



PHARMACEUTICAL AND REGULATORY ASPECTS OF FACE SERUMS

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ABSTRACT

Face serums represent one of the fastest-evolving categories within the modern skincare and cosmeceutical industry. Unlike traditional creams and lotions, serums are lightweight, fast-absorbing formulations enriched with high concentrations of active ingredients intended for targeted and enhanced skin delivery. Their pharmaceutical significance lies in their ability to simultaneously address dermatological and cosmetic concerns such as hyperpigmentation, premature aging, dehydration, oxidative stress, acne, and barrier dysfunction. This comprehensive review focuses on the pharmaceutical aspects of face serums, including their classification, formulation design, evaluation parameters, marketed products, regulatory perspectives, and future prospects. Emphasis is placed on formulation challenges related to the stability of labile actives such as vitamin C and retinol, preservation issues in aqueous systems, and the balancing of efficacy with skin tolerability. The review further explores recent innovations such as nanotechnology-based carriers, peptide-based bioactives, biotechnological advances, and personalized skincare strategies as emerging trends in serum development.

KEYWORDS: Face serum, cosmeceuticals, formulation, evaluation, nanotechnology, antioxidants, topical delivery.

1. INTRODUCTION

The human skin serves as the largest organ of the body, functioning as both a physiological barrier and an aesthetic determinant of personal health and confidence. Over recent decades, dermatological science has evolved from basic emollient formulations to highly sophisticated cosmeceuticals—products that merge cosmetic elegance with pharmaceutical-grade efficacy.

Among these, face serums have emerged as a significant innovation. A serum is defined as a low-viscosity formulation that delivers concentrated bioactive ingredients directly to the skin. Unlike conventional moisturizers, which primarily create a protective barrier, serums are designed for rapid penetration and targeted biological action.^[1]

From a pharmaceutical standpoint, serums are notable for their:

- High active loading, often 10–20 times greater than that of traditional creams.

- Formulation challenges, particularly concerning chemically unstable actives such as retinoids and ascorbic acid.
- Delivery advancements, including nanocarriers, liposomes, and microemulsions.
- Regulatory implications, where classification may range from cosmetics to drugs, depending on claims.

Thus, face serums occupy a hybrid domain, bridging the gap between therapeutic dermatology and cosmetic science, warranting in-depth pharmaceutical evaluation.

2. CLASSIFICATION OF FACE SERUMS

2.1 Antioxidant and vitamin-based serums

These serums are formulated to combat oxidative stress caused by UV radiation, environmental pollutants, and physiological stress. Vitamin C (ascorbic acid) is widely used for its photo-protective and anti-aging effects, though it is unstable in aqueous solutions; stabilized derivatives like magnesium ascorbyl phosphate are preferred. Vitamin E (tocopherol) works synergistically

with vitamin C as a lipid-soluble antioxidant. Niacinamide (Vitamin B3) contributes to improved skin tone, reduction of hyperpigmentation, and enhanced barrier function. Plant polyphenols such as resveratrol and ferulic acid further strengthen antioxidant defenses. To maintain stability, these formulations typically require oxygen-impermeable containers, amber glass, or airless dispensing systems.^[3]

2.2 Hydration-focused serums (hyaluronic acid-based)

Hydrating serums constitute a leading segment in the cosmetic market. Hyaluronic acid (HA) can retain up to 1000 times its weight in water. Low molecular weight HA facilitates deeper dermal penetration, while high molecular weight HA predominantly maintains surface hydration. These serums are often supplemented with glycerin, panthenol, and aloe vera to enhance moisturization. Due to HA's susceptibility to enzymatic degradation by hyaluronidase, careful selection of compatible preservatives is essential for product stability.

2.3 Peptide and growth factor serums

Peptide-based formulations contain short chains of amino acids that act as signaling molecules or structural components. Signal peptides stimulate collagen production, carrier peptides deliver essential minerals, and neurotransmitter-inhibiting peptides, such as Argireline, provide effects similar to botulinum toxin. Growth factors, including epidermal growth factor (EGF), support tissue regeneration. Because peptides are chemically unstable, encapsulation in liposomes or nanoparticles is often required to preserve bioactivity.^[9]

2.4 Retinoid serums

Retinoids, including retinol and its derivatives, are widely recognized for anti-aging and acne management. They enhance collagen synthesis and accelerate cellular turnover. Given their sensitivity to light and oxidation, retinoid formulations necessitate encapsulation, incorporation of antioxidants, and opaque packaging to ensure efficacy.

2.5 Exfoliating serums (AHA/BHA-based)

Serums containing alpha-hydroxy acids (AHAs) like glycolic and lactic acids promote gentle exfoliation and skin renewal, whereas beta-hydroxy acids (BHAs), such as salicylic acid, are particularly effective for acne-prone skin. Maintaining optimal pH and concentration is critical to achieve a balance between therapeutic effect and skin tolerability.

2.6 Botanical and plant extract serums

Plant-derived serums address the rising demand for natural cosmeceuticals. Commonly used extracts include *Centella asiatica* for healing, *Glycyrrhiza glabra* for brightening, and *Aloe vera* for soothing properties. Standardization of bioactive constituents is essential to ensure consistent performance and reproducible efficacy.

3. FORMULATION AND EVALUATION OF FACE SERUMS

3.1 Ingredient selection

The formulation of face serums involves careful selection of excipients to ensure efficacy and safety. Common components include solvents like water and ethanol, humectants such as glycerin and sorbitol, emollients including silicones and esters, stabilizing agents like EDTA and BHT, and preservatives such as parabens or phenoxyethanol. Each ingredient is chosen to contribute to product texture, stability, and skin compatibility.^[2]

3.2 Stability considerations and packaging

Active compounds like Vitamin C and retinoids are sensitive to degradation from light and oxygen. Strategies to maintain stability include incorporation of antioxidants, minimizing oxygen exposure during filling, and using packaging systems such as airless dispensers to protect the formulation.^[4,8]

3.3 Rheological and sensory properties

Consumer perception depends heavily on rheological and sensory characteristics. Parameters such as viscosity, spreadability, and absorption rate are critical. Rheology modifiers, for example carbomers and xanthan gum, are employed to enhance texture, maintain uniformity, and ensure consistent application.

3.4 Analytical and clinical assessment

Face serums are evaluated through both laboratory and clinical methods^{[10]:}

In vitro: Techniques like HPLC and LC-MS quantify active ingredients, while permeation studies (e.g., Franz diffusion cells) assess skin delivery.

In vivo: Skin parameters including hydration, wrinkle reduction, and pigmentation are measured using instruments such as corneometers and profilometers.

Clinical validation: Human trials confirm product claims, ensuring efficacy and consumer safety.

4. REGULATORY AND LABELLING CONSIDERATIONS

In India, face serums are regulated under the Drugs and Cosmetics Act, 1940 and associated Rules, where they are generally classified as cosmetics unless therapeutic claims are made, in which case drug regulations apply. Labelling must comply with the Bureau of Indian Standards (BIS) requirements, mandating declarations such as ingredients, manufacturer details, batch number, and use-before date. Labelling, packing and standards of cosmetics have been prescribed under Part XV of Drugs and Cosmetics Rules 1945.^[7]

In the United States, the Food and Drug Administration (FDA) oversees cosmetic products under the Federal Food, Drug, and Cosmetic Act (FD&C Act), where a face serum is considered a cosmetic unless it claims to alter the skin's structure or function - triggering drug

classification. Labelling must be truthful, non-misleading, and compliant with 21 CFR Part 701.

In Europe, face serums fall under the EU Cosmetics Regulation (EC) No. 1223/2009, requiring safety assessment, product information files (PIF), notification on the Cosmetic Products Notification Portal (CPNP), and ingredient compliance with Annex listings. Across all three regions, accurate labeling, ingredient transparency, and avoidance of unsubstantiated claims are essential to ensure regulatory compliance and consumer safety.

5. APPLICATIONS AND MARKETED PRODUCTS

Face serums are utilized for a variety of cosmetic and therapeutic purposes. Anti-aging effects are achieved through actives such as retinoids, peptides, and antioxidants. Brightening formulations commonly include Vitamin C, niacinamide, and licorice extract, while hydration-focused serums employ hyaluronic acid and panthenol. Anti-acne serums typically contain salicylic acid or retinoids. Marketed products often feature synergistic combinations to enhance efficacy, such as Vitamin C with Vitamin E and ferulic acid, hyaluronic acid paired with peptides and panthenol, or retinol combined with niacinamide and ceramides.^[6]

6. SAFETY CONSIDERATIONS, CHALLENGES, AND EMERGING TRENDS

6.1 Safety considerations

Certain active ingredients may pose safety concerns. Retinoids can cause skin irritation and increase photosensitivity, Alpha-hydroxy acids (AHAs) may lead to redness or peeling at higher concentrations, and botanical extracts carry the potential for allergic reactions.

6.2 Formulation challenges

Key challenges in serum development include maintaining chemical stability of sensitive actives, creating preservative-free formulations while ensuring microbiological safety, and achieving an optimal balance between potency and skin tolerance.

6.3 Future perspectives

Emerging trends focus on advanced delivery systems and personalized skincare. Nanotechnology, including liposomes, niosomes, and nanostructured lipid carriers, improves bioavailability of actives.^[5] AI-guided, microbiome-friendly formulations enable personalized treatment, while biotechnologically derived ingredients, such as recombinant peptides and growth factors, offer enhanced efficacy. Sustainability is also gaining prominence, with biodegradable packaging and eco-friendly chemistry being incorporated into modern serum development.

7. CONCLUSION

Face serums have emerged as essential components of modern skincare, combining cosmetic elegance with

pharmaceutical innovation. Their effectiveness relies on precise formulation design, stability management, and evidence-based efficacy. With diverse functions - including anti-aging, hydration, brightening, and acne control - serums require adherence to safety and regulatory standards. Future developments are likely to focus on sustainable, biocompatible, and personalized formulations, further bridging the cosmetic-pharmaceutical interface.

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