International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 3, March 2025 **ijppr.humanjournals.com** ISSN: 2349-7203

Formulation and Evaluation of Film Forming Spray from Methanolic Extract of *Clitoria ternatea* Flower

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Received: 2025-3-05 Revised: 2025-3-16 Accepted: 2025-3-23

ABSTRACT

The current study focuses on creating and testing a film-forming spray with the methanolic extract of the flower of Clitoria ternatea, which is well-known for its potent antibacterial and antioxidant qualities. The main goal was to create a topical spray that could improve the stability and effectiveness of the active phytoconstituents by creating a protective layer on the skin's surface. Cold maceration was used to create the methanolic extract, which was then examined for phytochemical components to confirm the presence of phenolic compounds, flavonoids, and tannins. To obtain the right viscosity, spreadability, and quick-drying qualities, different formulations were created by maximizing the quantity of plasticizers such glycerin and film-forming agents like polyvinyl alcohol (PVA). The physicochemical characteristics of the prepared sprays, such as pH, viscosity, drying time, film thickness, and adhesion, were assessed. Antimicrobial efficacy was evaluated against common skin infections, and in-vitro antioxidant activity was evaluated using the DPPH assay. The ideal formulation produced a protective layer for the skin by exhibiting favorable film-forming properties, quick drying, and enough adherence. It demonstrated strong antibacterial and antioxidant activity, underscoring its promise as a safe and all-natural topical film-forming spray. Therefore, this study opens the door for further research into the therapeutic potential of Clitoria ternatea flower extract by presenting a novel method for using it in dermatological applications.

Keywords: *Clitoria Ternatea* flower, Film Forming Spray, Wound Healing.

INTRODUTION:

Topical drug delivery techniques have a large accessible surface area, are designed to have systemic or local effects, and bypass first-pass metabolism, the effects of low pH, and gastrointestinal tract enzymes.[1] Usually, medications administered topically are produced using a dosage technique, like a patch, gel, lotion, cream, ointment or spray to improve pharmacokinetic properties or therapeutic efficacy. The problem is that patches might be intentionally misused and yet leave behind drug traces after use. Additionally, patch preparations are commonly associated with blistering, irritation, and hypersensitivity.[2]

Problems with production scaling up are also commonly caused by drugs that are difficult to stable and have the potential to crystallize in storage. The ease with which they can be attached to clothing while moving and the possibility of wound cross-infection from finger application are the disadvantages of other semisolid preparations. [3, 4]

Compared to traditional topical dosages, sprays offer several advantages, such as ease of use, reduced irritability, sterility of the dosage, better covering of the skin or wound, consistent drug dispersion upon application, and adjustable dosage.

Many developments have been made in recent decades to provide efficient and effective spray preparations.

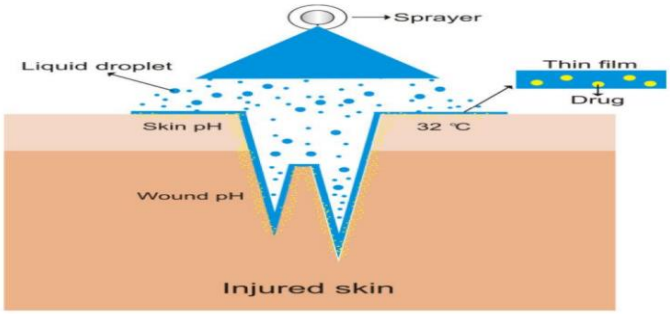
Among these are film-forming sprays (FFS), which have found application in a range of sectors, such as agriculture, food manufacturing, cosmetics, and medicine. Typically, FFS consists of enhancers, polymers, and active chemicals distributed in organic solvents. A thin, non-sticky coating can enhance the drug's permeability and contact time, leading to continuous drug release, in addition to preventing crystallization, which would free up more medication for therapeutic effects. [5–7]

The types of polymers, excipients, and sprayers frequently employed in FFS are examined in this paper, along with the assessment criteria needed to assess the quality of FFS for improved development. [8] The type of nozzle, aperture size, spray pressure, and liquid composition all have a significant impact on FFS's spray capability. Studying FFS's viscoelastic, in situ gel, pH, and heat-sensitive characteristics is essential to identifying the factors that must be considered when selecting polymers, solvents, and other excipients.[9]

Mechanism of film-forming spray :

The medicine is progressively released from the polymer matrix using a technique similar to a patch.However, unlike topical patches and other topical medicines, films form in the pattern of the skin or wound because deep indentations can be exposed to tiny droplets of the film-forming solution. This, in course, makes it considerably simpler for medications to enter the intended tissue. Both local and systemic effects can be controlled by adjusting the drug dosages in a filmforming spray based on the volume of solution used in each spray. Furthermore, an FFS efficiently and uniformly dispenses drugs. Convenience of use can also increase patient compliance.[10]

The thin layer can be easily removed with water. In addition to improving patient comfort during activities, this thin, non-sticky film is superior than patches, ointments, gels, etc. that have a rough, sticky sensation when applied. Furthermore, the thin layer facilitates the penetration of moisture from the wound, maintaining balance.[11] Inappropriate wound humidity might result in infection or discomfort, much like with patch preparations. Any kind of sprayer is used to generate droplets of the film-forming fluid. Every sprayer has a different potential for usage in medical settings, despite differences in characteristics and intended uses. [12,13]



FILM FORMING SPRAYERS

Ordinal Spray: [14]

Ordinal spraying is a spraying technique that doesn't require any specialized equipment. It usually employs a plastic or aluminum container with an aperture size of 0.3 mm and a dip tube diameter of 1.2 mm. Usually, a spray angle of 78.69° to 87.39° is produced. The average amount of film-forming solution that can be sprayed is 0.11–0.35 g or -mL. The average leakage rate for ordinary spray containers is between 0.01 and 0.03 percent. Ordinal sprays come in two varieties: horizontal and vertical. The 3 K® Horizontal Spray Nozzle (Ursatec, St. Wendel, Germany) is said to be able to maintain the sterility of the film-forming solution both during usage and storage.

Metered Dose Spray:[15]

The metered dosage spray (MDS) is one type of sprayer that has the ability to adjust the amount of spray. Usually, this tool is employed to deliver preparations to the systemic compartment via the transdermal or transmucosal pathways.

When evaluating a film, the spray volume needs to be considered because it is connected with the drug's dosage. creating a spray. The MDS spray volume can be influenced by the bottle's volume, the uniformity of the particle dispersion, and the position of the

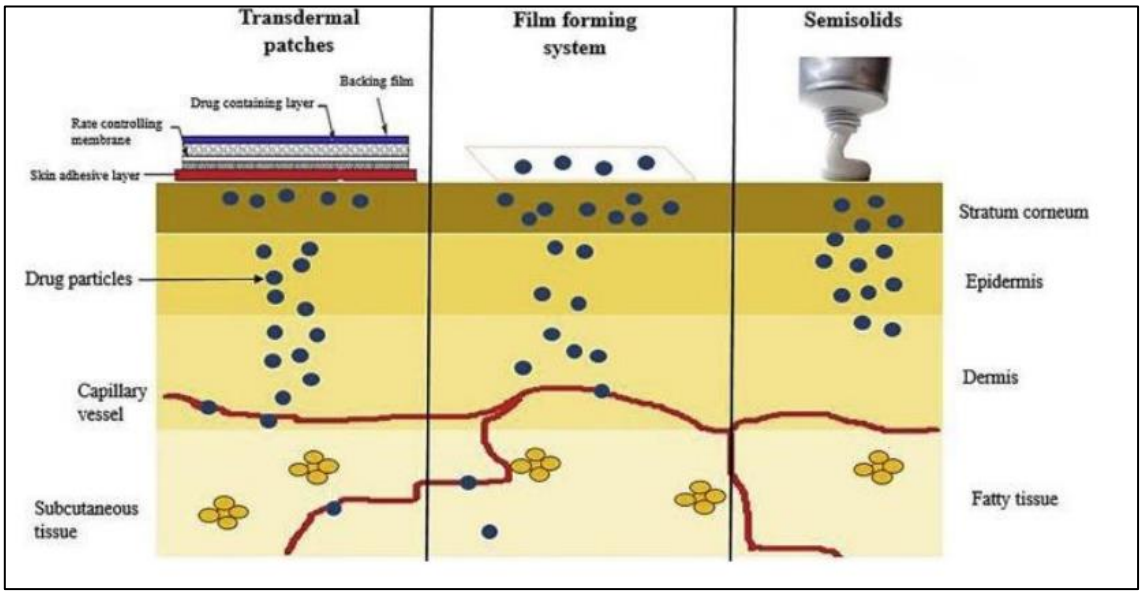
container while in use. The usual amount of FFS that can be sprayed is 90–102 mL.The average spray angle for MDS is 83.51°.20 The average leakage rate for an MDS container is 0.01 to 0.02 percent.

Electrostatic sprays: [16]

Electrostatic spray (ES) is widely used in agriculture for pesticide application. ES can improve droplet formation speed, uniformity of coverage, and deposition efficiency while reducing drift loss. The effectiveness of ES is influenced by the solution's viscosity, surface tension, and electrical resistivity. The droplets that ES produces have vary in size from 4 to 26 µm and have an average diameter of 6.3 to 12 µm.

Ultrasonic spray:[17]

The ultrasonic spray has a lot of potential as a film-forming solution. The resulting droplet can grow to the nanoscale and possesses thin-film characteristics. At both low and high pressures, the ultrasonic spray nozzle can produce uniform droplets with a diameter of less than 10 µm. The nozzle of the ultrasonic spray has a 0.5 mm diameter and produces droplets that are between 1 and 10 µm in size. The electrode's resonance frequency is 10 MHz. An ultrasonic spray can produce layer-by-layer (LBL) coating films for use in the medical industry with more homogeneous particle sizes than a conventional layer-by-layer (LBL) spray. Each type of sprayer has specifications that match specific polymers. Numerous synthetic and natural polymers have been used in the FFS process.



Excipients Used in Film-Forming Sprays:

In addition to the polymers, other excipients are added to improve the preparation's quality and therapeutic effectiveness.

Crosslinkers: [18]

The use of crosslinkers can affect the polymer's glass transition, elasticity, viscosity, solubility, and film stiffness. The use of NaCl as a crosslinker in gellan gum, which enhances and accelerates film production, also affects the gel's sensitivity to temperature. NaCl also improves the cell encapsulation of gellan gum.

Permeation Enhancers: [19,20]

Eutectic mixtures are commonly used to increase the uptake of medications. Among the strongest eutectic mixes is a blend of camphor and menthol. Because menthol and camphor combine to form a hydrophobic mixture, it can be utilized as a penetration enhancer for drugs that are likewise hydrophobic. However, menthol and camphor might cause leaching and the formation of skin pores. A combination of menthol and camphor creates a warm feeling that is progressively followed by a cold one.

Solvent:[21]

The FFS system uses both volatile and non-volatile solvents. Achieving equilibrium in the film's drying rate is the aim. Films that harden and dry out too quickly make it more difficult for drugs to escape and penetrate. The active ingredient is frequently diluted in the solvent until it approaches saturation in order to expedite the film drying process.

Application of film-forming spray:

The industry offers a wide variety of FFS applications. Most products are made to handle and care for wounds. Common injuries that can be treated include burns, diabetic wounds, and incised wounds following surgery or sharp object contact. The FFS system is utilized by these products.

CLITORIA TERNATEA: *[23-31]*

The perennial leguminous twiner Clitoria ternatea, also known as butterfly pea, is native to tropical Asia and has since spread extensively over South and Central America, the East and West Indies, China, and India, where it has established itself as a native species. It belongs to both the Papilionaceae subfamily and the Fabaceae family. Clitoria ternatea, also called the blue pea, kordofan pea (Sudan), cunha (Brazil), or pokindong (Philippines), is an old-world legume that grows rapidly in the summer.The majority of the 60 species of Clitoria L. are found in the tropical zone, while several are also found in temperate areas. The species that is most frequently observed is Clitoria ternatea. It is a woody genus with papilionaceous, colorful blooms, stalked ovaries, and an infundibular calyx with persistent bracteoles and stipules.[23]

Several species of Clitoria are used medicinally to cure gonorrhea, increase fertility, regulate menstrual flow, and stimulate sexual desire. According to Fantz, 23 species of Clitoria have commercial applications as refrigerants, diuretics, and antihelmintics. In Indian traditional medicine, this plant is referred to as Kokkattan (Tamil), Aparajit (Hindi), and Aparajita (Bengali). In Ayurvedic texts, it has a number of synonyms, including Aparajita, Girikarnu, Asphota, and Vishnukranta, which are Sanskrit names. English names include Winged Leaved Clitoria, Mazerion, and Butterfly Pea. Local names include Gokarna (Mar), Aparajita (Hin), Aparajita (Beng), Gorani (Guj), and Buzrula (Arabic). Because it is highly pleasant to livestock and adapts well to a variety of climates, the plant is mostly utilized as feed. Nowadays, many people grow this species as a decorative and therapeutic plant. [24,25] At room temperature (30 ± 2 °C), 750 g of air-dried C. ternatea flowers were extracted three times (6 days each) using 95% MeOH (4 X 500 mL). In a vacuum, the mixed methanolic extract was evaporated. It highlights the importance of doing the sequential partition fraction of methanol crude extract (30.7 g) prior to fractionation. After the resultant methanolic extract residue was suspended in 1000 milliliters of hot water, it was extracted using $CHCl_3$ and EtOAc in succession, and the solvent was recovered by simple distillation. When the solvent evaporated at lower pressure, the crude extracts $CHCl_3$ (27.0 g) and EtOAc (24.5 g) were produced, respectively.[26]

Since ancient times, C. ternatea's benefits have been acknowledged. It is used as a natural food additive and is thought to be a natural remedy for a variety of illnesses. Neda et al. have identified and published the nutritional composition of C. ternatea flowers in addition to the phytochemical components. The moisture content is 92.4%, while the percentages of fat, carbohydrate, fiber, and protein are 2.5, 2.2, 2.1, and 0.32%, respectively. Iron (0.14 mg/g), calcium (3.09 mg/g), magnesium (2.23 mg/g), potassium (1.25

mg/g), zinc (0.59 mg/g), and sodium (0.14 mg/g) were also found to be abundant in the flowers. The positive effects are caused by a variety of phenolic chemicals found in the plant, particularly in the flower petals. Numerous bioactive substances, including alkaloids, tannins, glycosides, resins, steroids, saponins, flavonoids, and phenols, are found in C. ternatea. Malonylated flavonol glycosides were also reported to have been extracted from flower petals in another investigation.[27]

The drug is typically found as leaves and leaflets, with the rachis broken with or without intact leaflets. It is a perennial twining herb with seven elliptic and obtuse leaflets. Pinnate 5-9 foliolate leaves are present. Style bearded below the stigma, flowers are ostentatious, and the blue or white petals are uneven. Pods of fruits are compacted and linear. Each pod contains six to ten seeds and is flat and 5-7 cm long. There are six to ten black seeds. Plant fruits in the winter and flowers in the wet season. Clitoria ternatea has solitary, incredibly beautiful blooms with a creamy white tint, while Clitoria purpurea has dark blue papilionaceous blossoms.[28]

Antioxidant Activity:

The stable DPPH radical (Blois technique) was used to test the extract's antioxidant activity in terms of its capacity to donate hydrogen or scavenge radicals. A DPPH solution (0.3 mmol/L) in methanol was made, and 1 mL of this solution was mixed with 1 mL of the sample at different concentrations and quercetin, the reference molecule. Absorbance was measured at 517 nm after the sample was agitated violently and allowed to stand at room temperature in the dark for 30 minutes. By comparing the absorbance values of the test and control samples, the percentage of inhibition was determined (Alam, Bristi, & Rafiquzzaman, 2013). (Abs control − Abs sample/Abs control) times 100 is the percentage inhibition (1%).[29]

Wound healing effect:

The wound-healing properties of Clitoria ternatea seed and root extracts. When given orally by gavage and topically as an ointment, Clitoria ternatea seed and root extracts markedly enhanced wound healing in excision, incision, and dead-space models. These outcomes were similar to those of ointment containing cotrimoxazole. The results of the investigation also demonstrated that Clitoria ternatea impacted the proliferative, remodeling, and inflammatory stages of wound healing. Standardized Clitoria ternatea leaf extract's capacity to cure wounds was assessed using a variety of enzymatic models, the majority of which are connected to skin wounds. Hyaluronidase, elastase, and matrix metalloproteinase-1 (MMP-1) inhibitory activities were assessed in the methanol extract and fractions in comparison to standard oleanolic acid. [30]

Antibacterial activity:

The development of bacteria resistant to antibiotics severely reduces the efficacy of existing medications, leading to infection treatment failure. In addition to looking for novel antibacterial chemicals, different strategies must be developed to address this challenge. A variety of techniques, including broth or agar dilution and disc diffusion procedures, can be used to investigate the in vitro activity of an antimicrobial (antibacterial or antifungal) drug. The antibacterial properties of C. ternatea flowers were the subject of several investigations. Bacillus cereus, Bacillus subtilis, Bacillus thuringiensis, Staphylococcus aureus, Streptococcus faecalis, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Salmonella typhi, Enterobacter aerogens, Proteus mirabilis, and Herbaspirillum spp. were among the twelve bacterial species that were tested against the methanol extract of C. ternatea flowers.[31]

Anti-inflammatory activity:

Since they are known to impact both COX-1 and COX-2, the non-steroidal antiinflammatory medicines (NSAIDs) that are currently on the market, such as aspirin and acetaminophen, are linked to adverse effects, especially gastrointestinal and cardiovascular ones. To achieve adequate pain relief while lowering the hazards associated with NSAIDs, new or alternative approaches must be developed. [31]

Clitoria ternatea flower were collected from the local market . Optimization of excipients for film forming spray: Optimization of spray formulation includes selection and study of solvent systems, polymers, plasticizers, and other adjuncts such as methyl salicylate, menthol, and concentrations. The effect of the spray on the appearance was visually observed and applied to the skin and better aids were selected for the next attempt.6-8 Selection of solvent system: *Clitoria ternatea* flower is soluble in organic alcohol solvents, immobilizer oil, paraffin oil and propylene glycol. It is not soluble in water. Water and ethanol were used as solvents in varying concentrations. Selected solvents such as water and ethanol are safe and these common solvents are used in topical solutions and preparations.7 Selection of type and concentration of polymer: PVPK30 and HPMCE5 were selected to test their ability to spray to form a film of *Clitoria ternatea.*

As shown in Table 1, the various film-forming polymers were PVPK30 and HPMCE3 at different concentrations of 1.0, 2.0, 3.0, 4.0, and 5.0% by weight. Apply a film-forming spray to the skin. The polymer was selected based on the physical properties of the film. Focus on film thickness, smooth, clear white spots on the surface, and quick-drying.

TABLE 1. Preparation of film forming spray using various type and concentration of polymers

Ingredients	Formulation (%w/w)									
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
HPMC E5	1.0	2.0	3.0	4.0	5.0	-	-	-	-	-
PVP K30	-	-	-	-	-	1.0	2.0	3.0	4.0	5.0
Ethanol	49.5	49.0	48.5	48.0	47.5	49.5	49.0	48.5	48.0	47.5
Water	49.5	49.0	48.5	48.0	47.5	49.5	49.0	48.5	48.0	47.5

Selection of the type of plasticizers:

Propylene glycol (PG) and polyethylene glycol 400 (PEG 400) were selected to study their spray-forming flexibility. The various plasticizers are propylene glycol and PEG 400 at a concentration of 1.0% by weight as shown in Table 2. Apply the film forming spray to the skin. Polymers are selected based on the physical properties of the film. Focus on fragile film and white spot on the surface.

Ingredients	Formulation w/w			Function
	F1	F2	F3	
PVP K30	3.0	3.0	0	Film forming agent
HPMC E5	-	-	2.0	Film forming agent
Propylene glycol	1.0	-	-	Plasticizer
Polyethylene glycol 400	-	1.0	1.0	Plasticizer
Methyl salicylate	3.0	3.0	3.0	Active ingredient
Menthol	1.0	1.0	1.0	Active ingredient
Clitoria ternatea	0.02	0.02	0.02	Active ingredient
Purified water	37.98	37.98	37.98	Solvent
Methanol	54.0	54.0	54.0	Solvent

Preparation of film forming spray :

The spray changed into organized with the aid of using easy answer method. First the polymeric answer device changed into made with the aid of using dissolving polymers in ¾th amount of water and stirring the usage of magnetic stirrer. *Clitoria ternatea* changed into dissolved in ethanol and introduced right into a polymeric answer. Then the plasticizer changed into introduced and changed as much as very last weight with water. After screening the excipients (polymers and plasticizers) in formulation, the topical movie forming sprays from *Clitoria ternatea* have been developed, introduced different elements along with methyl salicylate and menthol as counterirritant that each dissolved in ethanol, combined properly to absolutely formulation.

Evaluation of film forming spray formulations:

Physical characteristics:

Clitoria ternatea film forming spray were set separately at room temperature (30±2 °C) for 0, 7, 14 and 28 days, lucidity of solution, film thickness development and white spot on surface were recorded by visual observation.

Evaporation time:

Film forming spray droplets were spread on a bagasse paper that is suspended at a sensitive balance in a fume hood. Weight loss of the bagasse solvent/paper liquid is measured as a function of time as the solvent evaporates using analytical elements balance.

Volume per spray:

The following quantifiable tests for the spray formulations were also performed. Average weight per dose is a vital quantitative parameter to be evaluated. Ten sprays were actuated into a glass beaker where on analytical balance and then calculated volume per spray.

pH :

About 20 ml of film forming spray solution was taken in a 30 mL glass beaker. The pH was determined using digital pH meter. The measurement of pH of each formulation was done in triplicate and mean values were calculated. pH was determined at every 0, 7, 14 and 28 days.

DISCUSSION:

The selected solvents were highly purified water and methanol . Both solvents were safe, less expensive and common solvents used in solution preparations. Water attainable with homogenous and clear solution. All the polymers were entirely dissolved in water. In instance of methanol, clitoria ternatea flower extract in was found clear. Water part and metanol part were mixed, the mixture gave clear (F1,F2,F3). After 14 days, F1 and F3 were changed a little too light yellow clear in appearance. The upshot of solvent on evaporation time was recorded. It was established that ratio of 37.08 : 54.00 (water : ethanol) was the most appropriate solvent system ratio for spray formulations due to its capability to evaporate rapidly on application.

The film forming polymers: PVP K30 and HPMC E5 were selected for inspection of uniform thick film formation. The PVP (polyvinylpyrrolidone) K30 is a hygroscopic, amorphous polymer in nature. It is are miscible in water and organic solvents. As the concentration of PVP K30 was augmented from 1% to 5 % by weight, the viscosity was progressively amplified. With a higher value polymer concentration, the resultant gel formed was more viscous in nature and the tightness of the swollen hydrogel network was also increased. Compared with the other polymers, HPMC E5 increased from 1.0% to 5.0% by weight, the viscous was gradually enlarged, at concentration 3.0-5.0% by weight depicted white spots. Spray formulations F1 and F2 were formulated using PVP K30 ,1.0 to 5.0% by weight, PVP K30 at 3.0% by weight exhibited thin film, smooth and clear that shaped satisfactory films. Formulations F3 was articulated using HPMC E5 1.0 to 5.0%% by weight, HPMC E3 at 2.0% by weight fashioned acceptable films. All formulations F1-F3 were signposted slow drying films. Therefore, the formulations were established to increase rate of drying time by varies concentration of solvent. The formulations F1-F3 were primed to examine the result of different plasticizers. Propylene glycol and PEG 400 were nominated for exploration of their flexibility of spray formulation using 1.0% by weight. The results depicted that similar of film appearance, clear film, and smooth surface and not to breakdown. F1-F3 gave clear solutions while after 14 days F1 and F3 offered light yellow solution those compose of PVP K30 as polymer and detected a wobbly of pH. F2 gave clear solution and denoted white spot after applied. Film forming sprays were developed by added methyl salicylate and menthol as counterirritant for synergistic clitoria ternatea activities. Methyl salicylate and menthol were added produce heating and cooling sensation after application of spray (time around 5 min). The films on skin could be easily washed off with water. Comparing the physical characteristics of films, evaporation time and pH, formulation F2 was found to be better as compared to other formulations.

CONCLUSION:

clitoria ternatea for the skin may have the following benefits like anti-inflammatory, anti-fungal, antiseptic.It may also promote wound healing activity.

The topical filmforming spray is one of formulations are medicines that reduce the sensation of pain in the area to which applied. The method of preparation of film forming spray was simple.

The developed film forming spray formulations were clear, smooth and flexible in physical appearance.

The evaluation studies were presented ability to evaporate rapidly on applies, pH becomes similar to that of normal skin offered of lower skin irritation.

Spray is more convenient to use, can be applied easily thus improve patient acceptance and compliance.

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How to cite this article:
R.Divyaparvathi et al. Ijppr.Human, 2025; Vol. 31 (3): 288-295.

Conflict of Interest Statement: All authors have nothing else to disclose.