

## A Review on: Herbal Thin Film Forming Solution

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### ABSTRACT:

The strength of any Partial formulation deepens effective level. This limitation can be overcome by development of enhanced bioavailability and better stability of phyto constituents the better therapeutic effect. Several novel herbal delivery systems have been successfully developed. Topical film forming system is novel approach for treatment of skin diseases give both topical and transdermal treatment, FFS is defined a non-solid doses form which produces film in situ i.e., on the evaporation of vehicle excipients in the formulations form film on skin. Skin is considered as an important route of administration of drugs for both local and systemic effects. Drug delivery through the skin is crucial for local and systemic effects. Drug delivery methods known as "topical film forming systems" are administered topically, adhere to the body, and create a delicate transparent film that carries active components to bodily tissue. Topical film forming systems are such developing drug delivery systems meant for topical application to the skin, which adhere to the body, forming a thin transparent film and provide delivery. Of the active ingredients to the body issue. Formed Film acts as a matrix for sustained release of drug and it also improves the Patient compliance. It can provide some. Desirable performance over conventional pharmaceutical dosage formulation such as easily applied, improve drug delivery, reduce dose Frequency, omitted first pass effect, and enhance drug delivery. The effectiveness of topical therapy depends on the physicochemical properties of the drug and adherence of the patient to the treatment regimen as well as the System's ability to adhere to skin during the therapy so as to promote drug penetration through the skin. Barrier conventional. Formulations for topical and dermatological administration of drugs have certain limitation like poor adherence to skin, poor permeability and compromised patient Compliance. These are and film Forming polymers various hydrophilic and hydrophobic polymers are used to give desired...

Film properties, used either single or in combination with too of more polymers. The transparency is an appreciable Feature of this polymeric system which greatly. Influences the Patient acceptance. Further the various types of film forming system (sprays/solutions, gels and emulsion) along with their evaluation parameters have also been reviewed.

**Key words:** Film forming solution, Epidermis, Topical drug delivery, Gelling agent, plasticizers drug.

### I. INTRODUCTION:

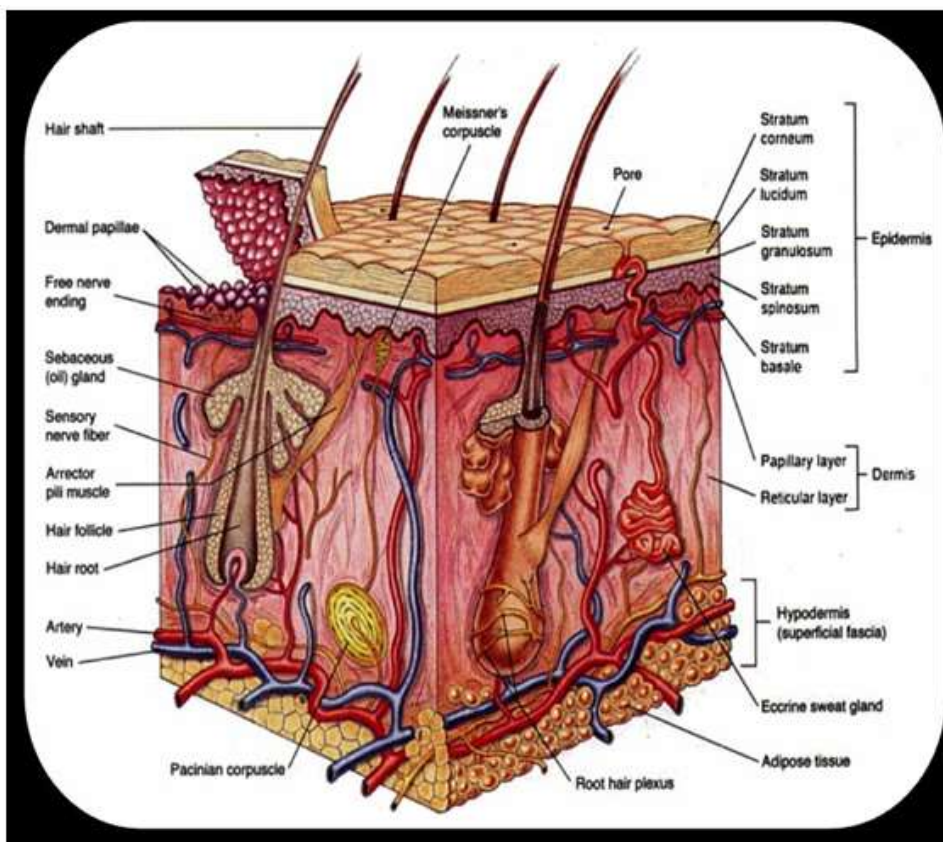
Film forming Solution (FFS) is defined as non- Solid doses form which produces film on the evaporation of vehicle, the formulations form excipients in the formulation form film on skin. This is the drug and film forming polymer system, formed film acts as a matrix for Sustained Release of drug [1]. The skin is the most readily accessible organ of the body and acts as a barrier against the micro and macromolecules of the environment because of its low permeability to such Substance [2]. The skin of an has approximately Average adult body surface area and it receives about one third of The total blood circulating throughout The body [3]. FFS (film forming system) is a novel technique that skin applications Can replace Convention preparations. It's a liquid medication format that upon applying to the undergoes in-situ film formation. These formulations Consist of the drug and additives in a Carrier, which, upon Contact with the skin, evaporates, leaving behind a film Comprising both excipients and the drug. A solid polymeric Substance Can be formed Serves as "a resulting film, which drug release matrix for Controlled drug delivery, or a liquid film Can be left behind, which is rapidly absorbed by the stratum-Carenum [4]. Therefore There is a need for development of a dosage form which permits less frequent dosing by maintaining a close Contact with the skin for prolonged time period thereby improving the Patient Compliance. Film forming

system (ffs) is a novel approach which can be used as an alternative to Conventional topical and transdermal formulations. It is defined as non-Solid dosage form that produces. A film in situ, after application on the any other body Surface, skin or These systems Contain the drug and film forming excipients in a vehicle which upon contact with the skin. Leaves behind a film of excipients. Along with the drug upon solvent evaporation the formed film can either be a solid polymeric material that acts as matrix for Sustained release of drug to the skin or a residual liquid film which is rapidly absorbed in the Stratum carenum [5]. Topical drug delivery Is designed to achieve either systemic or localized. Effects and offers several advantages, including by passing initial metabolic processing, avoiding the impact of acidic Conditions and activity in the Leveraging enzymatic activity in the digestive system and leveraging the extensive available Skin Surface [6]. Topical medications are often designed as a spray, gel, Cream, ointment, lotion, patch or other dosage method to Improve pharmacokinetic Properties or therapeutic efficiency [7]. Compared to the other topical dose, sprays provide a number of benefits Such as being simple to apply having a minimal risk causing irritation being sterile providing excellent coverage, for an area or wound distributing the medications, evenly when applied and having a Variable dose [8]. The goal of drug administration through Skin is for topical treatment of skin diseases or for transdermal absorption of drug's in the Systemic Circulation. The topical route offers a large and varied surface In addition to the ease of application Via self-administration and provides an alternative to anal delivery of drug's as well as hypodermic injection [9]. film formation facilitates the prolonged. Administration to the skin and drying of film improves its skin retention ability it improves the treatment of skin infection. It also improves the

patient compliance [10]. Percutaneous absorption of drug through Skin mainly occurs via stratum Carenum. Stratum carenum is made up of dead, Keratinized epidermal cells having thickness of 10 um and acts as Barrier for Permeation of drug's. Therefore transport of drug molecules. Across the skin is Difficult [11]. Compared to Conventional topical application a thin. Adhesive layer Develops, which Can extend the duration of contact and the drug g's ability ty to Permeate leading to a sustained release of medication This can also prevent the Crystallization, making more of the medication accessible to provide therapeutic Advantages [12]. The rate and extent of drug absorption thorough skin depends on the Skin physiology and physicochemical properties of drugs as well as the delivery System. The Current dosage forms, i.e. patches, ointment Creams, etc., are associated with several limitations patches have Various disadvantages Most commonly skin irritation [13]. After application of the formulation to the Skin, the Composition of the film forming System changes significantly due to the loss of the Volatile components of the Vehicle which results in formation of residual film on the skin surface. In this process the concentration fan of drug Increases, reaching Saturation Level and with the possibility of reaching super saturation level and on the in the enhanced drug flux through the Skin by increasing the thermodynamic acuity of the formulation wound affecting. The skin's barrier, thereby the Side efforts or thereby reducing the side effects or irritation [14,15].

### 1. Skin Anatomy and Physiology:

The Skin Is a function as the main physical barrier which protects us from external environment. It is generally described in terms of three tissue layers as depicted in figure...



One of the best biological barrier and it is largest organ of human body and contributes to 16%-18% to normal body weight and total area about 2 m [16,17].

**Skin composed of 3 main layers:**

- Epidermis
- Dermis
- Subcutaneous

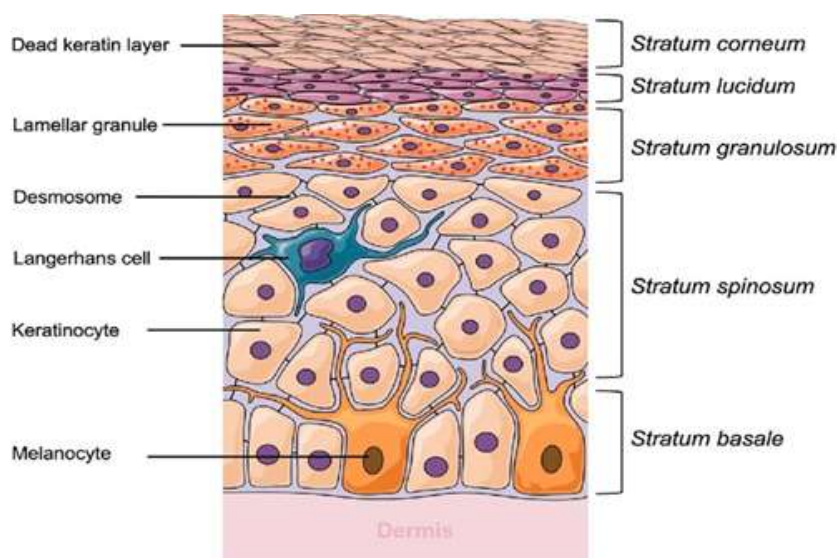
**Epidermis**

It is the squamous, stratified, keratinized epithelial layer (20-200 µm thick). It can produce yellow and brown black pigment melanin which contributes color and absorb UV light. Microscopic sections of the epidermis show two main parts: the Stratum Corneum (SC) and the stratum germinativum. The stratum corneum is the outer most Horney, very thin layer and consists of

compacted flattened, dehydrated, keratinized cells in stratified layer. It can resist over 80% of skin permeability. It also consists of nearly non-permeable cornified cells called corneocytes. Keratinized layer of skin is responsible for keeping water in the body and other harmful chemicals out which making skin natural barrier for infection[18].

Stratum Lucidum is the additional thin layer of keratinized cells which are located beneath the stratum corneum. Mainly present on the palm of hand and on feet soles.

Stratum Granulosum is a layer where keratinization begins. In this layer, lamellar granules appear and merge with the cell membrane, and these cells release glycopospholipids into intercellular space that forms the main constitute of the water permeability barrier.



Stratum Spinosum the spinous cell layer of the skin composed of keratinocytes with a characteristic “prickly appearance due to the presence of desmosomes, important structural filament called cytokeratin.

Stratum Basale is a continuous single layer consists of columnar epithelial cells also called basal layer or stratum germinativum. It consists of Melanocytes, Langerhans and Merkel cells.

#### Dermis:

It is composed of connective tissues connected tightly to epidermis by a basement membrane. It consists of hair follicles, sweat glands, sebaceous gland, lymphatic vessels, and blood vessels. The blood vessel in dermis provides nourishment and waste removal from its own cells. It is responsible for biochemical and biological degradation of material transported across skin. Beneath the dermis, the fibrous tissue opens out and merges with the fat-containing subcutaneous tissue.

#### Subcutaneous

Subcutaneous fat layer serves cushion for the dermis and epidermis. It also provides a thermal barrier. It consists of loose connective tissue, adipose tissue and elastin. It serves as a fat storage area; regulate temperature, nutritional support and mechanical protection. It carries main blood vessels and nerves to skin and may contain sensory organs [19].

#### 2.Mechanism Of Action:

##### Mechanism of film formation and permeation

Film forming system is applied directly to the skin and it forms a thin, transparent film in situ upon solvent evaporation as shown in Figure [20].

After application of the formulation to the skin, the composition of the film forming system changes significantly due to the loss of the volatile components of the vehicle which results in formation of residual film on the skin surface. In this process the concentration of drug increases, reaching saturation level and with the possibility of reaching super saturation level on the skin surface. Super saturation results in the enhanced drug flux through the skin by increasing the thermodynamic activity of the formulation without affecting the skin’s barrier, thereby reducing the side effects or irritation.

The concept of super saturation can be explained by the modified form of Fick’s law of diffusion. The Fick’s law of diffusion given by International Journal of Chemical & Pharmaceutical Analysis July-September 2021

Eq.

$$J = DKCV / h$$

Where

J-Rate of drug permeation per unit area of skin per unit time (flux)

D-Diffusion coefficient of drug

Cv-Concentration of drug

h-Thickness of barrier to diffusion

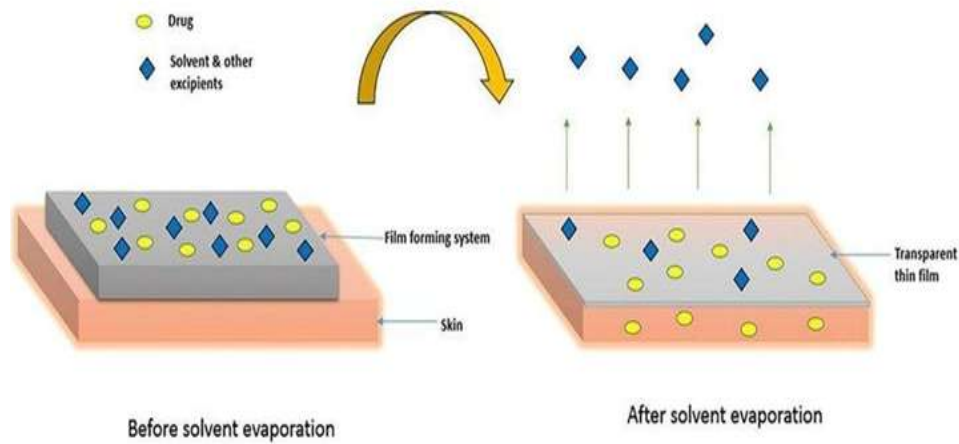
From this equation, it is clear that the rate of drug permeation across the skin is proportional to the concentration of the drug. However this is true when the entire drug is dissolved in the vehicle.

Equation describes the modified form of Fick's law of diffusion:

JaDiyh

Where, a-thermodynamic activity of drug within formulation ythermodynamic activity of drug within membrane

According to this equation, the flux of the drug is directly proportional to the thermodynamic activity of the system, which is related to saturation. However increasing the super saturation increases thermodynamic instability[21].



### 3.Method of Preparation:

By using the dispersion method the solutions of Eudragit RS PO and Hydroxypropyl cellulose were prepared in ethanol. Eudragit RS PO was sprinkled over 5 mL of ethanol containing tritely citrate (12.0% w/w of Eudragit RS PO). Hydroxypropyl Cellulose was sprinkled over 5 mL of ethanol separately. Both solutions were kept for swelling for 24 hours to get clear solutions. With

continuous stirring, these polymeric solutions were mixed properly. Accurately weighed quantity (1 g) the buds extract was dissolved in 5 mL ethanol and used as an active drug. The drug solution and polymeric dispersion were mixed properly with continuous stirring was made up to the mark using ethanol. The quantities were taken for a 50 ml solution [22, 23].

Sr. no.	Ingredient	Quantity
1.	Drug	1
2.	Eudragit RSPO(w/v)	12
3.	HPC (w/v)	6
4.	Triethylcitrate (w/w)	0.93
5.	Ethanol:Water(v/v)	70.30

A



B



#### 4. Topical Formulation For Skin Therapy:

##### 4.1. NOVEL DOSAGE FORMS:

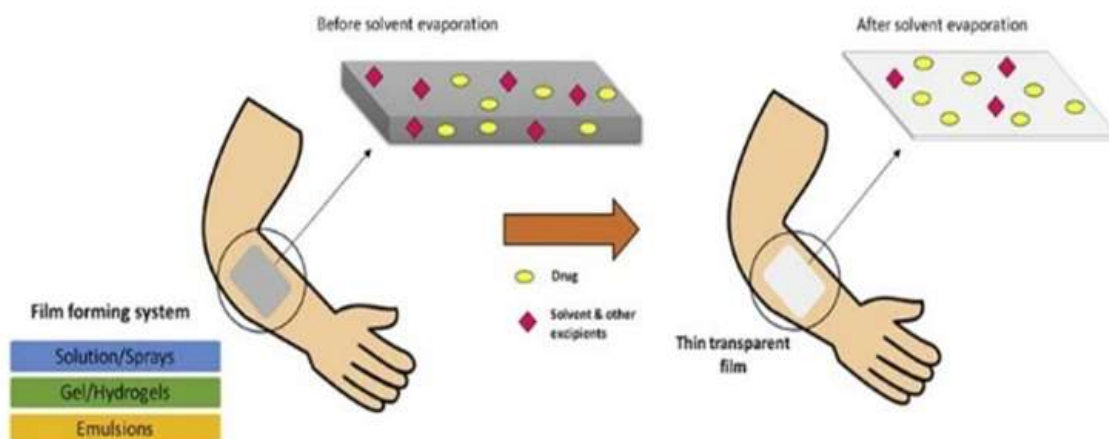
**4.1.1. Topical gels:** Gels are transparent to opaque semisolids containing a high ratio of solvent to gelling agent. Gels are prepared by entrapment of large amounts of aqueous or hydroalcoholic liquid in a network of colloidal solid particles, consisting of inorganic substances, such as aluminium salts or organic polymers of natural or synthetic origin. Depending upon the nature of colloidal substance and the liquid in the formulation, the gels range in appearance from entirely clear to opaque. Generally, topical gels are organic polymers based formulations, which gives an aesthetically pleasing, clear, sparkling appearance to the product, and are easily washed off the skin with water.



**4.1.2. Topical patches:** A topical patch is the adhesive patch with a medicinal substance which is placed on the skin to deliver a specific dose of medication through the skin and into the bloodstream. The adhesive is covered by a release liner, which needs to be peeled off before applying the patch on the skin.



**4.1.3. Topical films:** These are medicated transparent polymeric films similar to topical patches. The only difference is that films do not contain adhesive polymer.



**4.1.4. Topical sprays:** Topical sprays are dosage forms in which polymeric solution of drug is sprayed over the intact skin so as to get a sustained release of drug from the polymeric matrix. The drug is present in saturated form in the polymer matrix. As the organic solvent vehicle evaporates, slowly the drug diffuses through the polymer matrix and passes from the skin barrier [24].



Dig :-spray

#### 4.2. CONVENTIONAL DOSAGE FORMS:

**Oleaginous and emulsified ointments:** Various oils such as olive oil, vaseline, paraffin, and plastibase are the most frequently used vehicles for oleaginous ointments. These ointments are free of water, absorb little water, and are insoluble in water. They are also called water-repellant ointments. The vehicle itself protects and softens the skin and work as an anti-inflammatory. Oleaginous ointments are the least stimulative, and are applied on all kinds of eruptions. (Examples: white petrolatum, zinc oxide ointment, various steroids)

**Emulsified ointments** are water-in-oil ointments containing emulsifiers such as polyethylene glycol. Because of the cooling sensation they bring with application. Emulsified ointments are commonly called cold creams. They are more protective and less sticky than creams (see below) and are easily washed off with water. They are mostly applied on dry lesions.

**4.2.1. Creams:** Creams, also called oil-in-water emulsive vehicles, are semisolid mixtures of oil suspended in water containing emulsifiers. Creams are less sticky than ointments, and the colour disappears when they are applied thinly (vanishing cream). Since they do not stain clothes, creams are readily accepted by patients, and compliance with application is ensured. However, they may be irritating, and less protective than ointments.

Although creams are useful for erythema and papules, they should not be used on eroded or moist sites.



**4.2.2. Lotions:** Lotions are liquids with water as an agent mixed in. When applied topically, the liquid evaporates, and gives cooling, astringent and protective effects. The agent remaining on the skin acts pharmacologically. In addition to water, the following are often used as liquid vehicles for lotions: alcohol, propylene glycol, glycerin, and zinc oxide oil (a 1:1 mixture of zinc oxide and olive oil). Some lotions require shaking prior to application. They are known as shake lotions

**4.2.3. Tinctures:** agents dissolved in alcohol or in alcohol and water. **Aerosols:** vaporized liquid agents. After application, it dries to become a thin adhesive film on the skin. Gels with high solvent content are called jellies. These are used on mucous membranes to protect lesions from friction.

**4.2.4. Powders:** The main ingredients of powders are zinc oxides, talc (magnesium silicate), and starches. Powders dry affected sites by absorbing moisture. They also give cooling to the skin, reduce friction, and smooth the skin surface. They are effective in preventing miliaria and intertrigo.

**4.2.5. Liniments:** Liniments are aqueous mixtures and zinc oxides, phenol or glycerin. They dry fast on the skin. They are effective in cooling the skin and relieving itching. Carbolic Acid liniments are used for erythema and papules of, for instance, varicella; however, they must be avoided.

**4.2.6. Pastes:** Pastes are highly viscous mixtures of oil-based substances and microparticles of powder. In this they resemble oleaginous ointments; however, pastes contain more powder than oleaginous ointments do [24].

#### 5. Evaluation:

For the assessment of properties of the film, films were produced with a solvent evaporation technique by pouring 1 ml of the preparation on the glass slides of dimensions 2cm x 5cm. The films were left to dry for 5 minutes at room temperature. Then some of distilled water

Was sprayed on the films and cut into the dimensions of 1cm x 1cm and used for following evaluation parameters: Clarity, pH, and viscosity: The formulation was tested clarity, pH, and viscosity. Clarity was checked visually and pH of the formulations was checked using digital pH meter. The rheological properties of films were determined by the Brookfield viscometer. Viscosity values of the formulations were recorded at varying shear rates.

**5.1 Cosmetic attractiveness:** The cosmetic attractiveness of the film was assessed by visual examination of the dry films. Transparent films with low skin fixation. Had a high attractiveness as they were almost invisible. Opaque films and films with medium skin fixation were considered less attractive as they exhibited an increased visibility and a slight wrinkling of the skin. Whitish films and films causing heavy wrinkling of the skin due to strong skin fixation displayed only a low attractiveness.

**5.2 Thickness:** The films were cut into a size of (1cm x 1cm) and the thickness of the film using a digital Vernier calliper. Each film was measured at five positions (central and the four corners) and the mean thickness was calculated.

**5.3 Outward Stickiness:** The stickiness of the outer surface was tested by pressing cotton wool on the dry film under low pressure. Depending on the quantity of cotton fibers that were retained by the film the stickiness was rated high (dense accumulation of fibres on the film), medium (thin fiber layer on the film), or low (occasional or no adherence of fibers).

**5.4 Weight variation test:** For each formulation, three film samples (1cm x 1cm) were used. Each film sample was weighed individually and the average weight was calculated.

**4.5 Integrity on skin:** The formulation was applied to the forearm of a volunteer as described for the assessment of the drying time. The dry film was then worn overnight by the test subject. After 24 hours the test area was examined visually for completeness of the film, appearance of cracks or flaking.

**5.6 Drying time:** For the assessment of the drying time, the formulation was applied to the inner sides of the forearm of a volunteer, who participated in the study on informed consent basis. After 2 minutes a glass slide was placed on the film without pressure. If no remains of liquid were visible on the glass slide after removal, the film was considered dry. If remains of liquid were visible on the glass slide the experiment was

repeated until the film was found to be completely drack.

**5.7 Films moisture content:** To determine the moisture content (MC) of films, approximately 50 mg of the film were dried at 105 °C for 24 h (until the equilibrium weight was attained). The weight loss of the sample was measured, and MC was calculated as the percentage of water removed from the system. Three measurements were obtained for each sample

**5.8 Water solubility:** Solubility was determined as the content of dry matter solubilized after 24 hours of immersion in water. Two pieces of each sample, previously dried until constant weight, were immersed in 50 mL of water (at 23 °C). After 24 hours of immersion with agitation, the pieces of film were taken out and dried until constant weight in an oven at 105°C, to determine the weight of dry matter not solubilized in water. The percentage of soluble material (SOL) was considered as the solubility of films in water. Three measurements were obtained for each sample [25, 26].

## 6.Future Aspects:

Since ancient times, herbal drugs were known for medical and therapeutic values. But there was always a lack of documented evidence, so even though the herb had health benefits, people preferred synthetic or allopathic medicines, as they were developed under strict regulations and guidelines of Europe, Australia and likewise hence people were rest assured that marketed products are safe and efficacious. Although such was the condition, since, few decades herbal medicines are getting popular in global market as the basic query about quality and validation of product is been taken care of and so is become prime choice in global market. The film forming system presents a novel platform to deliver drugs to the skin Both topical and transdermal. These film forming systems are simple and offer Advantages of transparency, non-greasy, lower skin irritation, wipe off resistance, Longer retention, greater increased dosage flexibility, improved patient compliance And aesthetic appearance Although Considerable work has been done on these Systems, not much data are available on its delivery efficiency. Hence the Marketed products available are less. Since, it has high antioxidant property in its leaf buds. Our study Proved that Formulated thin film forming solution also have shown good results for Antioxidant activity similarly as leaf buds. Hence this can be helpful approach in The treatment of dark spots and



melasma. Additional research is necessary to Prove the relevance of film forming system as transdermal dosage form, but the Obtained results are encouraging for further development of this novel topical Drug Delivering system.

## II. CONCLUSION/DISCUSSION:

The film forming system is a better alternative to the both topical and transdermal conventional formulations. These film forming systems are simple and offer advantages of transparency, non-greasy, lower skin irritation, wipe off resistance, longer retention, greater increased dose flexibility, improved patient compliance and aesthetic appearance been done Although considerable Work has on these are available system, not much data on its delivery efficiency. It remains adhere to the affected part for longer time period, provide sustained release drug The film forming system presents a novel platform to deliver drugs to the skin both topical and transdermal. These film forming systems are simple and offer advantages of transparency, non-greasy, lower skin irritation, wipe off resistance, longer retention, greater increased dosage flexibility, improved patient compliance and aesthetic appearance Although considerable work has been done on these systems, not much data are available on its delivery efficiency.

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