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Review Article

Review On Film Forming Spray for Topical Drug Delivery

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ABSTRACT

In contrast to conventional topical preparations, film-forming sprays offer a number of benefits, such as uniform drug dosage and distribution, improved bioavailability, less irritation, continuous drug release, and accelerated wound healing via moisture management. In film-forming sprays, polymers and excipients improve preparation qualities and increase the stability of active components. All types of polymers and excipients will produce films with different characteristics. The different types of polymers and excipients, as well as their evaluation criteria, must be investigated in order to create a more suitable kind of film-forming spray. The selected literature included studies on the use of polymers as film-forming matrices and the potential medical applications of these sprays. In this article, we discuss the types and quantities of excipients and polymers, sprayer types, testing, and important aspects that determine the sprayability and film qualities. Both natural and synthetic polymers with in situ film or viscoelastic capabilities can be used to enhance topical medication administration, according to the review.

INTRODUCTION

The human body's largest organ is the skin. It offers defence against environmental consequences such as UV radiation, physical and chemical attacks, contact with dangerous microbes, and discomfort. [3, 23] Due of its poor permeability to environmental micro and macromolecules, it also acts as a barrier against them. Although transdermal drug delivery has greatly enhanced medical practice, it is still in its infancy as a substitute for oral medicine administration and hypodermic injections. [4] The advantages of topical medication distribution include avoiding the effects of acidic environments and enzyme activity in the digestive system, making use of the vast amount of available skin surface, and avoiding initial metabolic processing. It is designed to have either localized or systemic effects. [4] The stratum corneum, a protective layer of non-living, keratinized epidermal cells that is 10 micrometres thick, is the

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main route by which drugs are absorbed through the skin. [5]) The process by which drugs move through the skin is referred to as drug permeation. Therefore, it is difficult for drug molecules to get through the skin. [6] In order to enhance pharmacokinetic characteristics or therapeutic efficiency, topical drugs are frequently created as sprays, gels, creams, ointments, lotions, patches, or other dosing methods. [8] Sprays have several advantages over other topical doses, including being easy to apply, having a low chance of irritating the skin, being sterile, offering superior coverage for a wound or area, dispersing the drug uniformly when applied, and having a variable dosage. [10] In contrast to traditional topical treatments, a thin, sticky film forms, which might prolong contact time and the drug's penetration capacity, resulting in a longer-lasting release of the medicine. Additionally, by preventing crystallization, more of the drug may be available to offer therapeutic benefits. [11] A novel technique known as FFS (film forming system) can replace conventional skin preparations and treatments that are absorbed by the skin. Applying this type of liquid medication to the skin or another surface creates an in-situ film. A film containing the medication and excipients is left behind after the carrier containing the medication and additives evaporates when it comes into contact with the skin. A solid polymeric substance that serves as a drug release matrix for controlled drug delivery or a liquid that is rapidly absorbed by the stratum corneum 10 could be the resulting film. [12]. The methods used to build a controlled medication release FFS to improve therapeutic efficacy are discussed, as are the potential future developments of this technology in the pharmaceutical sector. [12,70]

Methodology:

Human skin is composed of two primary layers: the epidermis and the dermis. The stratum corneum, the outermost surface, is where the four layers of the epidermis are found. ([70]) The dermis, which lies beneath the epidermis, ensures the skin's suppleness and controls body temperature. It is mostly composed of collagen and matrix-encased elastic fibers. The dermis contains sensory nerves, lymphatic channels, and blood vessels. The stratum corneum restricts the quantity of drug absorption based on its penetration ability. Drugs can enter the stratum corneum through a variety of pathways, including trans-epidermal, trans-follicular, and trans-glandular. The medicine and formulation determine how deeply they permeate the skin.

Mechanism:

The film-forming system is applied directly to the skin and forms a thin, transparent coating once the solvent evaporates. The formulation undergoes a substantial change after being applied to the skin, creating a long-lasting layer on the skin's surface due to the evaporation of volatile components in the carrier. During this phase, the concentration of the medication increases until it reaches saturation, and it may even approach supersaturation. Through an improvement in the thermodynamic activity of the skin without compromising its protective barrier, supersaturation raises the drug flux. This formulation won't produce irritation or adverse effects when applied. ([49, 55]) The explanation for supersaturation can be found in a modification of Fick's equation of diffusion. Fick's law of diffusion is represented by the equation below:

J = DKCv/h

In this equation:

- J stands for the rate of drug permeation (flux).

- D represents the diffusion coefficient of the drug.
- CV is the concentration of the drug.
- H signifies the thickness of the barrier to diffusion.

This formula demonstrates the clear proportionality between medication concentration and skin penetration rate. On the other hand, this occurs when the medication totally dissolves in the vehicle. This equation shows a direct and obvious relationship between drug flux and the thermodynamic activity of the system, which is related to saturation. [22]. Nevertheless, the thermodynamic instability rises with the supersaturation. After skin application, FFS solves the instability issue by generating supersaturated systems. In contrast to other transdermal administration methods, it therefore enhances drug penetration via the skin. [68, 71]

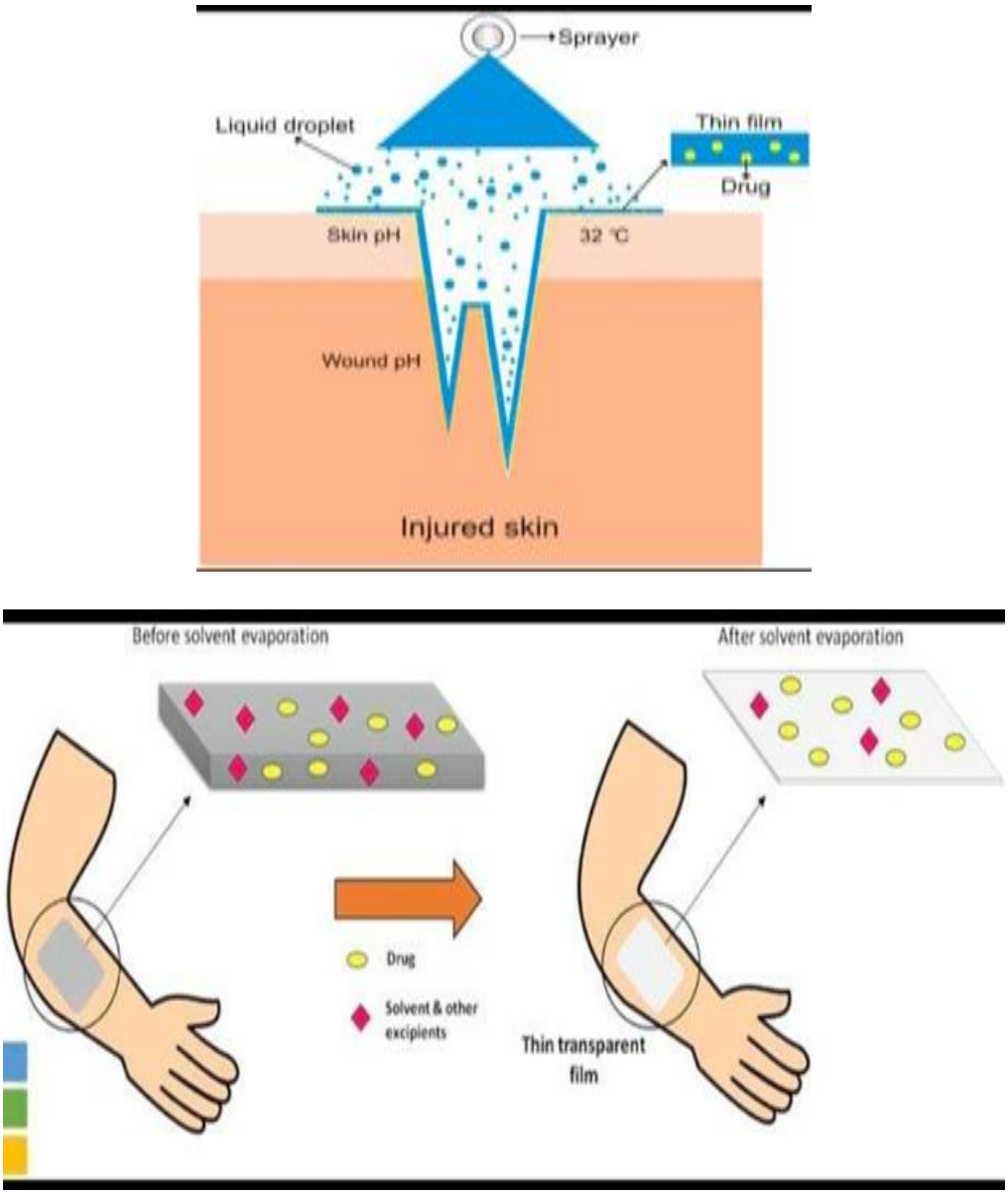

Fig.1 Mechanism of film forming system

Different Type of Film-Forming Sprayers:

A. Ordinal Spray:

Ordinal spraying is a type of spraying that usually employs a container made of plastic or aluminum that has an aperture size of 0.3 mm and a dip tube diameter of 1.2 mm. When spraying, this type of spray doesn't require any specialized technology. It is frequently possible to spray 0.11-0.35 g or -mL of film-forming solution, with an average angle of 78.69 87.39°. [24, 26] The average leakage rate of a standard spray bottle is between 0.01 and 0.03%. [63,66] 34 Ordinal sprays can be either horizontal or vertical. The 3 K® Horizontal Spray Nozzle is said to be able to maintain the sterility of the film-forming fluid during both storage and use. The spray force of the ordinal spray is also influenced by the kind and concentration of polymer used. [66].

B. Metered Dose Spray:

The metered dosage spray (MDS) is one spraying device with a variable spray output. This apparatus is typically used to administer medications via the transdermal or transmucosal routes to the systemic compartment. Because the spray volume is related to the medicine dosage, it must be taken into account while evaluating a film-forming spray. The amount of MDS that may be sprayed depends on the bottle's volume, the homogeneity of particle dispersion, and the container's position when in use. Typically, 90 to 102 mL of FFS can be sprayed. 30, 32, and 33: For MDS, the typical spray angle is 83.51°. (22) A MDS container's typical leakage rate ranges from 0.01 to 0.02%. 30. [67],

C. Electrostatic Spray:

One common technique for applying pesticides in agriculture is electrostatic spraying (ES). Drift loss, droplet formation speed, cover-age uniformity, and deposition efficiency can all be improved by ES. [75] The effectiveness of ES is influenced by the solution's electrical resistivity, surface tension, and viscosity. [76]. A solution must have conductivity between 108 and 105 S/m in order to be sprayed with ES. The typical droplet diameter produced by ES is between 6.3 and 26 meters. [38].

D. Ultrasonic Spray:

There is great potential for using ultrasonic spray to provide film-forming solutions. The resultant droplet can get close to the nanoscale and possesses thin film characteristics. The ultrasonic spray nozzle produces consistent droplets with a diameter of less than 10 m and can function at both low and high pressures. The nozzle of the ultrasonic spray has a diameter of 0.5 mm, and the droplet diameter ranges from 1 to 10 m. The resonance frequency of the electrode in use is 10 MHz. For medical applications, layer-by-layer (LBL) coating films with more homogeneous particle sizes can be created with an ultrasonic spray. [46] Each type of sprayer has specifications that match specific polymers. A range of synthetic and natural polymers have been used in the FFS system. [1]

Utilizations of Film-Forming Systems:

Film-forming technologies were first mostly used in the surgical and wound care industries. These systems, which were used as surgical adhesives and were in gel or solution form, were used to seal surgical wounds. For this purpose, the film-forming agents can be either natural materials like fibrin or manufactured compounds like cyanoacrylates. These formulations for wound care were specifically designed to either be free of pharmaceutical chemicals or contain antimicrobial agents to help prevent infections in the wounds. However, this technique is not limited to medical applications. Non-medical applications include the use of silicone film forming technologies in cosmetics and the delivery of active compounds in

cosmetics. formulations for cosmetic creams and ointments. Additionally, it has been used in transparent peel-off masks for moisture-related skin acne treatments, among other things. Additionally, the technique demonstrates the potential to serve as a base material for other protective membranes utilized in industrial settings. In order to protect employees from exposure to chemicals such as cleansers, caustic materials, alkaline solutions, hazardous compounds, infrared heat, UV light, and the like, these protective membranes are essential. Examples of this use include lotions and salves that are both water-attracting and water-repellent, as well as creams that are intended to protect against UV rays. [27, 31] Film-forming solutions are the most widely used type of film-forming systems. The primary ingredients are a volatile medium for the dissolution or dispersion of polymers, plasticizers, and other excipients. [27, 31]

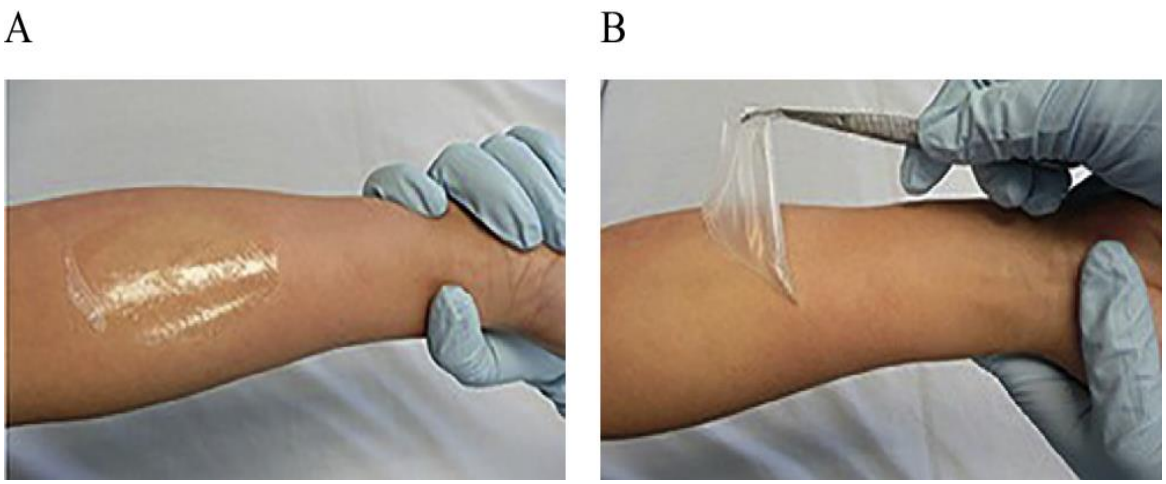

Fig 2: Film formation after application

Formulation Components for Film Forming System

1. Drug:

Independent of the dose form, medications must have certain properties in order to be applied topically via film-forming methods. These medications are usually very strong, absorb quickly through the skin, are not very uncomfortable, and show some resistance to an enzyme found in the epidermis. A drug's partition coefficient and other characteristics determine the skin penetration pathway it takes. A drug's molecular weight affects how easily it can pass through human skin; smaller molecules have a tendency to penetrate more easily than larger ones. [21] Given the lipid-rich makeup of the stratum corneum, the medication should be able to penetrate it efficiently whether it is intended for topical or transdermal use. When opposed to their hydrophilic equivalents, medications having a strong lipophilic component typically have better skin penetration. [56]

2.Permeation Enhancers:

Eutectic mixtures are commonly utilized to improve medication penetration. [24, 25, 66]) One of the most potent eutectic compounds is a combination of camphor and menthol. Since camphor and menthol combine to form a hydrophobic combination, they can be used as a penetration enhancer for drugs that are likewise hydrophobic. On the other hand, camphor and menthol might promote pore formation and skin peeling. The characteristic of a camphor and menthol blend is a warm sensation that

progressively turns into a cold one. ([1]) The eutectic mixture of camphor and menthol greatly increases the penetration of the antifungal drugs voriconazole, clotrimazole, and fluconazole in a Franz diffusion cell with nylon membranes. [24, 25, 66] Because camphor and menthol have hydrophobic properties, they can interact with the lipids in the stratum corneum to enhance drug penetration. [1]

3.Plasticizers:

Plasticizers are primarily used in FFS to increase the film's flexibility and skin-adherence. To create a transparent, flexible film that is low visible on skin, plasticizers are combined with polymers. The concentration of plasticizers to be used in FFS cannot be determined by any other rule because the polymer determines the plasticizer's effectiveness. The right amount of plasticizers will be used. When too many plasticizers are used, the film becomes smooth but sticky, and when too few are used, the film becomes brittle and has poor skin adherence. Plasticizers increase the film's tensile strength and reduce skin permeability to stop leaks. A leak could accelerate the degradation of the film's qualities. PEG and PG are said to contribute to the increased absorption of antifungal drugs. PG is useful for distributing drugs through the skin since it is a solubilizer in addition to being a plasticizer. The concentration must be considered because PG significantly affects the viscosity of the film-forming fluid. When coupled with ethanol or water, PG does not function well as a mixed solvent to prevent testosterone from crystallizing. 68 To improve drug penetration, less than 5% of PG is required. Additionally, PEG 400 can boost the amount of film-forming solution sprayed. As the concentration of PEG 400 rises, so does the amount per spray. Considering that PEG is a non-volatile solvent, this is linked to a drop in vapour pressure. [1, 27, 57]

4.Solvents:

The solvents are one of the most important components of FFS. It acts as a solubilizing agent for medications and polymers alike. The solvent is not a true part of the coating that forms on skin because of its quick evaporation. The only solvents used are those with a wide range of drug and polymer solubility. FFS solvents should be highly volatile at skin surface temperature, enabling for rapid drying while leaving the drug and polymer (form film) behind. The solvent's permeation-enhancing properties and direct impact on drug flux can promote drug transport through the skin, despite the extremely brief skin contact. The solvent must disperse properly in order to establish a smooth, uniformly thick coating on the skin. Water cannot meet these solvent criteria, hence volatile organic solvents such ethanol, ethyl acetate, isopropanol, etc. that have a quick drying time and improved patient compliance [15,24,58] are used instead.

Solvents	Properties
Ethanol	organic solvent, volatile, hydrophilic
Isopropyl myristate	organic solvent, lipophilic, penetration enhancer
Water	hydrophilic
Isopropanol	organic solvent, volatile, hydrophilic
Acetone	organic solvent, volatile, hydrophilic
Butanol	organic solvent

5.Polymers

There are numerous types of polymers that may be utilized to build these systems, and the FFS uses

them. These polymers can be employed either by itself or in conjunction with other film-forming polymers to produce the desired film properties. They fall primarily into two groups:

A. Natural and Semisynthetic Polymers

B. Synthetic Polymers

A. Natural and Semisynthetic Polymers

With water, cellulose and ethyl cellulose films are easily removed. [66]. Eudragit is usually combined with ethyl cellulose at a concentration of 5.02 to 5.25% to produce films with superior properties. According to reports, HPMC has a slow drying time. [26, 25] For the best film characteristics, the concentration should be 2%. The films produced by HPMC at these concentrations are translucent, thin, and smooth. [78]

A: Chitosan:

Apart from its film-forming capabilities, chitosan has antimicrobial, antioxidant, and mucoadhesive qualities that make it suitable for topical drug delivery. [79]. Chitosan has a relatively high surface tension. Chitosan is difficult to dissolve in water because of its surface tension, which increases with molecular weight and concentration. Usually, surfactants are used to make chitosan more soluble. [61] In making FFS from chitosan, Tween 80 can be used to reduce the surface tension. [81] The decrease in surface tension of chitosan goes hand in hand with an increase in the degree of deacetylation and its concentration, but the trend is not very significant. [81] The use of PEG 400 can also increase the stability and solubility of drugs in chitosan. Chitosan also has good conductivity with an increase in molecular weight so that it can be delivered using an electrostatic spray. Chitosan viscosity also decreases with increasing degrees of deacetylation. With these properties, chitosan can form films with denser droplet densities with smaller droplet diameters, ranging from 4–27 μm. Chitosan is also more hydrophilic at higher degrees (30–40 °C) such as on the skin and eyes. **[82]**

B: Xanthan Gum:

According to study, xanthan gum's viscosity has a significant impact on its spray-ability. The xanthan gum solution's surface tension and droplet size were both decreased by the addition of surfactants. It's interesting to see that neither the viscosity nor the flow properties altered much. Furthermore, when the concentration of xanthan gum increased, the spray angle and coverage area of the xanthan gum solution decreased. [80]

Polymer	Concentration (%b/v)	API	Sprayer
Chitosan	0.5–1.5	--	ES
Ethyl cellulose	0.1–10	Ethanolic extract solution of Psoralea corylifolia seeds, ketoprofen, fluconazole, voriconazole, and clotrimazole	Ordinal
Xanthan gum	<0.5	--	Ordinal
Methylcellulose (Methocel®E5)	5	Testosterone	Ordinal
HPMC phthalate (HPMCP®50)	5	Testosterone	Ordinal
Na-CMC	0.5–2	Immuno-globuli	Ordinal

C. Synthetic Polymers

a) Carbopol:

Additionally, carbopol displays thixotropy flow properties. [83]) Because carbopol can give or absorb wound moisture, it itself produces an amorphous hydrogel that is beneficial for open wounds. (84) Carbopol's viscoelastic nature permits deacetylation. Its permeability to water vapor does not, however, correlate with its hydrophilic character. In contrast to its elongation, chitosan's tensile strength will rise as its deacetylation levels rise. [1]

b) Eudragit:

Eudragit is available in various types with different pur- poses for use. Generally, these synthetic polymers are used as additives to tablets for modifying drug release. [85] However, Eudragit is also known to increase drug permea- tion in the skin, [66,86,87] so that its application in topical preparations is widely developed. Eudragit EPO, Eudragit E 100, Eudragit S 100, Eudragit RL 100, and Eudragit RS 100 produce transparent and shiny films while Eudragit RSPO and RLPO do not. Films produced by Eudragit EPO, Eudragit E 100, Eudragit RL 100, and Eudragit RS 100 cannot be washed away with water. In contrast, Eudragit S100 provides film that can be removed with water after being applied to the skin. The reason for this is because Eudragit S100 can dissolve at pH levels greater than 7. Furthermore, Eudragit S100 doesn't cause skin irritation. [22]. Reports state that Eudragit RS 100 has good sprayability, flexibility, and adhesiveness. At a concentration of 10.05% in a mixture with 5.02% ethyl cellulose, Eudragit RLPO produces outstanding films; however, use over 15% may hinder water washability. [24].

c) Lutrol:

Although Lutrol F-127 generates a more consistent dose of the drug in each spray with a lower standard deviation, it shares film properties and spray patterns with Carbopol 940. In comparison to Carbopol 940, Lutrol F-127 also creates films with superior drug release. No complaints of skin irritation have been made. [67]

d) Plasdone:

Plasdone is more effective than other polymers at increasing testosterone penetration, according to research by Lu et al. [27]). The sequence Plasdone > Eudragit EPO > PVP K30 > Eudragit RL was the most effective for testosterone penetration. This resulted from the polymer's ability to prevent testosterone from crystallizing, which raises its flow.

Polymer	Concentration (%b/v)	API	Sprayer
Carbopol®940	0.05–1	Ketoprofen and oxybutynin	Ordinal and MDS
Carbopol®971P	0.25–0.5	Beta-1,3/1,6-glucan	Ordinal
Eudragit®EPO	5	Ropivacaine	MDS
Eudragit®E100	2–10	Clotrimazole, methylphenidate, ropivacaine and testosterone	Ordinal and MDS
Eudragit®L100-55	5	Testosterone	Ordinal
Eudragit®RSPO	5	Ropivacaine	MDS

Eudragit®RS100	5–15	Fluconazole, clotrimazole, methylphenidate, and testosterone	Ordinal andMDS
Eudragit®RLPO	5–15	Voriconazole, clotrimazole, and dexketoprofen	Ordinal andMDS
Plasdone®S630	5	Testosterone and dexketoprofen	MDS
Lutrol®F-127	0.05–0.2	Oxybutynin	MDS

Evaluation Tests:

A) pH:

The pH value is checked and adjusted to improve the stability of the active component or make it suitable for the application site. Diabetic wounds have a pH between 6.5-8, while burns heal faster below [7.32.] During the healing phase, the preparation's pH adjustment aims to prevent inflammation and changes in the wound's physiological state. Furthermore, the amount of medication that penetrates the skin might be influenced by the dosage's level of ionization. [(1, 24, 31)]

B) Viscosity:

The density of the polymer will vary depending on its type and attention. This is an important characteristic, particularly in MDS, since the film forming result's density will impact its spreadability. The spray's content area can be dropped by adding the film- forming result's attention. [(61)]

C) Film formation/Film flexibility:

Either a Petri dish or an excised rabbit skin is used to produce the films. Film-formation, with or without precipitation of the film-forming polymer, is assessed and scored as complete and uniform, incomplete, or non-uniform. The film's aesthetic qualities are described as opaque or transparent, sticky or dry, and peelable or not. Stretching the skin in two or three directions allows for the evaluation of cracking and skin fixation, which are the basis for film flexibility. If there is neither cracking nor skin fixation, the film is regarded as flexible; if both are present, it is rated as non-flexible. [(15)]

D) Evaporation time:

Another name for the evaporation period is the drying time. The film's evaporation is measured to determine how quickly the film forms once the solution is sprayed. To find the drying time, the cleaned petri dish was sprayed with the batch film-forming solution that had been tuned. After a predetermined amount of time, a glass slide was placed stress-free on the film. If there is no more moisture visible on the glass slide, the film is considered dry. The rate of film formation is determined by the drying time. After three iterations of this procedure, the average evaporation time was determined. [(13)]

E) In vitro Drug Penetration/Release Study:

Franz diffusion cells are typically employed in this test as compartment separators together with cellulose membranes (pore size 0.45 m), nylon membranes (pore size 0.22 mm), or silicone membranes. The medium is phosphate buffer with a pH of 7.4. The film-forming solution is added to the donor compartment once the compartment system is prepared. At specific time intervals, a sample of the solution that diffuses through the cells is obtained, and the equipment is then used to

measure it. Following the collection of samples, the same amount of fluid is replaced. [2,24,46]

F) Spray angle:

The solution (d) was sprayed horizontally onto a white sheet that was held 10 cm distant. On the paper, the circumference of the circle was measured three times from various perspectives. The diameter is used to calculate the radius (r). The spray angle (θ) can be obtained using formula [65].

Spray angle (θ) = tan -1 (L/r)

Where, L = distance between sheet and spray nozzle.

R = radius of spray region

G) Spray pattern:

By passing the spray through the TS onto white paper, the spray pattern was evaluated. To aid in visibility, 1% methyl orange was dissolved in each formulation. At a distance of 2.5 to 3.0 cm from the plate, the paper was clipped to the ship and sprayed with the mixture. The diameters of the spots created by spray testing were measured and observed. Each reading was averaged after this was done three times1. [65].

H) Average weight per dose:

The containers' initial weight was noted. The containers were weighed once again after five successive deliveries were sprayed and foamed. The average weight per dose was calculated by dividing the difference between the containers' original and final weights by the number of deliveries. [66].

Average weight per dose (W)=Initial weight(W0)-Final weight(W1) /Number of deliveries.

(I)Leak test:

This test assessed the pump seal's effectiveness and its capacity to hold the product's contents. For three days, the filled container sunder test was kept upright at 30 degrees, and the contents were weighed both before and after the three days to make sure everything was in order. the formulation leaking out of the container. [66,]

Marketed product of film forming spray:

Product	Drug	Company	Formulation type
Lamisil Once®	Terbinafine hydrochloride	Novartis Consumer Health, Australasia, Pty Ltd	Film forming Solution.
Axiron®	Testosterone	Lilly USA, LLC	Film forming spray.
Medspray® the Patch-in-a Can®	Terbinafine hydrochloride	Med Pharm Ltd, UK	Film forming spray.
Liqui-Patch technology	Testosterone hydrocortisone	Epinamics GmbH, Germany	Film forming spray.
Durapeel Technology	Ropivacane	Crescita Therapeutics, Inc	Film forming gel
Pharma Dur® Technology	Hydroquinone	Polytherapeutics, Inc	Film forming emulsion-gel

CONCLUSION:

FFS can be a promising drug delivery system with various benefits. Spray film-forming systems are

modern drug delivery systems used for local, topical and transdermal delivery. Natural or synthetic polymers can be used as drug matrices and film formers following the need for increased stability and therapeutic effectiveness of the active sub- stance. Sprayers help form droplets with better and more uniform distribution and dosage of drugs.

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