



A Review on Topical Film Forming Spray

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Abstract

Some disadvantages of conventional medication formulations for topical application include low permeability, poor adhesion to skin, and reduced patient compliance. These new drug delivery methods intended for topical administration are called topical film forming systems. The skin, which clings to the body to create a thin, translucent layer that allows active ingredients to be delivered to bodily tissue over an extended period of time. The current study's goal was to develop and assess spray-based film-forming techniques for bacterial and fungal diseases. Film-forming polymers were added to the solvent system to make the formulation, and then the plasticizer and medication were added. Clotrimazole combined with ethyl cellulose and Eudragit RS 100 as film formers, PEG 400 and PEG 5000 as plasticizer, to create two distinct film-forming spray solutions using acetone and ethanol as the solvent combination. Using Design Expert 13 software, 32 factorial design was used for optimisation.

A number of factors, including viscosity, drying time, spray angle, film formation time, drug release, antimicrobial activity, pH, and water washability, were assessed for the optimised formulations. Film-forming methods offer advantages such as controlled release, lower dosage, water resistance, preventing secondary infections, and decreased wiping risk, which will make them an excellent platform for topical treatment against a variety of skin illnesses. In contrast to the traditional semisolid dosage forms, such as contact-free application, peel-out, etc.

Keywords: Topical, Controlled release, Film-forming spray, Infections, and Dosing

Introduction

Topical Drug Delivery

Topical medications have a long history. The Egyptians, Chinese, and Babylonians employed ointments and salves produced from animal, mineral, or plant extracts to treat a wide range of illnesses thousands of years ago.^[1-2]

Since many topical medications are so successful, they are currently prescribed extensively in many nations and have led to the discovery of several highly potent monomers. Still, there are several topical medications that these days appear a little confusing. For instance, the Kahungynaecological papyrus describes injecting a substance—possibly

crocodile excrement—into the vagina for contraception after treating it with kefir or honey.

Many attempts have been undertaken to increase the effectiveness of topical medications, and many beneficial outcomes have been attained. Ancient Egyptians infused their perfumes with essential oils or ointments to improve the active components' transdermal absorption efficiency.^[3]

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Cocaine is the term given to an alkaloid that German chemist Niemann isolated from coca leaves. This is the first widely recognised topical small molecule medication. The first recorded use of cocaine as a local anaesthetic in a therapeutic setting was in 1884^[4]

Topical Film Forming Spray

Using the polymer as a matrix for film formation, an FFS is a drug delivery system that takes the form of a sprayed solution and forms a film upon contact with the intended therapeutic site.^[5,6,7]

Once the film is formed, the medication is released in a manner akin to that of a patch, whereby the drug is released gradually from the polymer matrix^[8]

Nevertheless, since deep indentations can be exposed to tiny droplets of the film-forming solution, films form in the pattern of the skin or wound as opposed to topical patches and other topical preparations. Naturally, this makes it much easier for drugs to reach the intended tissue. To manage systemic or local effects, drug dosages in film-forming sprays can also be modified based on the volume of solution used in each spray. Additionally, an FFS distributes medications evenly and spreads effectively. Additionally, convenience of use might improve patient compliance.

In addition, this thin, non-sticky film makes patients more comfortable during activities than patches, ointments, gels, etc., which have a rough, sticky sensation when applied.^[9,10] To keep the equilibrium, the thin film also makes it easier for wound moisture to penetrate. As with patch preparations, improper wound humidity can lead to infection or discomfort.

Any type of sprayer is used to spray the film-forming solution in order to form droplets. While the features and intended applications of each sprayer vary, they all have particular potential for usage in medical settings. The description of several sprayer types that could be employed as medication delivery systems in film-forming systems is provided below.

Types of Film Forming Spray

Ordinal Spray

The ordinary spray is a kind of spray that uses a plastic or aluminium container with a dip tube

diameter of typically and doesn't require any special technology. 0.2 mm in diameter and a 0.3 mm aperture. The spray angle generated is 78.69–87.39° on average.^{40–42} Film-forming solution can be sprayed in an average of 0.11–0.35 g or mL.^[11,12,13] An ordinal spray container has an average leakage rate of 0.01–0.03%.³⁴ A vertical or horizontal ordinal spray is possible. It has been stated that the 3 K® Horizontal Spray Nozzle (Ursatec, St. Wendel, Germany) can keep the film-forming fluid sterile while it is being used and stored. The kind and concentration of polymer utilised affects the ordinal spray's spray force as well.³¹ Preparing extracts is another usage for the ordinal spray.^[14]

Meter Dose Spray

One spray device that allows you to modify the volume of spray is the metered dosage spray (MDS). Typically, this instrument is utilised to administer medications to the systemic compartment through the transmucosal or transdermal method. Because it is connected to the drug's dosage, the spray volume must be taken into account while assessing a film-forming spray. The amount of MDS spray that is available in the bottle, the uniformity of the particle dispersion, and the location of the container when in use can all affect the spray volume.^[15]

Electrostatic Spray

In the agriculture sector, electrostatic spraying (ES) is widely utilised for pesticide application. Enhancement of the deposition efficiency, uniformity of coverage, speed of droplet production, and reduction of drift loss are all possible using ES.⁴⁶ The way that ES performs is impacted by the solution's electrical resistivity, surface tension, and viscosity.⁴⁷ If the conductivity of a solution is not between 10⁻⁸ and 10⁻⁵ S/m, ES cannot be sprayed on it.⁴⁸ The droplets generated by ES have an average diameter of 6.3–12 µm and range in size from 4–26 µm.^[16,17]

Ultrasonic Spray

Using ultrasonic spray to apply film-forming solutions has a lot of possibilities. The resultant droplet has thin-film properties and can get as small as a nanometer. Both low and high

pressures can be used with the ultrasonic spray nozzle to produce homogenous droplets less than 10 µm in diameter. The ultrasonic spray nozzle has a diameter of 0.5 mm and a droplet diameter ranging from 1 to 10 µm. The electrode that is being used has a resonance frequency of 10 MHz. When used in the medical field, an ultrasonic spray can create layer-by-layer (LBL) coating films with more uniform particle sizes than standard LBL sprays.^[18]

Diseases:-

Candidiasis

Candida is a type of fungus that can cause opportunistic infections like candidiasis. Yeasts, moulds, and dimorphic fungi are examples of eukaryotic creatures that are classified as fungi. Yeasts include candida. The most typical way that candidiasis develops in immunocompromised people is as a secondary infection. Moniliasis, thrush, and candidosis are among synonyms for candidiasis. These can be seen frequently in the vagina, penis, gastrointestinal tract, or oral cavity, among other places.

They only turn pathogenic when the right circumstances come together. It may impact the penis, vagina, oral cavity, or other bodily parts. Thrush is the colloquial term for oral candidiasis. It appears as white patches on the neck, tongue, and other oral tissues. Additional thrush symptoms include soreness and difficulty swallowing. A Candida infection of the vagina is referred to as a yeast infection.^[19]

Tinea Pedis

Tendinapedis is more common in those with diabetes and in people who wear occlusive shoes. Usually, erosions between the toes and itchy scales are the first signs of tineapedis. Certain people may develop medial and lateral aspects as well as the soles of their feet with patches of hyperkeratosis and underlying erythema. On rare occasions, patients with this disorder may develop tineacorporis, onychomycosis, and tineamanuum simultaneously with painful bullous lesions. If tineapedis is left untreated, it can worsen peripheral vascular disease, diabetes, and immunocompromised patients' cellulitis, pyoderma, and osteomyelitis. This subject covers the pathophysiology and aetiology of tineapedis

and emphasises the vital responsibilities that the interdisciplinary healthcare team plays in diagnosing, treating, and preventing complications and recurrence of the illness. Trubrum is responsible for around 70% of instances of tineapedis.^[20,21]

Jock Itch

The fungus known as dermatophytes, which typically reside on skin, hair, and nails, are the cause of jock itch. Because of the buildup of moisture in the buttocks and thighs, fungus grows uncontrollably and begin to produce symptoms. Since the fungus can spread from an infected individual to others through clothing sharing, it is quite contagious as well as towels. After working out, staying in sweat-soaked clothing encourages the fungus to spread quickly. The fungus can linger on a variety of surfaces, including workout equipment, and it causes musty scent. Individuals who exercise more frequently sweat more, which is a major contributing factor to jock itch. The musty odour also gets stronger depending on how bad the illness is, and regular bacteria that live in skin folds can also contribute to the odour of a jock. Thanks of the fungus's ability to transfer from hands to contaminated towels or bedsheets, the illness typically moves from the feet to the groin areas.^[22,23]

Classification of Film Forming Spray

A thorough examination of the current clinical and technological classification of wound dressings is required to comprehend the placement of in situ spray filmforming systems, as well as the future directions for their advancement and usage recommendations. In medicine, wound dressings are dose forms used to treat patients who have skin damage. In practical surgery, this group's medications and medical equipment are still in high demand. For instance, as it is the most practical and economical method, treating purulent wounds under the dressing is the primary strategy used in clinical practice.^[24]

Though general trends are noteworthy, practitioners and experts are still at odds about how to classify wound dressings. Dressings can be

categorised based on a number of factors, including the presence of active ingredients (both medicated and non-medicated), the ability to absorb substances, the origin (animal, herbal, or synthetic), the method of application (primary dressings applied directly to the wound, secondary dressings applied to cover the primary dressing), the interaction of the dressings with the tissues (passive/inert dressings, interactive/bioactive dressings), the presence of advanced characteristics (vapour permeable films, hydrocolloid dressings, hydrogels or fibrous hydrocolloid dressing, polyurethane matrix hydrocolloid dressing, hydrocolloid dressing, and hydrocolloid^[25]

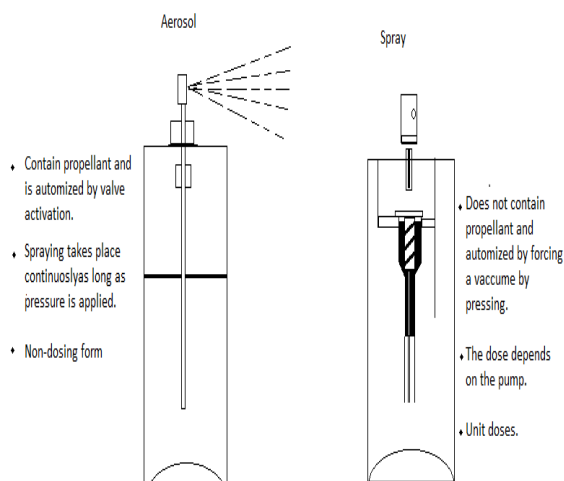


Fig-1 Difference between Spray & Aerosol Mechanism Of Film Forming Spray

The papers on spray film-forming systems seem to discuss three different film creation mechanisms: coalescence, evaporation, and cross-linking. However, it is evident that these systems are complimentary in spite of their divide. certain situations, but some are more important than others. Coalescence-based, or the third mechanism, is frequently found in tablet coatings.

Typically, a dispersion based on water is created, and coalescence happens when the solvent evaporates due to forces mediated by the surface. film generation via evaporation linked to a high solvent content and a low solids content. The method of film production in aerosol spraying is probably related to coalescence, while the

mechanism in spraying via spraying is more akin to an evaporation-based mechanism.

The nature of the polymers should ideally determine the mechanism and, consequently, the spraying system. However, this has not been extensively discussed in the literature to date, and the methods already in use are more empirical when it comes to the creation of SFFSs.

Cross-linking and exposure to a stimuli or external material are two separate mechanisms. While it is popular in other sectors and can be used as an alternative to the preceding two methods with exclusive coating qualities, it is scarcely used at the moment in the creation of SFFSs.

It is evident that aerosols and sprays produce films with distinct formation periods; the latter evaporating more slowly due to the spray's substantially higher solvent content. The writers list various times for the formation of films: Sprays areIt's likely that this will have an impact on the film's vapour permeability, which is crucial for skin breathing and wound surfaces. It is challenging to assess the propellant's impact. ^[26]

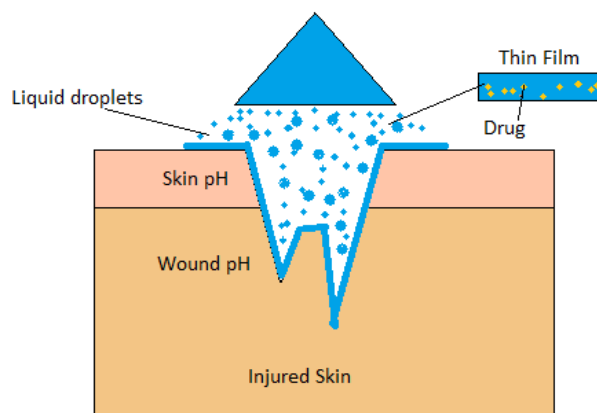


Fig-2 Mechanism of film forming spray

Components of Film Forming Spray

1. Active Pharmaceutical ingredients
2. Film forming polymer
3. Plasticizer
4. Volatile solvent

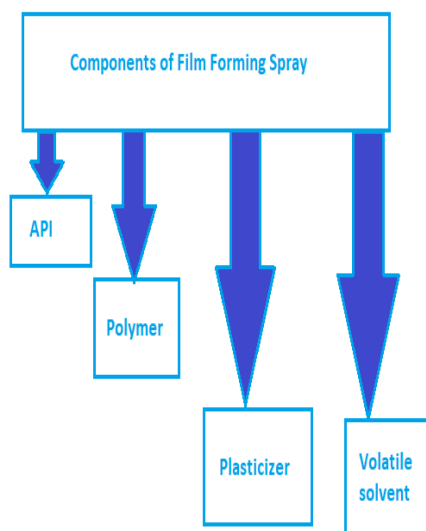


Fig-3 Film Forming components

Active Pharmaceutical ingredients

The medication must penetrate the stratum corneum, the skin's outermost layer, in order to be applied topically. The initial lipophilic barrier in the skin is called the stratum corneum. Thus, a medication with a high lipophilicity can more readily permeate the stratum corneum. over the hydrophilic medication. Log P Therefore, the medication that has a log P greater than two is the most appropriate and requires little to no penetration enhancer.^[27,28,29]

A few more variables, such as the drug's molecular weight and size, are also crucial in the drug's ability to penetrate the skin in addition to lipophilicity. A medication that transfers well through the skin is one with a size of less than 500 Dalton.^[30]

Film forming polymer

The creation of films depends critically on film-forming polymers. The most significant influence on the substantivity of the formulation comes from the choice of film-forming polymer. Polymers can be used separately or in combination. It's critical that they are able to create a thin, flexible, transparent, and durable film. There are essentially two types of film formers.

Polyvinylpyrrolidone (PVP)

PVP's solubility in water and organic solvents makes it possible to choose a more flexible

solvent for FFSs.¹⁵Excellent biocompatibility, high hygroscopicity, and the capacity to boost bioadhesive strength. PVP was therefore examined in a number of wound study clothes. PVP may occasionally be substituted with polyvinylpyrrolidone-vinyl acetate copolymers.^[31]

Polyvenyl alcohol (PVA)

PVA in FFSs is an issue and a constraint due to its poor hydrophilic nature, hard film formation, and inadequate flexibility.^{16–17}Therefore, for stable hydrogels, a small percentage of PVP (0.5–5%) in a PVP–PVA mixture has been recommended.^[32]

Chitosan

Chitin is the source of chitosan. It is biocompatible and has a certain biological action. Usually, it is used in the production of wound dressings. PVP and chitosan together have antibacterial properties.^{19–21} Its mucoadhesive properties are beneficial to the film-forming system. While chitosan is insoluble in water and organic solvents, it is soluble in acidic media solvents.^[33,34]

Polymethacrylates

Film-forming systems frequently use polymethacrylates. There are several variations of Eudragit, each with unique properties. These man-made polymers are frequently added to tablets to alter the way drugs release. Conversely, eudragit is reported to elevate drug penetration via the skin.^[35,36,37]

Plasticizer

A crucial part of the film-forming formulation are plasticizers. They must be very slightly added to the formulation in order to provide the film the required flexibility and to improve the film's ability to absorb water.³¹Certain plasticizers have drug-like properties. diffusion boosters in addition to giving the movie flexibility. They function by a mechanism that lowers the film's glass transition temperature.³²Plasticizers can support stable API.^[38,39,40]

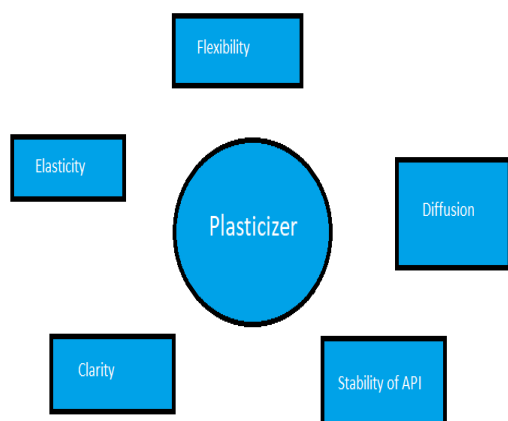


Fig-4 properties of Plasticizer

Plasticizer used in film forming spray:-

Table -1 Types of plasticizer

Sr.no	Plasticizer	Properties
1	DibutylPathalate	Plasticizer
2	Triacetin	Versatile water or oil miscible solvent plasticizer
3	Polysorbate 80	Non-ionic solublizer,plasticizer,emulsifier, Coemulsifier
4	Propylene glycol	Polymeric solublizer, plasticizer
5	Triacetin	Versatile water or plasticizer
6	PEG 400	Plasticizer
7	Sorbitol	Versatile water or plasticizer
8	Glycerol	Stabilizing agent and plasticizer ^[41,42]

Solvents :-

In order to balance the film's drying rate, the FFS system can employ both volatile and non-volatile solvents. Drugs find it difficult to penetrate and escape from films that harden and dry up too soon. Solvents are mostly utilised in mixture to achieve the necessary and sufficient effects on the drug release, film formation, and drying time.

The solvent and skin type need to be compatible. It also shouldn't irritate the skin, even if the evaporation process damages the skin barrier. It is necessary for the film-forming polymer to dissolve or disperse.

3–4.Less time should be needed for the formation of the film. It shouldn't happen too quickly to interfere with the formation of the film.³⁵Particularly good solvents for film-forming formulations are isopropanol and ethanol. Propylene glycol and isopropyl myristate both have extra penetration-enhancing qualities, but they don't evaporate.^[43,44]

Solvent used in film forming spray

Table-2 Types of Solvents

Sr.No	Solvent	Nature
1	Ethanol	Volatile
2	Isopropyl Alcohol	Volatile
3	Isopropanol	Volatile
4	Butanol	Volatile
5	Water	Non-Volatile
6	Acetone	Volatile
7	Isopropyl Mystrate	Non-Volatile
8	Propylene Glycol	Non-Volatile

Advantage of Film Forming Spray

- Uniform distribution of drug & dosage
- Improved bioavailability
- Less irritation
- Accelerate healing of wounds
- Prolonged drug release

Limitation of film forming spray

- Low permeability of the skin.
- Exclusive to potent substances.
- Unsuitable for big molecules (e.g., more than 500 Dalton's)
- Patch is not suited for skin adhesion; chemicals may cause skin harm; excessive solvent use with this approach is not recommended due to the limited solubility; If they irritate the skin, they are completely inappropriate.^[45]

Factor affecting topical permeation

Physiochemical properties of drug substances

- Partition coefficient
- Solubility of drug
- Concentration of drug
- Particle size of drug
- Polymorphism
- Ionization constant of drug
- Molecular weight of drug^[46]

Marketed Film Forming Spray :-

Product	Drug	Company	Formulation Type
Lamicil once®	Terbinafine Hydrochloride	Novartis Consumer Health, Australia PVT LTD	Film Forming Solution
Axiron®	Testosterone	Lily, USA, LLC	Film Forming Spray
Med Spray® the patch in a can®	Terbinafine Hydrochloride	Medpharma LTD, UK	Film Forming Spray
Liqui patch technology	Testosterone Hydrocortisone	Epinamics Gm Bh, Germany	Film Forming Spray
Durapeel technology	Ropivacaine	Crescita, Therapeutic, Inc	Film Forming gel
Pharma Dur® technology	Hydroquinone	Polytherapeutic, Inc	Film Forming Emulsion-gel

Table-3 Film forming marketed product



Fig-5 Marketed product

Conclusion

The film-forming system is a ground-breaking method of delivering pharmaceuticals to the skin. It offers a flexible approach to drug delivery that includes both surface application and skin absorption.

These systems are distinguished by their ease of use and numerous benefits, such as transparency, absence of greater patient compliance, greasiness, less skin irritation, resistance to removal, extended drug presence, improved dosage adjustment, and an aesthetically pleasing design. There is little information currently available on the effectiveness of drug delivery utilising these methods, despite substantial research efforts in this area. As a result, the market offers comparatively few products. More investigation is necessary to demonstrate the film-forming system's suitability as a transdermal medication delivery technique. The preliminary results, however, are encouraging and encourage further research into this ground-breaking method of topically administering medication.^[47]

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