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Film Forming Spray Floraderm Promist: For The Treatment Of Skin Lesions In Geriatric Patients

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ABSTRACT

As people become older, their skin changes in structure and function. For example, the epidermis gets thinner, the dermal collagen and elastin are lost, and the sebaceous glands become less active. This makes the skin more likely to become dry, irritated, and take longer to heal. Filmforming sprays (FFS) like Floraderm Promist offer a new way to treat skin lesions in older people by putting a polymeric film on the skin that protects, hydrates, and breathes. This review talks about the ingredients, how Floraderm Promist works, and how it could be used as a medicine. The formulation contains herbal constituents including turmeric, manjistha, calendula, tulsi, aloe vera, and inulin from chicory root, as well as excipients like pullulan/xanthan gum, rose water, potassium sorbate, and citric acid. Together, these parts have anti-inflammatory, antibacterial, wound-healing, and microbiome-balancing actions. The polymeric layer helps with sustained release, keeps the area moist, stops secondary infections, and speeds up tissue regeneration. Floraderm Promist is a good, patient-friendly alternative to traditional topical treatments. It is especially good for older skin that needs delicate, continual care.

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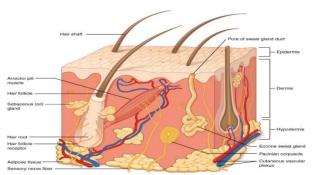
INTRODUCTION:

The skin is the largest organ in the body, serves as a protective barrier against environmental insults, microbial invasion, and physical injury¹². The epidermis, dermis, and hypodermis are the three primary layers that make it up.

1) Epidermis: It is the outermost skin layer made up of keratinocytes in several layers. Divided into five layers – Stratum Basal (location for cell division), Stratum spinosum, Stratum granulosum, Stratum lucidum (present only in the thick cell),

Stratum coreum (It is the outermost layer consist of dead, flattened cells dispersed in lipid bilayer)

- 2) Dermis: It is located below the epidermis consist of connective tissue, primarily collagen and elastin. It is bounded by blood vessels, lymphatic nerves, sweat glands, sebaceous glands and hair follicles. Involves in thermoregulation and immune function. Vascular nature of these layers is of prime importance for the systemic drug absorption in TDDS.
- **3) Hypodermis:** It is the innermost layer, consisting of connective tissue and adipose tissue. Works in insulation and storing energy. Also contains large nerves and blood vessels.



As you get older, the epidermis gets thinner, the dermal collagen and elastin break down, and the hypodermis loses fat cells. This makes the skin thin, dry, and sensitive. Older people also have less active sebaceous glands and wounds that take longer to heal. These changes in the body show that older skin needs particular skin care products that are made to protect, soothe and heal it. Floraderm Promist is a healing and hydrating spray that act as a protective biofilm, like a liquid bandage, while keeping the skin hydrated and the microbiome in balance.

Film Forming Spray (Floraderm Promist)

Film-forming sprays (FFS) are liquid (or metered) topical formulations that are sprayed onto the skin. The solvent evaporates, leaving behind a thin, sticky polymeric film². Compared to lotions, ointments, and patches, these films can hold drugs in place, protect them, and distribute them more slowly and steadily. They also have better transparency and are more acceptable to patients.

Advantages of film forming spray:

- 1. Uniform dosage and coverage over a vast area—easily cover uneven surfaces and spread actives evenly.
- 2. Long-lasting contact or sustained release: the polymer matrix allows for longer release and better pharmacokinetics than semisolids.
- 3. Better patient compliance and looks thin, frequently clear films that aren't greasy look good.
- 4. Less irritation and fewer doses—less local irritation and fewer doses because of prolonged release.
- Flexible devices: they come as metered-dose containers (which give correct actuation volumes) or pump sprays for varied medical uses, such as wounds, antiseptics, and painkillers.

Disadvantages of film forming spray:

- 1. Choosing the right solvent and excipient: many systems use volatile organic solvents or propellants, which can be dangerous, smell bad, and be against the law.
- 2. Mechanical fragility: If the formulation (polymer/plasticizer ratio) is not right, films

- might be brittle, flake, or lose their grip.
- 3. Variable drug permeation: The polymer, solvent, and plasticizer selections have a big effect on how well the drug gets through the skin and how quickly it is released. Getting a consistent systemic distribution can be hard.
- 4. Limitations of spray devices: metered delivery necessitates validated containers (actuation volume fluctuation, clogging, spray pattern).
- 5. Stability and microbial issues: Liquid formulations and films need to be examined for drug stability, solvent loss, microbial limitations, and storage conditions.



B] INGREDIENTS Turmeric:



- Biological Source: Comes from the rhizomes of the Curcuma longa plant and belongs to the Zingiberaceae family. India, China, Indonesia, and other tropical Asian countries are where this comes from [5].
- Curcuminoids (curcumin, demethoxycurcumin, bisdemethoxycurcumin), volatile oils (zingiberene, turmerone), proteins, and carbohydrates are all chemicals that make up this substance.
- Uses: Antioxidant, anti-inflammatory, wound healing, antibacterial, and hepatoprotective
- Benefits of Curcumin for Skin Lesions and Rashes: It lowers inflammation, stops infections from microbes, speeds up healing, and eases itching.

Calendula:



- **Biological Source:** Comes from the flowers of Calendula officinalis. It belongs to the Asteraceae family. Geographical Source: Grown in India, the US, and Europe, but native to the Mediterranean [4].
- Chemical components include flavonoids (quercetin and isorhamnetin), triterpenoids, carotenoids (lutein and zeaxanthin), saponins, and volatile oils.
- Uses: antifungal, antibacterial, antiinflammatory, and relaxing agent.
- Benefits for skin lesions and rashes: It helps produce granulation tissue, calms redness and irritation, and speeds up the healing of wounds, rashes, and eczema.

Manjistha:



- Biological Source: Roots of Rubia cordifolia Family: Rubiaceae India, Sri Lanka, China, and Southeast Asia are all places where it comes from.
- Anthraquinones (purpurin, munjistin), glycosides, tannins, and resins are some of the chemicals that make up this substance.
- Uses: cleans the blood, reduces inflammation, protects the liver, and fights free radicals.
- Benefits for skin lesions and rashes: detoxifies the skin, decreases redness, clears up acne and eczema, and helps with persistent skin problems and itching [3].

Holy Basil (Tulsi):



- Biological Source: The leaves and other parts of Ocimum sanctum that grow in the air Liliaceae is the family.
- Geographical Source: Grown a lot in India, Nepal, Thailand, and tropical Asia.
- Essential oils, eugenol, ursolic acid, rosmarinic acid, and flavonoids (orientin and vicenin) are some of the chemicals that make up this substance.
- Antibacterial, antiviral, antifungal, adaptogenic, and wound healing are some of its uses.
- Benefits for skin lesions and rashes: stops infections, stops itching, soothes irritated skin, and protects against germs.

Aloe Vera:



- Biological Source: Aloe barbadensis leaves Family: Asphodelaceae (previously Liliaceae).
- Where it comes from: It grows naturally in North Africa and is grown in India, the US (Texas and Florida), China, and the Mediterranean [5].
- Chemical Components: Polysaccharides (acemannan, glucomannan), anthraquinones (aloin, emodin), vitamins (A, C, E, B12), amino acids, and minerals.
- It can be used to hydrate, heal wounds, reduce inflammation, and make skin look younger.
- Benefits for Skin Lesions/Rashes: It adds moisture, protects the skin, lessens irritation, speeds up healing, and calms itching and dryness.

Inulin from Chicory Root:



- Biological Source: The roots of Cichorium intybus is the biological source. Asteraceae is the family name.
- Geographical Source: This plant is native to Europe and is grown in India, North America, and the Mediterranean.
- Chemical Components: Inulin (a kind of fructan polysaccharide), coumarins, sesquiterpene lactones, vitamins, and tannins
- Uses: as a prebiotic, liver tonic, mild laxative, and diuretic.
- Benefits for Skin Lesions/Rashes: It works as a
 prebiotic for the skin microbiome, helps
 maintain a healthy balance of bacteria,
 strengthens the skin barrier, lowers the chance
 of infection, and speeds up healing.

Pullant / Xanthan Gum:

- Biological Source: The fungus Aureobasidium pullulans makes pullulan, which is a natural polysaccharide. Xanthan gum is a polysaccharide with a high molecular weight that is secreted by Xanthomonas campestris bacterium [1].
- Geographical Source: Countries including Japan, China, India, and the United States make it for sale.
- Uses: In cosmetic and medicinal products, it is used to make films, keep things stable, and thicken things. Helps make dressings that can be sprayed on and stick to skin.
- Benefits for Skin Problems: It creates a biofilm over the Skin that protects it like a "liquid bandage." Keeps the right amount of moisture and stops germs from getting in. Helps wounds heal faster and keeps skin that is thin and old safe.

Rose Water:

- Biological Source: This is made by distilling fresh petals of the Damask rose.
- Geographical Source by region: Most of the time, it is grown in India (Kannauj, Rajasthan), Bulgaria, Turkey, and Iran.
- Uses: Used in cosmetics and skin care products to add scent, calm, and chill the skin.
 In herbal sprays, it works as a natural toner and

diluent.

 Benef for Skin Lesions: It cools and calms down inflamed skin [13]. Lessens redness and irritation in small cuts or irritated regions. Encourages gentle healing and makes old, dry skin feel better.

Potassium Sorbate:

- Biological Source: It is a synthetic salt of sorbic acid, which comes from the berries of the mountain ash tree (Sorbus species).
- Geographic Source: Made at factories all around the world, with China, the US, and Europe being the biggest producers.
- Uses: Used in cosmetics and medicines to keep fungi and bacteria from growing.
- Benefits for skin lesions: Keeps the solution free of microbes, making sure it's suitable for skin that is open or healing. Stops secondary infections and makes the product last longer[10].

Citric Acid:

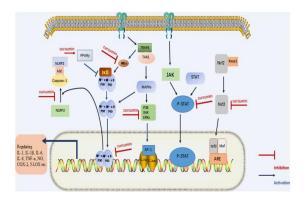
- •Biological Source: You can get it from citrus fruits like lemons, oranges, and limes, or by fermenting it with Aspergillus Niger.
- Geographical Source: Made a lot in India, China, and Italy.
- Uses: Used in formulations to change the pH, protect against free radicals, and bind to metals.
- Benefits for Skin Problems: Keeps the pH of the skin acidic, which keeps it from getting irritated. Encourages gentle exfoliation and the growth of new skin cells. Makes herbal actives in the spray more stable and able to get deeper into the skin.

Sr.	Ingredients	Parts Used	Major Constituents	Role / Action
No.	Ü			
1.	Turmeric	Rhizome	Curcumin	Anti-inflammatory, antimicrobial, healing agent
2.	Manjistha	Roots	Rubiadin	Blood purifier, skin generation
3.	Tulsi	Leaves	Eugenol	Antimicrobial, anti - itching, cooling
4.	Calendula	Flowers	Calenduloside	Wound Healing, soothing, promotes tissue
				repair
5.	Chicory Root	Roots	Inulin	Prebiotics – balances skin microbiome
6.	Alovera	Leaf gel	Aloin	Soothing, hydrating base
7.	Rose water		Phenyl ethanol glycosides	Fragrant, cooling diluent
8.	Pullant/ Xanthangum		Pullan/ Xanthan polysaccharides	Biofilm forming agent (liquid dressing)
9.	Potassium Sorbate		Sorbic acid	Safe neutral, Preservative
10.	Citric acid		Citric acid	PH adjustment to 5.5 - 6

Mechanism of action of Floraderm Promist (Film forming Spray)

1. Anti-Inflammatory Mechanism of Curcumin

There are four parts to inflammation: inducers, sensors, mediators, and effectors [6]. Curcumin exhibits anti-inflammatory properties modulating many signalling pathways. It attaches to Toll-like receptors (TLRs) and changes the NFκB, MAPK, AP-1, JAK/STAT, and PPARγ pathways, which lowers the production of inflammatory mediators. It can also stop the NLRP3 inflammasome from working, which stops pro-inflammatory cytokines and caspase-1 from being activated. Curcumin decreases the levels of mediators such IL-1, IL-6, IL-17, TNF-α, iNOS, and MCP-1. Clinical research has indicated that it lowers the levels of CRP and TNF. Curcumin modulates dendritic cells, Th17, and Treg cells immunologically, preserving the Th17/Treg equilibrium by inhibiting the IL-23/Th17 pathway. Curcumin also lowers oxidative stress by blocking NADPH oxidase, turning on antioxidant enzymes, and changing the Nrf2-Keap1 pathway. These actions work together to show how it helps decrease inflammation[5].



2. Inulin is a soluble dietary fiber that comes mostly from chicory root. It is well known as natural prebiotic that helps the microbiome. It doesn't break down in upper GIT and gets to the colon whole, where good bacteria Bifidobacterium and Lactobacillus selectively ferment it. This fermentation process makes short-chain fatty chain

acids (SCFAs) such acetate, propionate, and butyrate. These acids help decrease the pH of intestines, stop the growth of harmful bacteria, and give colonocytes energy. Through receptors like FFAR2/3, these SCFAs also operate as signaling molecules, changing the host's metabolism, glucose and lipid levels, and immunological responses. In addition, inulin reinforces the intestinal barrier by increasing the production of tight junction proteins and mucin. This makes the gut more stable and stop microbes from moving about. Inulin from chicory root is being root is being studied more and more for use in topical products like film-forming sprays. In these products, it may act as a prebiotic substrate for good skin germs while also keeping bad bacteria from growing. Inulin not only stays in contact with the skin for a long time when it is embedded in a thin polymeric film, but it also helps keep the microbiota balanced, the skin hydrated, and the barrier strong, which is good for both the skin and the gut.

3. Synergistic Actions & Relevance to Aging Skin

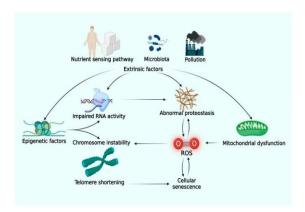
- Aging Process

The process of ageing changes an organism from a younger to an older one, which is usually less healthy. The socially accepted age range for being "old" or "aged" is normally between 60 and 70 years old, yet the process of ageing happens all the time [1]. Biologic ageing is a cellular and molecular process that causes all of the organ systems to lose their ability to work and their structure.

a) Molecular mechanism of aging

Genetic and epigenetic changes, the buildup of aberrant proteins, oxidative stress and mitochondrial malfunction, and cellular senescence are all thought to be important intrinsic mechanisms that lead to ageing. Pollutants, bacteria, and nutrients in the food are examples of extrinsic factors that can speed up or slow down the ageing process by affecting intrinsic systems.

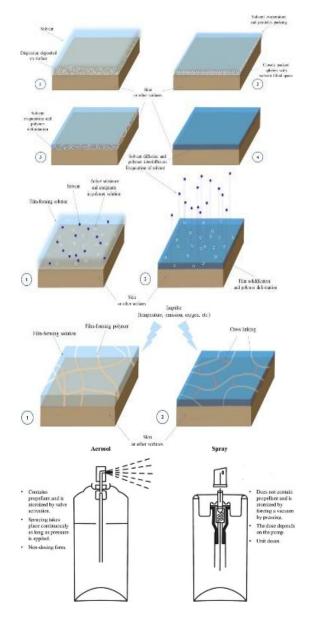
Abbreviations: (RNA) stands for ribonucleic acid, and (ROS) stands for reactive oxygen species.



4. Film forming / liquid bandage action

Film-Forming / Liquid Bandage Action

- After the solvent has evaporated, spray film-forming systems (SFFSs) or liquid bandages put a thin coating of polymer on the skin [2].
- This layer acts as a physical barrier, keeping dust, bacteria, and other things from getting into the wound
- The barrier stops cross-contamination and lowers the chance of getting a second illness.
- The created film is clear, so you can see the wound without taking it off, unlike regular gauze dressings.
- The film is also stretchy and flexible, so it may move with the skin without breaking.
- The coating keeps the wound moist by keeping the surface hydrated, which is very important for speedier healing.
- Keeping the right amount of moisture in the skin stops hard scabs from forming, which could slow down re-epithelialization.
- The film also helps cells move and grow near the wound bed, which speeds up tissue recovery.
- It also lets gases like O_2 and CO_2 pass through it easily, which stops tissue maceration.
- Some formulations are made to let vapor through, which lets you control how much fluid evaporates and keeps everything balanced.
- This combined virtue of sealing protection and regulated breathability mirrors the function of an optimal wound dressing.
- Spray bandages lessen pain and discomfort compared to frequent dressing changes in older methods.
- They also promote patient compliance due to their simplicity of application and non-invasive removal.
- Advanced SFFSs may also include active drugs like antibiotics, antiseptics, and anti-inflammatories in the film.
- Spray film-forming systems, in general, create a safe, moist, breathable, and healing-conducive environment for effective wound care.



Film forming spray for disease (Skin Lesions)

Skin Lesions are the spots on your skin that seem different from the skin around them. These are frequent and can happen when skin gets hurts or damaged, or even sunburn.

These can be autoimmune disease. Most skin lesions are not malignant and do not hurt at beginning but they can be something more dangerous.

Symptoms of skin lesions could vary depending on what type of lesion you have or got. General Symptoms include:

Abnormal growth on your skin, Itchiness, Swelling, Pain

Color change on your affected area of skin (red, blue, black etc.)

Types of Skin Lesions:

1] Primary lesion- These are the vast of majority.

They can be treated with creams, ointments, lotions, gels. The medications that you take orally that target the specific type of lesion. They may require surgical treatment to remove it from your skin [12].

Primary lesions are changes in your skin that aren't associated with other conditions and can include:

- -A flat mark on skin of different color than your original skin tone (macule or patch).
- -An elevated, pimple like bump (papule or plague). -An elevated, solid bump(nodule).
- -A blister filled with fluid or blood (vesicle or bulla).
- -An elevated pimple filled in with pus or white fluid(pustle).
- -An elevated bump that extends below the skin's surface that's filled with thick, yellow fluid (keratin cysts).

EXAMPLES of Primary lesions include acne, birthmarks, insect bites and sunburns.

- 2] **Secondary Lesions:** These are changes occurred during Primary lesions. This can happen because of itching, another direct injury or skin lesion that shows up as a part of a more complex, underlying condition[12]. Secondary lesions include:
- -Thin, wrinkled skin (atrophy).
- -Dried fluid around a wound (crust).
- -Deflated, wrinkled skin (erosion).
- -Painful breaks in the skin (fissures).
- -Flaky, peeling skin (scale).
- -Pale or red raised skin tissue (scar).
- -Open sore (ulcer).

EXAMPLES of Secondary lesions include stabbing, cuts and scrapes due to itching or dry skin from psoriasis or any type of allergy.

Procedure: (Film Forming Spray): 1.Preparation of Herbal extract:

- Turmeric, manjishtha, calendula, tulsi, chicory, and aloe vera are dried, ground into a powder, and then put through hydroalcoholic extraction using an appropriate solvent solution (for example, ethanol: water 70:30 v/v) while stirring continuously at 40 50°C for 6-8 hours.
- Using a rotary evaporator, the extracts are filtered using Whatman filter paper and then concentrated under low pressure to make a semi-solid extract.
- The extracts are kept at 4°C until they are mixed with something else.
- This procedure makes sure that the most active phytochemicals are extracted while keeping their biological activity.

2. Preparation of film forming Base:

- Xanthan gum (0.5–2% w/v) is carefully mixed into rose water in a clean, dry beaker while stirring constantly to keep lumps from forming.
- The mixture is left to hydrate for 30 to 60 minutes, which makes a gel-like basis that is all the same.
- Then, citric acid is added to bring the pH down to 5.5–6.0, which is the best range for older skin.
- Potassium sorbate (0.1–0.2% w/v) is added as a preservative to make sure that the formulation is safe against microbes.
- Addition of Herbal Extracts:
- The concentrated herbal extracts that were made earlier are slowly added to the moistened xanthan gum base while swirling constantly to make sure they are evenly mixed.
- A magnetic stirrer or mechanical stirrer is used to mix the ingredients together for 15 to 20 minutes, or until the mixture is smooth and thick.
- At the end, aloe vera gel is added to keep sensitive phytoconstituents from breaking down and to make the product more moisturizing.
- Final Adjustments and Quality Control:
- After mixing, the formulation is checked for lumps, clarity, and uniformity by looking at it.
- We verify the final viscosity, pH, and ability to make a film.
- To get the best film thickness and drying time, you can change the amount of xanthan gum.
- Then, the produced mixture is put into sterilized spray bottles and kept in a cool, dry place. The film forming polyherbal spray (Floraderm Promist) has been produced is now ready to be tested.

Evaluation Parameters:

- 1) Organoleptic properties color, odor and appearance
- 2) **pH of formulation** It must be skin friendly (typically 5.5-6 for geriatric skin)
- 3) Stability studies
- 4) Film formation
- 5) Viscosity
- 6) Irritation Patch Test

List of equipment's for Preparation and evaluation

A. For Preparation:

- 1. An **analytical balance** is used to weigh herbal extracts and other substances accurately.
- 2. **Magnetic stirrer with hot plate** for mixing extracts and breaking down polymers.
- 3. **Rotary evaporator** used to concentrate herbal extracts at lower pressures.
- 4. Beakers, conical flasks, and measuring

cylinders are used to make solutions.

- 5. A **funnel** and **Whatman filter paper** to filter herbal extracts.
- 6. **Spray bottles (either metered or pump)** for the final formulation.
- 7. **pH meter** to change the pH of the formulation so that it is good for skin.
- 8. **Micropipettes or syringes** for adding small amounts of liquid exactly.
- 9. An **oven or desiccator** can be used to dry film samples if they need to be tested mechanically.

For Evaluation:

- 1. Viscometer or Brookfield viscometer to measure viscosity.
- 2. A micrometer, an optical microscope, can be used to measure the thickness of a layer.
- 3. **Franz diffusion cell** used to study how drugs are released and how they get through the skin in vitro.
- 4. **pH** meter to assess the pH of the final formulation.
- 5. **Incubator or humidity chamber** for investigations on stability and how much moisture is taken up.
- 6. Microbial limit test equipment, like agar plates and an incubator, for testing microbes.
- 7. A **timer or stopwatch** to keep track of how long it takes for the film to dry.

CONCLUSION:

Floraderm Promist is a promising herbal topical preparation that forms a film and is made specifically for ageing and damaged skin. Its mix of natural ingredients, like turmeric, calendula, manjistha, tulsi, aloe vera, and inulin, work together to heal, reduce inflammation, fight free radicals, kill germs, and promote the growth of good bacteria. These chemicals not only help heal skin lesions, rashes, and wounds, but they also restore moisture and keep the natural balance of the skin microbiome, which is very important for the health of older skin. The film-forming spray technology has certain unique benefits, such as even coverage, long-lasting release, low irritation, and a breathable protective biofilm that works like a liquid bandage. This makes the skin regeneration process easier by keeping it moist, letting oxygen in, and keeping dirt and other things from getting Tests for pH, viscosity, stability, and film formation show that the recipe is safe, stable, and good for older people to use. Floraderm Promist is a new, natural, and effective way to treat skin problems such lesions, dryness, and age-related disorders without using synthetic topical agents. It combines traditional herbal knowledge with modern formulation technology.

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