stop stirring of casting solution up to 45 min. The dried backing membrane glass Petridis is eliminated from hot air oven after overnight.

The formulated casting solution pour into open glass include dried backing membrane and transfer into hot air oven at 60 C for six hrs. After the complete drying of transdermal film the dried film is eliminated from glass mould.[12]

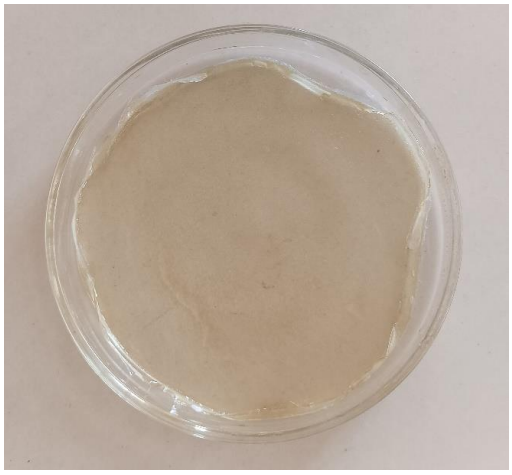


Fig 4: Prepared transdermal patch.

Fig 5: Peeling of prepared transdermal patch.

Evaluation of patch

1. Physical appearance

The colour, clarity and smoothness of the formulated patch were examined.[13]

2. Moisture content

The formulated films were weighed separately and stored in a desiccator containing calcium carbonate at room temperature for 24 hours. The films have been weighed repeatedly after defined interval until it showed a sustained weighed.

The moisture content was calculated by using the formula:[13]

$$Moisture\ content = \frac{Initial\ weight - final\ weight}{Initial\ weight} \times 100$$

3. Thickness of patch

The patch thickness tester (vernier calliper) is used to measure the thickness separately for each of the four patch formulations to check the thickness of the patch. Measurements are taken at 3 different position for each patch.[13]

4. Folding endurance

The patch is again and again folded the same manner for the folding resistance until broken. Then, the number of folds is considered the value of the resistance to the folding of a patch.[13]

5. Weight Uniformity

The formed patches were dried at 60C for 4hrs. The specified area of patch were cut in different parts of the patch and weighed on digital balance. The average weight were calculated.[14]

RESULTS AND DISCUSSION

1. Extractive value: The extractive value of *Ocimum sanctum* (Tulsi) was found to be 3.67 %.

Fig. 6: Obtained extract.

2. Phytochemical screening: the extract shows the presence of cardiac glycoside, saponin, tannins, steroids and polyphenols whereas alkaloids and saponins were absent as shown in table 2.

Table 2: Phytochemical screening result.

S.no	Test for	Observation
1.	Alkaloids	+
2.	Cardiac glycosides	++
3.	Saponin	-
4.	Steroids	++
5.	Tannins	++
6.	Polyphenols	++

(where + means moderately present, ++ actively present, (-) absent)

3. Organoleptic properties: The prepared patches were translucent, light green coloured, congealed preparation showing great flexibility as given in table 23.

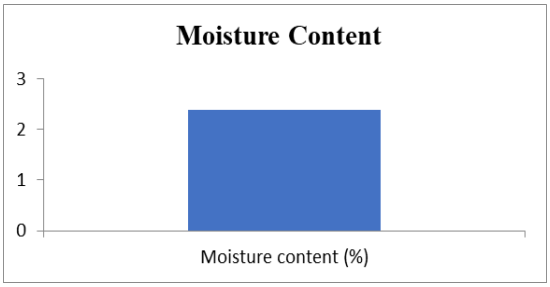
Table 3: Organoleptic properties of the prepared patches.

S.no	Physical characteristic	Result
1.	Appearance	Congealed preparation
2.	Colour	Light green
3.	Clarity	Translucent
4.	Flexibility	Great

4. Moisture content: The average moisture content of prepared patches was 2.39% as given in table 4.

Table 4: Moisture content of the prepared patches.

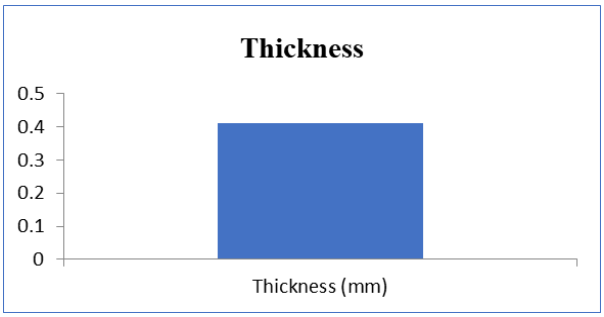
S.no	Moisture content (%)
1.	2.40
2.	2.39
3.	2.41
4.	2.39
Average	2.39



5. Thickness of patch: the average thickness of the prepared patches was 0.411mm as given in table 5.

Table 5: Thickness of the patches.

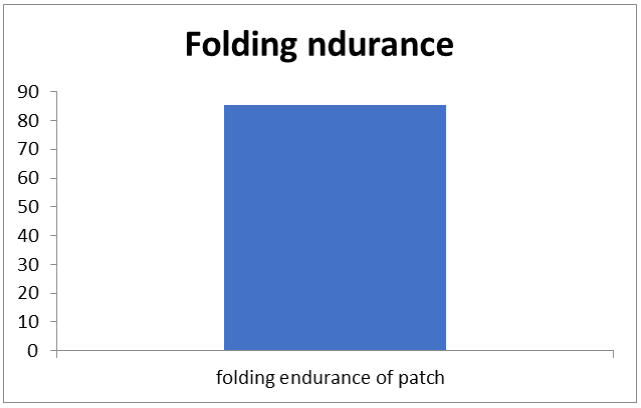
S.no	Thickness (mm)
1.	0.410
2.	0.412
3.	0.410
4.	0.415
Average	0.411



6. Folding endurance: the average folding endurance of prepared patches was 85.25 as given in table Table 6

Table 6: Folding endurance of patch.

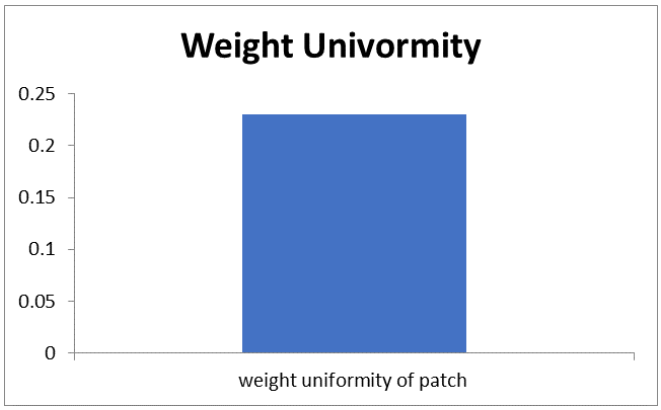
S.no	Folding endurance
1.	79
2.	85
3.	87
4.	90
Average	85.25



7. Weight uniformity: the average weight of prepared patches was 0.230 gm as given in table.

Table 7: Weight uniformity of patch.

S.no	Weight (gm)
1.	0.230
2.	0.232
3.	0.230
4.	0.229
Average	0.230



CONCLUSION

Transdermal patches of *Ocimum tenuiflorum* (Tulsi) were successfully prepared by using polymer matrix composed of HPMC and PVP along with plasticizers like PEG to enhance flexibility and adhesion. The transdermal patches of Tulsi were prepared by solvent evaporation method and evaluated for different parameters. This study focuses on patch formation and were evaluated for various physicochemical parameters to assess their suitability for drug delivery The physical appearance, thickness of patches, moisture content, folding endurance, and weight uniformity of the patches were evaluated which shows the satisfactory results. This research highlights that Tulsi may be incorporated into the transdermal drug delivery system the formulated patches demonstrated promising physical and mechanical properties , supporting their potential use as a convenient and efficient route for herbal drug administration .Therefore there is a scope for further pharmacokinetic and pharmacodynamic studies to fully establish the therapeutic effectiveness and safety of Tulsi when delivered trans dermally.

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