Foams with function

Advancing topical drug delivery through formulation innovation

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Executive summary

Topical therapies are uniquely positioned to deliver targeted treatment with minimal systemic exposure, but translation from lab efficacy to real-world effectiveness is frequently limited by formulation and delivery challenges. Problems such as chemical and physical instability, inconsistent dosing, poor aesthetic properties and difficult application can reduce adherence and impact clinical outcomes. However, when methodically formulated, engineered and packaged, foams and advanced semi-solid dispersions can successfully overcome many of these limitations.

This whitepaper outlines how foam formulations and optimized packaging systems, including a novel Bag-on-Valve (BoV) patented technology and aerosols, can improve stability, dosing uniformity, patient adherence and market differentiation. By reviewing scientific trade-offs, such as solubilization versus suspension, particle engineering and excipient strategies, topical drug delivery developers can achieve foams with both performance and pleasing sensory attributes. Container–closure systems are equally important, as they protect product integrity and enable precise dispensing throughout the product life cycle, thereby strengthening regulatory and commercial positioning.

The right combination of formulation science, process engineering and packaging expertise can transform complex ideas into launch-ready products. By partnering with pharmaceutical sponsors, we help mitigate technical risks, accelerate development timelines and deliver differentiated topical therapies that perform in the real world. With Formulated Solutions in your corner, mediocre topical drug products have met their match — our approach changes the game by ensuring impact with every action.

01 Introduction: The promise of foam-based drug delivery

Foam formulations, such as mousses, shaving foams and whipped lotions, are familiar to consumers in personal care, but their adoption in prescription dermatology has been comparatively limited. Traditional creams and ointments are often developed based on an old-school mentality which is based on previous history and regulatory experience, even though they can present several real limitations: greasy residues, long drying times, variable patient acceptance and dosing variability from manual application. These aesthetic and handling drawbacks can directly affect adherence in chronic conditions[1], including psoriasis, atopic dermatitis and chronic pruritus, where consistent daily application is critical to outcomes.

Market pressures are reinforcing the need for intentional topical delivery innovation. The prevalence of chronic dermatologic conditions is rising and patients are demanding more convenient formulations[2], leading to intense competition among drug sponsors.

Foams provide an appealing alternative. The microstructure of a foam consists of a gas dispersed in a continuous liquid phase, which enables rapid spreadability, a light feel and efficient coverage with less product. When designed as drug-containing dispersions, foams can deliver active pharmaceutical ingredients (APIs) uniformly over complex skin surfaces while minimizing the tactile negatives associated with creams and ointments. Foam vehicles also couple well with modern packaging solutions that preserve product integrity and ensure consistent dosing.

In the challenging topical delivery environment, reformulation into a foam or optimized semi-solid can be game-changing, providing both a clinical benefit and a commercial lever for differentiation and lifecycle management.

02 Scientific challenges in small molecule dispersions

Formulating small molecule APIs into foams requires solving a network of interconnected problems, including ensuring chemical and physical stability, controlling rheology and selecting packaging that maintains performance. Each decision influences not only bioavailability, but also the patient's experience and the manufacturability of the final product.

Formulation integrity over time

Topical dispersions must remain stable throughout manufacture, distribution and patient use. Instability threatens both dosing accuracy and patient trust. Common risks include:

- **Phase separation:** Density differences between the continuous phase and suspended particles can lead to sedimentation, producing non-uniform doses.
- **Oxidative degradation:** APIs and excipients prone to oxidation can lose potency and may generate odor or color changes.
- **Microbial growth:** Water-based systems require reliable preservative systems or risk contamination.
- **Viscosity drift:** Changes in temperature, polymer breakdown or solvent migration can alter viscosity, affecting spreadability and dose delivery.

Mitigation requires a coordinated approach that combines formulation controls and process controls. Formulation strategies include using antioxidants and chelators to slow oxidative pathways and incorporating robust preservative systems, validated by Preservative Efficacy Testing, to prevent microbial growth. Rheology modifiers are selected to both resist sedimentation and maintain the product's desirable texture and feel. To ensure the foam itself is stable, emulsifiers are used to strengthen the liquid films that form the bubbles. Process control strategies are equally important and involve optimizing manufacturing parameters such as homogenization energy, temperature and the order of ingredient addition to achieve a reproducible and stable product microstructure.

Stability testing must also be comprehensive. Beyond real-time shelf studies, stress testing under thermal, oxidative, light, freeze–thaw and agitation conditions ensures confidence in performance. Rheology and particle distribution monitoring over time confirm dosing consistency.

Solubility vs. suspension strategies

Topical APIs can often present solubility challenges. For instance, an API may be poorly soluble in water but soluble in an oil phase, necessitating a two-part emulsion system. This requires developers to carefully evaluate solubilization and suspension delivery strategies.

- **Solubilized delivery** dissolves the API in the vehicle, often enhancing permeation and uniformity. However, solubilization can demand cosolvents or surfactants that increase irritation risks or destabilize the system.
- **Suspension delivery** disperses the API as solid particles, which may improve chemical stability but increases the risk of sedimentation and dosing inconsistency if not properly engineered.

The optimal choice should be one that balances bioavailability, tolerability and manufacturability. Useful strategies include surfactant or polymeric solubilizers to maintain dissolution, cyclodextrin complexation to enhance solubility without excessive surfactant use and rheology controls that immobilize suspended particles. Hybrid approaches, where part of the API is solubilized for rapid onset and the remainder suspended for sustained release, are also available, offering the best of both worlds.

Micro-suspensions

A micro-suspension in a hydrophobic foam base represents a particularly effective strategy for delivering a poorly soluble API. This approach provides excellent stability by using a structured polymer network to suspend micronized particles, while a small amount of surfactant wets the particles and permeation enhancers are included to ensure optimal local delivery.

Impact of API particle size and surface characteristics

Particle engineering is central to suspension stability and bioavailability:

- **Micronization and nanosizing** reduce settling velocity and increase apparent surface area, potentially improving dissolution rate and absorption.
- **Surface coatings** can either be lipidic or polymeric and reduce particle aggregation, modulate wettability and can include protective antioxidants for labile APIs.
- **Complexation with carriers** (e.g., cyclodextrins) modifies solubility and surface energy, improving distribution in the vehicle.

Analytical control via laser diffraction, dynamic light scattering and microscopy ensures particle size distributions remain within the design window. Surface analysis also helps predict interfacial interactions that influence sedimentation and compatibility with excipients.

Packaging and dispensing considerations

Packaging is an active part of formulation design, as a container–closure system can make or break product performance. Both aerosols and BoV can be used for foams and semi-solids, with each system presenting a unique set of benefits and considerations.

Bag-on-Valve fundamentals

The BoV system is increasingly recognized as a premier packaging choice for delicate or whipped formulations. Its foundational advantage lies in its ability to isolate the product from propellants and the external environment, which protects formulation integrity while enabling precise, repeatable delivery.

At the heart of a BoV system is an outer canister of aluminium or polyethylene terephthalate (PET) and an inner flexible, multi-layer laminate bag that holds the product. The bag is welded to a precision valve and the space between the bag and the can is filled with an inert propellant such as compressed air or nitrogen. When the actuator is pressed, the valve opens and the pressurized gas transmits force to the bag, squeezing product out through the orifice. The bag collapses progressively, maintaining an airtight seal between product and propellant. This design preserves formulation purity, prevents propellant ingress and supports a consistent spray or foam characteristic throughout the lifetime of the product.

Key advantages of BoV

- **Barrier protection:** The outer can is an impenetrable barrier against light, oxygen and external contaminants, reducing oxidative and photolytic degradation.
- **Hermetic product isolation:** The laminate bag hermetically seals the product, eliminating contact with propellant and reducing contamination risk.
- **Dose uniformity:** The system provides stable, controlled flow regulated by actuator geometry, maintaining consistent spray pattern and foam quality.
- **Versatility:** BoV can handle liquids and viscous matrices (gels, semi-solids), making it suitable for oxygen-sensitive or sterile applications.
- **User experience:** Actuator engineering yields low actuation force and predictable output, improving ease of use for elderly or dexterity-impaired patients.

Technical considerations for BoV adoption

- **Material compatibility:** Multi-layer bags (PET/Aluminium/polyethylene (PE) laminates) must be selected to avoid extractables/leachables and maintain barrier performance for the specific API and excipients.
- **Propellant selection:** Inert gases, such as nitrogen, avoid flammability risks and do not dissolve into the product. The propellant must be controlled for pressure profile and temperature sensitivity.
- **Actuator and orifice engineering:** The actuator orifice size determines droplet or bubble size and thus the sensory and deposition profile of the foam. Controlled orifice design is central to reproducible foam structure.
- **Regulatory dossier:** BoV systems require demonstrations of container performance (compatibility, leachables, headspace oxygen, microbial ingress) and may affect stability claims and shelf-life testing protocols.

BoV in practice

For an oxygen-sensitive steroid dispersion, a BoV container enables a water-containing foam with minimal oxidative loss, while preserving preservative efficacy and enabling sterile fill strategies. For scalp treatments, BoV ensures even metered output and rapid patient acceptance.

Aerosol systems in topical drug delivery

Aerosols are one of the most mature and versatile product delivery technologies, proven across both consumer and pharmaceutical applications. From inhalers and antifungal sprays to hair growth foams, hemorrhoid treatments and sunscreens, aerosols demonstrate a fine balance of precision, efficiency and patient convenience. Their effectiveness stems from a finely engineered pressurized mechanism capable of transforming liquids into fine mists, stable foams or targeted streams for controlled application.

Engineering principles of aerosol systems

At the core of every aerosol is a pressure-driven design. A metal or plastic container is engineered to withstand a wide range of internal pressures. Within it lies a carefully formulated combination of two essential components:

- **Product phase:** The therapeutic or cosmetic formulation, which can range from solutions and emulsions to semi-solids or suspensions.
- **Propellant phase:** A liquefied gas, such as butane, propane, or isobutane, that maintains the internal pressure and drives product expulsion.

When the container is sealed, the propellant exists partly as a liquid and partly as vapor. Upon actuation, the vapor phase exerts pressure on the liquid phase, forcing a controlled flow of the formulation through a precision valve system. As the product exits the nozzle, the rapid vaporization of the propellant creates the desired end form determined by valve geometry and formulation rheology.

This interplay of physics and formulation science gives aerosols their hallmark performance: reproducible output, consistent spray patterns and flexible delivery options.

Key advantages of aerosols

- **Controlled and uniform dosing:** Each actuation delivers a consistent quantity of product, reducing variability in patient application.
- **Hygienic, closed system:** The sealed design minimizes contamination and extends shelf life without requiring preservatives.
- **Versatility of formats:** A single platform can accommodate sprays, foams, gels or streams by adjusting valve design and formulation rheology.
- **Enhanced user experience:** Smooth actuation, directional control and fast-drying delivery improve adherence and satisfaction.
- **Optimized stability:** By isolating formulation and limiting oxygen exposure, aerosol cans preserve product potency and performance.

03 Clinical and patient-centric considerations

Adherence and human factors are as important as formulation. A topically active API cannot achieve a clinical effect if patients avoid or inconsistently apply therapy.

Special populations

- **Pediatrics:** Application reluctance in children is a common barrier - foams reduce the tactile struggle for caregivers and children by being quick-drying, non-sticky and easy to dose. Foams can be developed with low-irritancy excipient sets (low surfactant, fragrance-free) and delivered through low-force actuators that parents find easier to manage.

- **Geriatrics:** Many older adults have impaired dexterity or cognitive challenges. BoV dispensers with ergonomically optimized actuators and predictable outputs lower the physical demand of dosing and reduce spills to help improve consistent use.

- **Specialty uses:** Burn care, scar management and rare dermatologic disorders often involve fragile skin or irregular surfaces; foam's gentle, non-abrasive application and superior spreadability make it an attractive option for these indications.

Adherence behavior and real-world use

Behavioral research consistently shows that sensory attributes shape long-term use3. Greasy formulations cause social stigma and non-use and sticky or strongly fragranced products can provoke irritation or aversion. Sensory endpoints that support adherence include minimal residue, rapid drying, neutral scent options and a pleasant finish.

Real-world data and market research should be integrated into formulation endpoints. Sensorial panels, clinician feedback and small-scale human factors studies early in development prevent late-stage setbacks and shape excipient choices that balance stability with patient appeal.

Foam benefits in application and spreadability

Foams expand on contact, enabling thinner, more uniform layers with less product. Specific advantages include:

- **Hair and scalp application:** Foam penetrates hair and coats the scalp more uniformly than creams, improving local bioavailability for antifungal or corticosteroid therapies.

- **Large body surface coverage:** Lightweight foams reduce the amount of work required to cover large lesions or areas, improving convenience.

- **Sensitive zones:** Foams reduce rubbing and mechanical irritation during application, which is advantageous for inflamed or ulcerated skin.

04 Differentiation through formulation innovation

While patient adherence and usability are essential to therapeutic success, they are only part of the equation. Topical innovation is both scientific and strategic. Foams can deliver measurable clinical advantages and provide routes to commercial differentiation.

Absorption and bioavailability optimization

Targeted excipient design with permeation enhancers (oleic acid, ethanol blends, short-chain esters), fatty acid carriers and microemulsion systems can help tailor the partitioning of API into the stratum corneum. Diffusion cell studies, tape stripping and in vitro–in vivo correlation (IVIVC) approaches can establish performance improvements. Where marketed foam products have demonstrated higher local tissue levels or faster onset relative to creams, sponsors have documented improved outcomes and patient preference.

User experience as a differentiator

Sensorial performance is a commercial lever. Non-tacky finishes, rapid drying times and optional fragrance variants allow segmentation by patient preference. Clinical claims for improved adherence supported by human factors and small real-world adherence studies amplify marketing messages and prescriber confidence.

Intellectual property and competitive strategy

Format innovation is a pragmatic IP strategy:

- **New delivery claims** (improved absorption profile, reduced dosing frequency) can support method-of-use or formulation patents.
- **Packaging patents** around specific BoV and aerosol actuator designs, valve geometries and bag laminate compositions create additional barriers to copycats.
- **Combination IP** tying a unique excipient system to a packaging solution strengthens lifecycle management beyond API patent expiry.

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The Formulated Solutions approach

We combine formulation chemistry, particle engineering, process design and packaging integration in an end-to-end model:

- **Science-driven formulation:** Our teams optimize solubilization vs. suspension strategies, select permeation enhancers and design rheology systems to balance stability with patient experience.
- **Particle and surface engineering:** Micronization, nanoformulation and surface coatings are leveraged where they deliver measurable improvements in uniformity and bioavailability.
- **Packaging integration:** Formulations are co-engineered with a range of containment systems, including aerosols and our novel, patented BoV technologies, to create differentiated products and provide partners with competitive and intellectual property advantages.
- **Regulatory & quality support:** Analytical method development (HPLC, particle sizing, rheology, headspace oxygen), extraction/leachable evaluation and stability protocols are established to support chemistry, manufacturing and controls (CMC) sections and shelf-life claims.

Our track record is solving the hard problems that allow topical products to succeed in the marketplace - robust chemistries, patient-centric delivery and manufacturable processes.

06 Unlocking the potential of foams with function

Foams represent a pragmatic, high-value pathway for transforming topical therapies. They simultaneously address stability, usability and differentiation - three pillars that determine real-world success. Combined with modern packaging such as BoV and aerosols, foam formulations can preserve product integrity, enable dosing precision, improve patient adherence and generate commercial and IP advantage.

Ever tried the Formulated Solutions approach?

Delivering excellence since 1999, we specialize in innovative solutions for pharmaceutical, consumer health, personal care and medical device applications.

Underpinned by a bedrock of reliable quality, our expertise in foams and container closure technologies and our focus on customer collaboration, can guide you through the complexities of topical delivery and help you achieve your product goals.

Discover how we can help you choose the ideal formulation and packaging option for your next project.

Contact us

References

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Is your topical product ready to deliver on its promise?

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