EJPMR, 2026, 13(4), 97-105 **Review Article** **Impact Factor: 8.158**

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

ISSN (O): 2394-3211
ISSN (P): 3051-2573
Coden USA: EJPMAG

FILM FORMING DRUG DELIVERY SYSTEMS: A COMPREHENSIVE REVIEW OF FORMULATION STRATEGIES AND PHARMACEUTICAL APPLICATIONS

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How to cite this Article: [*1]Ankur Patel, [2]Riya Raulji, [3]Rashika Jain (2026). Film Forming Drug Delivery Systems: A Comprehensive Review Of Formulation Strategies And Pharmaceutical Applications. European Journal of Pharmaceutical and Medical Research, 13(4), 97–105.

Article Received on 28/02/2026 **Article Revised on 19/03/2026** **Article Published on 01/04/2026**

ABSTRACT

Transdermal and topical drug delivery systems have continuously evolved to overcome the formidable physiological barrier of the stratum corneum. Among recent innovations, Film Forming Systems (FFS) represent a significant paradigm shift from traditional semi-solid formulations (creams, ointments) and transdermal patches. FFS are non-solid dosage forms that, upon application to the skin, undergo rapid solvent evaporation to form a thin, transparent, and adherent polymeric film in situ. This review provides a comprehensive analysis of FFS, exploring their formulation strategies, underlying mechanisms of action, and diverse pharmaceutical applications. It further classifies FFS into solutions, gels, emulsions, and sprays, detailing the natural and synthetic polymers utilised in their design. By highlighting key literature from the last decade, this review underscores the novel advancements in FFS. It proposes forward looking formulation concepts to address unmet clinical needs in dermatology and systemic drug delivery.

KEYWORDS: Film Forming Systems (FFS), Transdermal Drug Delivery, In situ Polymeric Films, Film Forming Sprays, Topical Drug Delivery, Penetration Enhancement, Sustained Release.

1. INTRODUCTION

The skin is the largest organ of the human body and an attractive route for drug delivery due to its ability to bypass hepatic first pass metabolism, provide sustained drug release, and improve patient compliance. However, conventional topical therapies (such as heavy ointments and creams) often suffer from poor cosmetic appeal, rub off onto clothing, and inconsistent dosing. While traditional transdermal patches address some of these issues, they can cause occlusion, local skin irritation, and lack flexibility in dosage adjustment.[1]

Film Forming Systems (FFS) have emerged as a highly effective and elegant alternative to bridge these gaps. An FFS typically consists of an active pharmaceutical ingredient (API), a film forming polymer, and a plasticizer dissolved or dispersed in a volatile solvent. When applied to the skin, the volatile solvent rapidly evaporates. This concentrates the drug on the skin's surface, creating a state of thermodynamic supersaturation. The resulting polymeric film acts as a sustained drug reservoir, maintaining continuous contact with the stratum corneum and driving a concentration gradient without disrupting the skin's protective barrier. The thin films formed are nearly invisible, non-sticky, resistant to rub off, and conform easily to the body's contours, significantly enhancing patient comfort, adherence, and clinical efficacy.[2]

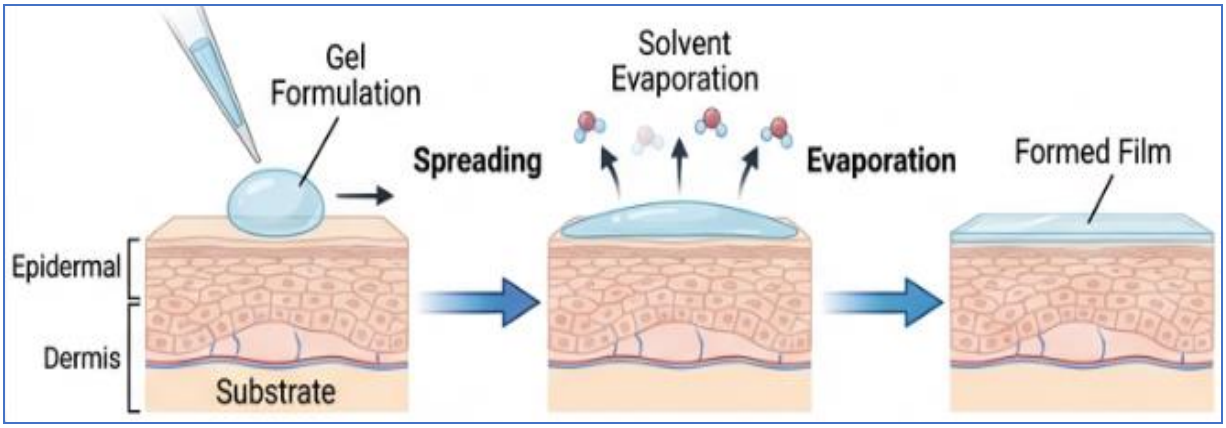

Figure 1: Film forming systems for drug delivery.

Film-forming systems (FFS) present a range of benefits alongside notable clinical and manufacturing challenges. On the positive side, FFS offer superior patient compliance due to their transparent, non-greasy, and cosmetically appealing finish that does not rub off on clothing. They also provide sustained drug delivery by acting as a prolonged reservoir, which significantly reduces the need for frequent application. Furthermore, these systems allow for dose flexibility, conforming perfectly to highly contoured body parts of any size, and promote enhanced drug flux, as rapid solvent evaporation creates localized thermodynamic supersaturation that drives the active pharmaceutical ingredient (API) deeper into the skin.[3] Despite these benefits, FFS face several limitations, primarily dose capacity constraints; their thin nature limits total payload, restricting them mostly to highly potent drugs. There is also a skin irritation potential, as high concentrations of volatile solvents can cause stinging, burning, or dryness on compromised skin. Finally, developers face formulation stability issues, such as the major hurdle of preventing solvent evaporation within the primary packaging, as well as complex manufacturing demands, since utilizing metered-dose pumps or pressurized canisters drives up production costs compared to simple tubes.[4]

2. TYPES OF FILM FORMING SYSTEMS

Film forming systems are exceptionally adaptable, allowing them to be developed into several distinct formulation types.[5-10] The selection of the appropriate vehicle depends heavily on the drug's physicochemical properties and the target treatment area, as summarised in Table 1.

Table 1: Comparative Analysis of Film-Forming Systems (FFS) for Topical and Transdermal Drug Delivery.

Formulation Type	Composition & Mechanism	Key Characteristics	Primary Advantages	Clinical & Manufacturing Limitations	Target Applications
Film Forming Solutions	**Composition:** Monophasic liquid (API, polymer, plasticizer dissolved in volatile solvents). **Mechanism:** Rapid solvent evaporation induces thermodynamic supersaturation, forming a thin polymeric film.	**Profile:** Optimal for highly soluble, low-molecular-weight APIs. **Drying:** Extremely rapid (typically < 2 minutes).	Highly cost-effective and simple to manufacture. Excellent patient compliance due to invisible, non-greasy finish. High thermodynamic drive enhances API skin penetration.	High volatile solvent content may cause stinging on compromised skin. Restricted to APIs soluble in the selected solvent. Risk of API crystallization at high concentrations.	Quick-drying treatments for intact skin (e.g., acne vulgaris, verrucae, systemic hormone delivery via estradiol sprays).
Film Forming Gels	**Composition:** Viscous solution incorporating	**Profile:** Accommodates hydrophilic and	Superior localized adhesion prior	Prolonged drying time relative to	Localized pain management (e.g., NSAID

	gelling agents (e.g., carbomers, cellulose derivatives). **Mechanism:** Gel matrix provides structural integrity, slowly releasing solvent to yield a flexible, localized patch.	select lipophilic APIs via co-solvents. **Rheology:** Elevated viscosity prevents application runoff.	to complete solvent evaporation. Prolonged residence time on the stratum corneum. High precision in dosage application.	simple solutions. Transient tackiness during the evaporative phase. Requires specialized mixing to mitigate air entrapment during production.	gels), superficial fungal infections, and mucosal cavity treatments.
Film Forming Emulsions (FFE)	**Composition:** Biphasic system (O/W) comprising aqueous/oil phases, emulsifiers, and film-forming polymers. **Mechanism:** Post-evaporation of the aqueous phase, oil droplets (containing the API) are encapsulated within a dry polymer matrix.	**Profile:** Engineered specifically for highly lipophilic or poorly water-soluble APIs. **Sensory:** Imparts a moisturizing feel compared to solvent-based solutions.	Significantly enhances bioavailability of difficult-to-formulate lipophilic drugs. Reduced volatile solvent content minimizes skin irritation. Provides concurrent hydration to the stratum corneum.	Complex formulation stability (susceptible to phase separation or creaming). High manufacturing complexity (multi-step emulsification). Emulsifiers may transiently disrupt the skin barrier function.	Delivery of heavy, lipophilic molecules; dermatoses requiring barrier repair and hydration (e.g., psoriasis, atopic dermatitis).
Film-Forming Sprays (SFFS)	**Composition:** Solution or suspension utilizing a metered-dose pump or pressurized aerosol canister. **Mechanism:** Dispensed as a fine mist; coalescing droplets rapidly evaporate to form a uniform, continuous film.	**Profile:** Versatile, demanding APIs stable under shear forces and pressure. **Coverage:** Highly uniform application over extensive surface areas.	"Touchless" application prevents mechanical trauma and patient distress. Exceptional hygiene profile (eliminates cross-contamination). Easily conforms to highly contoured or extensive anatomical regions.	High cost of primary packaging (pumps, valves, canisters). Environmental and safety concerns associated with aerosol propellants. Potential dosing inconsistencies due to nozzle occlusion or user variability.	Sensitive dermatological conditions (e.g., weeping wounds, severe burns, surgical incisions, painful neuropathies).

3. FILM FORMING POLYMERS

The choice of polymer dictates the film's flexibility, drying time, stickiness, and drug release profile. They are generally categorised into natural and synthetic polymers, as detailed in the comprehensive breakdown below Table 2.[11-13]

Table 2: Comprehensive Profile of Film Forming Polymers in FFS.

Polymer Category	Specific Polymer	Key Properties & Film Characteristics	Primary Functional Advantages	Formulation Challenges & Limitations	Ideal Clinical Applications
Natural (Cellulose)	Hydroxypropyl cellulose, Ethyl Cellulose, Hydroxypropyl methyl cellulose,	Forms clear, cosmetically elegant, and flexible films. EC adds hydrophobicity.	Highly biocompatible; allows for precise, tunable drug release by blending different grades.	Susceptible to microbial growth in aqueous phases; can be sensitive to electrolyte changes.	General dermatological use, sustained-release transdermal patches, and cosmetic dermatology.
Natural (Polysaccharide)	Chitosan	Cationic nature allows bioadhesion; forms durable, breathable films.	Inherent antimicrobial and accelerated wound-healing properties; excellent mucoadhesion.	Soluble only in acidic environments (low pH); lower mechanical strength than synthetics.	Burn care, diabetic foot ulcers, surgical site protection, and mucosal drug delivery.
Natural (Protein/Carb)	Sodium Alginate & Gelatin	Hydrophilic, highly water-absorbent; forms soft, biodegradable matrices.	100% biodegradable and non-toxic; highly soothing on compromised tissues.	Films can be mechanically weak and prone to rapid wash-off from sweat or water.	Oral mucosal lesions, temporary wound dressings, and pediatric formulations.
Synthetic (Acrylates)	Eudragit Series (RS/RL, L-100)	Excellent moisture resistance; forms highly durable, uniform films.	Provides highly specific, tailorable release kinetics (e.g., pH-dependent, sustained release).	Can be incompatible with certain basic drugs; formulations require precise solvent balancing.	Sustained-release transdermal delivery, moisture-resistant protective barriers.
Synthetic (Pyrrolidones)	Polyvinylpyrrolidone (PVP)	Forms highly transparent, exceptionally fast-drying films.	Excellent solubilizer for a wide range of APIs; visually imperceptible on the skin.	Highly hygroscopic (absorbs moisture); films become exceedingly brittle without plasticizers.	Quick-drying acne treatments, invisible localized pain gels, and cosmetic primers.
Synthetic (Alcohols)	Polyvinyl Alcohol (PVA)	Forms tough, highly flexible films with superior tensile strength.	Creates an excellent occlusive barrier, enhancing drug penetration via skin hydration.	Requires heating during the manufacturing process to fully dissolve; slower drying times.	Peel-off masks, occlusive transdermal delivery, and protective barrier films.

4. CRITICAL EXCIPIENTS IN FILM FORMING FORMULATIONS

While the film-forming polymer provides the structural matrix, the clinical success, aesthetic appeal, and drug release kinetics of an FFS heavily depend on the synergistic action of other key excipients.[14,15]

4.1. Volatile Solvents

The solvent is the driving force behind the in-situ film formation. It acts as a temporary vehicle that dissolves or disperses the API, polymer, and other excipients. Upon application to the skin, the solvent must evaporate rapidly to leave behind the polymeric film. This rapid evaporation triggers a state of thermodynamic supersaturation of the drug within the film, driving a

higher concentration gradient and pushing the drug into the stratum corneum.

Examples: Ethanol, isopropanol, and ethyl acetate are most commonly used due to their high volatility and skin acceptability. Water can be incorporated as a co-solvent to modulate the drying time and reduce the stinging sensation.

4.2. Plasticizers

Without plasticizers, many synthetic and natural polymers dry into hard, brittle films that crack easily with body movement. Plasticizers are low-molecular-weight molecules that embed themselves between the polymer chains. They decrease the intermolecular forces, increasing free volume and polymer mobility.

Examples: Propylene glycol, polyethylene glycol (PEG 400), glycerin, triethyl citrate, and dibutyl phthalate. The choice directly impacts the tensile strength, elongation at break, and peelability of the final film.

4.3. Chemical Penetration Enhancers

While the supersaturation effect inherently enhances skin penetration, some formulations require chemical penetration enhancers (CPEs), especially for delivering macromolecules. CPEs reversibly disrupt the highly organized lipid bilayer of the stratum corneum, creating transient micro-channels.

Examples: Fatty acids (oleic acid), terpenes (menthol, limonene), sulfoxides (DMSO), and Azone.

5. EVALUATION AND CHARACTERIZATION OF FILM FORMING SYSTEMS

To ensure clinical efficacy, patient compliance, and stability, FFS must undergo rigorous physicochemical and mechanical characterization as per below table 3.[16-24]

Table 3: Evaluation and Characterization of Film Forming Systems.

Evaluation Category	Specific Parameter	Significance & Purpose	Standard Methodology & Equipment	Desired Outcome
Physical& Rheological	Drying Time	Assesses patient convenience and cosmetic appeal. Determines how long it takes for the formulation to become touch-dry.	Measured by applying a standardized volume to a glass slide or skin model and observing the time to a tack-free state.	Typically, < 3–5 minutes for solutions and sprays; slightly longer for gels and emulsions.
	Viscosity & Rheology	Influences extrudability from tubes/pumps, spreadability on the skin, and prevention of runoff before drying.	Brookfield viscometer or cone-and-plate rheometer at varying shear rates.	Formulation should be easily spreadable but viscous enough to remain at the application site.
	pH Value	Ensures the formulation is non-irritating to the target application site (e.g., skin vs. mucosal membrane).	Digital pH meter on the liquid formulation or reconstituted film.	**4.5–6.5** for intact skin; tailored to specific physiological pH for mucosal applications.
Mechanical Properties	Tensile Strength & % Elongation	Evaluates the film's mechanical toughness and flexibility. Ensures the film won't rupture with normal body movement.	Texture Analyzer or Universal Testing Machine stretching a standardized strip of the dried film until it breaks.	High tensile strength with adequate elongation (flexibility) to conform to joint movements.
	Folding Endurance	Measures film brittleness. A high folding endurance ensures the film won't crack during wear.	Repeatedly folding the film at the same place until it breaks.	High folding endurance (> 200–300 folds) indicates excellent flexibility and plasticizer efficacy.
	Stickiness / Tackiness	Assesses the residual stickiness of the dry film to ensure it does not attract dirt or adhere to patient clothing.	Probe tack test using a Texture Analyzer or a simple thumb-tack test.	Low tackiness post-drying for optimal patient compliance and cosmetic elegance.
Performance & Biopharmaceutical	*In vitro* Drug Release	Determines the rate and extent to which the API is released from the polymer matrix into the surrounding medium.	Franz Diffusion Cell setup using a synthetic membrane and a suitable receptor medium.	Controlled, sustained, or immediate release profile matching the therapeutic target.
	Ex vivo Skin Permeation	Predicts actual clinical efficacy by measuring how much drug penetrates and permeates the stratum corneum.	Franz Diffusion Cell using excised animal skin (e.g., porcine ear) or human cadaver skin.	High API flux and steady state permeation aligned with the necessary therapeutic window.

Adhesion & Safety	Bioadhesion /Peel Strength	Measures how strongly the film adheres to the biological surface and the force required to remove it.	Texture Analyzer measuring the force required to detach the film from a skin model or mucosal substrate.	Strong enough to remain intact for the treatment duration, but easily removable without skin trauma.
	Skin Irritation (Safety)	Ensures the solvents, polymers, and excipients do not cause erythema, edema, or sensitization.	Primary skin irritation tests (e.g., Draize test on animal models) or *in vitro* reconstructed human epidermis models.	No visible signs of erythema or edema (Irritation score of 0).

6. LITERATURE & NOVELTY IN FILM FORMING SYSTEMS

Over the past decade, research in the domain of Film-Forming Systems (FFS) has witnessed a significant paradigm shift. Early formulations primarily focused on simple polymer-plasticizer-solvent mixtures designed for basic topical protection or passive, zero-order transdermal drug release. However, recent literature demonstrates a rapid evolution towards highly engineered, multifunctional, and targeted delivery platforms that address complex clinical challenges.

Modern advancements have successfully integrated nanotechnology—such as solid lipid nanoparticles, transferosomes, and exosomes—into polymeric matrices to overcome the traditional limitations of passive diffusion, driving drugs deeper into the epidermal and dermal layers. Furthermore, there has been a remarkable surge in the development of "smart" stimuli-responsive polymers that react dynamically to physiological triggers (such as variations in wound pH or body temperature), enabling on-demand drug release.

Innovation has also expanded beyond traditional intact skin applications. Recent studies have explored the integration of dissolvable microneedle arrays for macromolecule and vaccine delivery, as well as the use of highly mucoadhesive thiolated polymers for wet mucosal surfaces. Beyond formulation chemistry, device engineering—particularly the transition from standard spray nozzles to metered-dose actuation and electrostatic sprayers—has become a critical area of focus to ensure absolute dose uniformity and reproducibility.

The following table 4. summarises key milestone studies, highly novel formulation strategies, and the evolving technological trends published over the last ten years, highlighting the continuous innovation driving FFS technology forward.[25-35]

Table 4: Literature & Novelty in Film forming systems.

Author(s) & Reference Source	Summary of Importance / Novelty with Explanation
Rawool et al. *Expert Opinion on Drug Delivery* (2026)	**Nanocarrier-FFS Hybrids:** Highlights the integration of lipid nanoparticles into FFS. **Explanation:** This dual-delivery mechanism uses the polymeric film to create a sustained surface reservoir that prevents nanoparticle wipe-off, while the lipid nanocarriers actively drive antifungal agents deep into the epidermal layers, overcoming the traditional limits of passive diffusion.
Mai et al. *International Journal of Pharmaceutics* (2025)	**Microneedle & Film-Forming Gel Combination:** Demonstrates a groundbreaking strategy for vaccines. **Explanation:** The formulation is applied over dissolvable microneedles. The FFS not only seals the micro-punctures to prevent infection but stabilizes delicate vaccine proteins at room temperature for 30 days. This bypasses the need for cold-chain logistics while providing immunity equivalent to intramuscular injections.
Morales-Becerril et al. *AAPS PharmSciTech* (2024)	**Film-Forming Emulsions (FFE):** Advances the formulation of O/W emulsions into *in situ* films. **Explanation:** The critical novelty lies in successfully encapsulating oil droplets within a dry polymer matrix upon water evaporation. This drastically improves the payload capacity, solubility, and transdermal permeation of highly lipophilic drugs that cannot be formulated in standard alcohol-based FFS.
Zhao et al. *Acta Biomaterialia* (2023)	**Stimuli-Responsive "Smart" FFS:** Introduces an intelligent, thermo- and pH-responsive film-forming hydrogel for chronic wounds. **Explanation:** The system is easily sprayable at room temperature but undergoes a rapid sol-gel transition upon contact with body heat. Furthermore, the polymer matrix is engineered to degrade and release growth factors *only* when the wound bed pH shifts to an alkaline state, visually signaling a bacterial flare-up.
Vora et al.	**Ultra-Deformable Vesicular FFS:** Explores the embedding of transferosomes into film-forming solutions. **Explanation:** Standard FFS struggle with high-molecular-weight drugs. By loading the drug

Journal of Controlled Release (2022)	into highly flexible transferosomes, and using the dried polymeric film as an occlusive backing, the osmotic gradient is amplified, forcing the vesicles to squeeze through the intact stratum corneum for systemic delivery.
Pünnel & Lunter *Pharmaceutics* (2021)	**Weblike Film-Forming Systems:** Departs from the traditional continuous flat sheet film. **Explanation:** Using specific phospholipids and polymers, these systems dry into a structured, microscopic web on the skin. This unique morphological novelty increases the surface area of contact and significantly improves the delivery flux of active molecules into deeper skin layers without complete occlusion.
Mhatre et al. *Drug Design, Development and Therapy* (2020)	**Advanced Sprayer Mechanics:** Shifts the innovation focus from polymer chemistry to device engineering. **Explanation:** Highlights the use of electrostatic and ultrasonic sprayers to actuate the FFS. This produces uniform, nano-sized droplets that coalesce into flawless, layer-by-layer thin films, eliminating the "coffee-ring effect" (uneven drug distribution) seen with standard mechanical pump sprays.
Laffleur et al. *International Journal of Pharmaceutics* (2019)	**Thiolated Polymers for Mucosal FFS:** Expands FFS application from dry skin to wet mucosal surfaces (buccal/vaginal). **Explanation:** Standard FFS wash away in wet environments. This study utilized thiolated polymers that form strong, covalent disulfide bonds with mucosal glycoproteins upon application. This creates a highly mucoadhesive film that resists saliva washout, providing sustained drug release in the oral cavity.
Kathe & Kathpalia *Asian Journal of Pharmaceutical Sciences* (2017)	**Green FFS Formulations:** Replaces synthetic plastics with biodegradable, natural zein (corn protein) and essential oils. **Explanation:** Proved that natural proteins can form highly durable, flexible films without synthetic plasticizers. The essential oils act in a dual capacity: as natural permeation enhancers and intrinsic antimicrobials, making this an ideal, eco-friendly formulation for pediatric and veterinary wound care.
Ranade, Bajaj, et al. *European Journal of Pharmaceutical Sciences* (2017)	**Metered-Dose Topical Sprays:** Pioneers the clinical translation of FFS into precise dosing devices. **Explanation:** The study proved that replacing a standard spray nozzle with a metered-dose valve allows FFS (using drugs like Ropivacaine) to deliver an exact, reproducible dose of medication. This allows FFS to replace systemic injections for highly accurate, localized, long-lasting pain management.

7. CONCLUSION AND FUTURE PERSPECTIVES

Film Forming Systems (FFS) have successfully bridged the gap between patient compliance and therapeutic efficacy in topical and transdermal drug delivery. By providing a non-obtrusive, highly adherent, and supersaturated drug reservoir, FFS overcome the classic limitations of messy ointments, bulky creams, and rigid traditional patches. The last decade of research highlights a clear evolution from simple polymeric solutions to complex nano-emulsions, microneedle-hybrids, and metered-dose sprays. This demonstrates the vast, untapped potential of FFS technology to transition from simple cosmetic or localized pain relief applications into advanced vehicles for systemic delivery and complex disease management.

Future Perspectives: Novel Formulation Concepts To further push the boundaries of transdermal and topical therapies, future research and formulation development could explore the following highly innovative concepts.[36-40]

1.Colorimetric Theranostic Film-Forming Spray for Diabetic Foot Ulcers A "theranostic" system combining a broad-spectrum antimicrobial with biocompatible, color-changing halochromic sensors (like anthocyanins).When applied to an ulcer, it forms a breathable barrier. If bacterial colonization begins, the local pH shifts to highly alkaline. The film visibly changes color, alerting the patient and physician to the infection before clinical symptoms appear, while simultaneously releasing the antimicrobial agent.

2. Stimuli-Responsive, Probiotic-Loaded Nanoemulgel Film for Atopic Dermatitis Atopic dermatitis is characterized by a disrupted skin barrier, alkaline skin pH flare-ups, and an overgrowth of *S. aureus*. Formulating a pH-sensitive polymer combined with a nanoemulsion containing barrier-repairing ceramides and freeze-dried probiotics (e.g., *Staphylococcus hominis*) creates a smart liquid bandage. If the skin pH rises during a flare-up, the film swells, releasing ceramides and activating the probiotics to restore the microbiome.

3. Chronotherapeutic Film-Forming Gel for Morning Rheumatoid Arthritis Rheumatoid arthritis patients suffer from severe morning joint stiffness due to overnight spikes in inflammatory cytokines. A time-delayed film-forming gel containing an NSAID embedded in a slow-eroding polymer matrix (e.g., HPMC and Eudragit RS) could be applied before bed. The matrix delays release for 4 to 6 hours, ensuring peak tissue concentration exactly when the morning pain flare-up occurs.

4. Exosome-Loaded Film-Forming Emulsion (FFE) for Targeted Alopecia Therapy To combat the poor follicular penetration and scalp run-off of traditional hair loss treatments, an aqueous-based Film-Forming Emulsion (FFE) loaded with exosomes (nanovesicles rich in growth factors) could be utilized. As the volatile phase evaporates, the polymer matrix forces the exosomes downward, acting as a sustained-release patch directly over the hair follicle to drastically improve growth factor uptake.

5. Dual-Action, UV-Shielding Film-Forming Solution for Non-Melanoma Skin Cancer Topical treatments for actinic keratosis leave inflamed skin vulnerable to UV damage. A film-forming solution containing chemotherapeutic-loaded solid lipid nanoparticles (SLNs) combined with transparent UV-blocking agents (like zinc oxide nanoparticles) integrated into the polymer matrix creates a "liquid patch." It drives the drug into the tumor microenvironment while physically protecting the degrading cancer tissue from further sun-induced DNA damage.

6. Anti-Lick, Waterproof Film-Forming Spray for Veterinary Wound Care In veterinary medicine, animals often lick or chew off traditional bandages. A highly hydrophobic film-forming spray utilizing strong, flexible synthetic polymers combined with an antimicrobial and an intensely bitter-tasting compound (e.g., denatonium benzoate) could provide a solution. It dries into a waterproof barrier; if the animal attempts to lick the wound, the extreme bitter taste acts as an immediate chemical deterrent, providing a stress-free alternative to physical collars.

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