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A Review on Film Forming Gel (FFG)

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ABSTRACT

Film forming gel are a novel approach in this area that might present an alternative to the conventional dosage forms used on the skin, such as creams, ointment, gels or patches. The polymeric solution is applied to the skin as a liquid state and forms a thin, transparent invisible film in situ by solvent evaporation. Film forming systems (FFS) are simple innovative, novel approach offers an advantages of thin, transpernt gel, self-drying, non-sticky, non-greasy, flexibility. Transdermal drug delivery system (TDDS) has been one of the most innovative and novel approaches of drug deliverises. Tdds and dermal drug delivery system can provide some desirable performances over conventional pharmaceutical dosage formulation such as avoiding gastrointestinal disturbances, hepatic 1st pass metabolism, increases drug bioavailability, reduction in dosing frequency, stabilizing drug delivery profiles. The aim of this review was to search for alternatives to the conventional dosage forms in order to reduces skin irritation, inflammation, redness and improve skin adhesion properties, increases the drug release and improve patient compliance.

KEYWORDS: *film forming gel, transdermal drug delivery sytems, gelling agent, and evaluation parameter and application*

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INTRODUCTION

The skin is very important route for trandermal or dermal delivery of pharmaceutically active substances. The skin is an most rapidly accessible organ of the body & acts as a barrier against the macro & micromolecules of the environment because of its less permiability to such substances [1]. and surface area of adult body has approximately 2 m2 recives about one-third of the total blood circulation throughout the body [2-4]. Percutaneous absorption of drug content through the skin mainly occurs via stratum corneum. Stratum corneum is made up of dead, flattend, dehydrated keratinized epidermal cells having thickness of 10-15µm and acts as a obstacle for permeation of drugs. Therefore transport of drug molecules beyond the skin is tricky [5-7].

Film forming polymeric solutions area innovative approach in this area that might present an alternative to the conventional dosage forms used on the skin, such as creams, ointments, gels or patches. The aim of drug administration through the skin is for topically treatment of various skin diseases or transdermal absorption of drugs 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 oral delivery of drugs as well as hypodermic injection [8]. The rate and extent of drug absorption through the skin depends on the skin physicochemical properties and physiology of drugs as well as the delivery system. The recent dosage forms such as cream, ointments, patches, etc., are associated with several limitations. TDDS Patches have various disadvantages, most commonly local skin irritation and high cost [9-14]. Film forming system (FFS) is a novel and innovative approach which can be used as an alternative to conventional topical and transdermal dosage formulations. It is defined as non-solid dosage form (such as gels and solution), it produces a film in situ i.e. after application on the skin. The formed film can either be a solid polymeric material that acts as matrix for sustained release of drug through the skin or a residual liquid films which is rapidly absorbed in the stratum corneum [4, 15-20].

Film forming system in that apply a thin layer of the formulations (strata) as shown in **FIG.1** directly to the affected area and allow the gel to dry in 5-6 min to forms film and to maintained in contineous contact with the skin (24 hrs /day).

A **B**

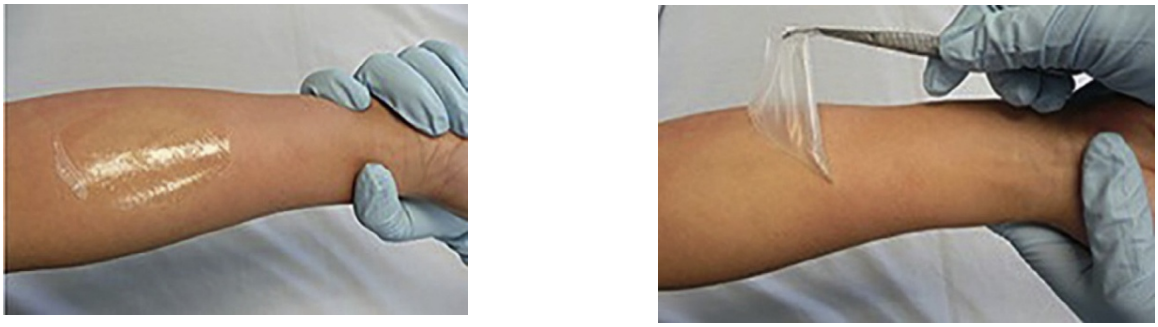

FIG.1- APPEARANCE OF FILM FORMING SYSTEM: (A) FORMATION OF TRANSPARENT FILM ON APPLICATION; (B) NON-TACKY, FLEXIBLE, EASILY PEELABLE FILM AFTER DRYING [21].

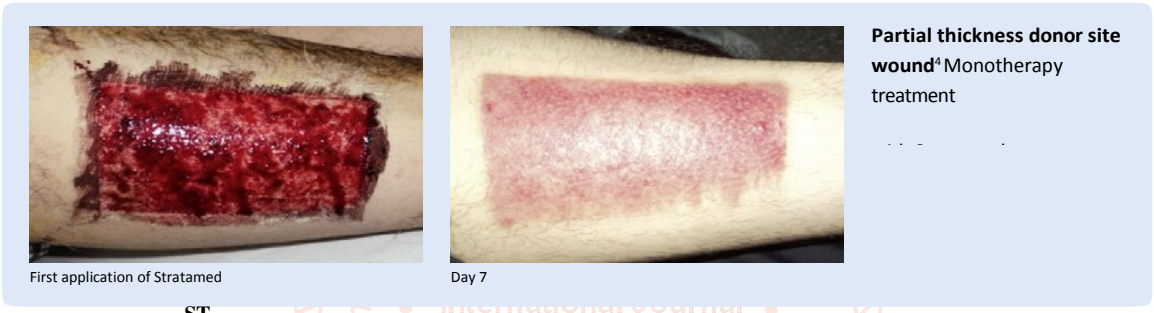

FIG. 2- 1ST APPLICATION OF STRATAMED (FFG) AND AFTER 7DAYS

- Reduces and normalizes the inflammatory response.
- Provides symptomatic relief (redness/discoloration, itching, discomfort, pain) [22].
- Immediately decreases post-inflammatory burning sensation by reducing erythema and superficial skin temperature [23].
- Marketed film forming gel example with used and treatment as following **Table 1.**

TABLE.1- MARKETED FILM FORMING GEL WITH USE AND TREATMENT[23].

Stratamed®	Superficial wounds, wound dressing, burns.
Strataderm®	For the prevention and treatment of hypertrophic scars (old and new scars) and keloids.
Stratacel®	Superficial damaged skin layer such as wound dressing for sensitive skin.
stratamark®	For the prevention and treatment of stretch marks.
StrataXRT®	Innovative wound dressing for radiation dermatitis.
StrataCTX®	Cutaneous reactions, like eruptions, hand-foot syndrome.
SVR X SVRxerial 40	Damaged and thickened nails.

MECHANISM OF FILM FORMATION AND PERMEATION:

Film forming system is applied directly to the skin and it forms a thin, transparent film *insitu* by solvent evaporation as shown in **Fig.3**. After application of the formulation to the skin, the composition of the FFSs changes significantly due to the loss of the volatile components of the vehicle which results in the 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 supersaturation level on the skin surface. Supersaturation 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 [24-25].

The concept of supersaturation can be explained by the modified form of Fick's law of diffusion is given by Eq. (2.1)

$J=DKCv/h$ .....(2.1)

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 explained that the rate of drug permeation beyond the skin is proportional to the concentration of the drug. However this is true when all the drug is dissolved in the vehicle.

Equation(2.2) describes the modified form of Fick's law of diffusion:

$J = \alpha D/\gamma h$ …….(2.2)

Where,
a=thermodynamic activity of drug within formulation
γ=thermodynamic 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 supersaturation as well as thermodynamic instability [26].

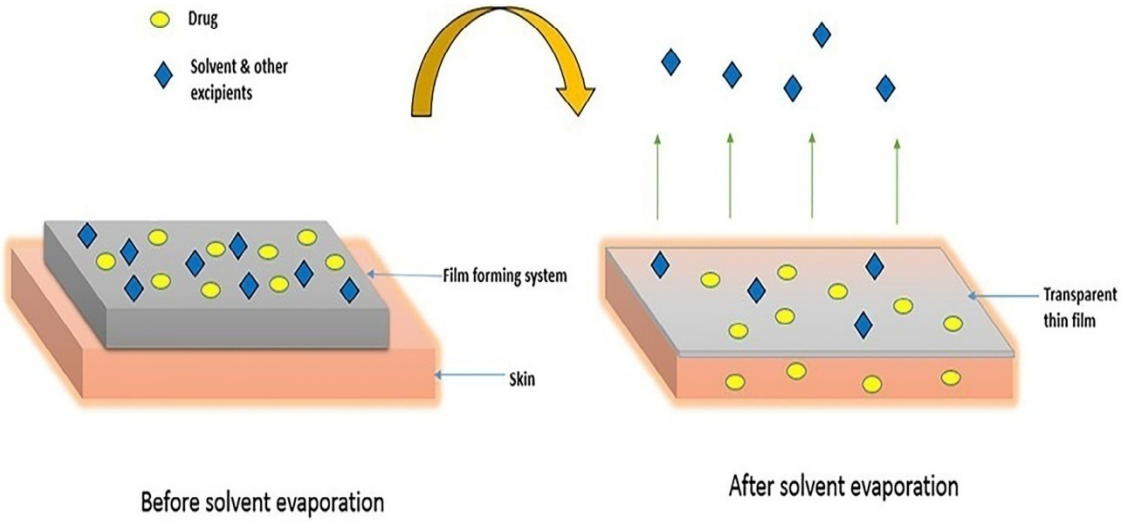

FIG. 3 MECHANISM OF FILM FORMATION

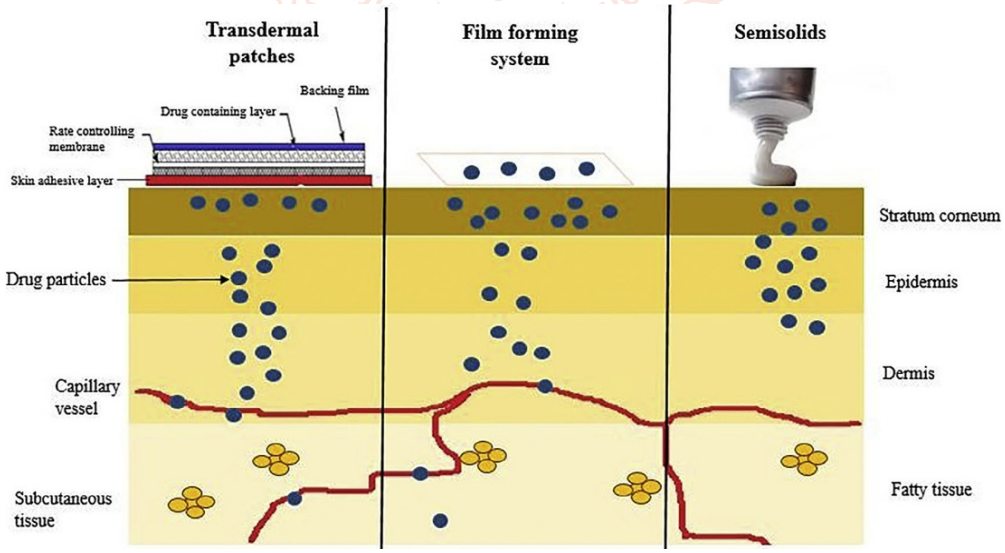

FIG. 4 RELEASE PROFILE OF THE TOPICAL AND TRANSDERMAL DRUG DELIVERY SYSTEMS.

- FFSs creates supersaturated systems immediately after application to the skin, overcoming the problem of instability.
- Its improves the drug permeation through skin and compared to other transdermal dosage forms.
- The delivery efficiency of the film forming solutions for ethinylestradiol was investigated.

- The permeation of ethinylestradiol from the FF solution prepared with or without enhancer was compared to the permeation from the patch through human skin (epidermis) in vitro e.g commercially available patch (EVRA®).
- The film forming formulations such as solution, gel showed a higher permeation than the commercial transdermal patch.
- Film forming formulation is prepared without enhancer and transport more than double ethinylestradiol than the marketed patch.
- The formulation is delivered with enhancer about seven times as much ethinylestradiol as that of the marketed patch.
- This systems prove to be useful in enhancing the drug permeation [27].

COMPONENTS OF FILM FORMING SYSTEM:

Suitable for drug :

Drug molecule plays a very important role in the successful development of a topical gel formulation. Transdermal application of film forming systems, the drugs need to have suitable properties which are independent of the dosage form.

- Generally the drugs which are applicable to these systems are highly potent which permeation through the skin rapidly, which cause no skin irritation.
- Only potent drugs for route of application with a daily dose of less than 10 mg.
- Molecular weight of drug is important in drug permeation as small molecules crossing human skin than large molecules.
- Size of the molecule below 500 Da for sufficient mobility in the skin structure.
- Drug passing through the lipophilic as well as hydrophilic are in the skin into the systemic circulation way [28].
- The ideal properties of the drug suitable for transdermal drug delivery system are listed in **Table 2.**

TABLE 2. IDEAL PROPERTIES OF DRUG FOR TRANDERMAL DELIVERY [21].

Parameter	**Properties**
Dose	10mg or less
Mole. wt	Less than 500 Da
Melting point	<200 °C
Partition coefficient log p (octanol/water)	Between 1 and 3
Hydrogen bonding group	< 2
PH value	Between 5 and 9
Skin reaction	Non irritating and non-sensitizer

Polymer:

- Polymers are the foundation of the FFSs and a variety of polymers are available for the preparation of these systems.
- These Polymer used to control drug release is a modification of the film-forming polymer as a functional excipient.
- These polymers can be used another film forming polymers and in combination or alone [29].
- These polymers should form a clear, transparent and flexible film at skin temperature (28 °C-32 °C).
- Should have a certain inherent affinity and flexibility to the skin to avoid the usage of excessive amounts of plasticizer [30].
- The list of polymers along with their molecular weight and properties are mentioned in **Table 3.**

TABLE 3-FILM FORMING POLYMERS

Polymers	Properties
Hydroxypropyl Methylcellulose (HPMC) HPMC (E4M, E15, E50M K4M)	➢ Produce a light, non-greasy uniform film with good texture. ➢ Produces a smooth clear spreadable gel ➢ Effective in conc. Of 2-6% as gelling agent. ➢ Do not interact significantly with other ingredients. ➢ Surface active agent, therefore adsorbs water providing easy dispersion, lubricity and comfort feel in occlusive state on application to skin[31].

Ethyl cellulose (EC)	➢ Nontoxic, nonirritating, nonallergic material ➢ Good film forming properties that form tougher films[32]. ➢ Water insoluble[33-35].
Hydroxypropyl cellulose	➢ Nonionic, pH insensitive polymer ➢ Water soluble[36].
Polyvinyl pyrrolidine (PVP) (PVP K30, PVP VA64)	➢ Solubility in water and other solvents ➢ Adhesive and binding property ➢ Acts as a bioavailability enhancer[37]. ➢ Are high hygroscopicity, good biocompatibility [38-39].
Polyvinyl alcohol (PVA)	➢ Water soluble ➢ Excellent film forming and adhesive properties ➢ Non-toxic and biocompatible[40]. ➢ Low hydrophilicity, rigid film generation and insufficient elasticity [41-43].
Chitosan	➢ Excellent film forming ability ➢ Opens the tight junctions of mucosal membrane, thereby enhancing the paracellular ➢ Permeability and penetration of drug[44]. ➢ Controls drug release[45]. ➢ Good biocompatibility[46].
Eudragit (polymethacrylates copolymer) Eudragit RS 100, RL 100, NE, RS 30D, S 100	➢ Transparent, elastic, self-adhesive ➢ Good adhesion to the skin[47].
Silicones Polydimethylsiloxane (PDMS)	➢ Water vapor permeable film ➢ Adequate substantivity and durable film[48].
Acrylates copolymer Avalure® AC 118, AC 120	➢ Tough, breathable, abrasion resistant films[15].

Solvent:

The solvents is important component in film forming system. These solvent used in film forming systems for solubilizing the drugs as well drug permeation through the skin[49]. The drug a suitable solvent for a FF solution is required to its high volatile to provide short drying times and a good patient compliance. A suitable solvent used for the formulation of a FF polymeric composition such as ethanol, ethyl acetate or isopropanol with a better spreading as well as higher volatility [50].

A Common solvents used for topical and transdermal delivery are listed in **Table 4.**

TABLE.3- SOLVENTS USED IN TOPICAL SYSTEM[49].

Category	Example
Glycols	Propylene glycols, polyethylene glycols.
Alcohols	Ethanol, butanol, isopropanol, benzyl alcohol, lanolin alcohols, fatty alcohols.
Other solvents	Ethyl acetate, oleic acid, isopropyl myristate

Plasticizer:

In addition to polymers, plasticizers also contribute to drug delivery through the skin by not only reducing the glass transition temperature (Tg) of the formed polymeric films but also increasing drug diffusion[51]. Plasticizers are used in the film forming systems to impart flexibility to the film and improve the tensile strength of the film. Commonly used plasticizers are triethyl citrate, glycerine, dibutyl phthalate, polyethylene glycol, sorbitol, propylene glycol etc [52].

EVALUATION OF FILM FORMING GEL:

Physicochemical properties:

Formulations were subjected to evaluation of physical parameters like appearance, pH, phase transition time, film thickness, weight, viscosity, Spreadability.

Phase transition time:
Time taken by the gel transformed into film is known as phase transition time. Minimum 1 gram of gel was put on a petri dish which was spread in same thickness on it and kept on a hot plate at 37˚C and then time taken was noted until gel transformed into film[4].

Meassurment of film thickness:
Film thickness was measured by vernier calipers /screw gauge (using 0.02mm). The gel was spread on an area of 5 cm² demarcated on a petridish. This petridish was keept a side for 24 hr for drying and then the film was peeled off and the thickness was determined in triplicate and the average value was used[4].

Meassurment of film weight:
1 gram of the gel was placed on a petridish which was left for drying. after drying the resultant film was weighed on an electronic balance[53].

Drying time (min):
For the valuation of the drying time, the gel is applied to the internal sides of the forearm of a volunteer, who participated in the study on informed consent basis. After some time of period take another glass side was placed on the film without applying pressure. If no liquid is visible on the glass slide after removal, the film is considered as completely dry. If remains of liquid were visual on the glass side the experiment is repeated until the film was found to be fully dry. A good FFSs should have a minimum drying time to avoid long waiting time for the patient[54].

Rheological studies (cps):
Viscosity was measured by using Brookfield Viscometer LVDV II+ model. Gels were placed under the viscometer to determine the viscosity of the gel. Gels were placed under the viscometer by using S 64 spindle to determine the viscosity of the gel. The viscosity was determined at different RPM such as 10, 20, 50, 100 RPM and the corresponding viscosity and torque were noted[55].

Spread ability (cms):
Minimum quantity of the gel was placed between two glass plate and the glass plate on the top was gently slided on the bottom glass slide to determine the spread ability of the gel. Spread ability was measured on the basis of drag and slip characteristics of gels. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A 1 kg weigh was placed on the top of the two slides for 5* minutes in order to expel the air and to provide a uniform film of the gel between the slides. Excess of the gel was removed from the edges. The top plate was then subjected to pull of 100gms. With the help of string attached to the hook and the time (in sec.) required by the top slide to cover a distance of 7.5cm be noted. A shorter interval indicates better spread ability. Spread ability was calculated using the following formula:

$S = M \times L/T$

Where,
S = Spreadability,
M = Weight in the pan (tied to the upper slide),
L = Length of the glass slide,
T = Time (in sec.) taken to separate the slide completely each other[4].

APPLICATION OF FILM FORMING GEL:

- Gels are most commonly used for topical preparations and transdermal delivery for the treatment of various skin disease and infection.
- Stratamed® is the first film-forming silicone gel-based wound dressing approved for the use on superficial open wounds and compromised skin.
- Stratamed® can be used after dermatalogical intervention (Dermal abrasion, laser treatment, chemical peels, removal tattoos) surgeries, trauma, burns* etc.
- Silicone based gel is effective in promoting accelerated epithelisation, reducing the anti-inflammatory response and prevention of scarring.
- Silicone gel (FFG) is used in the treatment and prevention of abnormal scars because it can be used immediately on open wounds and damaged skin [56-57].
- On the basis of research article of FFG Formulation of example with there uses and treatment are listed in **Table 5.**

TABLE .5- FILM FORMING GEL FORMULATION WITH USES AND TREATMENT.	
Drug	**Used and treatment**
Indomethacin	Rheumatoid arthritis [53].
Terbinafine hydrochloride	Skin infection [58].
Clobetasol propionate	Skin infection [59].
Diclofenac diethylamine	Arthritis, traumatic pain [2].
Silver sulfadiazine (film forming hydrogel)	Burns [60].
Flurbiprofen	Rheumatoid arthritis [55].
Bifonazole	Fungal skin infection [61].
Miconazole nitrate	Fungal infection of skin [62].
Ketoprofen	NSAIDs [63].
Lornoxicam	NSAIDs used for osteroarthritis, rheumatoid arthritis, and inflammatory condition [64].

CONCLUSION:

Topical gel is safe and effective for use in the treatment of skin related various diseases. Film Forming systems (FFSs) present a novel platform to deliver drug through the skin for both topical and transdermal delivery. These FFS are simple and effective offers an advantages of self-drying, flexibility, non-sticky, non-greasy transpercny, lower skin irritation, wipe off resistance, improve skin retention ability, and patient compliance. This approaches does not only sustaind the relese of drug and enhanced percutaneous absorption. The concept of film forming gels can change to treatment concept of various diseases such as arthritis. A lot of work can be carried out in this field.

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