Formulation and evaluation of transdermal patch containing Marigold oil

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***Abstract*—Transdermal drug delivery systems are becoming more popular in the field of modern pharmaceutics: medication patches, controlled & sustained release, improved patient compliance, avoid first pass metabolism, reduce gastro intestinal issue, and easy to use & remove. The present study was carried out to develop matrix type transdermal patches containing marigold oil with different ratio of HPMC & EC by solvent costing method. Marigold oil was included as the active ingredient due to its anti-inflammatory property; these transdermal patches were successfully prepared by solvent costing method. Marigold refers to a group of flowering plants in the tagetes and Calendula officinalis; known for their bright yellow, orange and gold flowers. They are widely cultivated for their beauty & medicinal plants Marigold oil has healing and antiseptic properties and analgesic, anti-inflammatory property. The marigold oil was extracted using water as a solvent and Clevenger apparatus was used. The marigold oil loaded patches were evaluated for physicochemical parameters like: weight variation, thickness, moisture uptake, moisture content, folding endurance and drugs content value. It was observed that our results strongly indicated that the marigold oil containing transdermal patches loaded with marigold flower extract was a promising anti-inflammatory property.**

***Index Terms*—Marigold oil, Anti-Inflammatory, Patch.**

I. INTRODUCTION

Generally, Transdermal patches are referring to topical application who delivers the medicament to the healthy intact skin either for localized treatment of tissues underlying the skin or for systemic treatment. It offers many advantages over the conventional dosage forms or controlled release oral systems. It avoids first pass metabolism, increased patient compliance, avoids dose dumping and also provides constant blood levels (Goyal A, 2011). Their application is including wider range of drugs that is limited due to the significant barrier to penetration across the skin which is exist at the outermost stratum corneum layer of the epidermis. There formulation can be classified into two categories according to the target site of the action. One has systemic action after administration of patch and other shows local effects in the skin. In the case of patch, drug penetrates the skin, subcutaneous fatty tissue, and muscle in amounts sufficient to exert local therapeutic effects. Side effects like stomach bleedings, increased acidity, ulcer etc. are avoided by transdermal patches .

Calendula (Calendula officinalis L.) is in the order Asterales and belongs to the family Asteraceae; the genus name Calendula is received from the Latin word Calendae, which means ‘first day of each month’. The genus has 29 species (Missouri Botanical Garden, including Calendula officinalis L., which is cultivated as herbaceous, ornamental, medicinal and cosmetic purposes. These are origin from region of the Mediterranean Sea, and the plant is currently cosmopolitan and cultivated in many countries, Calendula is used for cosmetic purposes for manufacturing of moisturizing creams and for both pre- and post-sun exposure due to the presence of saponins, gums, mucilages and have large wetting abilities. Additionally, calendula has healing and antiseptic properties with actions that are sudorific gland analgesic, affect the bile duct, anti-inflammatory, antiviral, anti-emetic, and tone the skin with vasodilatation .

Plant Profile:

Tagetes erecta is stout, branching herb, native to Mexico and other warmer parts of America and neutralized elsewhere in the tropics and subtropics including India and Bangladesh.

Kingdom: Plantae
Order: Asterales
Family: Asteraceae
Subfamily: Asteroideae
Class: Magnoliopsida
Division: Magnoliophyta
Genus: Tagetes
Species: Erecta

Figure 1: Marigold

Vernacular Name:

Table 1: Vernacular Name of Marigold

Language	Name	Language	Name
Marathi	Zendu	Sanskrit	Sandu
Hindi	Genda	Punjabi	Tangla
Bengali	Genda	Malayalam	Chendumalli
Gujarati	Guliharo	Telugu	Bantichettu
Manipuri	Sanarei	Urdu	Genda
Konkani	Gondiphool	Kannada	Chenna Mallige

Cultivation And Economical Value:

The botanical name of “Marigold Flower” is Tagetes erecta. Flowers are eatable and also used as coloring agent and spices. It is used as substitute for saffron as a yellow dye for coloring and flavoring foods. They grow up to 50-80 cm in height, the leaves mid-green, shape as lanceolate and between 5 and 17 cm in length. There leaves and stems are covered with small hairs. It is cultivated extensively in Asia, India, China, and other countries with a tropical climate. For proper growth of marigold plant requires temperatures between 20°C and 30°C and a considerable amount of annual winter and rainfall to thrive. India consumes about 80% of its own Production. The quality of Indian marigold is considered as the best quality in the world. India exports marigold flower to discrete countries like Japan, Sri Lanka, Iran, North African countries, US and UK. In India, The production of marigold is concentrated in the southern part of the country, mainly in Andhra Pradesh, Tamil Nadu, Uttar Pradesh is the leading marigold producing state and the most important trading center for marigold. Tagetes erecta is the main species of commerce and distributed its flower in India, China and also in Shri Lanka, Indonesia, Jamaica and Peru. Erode. The specific time for cultivation and harvesting of marigold is given in Table 2(Majumder J, 2014) (Singh Yogendra, 2020).

Table 2: The optimum time for cultivation and harvesting of marigold

Season	Sowing time	Transplanting time	Harvesting time
Rainy	June-July	July-Aug	September-October, even up to December
Winter	September-October	October-November	November-December
Summer	January	February	March-April

Transdermal drug delivery systems:

Transdermal drug delivery systems are also known as rate-controlled drug delivery systems which is delivers a specific medication dose through the skin into our blood circulation that promotes demulcent on injured areas of the body. The primary objective of designing transdermal dosage is to improve the rate through the skin into bloodstream and simultaneously reduce the retention of drug and their metabolism in the skin. This dosage form does not affect to the gastrointestinal tract so there is no loss due to first pass metabolism. The medicament can be delivered without interfering with pH, enzymes and intestinal bacteria. This dosage form contains penetration enhancers that improve the permeation of medicament across the skin. TDDS gives more benefits over injectables and oral routes due to non-invasiveness, improved patient compliance.

Polymers are used during skin preparations, marking on the basis of transdermal drug delivery systems. The surface and bulk characteristics of that polymer can

give the desired interfacial, mechanical, chemical and biological function. Hydrophilicity, lubricity, smoothness and surface energy are surface property which is directs with biocompatibility with tissues and blood. There physical properties like durability, permeability and degradability. The polymer's choice and their physicochemical properties depend on the need for extensive biochemical characterization and specific preclinical tests for improving their safety .

Mechanism of Transdermal drug delivery system

Transdermal permeation of a drug moiety involves the following steps:

1. Sorption by stratum corneum
2. Permeation of drug through viable epidermis
3. Uptake of the drug moiety by the capillary network in the dermal papillary layer.
4. The drug must possess some physicochemical properties to reach target site via systemically through stratum corneum. The rate of permeation of drug moiety across the skin is governed by following equation:

$$dQ/dT = ps\ (Cd - Cr)$$

Where, Cd= concentration of penetrate in the donor phase (on the surface of skin);

Cr= concentration of penetrate in the receptor phase (body); and Ps is the overall permeability coefficient of the skin which is defined as

$$Ps = ksDss / hs$$

Where, K = Partition coefficient of the penetrant;

Dss = Apparent diffusivity of penetrant;

hs= Thickness of skin.

Main Ingredients Used for the Preparation of Transdermal Drug Delivery System

Liners- It provides the protection of patches during storage and the liner should be removed previous to use.

Adhesive- It served adhere the components of the patch together along with adhering the patch to skin.

Membrane- Its controls the drug releases from the multi-layer patches. It's also known as the permeation enhancer.

Drug- Drug reservoir is direct contact with release liner.

Backing- protects the patches from outer environment.

II. LITERATURE REVIEW

Mule et al. (2024), Extract can be made from every part of plant and this plant is a potential herbal drug known for its efficacy and safety and a natural source for development of future drugs with expectation of innovative drugs.

Savula et al. (2017), Different matrix type patches were prepared by varying polymer combination and polymer ratio.

Singh et al. (2020) The Tagetes erecta is an important medicinal plant with the diverse pharmacological spectrum and medicinally phytoconstituents.

III. MATERIAL AND METHODOLOGY

Collection and authentication:

Fresh and mature flower of marigold was collected from Chiraiyakot Mau Uttar Pradesh, India. The plant was further identified and authenticated from the department of botany, BHU Banaras, India by a voucher specimen.

Preparation of plant material:

The fresh Flower of marigold is collected from Pharmacy College Azamgarh. Then wash the flower with tap water and shade dry at room temperature for 4 to 5 weeks then dried flowers are grinding by mechanically and flowers are converted in the powder sample.

Method of extraction:

The minimum amount of dry floral material was required 7 gm for oil extraction was established through this technique, by means of a Clevenger system. The plant material was placed inside a round bottom flask with 25 ml distilled water and then boiled for 3 hr. After this time, the recovered emulsion of oil and water was extracted by using dichloromethane (3 × 15 mL), and then concentrated in under vacuum at 30 °C for evaporating the solvent as such as possible. The oil remaining in the flask was transferred to a 1.5 mL vial with a Pasteur pipette

IV. PHYSICOCHEMICAL ANALYSIS

Thin-layer chromatography:

TLC plates like 20 × 20 cm and pre coated with microcrystalline cellulose (Camag, Muttanez,

Switzerland). A volume of 1 µL of 1% extracts was spotted on the plates. One-dimensional TLC analysis was performed with some solvent like ethyl acetate: formic acid: acetic acid: water in volume ratio 100:11:11:26 as mobile phase. The mobile phase was two-dimensional . TLC analysis was observed in my plant -

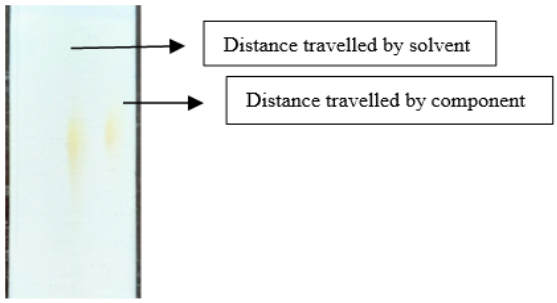

Figure 2 TLC Plate

Ash Value Determination (Mount cento furnace):
To calculate the total ash value of plant leaf dry powder, begin by precisely weighing 2-3 gram of the sample. Place the sample in a pre-weighed crucible and progressively incinerate in a muffle furnace at 500-600°C until it becomes white, indicating that all carbon has been removed. After cremation, cool the crucible in a desiccator to avoid moisture absorption. After cooling, weigh the crucible containing the ash. The total ash value is then computed using the following formula:
%ASH = [(ashed wt.) – (crucible wt.) \(crucible and sample wt.) – (crucible wt.)]× 100

Chemical test of marigold -

1. Test for alkaloids -
- Dragendorff's test: To 2-3 ml of filtrate, and few drops Dragendorff's reagent orange brown precipitate is formed.
2. Test for tannis & phenolic compound- lead acetate solution.
3. Test for Protein - 3 ml sample with 4 % NaOH and 1% CuSO4 pink color.
4. Test for steroids
- Solkowski reaction: Two ml of extract, add 2 ml of chloroform and 2 ml of concentrated H2SO4 shake well chloroform layer appears red and acid layer show greenish yellow flurosense.
5. Test for Glycosides -
- Modified Borntrager's test for C- Glycosides - To 5ml extract, add 5ml, 5% fecl3 and 5ml dilute HCL heat for 5 min in boil water bath. Cool and add benzene or any organic layer. Add equal valume dilute ammonia. Ammoniacal layer shows pink red color.
6. Test for monosaccharides-
- Barfoed's test - Mix equal volume of Barfoed's reagent and test solution, heat for 1-2 min in boiling water bath and cool, red precipitate is observed.

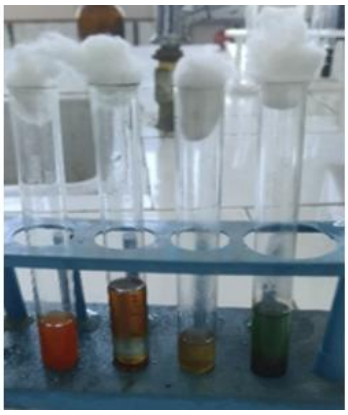

Figure 3 Chemical test

V. METHOD OF PREPARATION OF PATCH

The patches were prepared by using solvent evaporation method. Take 2 gm of PVA and 2 gm of PVP were mixed in 20 ml of distilled water over a hot water bath until dissolved. Then cooled down that mixture and added root extract about 0.5 ml, propylene glycol (0.5 ml), glycerol (0.5 ml) and mixed together with using mechanical stirrer at 800 rpm for 15 minutes under occluded condition. Then poured that mixture into a glass petri dish and dried in by placing funnel over it for 24 hrs. The films were removed by using blade by inserting along the edge of the film .

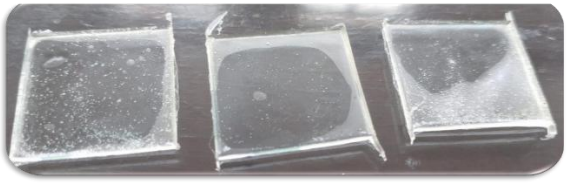

Figure 4: Patch formulation

Evaluation of transdermal patch:
1. Organoleptic Characteristics –
The physical appearance of developed patch was evaluated by using a naked-eye examination for its appearance, colour, clarity, flexibility, and smoothness.

2. Physicochemical Evaluation

A. Thickness of Patch – A Vernier caliper was used to measure patch thickness uniformity at 3 different places.

B. Determination of Surface pH –The pH of the patch is evaluated by swelling it with 1 ml of distilled water for two hours at room temperature before use. Then place the pH electrode on the surface of patch to record the pH value and make them to adjust itself for few minutes.

C. Folding endurance - Folding endurance is the number of times the patches can be folded in the same area without breaking.

D. Uniformity of weight - Each of the three patches were weighted for each batch, and the mean weight were determined .

E. Percent elongation test – It was determined from the below mentioned formula.

Elongation percentage = $\{ (L_1 - L_2) / L_2 \} \times 100$

VI. RESULT AND DISCUSSION

Fluorescence Test:

Table 3 Observation table of Fluorescence test

Sr. No.	Chemical name	Long UV	Short UV	Visible
1	Sample + Chloroform	Black	Pale Yellow	Orange
2	Sample + 1N NaOH	Black	Pale Yellow	Orange
3	Sample + Ammonia solution	Brown	Pale Yellow	Orange
4	Sample + Benzene	Black	Dark Green	Orange
5	Sample + Ethyl acetate	Black	Brown	Orange
6	Sample + Paraffin	Black	Light green	Orange
7	Sample + Glycerin	Black	Light Orange	Orange
8	Sample + Methanol	Black	Green	Orange
9	Sample + Hydrochloric acid	Black	Light green	Orange
10	Sample + Water	Black	Light green	Orange
11	Sample + Petroleum ether	Dark Brown	Yellow	Orange

Phytochemical test

Table 4: Observation table of Phytochemical test

Sr. No.	Test for	Result
1	Alkaloid	+
2	Protein	+
3	Staroid	+
4	Anthraquinone Glycoside	+
5	Reducing Sugar	+
6	Phenolic compound	-
7	Tannin	-

Evaluation of powder of marigold:

Table 5: Observation table for evaluation of powder of Marigold

Sr. No.	Test for	Result
1	Percent Ash	7%
2	Rf Value	0.533

Formulation of Patch:

Table 6: Observation table of patch formulation

S. No.	Ingredients	Amount
1.	Polyvinyl Pyrrolidone	2 gm
2.	Polyvinyl Alcohol	2 gm
3.	Propylethylene glycol 400	1 ml
4.	Glycerol	1 ml
5.	Distilled water	20 ml

Evaluation of patch:

Table 7: Observation table of patch evaluation

S. No.	Characteristics	Result
Organoleptic Characteristics	Appearance	Transparent
	Flexibility	Good
	Texture	Smooth
	Shape	Rectangular
	Size	2cm
	Smell	No smell

S. No.	Ingredients	Amount
1.	Thickness	0.1cm
2.	Surface pH	7
3.	Folding endurance	Good
4.	Uniformity of wt.	0.15gm
5.	Percent elongation test	175cm

VII. DISCUSSION

The extraction of marigold was happened by Clevenger method of extraction and the transdermal patch of marigold was formulated successfully. The various parameters were evaluated like thickness, weight uniformity, folding endurance, percentage of moisture content, we can conclude that all formulations show better properties such as thickness,

weight uniformity, folding endurance, percentage of elongation test of patch.

VIII. CONCLUSION

The transdermal patch of marigold was formulated successfully by using polymer, plasticizer etc. by solvent casting method. As increase in the concentration of polymer increase the thickness of marigold. Percentage of moisture uptake reduced with enhances concentration of polymer. This study is giving an idea to formulate the patch of marigold through the polymer and innovation in the field of marigold genus.

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