

FORMULATION AND OPTIMIZING OF A SKIN BARRIER REGENERATING COSMECEUTICAL PRODUCT

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ABSTRACT. This study has as main objective the development and formulation of a skin barrier regenerating dermatocosmetic product for daily care, which incorporates effective emollients, such as Shea butter, an emollient and moisturizing cosmetic ingredient recognized for its regenerative effects, and an innovative emollient - Sucragel AOF (Glycerin (and) Prunus Amygdalus Dulcis (Sweet Almond) Oil (and) Sucrose LAURATE (and) Citrus Aurantium Dulcis (Orange) with moisturizing proven cosmetic efficacy and GATULINE® BIO SKIN-REPAIR (Alcohol (and) Water (and) onopordum Acanthium Flower/Leaf/Stem Extract), used in the developed formulation to support the cosmetic claimed of the product. An important study is the quality control of the regenerating cream by determining the physico-chemical characteristics and appropriate pharmacotechnical (pH, viscosity) characteristics, both initially and over time (30 days from the preparation of the product). The formulation is monitored under accelerated stability studies over a period of 30 days while maintaining the product at 4, 20 and 40 °C.

Keywords: *cosmeceutical, skin barrier regenerating, physico-chemical characteristics, accelerated stability studies*

INTRODUCTION

New insights about the function of the skin, as well as the development of new products for skin care, make it necessary to question or redefine the definitions of cosmetics and drugs.

The introduction of the term “cosmeceutical” enables us to classify more precisely a product with an activity that is *intended* to treat or prevent a (mild) skin (abnormality) [1]. In order to avoid introducing new definition criteria, it was

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suggested that cosmeceuticals are only regarded as a subclass within the domain of a cosmetic or drug.

The desire to maintain a youthful image combined with an emerging global market with disposable income has driven the development of many new industries. The cosmeceutical industry is based on the development and marketing of products that lie between cosmetics and pharmaceuticals. Although a number of products advertise predictable outcomes, the industry is largely unregulated and any consumers of cosmeceutical products should consult a dermatologist prior to use.

Dr. Albert Kligman originally coined the term cosmeceutical, describing a hybrid category of products found on the spectrum between drugs and cosmetics that exert a pharmaceutical therapeutic benefit but not necessarily a biological therapeutic benefit. Cosmeceuticals have become the fastest-growing segment of the personal care industry. Consumers and dermatologists alike can be overwhelmed with the sheer number of cosmeceutical products available. The multitudes of products are not strictly regulated, and consumers are often exposed to product information that is not scientifically sound or backed by rigorous clinical studies. Although certain cosmeceuticals may not deliver the effects they claim, there may be benefits because of their emollient action, although it is difficult to discern whether these effects can be attributed to the active ingredient or the vehicle. Recent trends in cosmeceutical development include those that address skin protection from radiation and oxidant damage, with a focus on nonirritating ingredients to improve the appearance of skin.

Skincare cosmeceuticals account for approximately 80% of the total U.S. and European cosmeceutical market. In 2011, the cosmeceutical market resumed growth rates close to those experienced between 2004 and 2007. U.S. demand for cosmeceuticals was projected to increase by 7.4% in 2012 and to continue to increase in the subsequent years (Figure 1) [2].

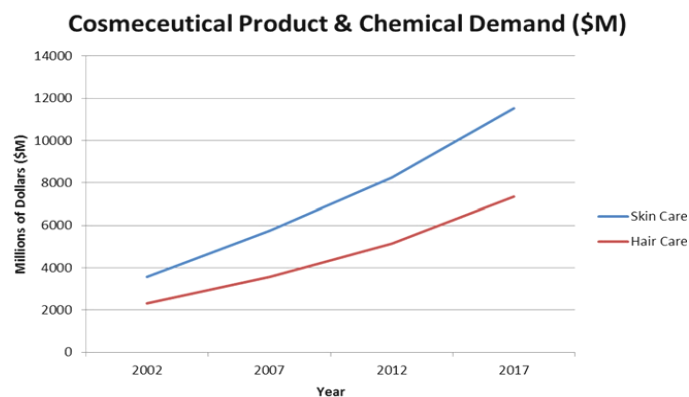


Fig. 1. Cosmeceutical product and chemical demand (\$M) for hair and skin care

The essence of innovative cosmeceuticals is their functional active ingredients. Hundreds of substances have been screened, synthesized, and tested and many have been included in commercially available products. The desired functions of a cosmeceutical might require a coordinating action of multiple ingredients. Moreover, there are problematic skin conditions that might change the interactive pattern and outcome between cosmeceuticals and skin. Scientific clinical evaluation is a must for research, development, and application of cosmeceuticals [3].

Millions of people suffer daily from skin dryness itching, scaling, and redness due to a large variety of causes. The skin barrier, composed of corneocyte and intercellular lipids, can only withstand a finite amount of damage until skin disease results. Predisposing factors to skin disease include low humidity conditions from cold dry weather and insufficient or defective sebum production [4].

“Dry skin” is a term used by consumers, cosmetic scientists, and dermatologists. Although this condition remains one of the most common of human disorders, it has never been defined unambiguously. Usually it is described in terms of symptomatology, its physical signs, and its etiology with names such as xerosis, dermatitis, winter itch, rough skin, dry skin, and chapping. However, dry skin is characterized by a rough, scaly and flaky skin surface, especially in low humidity conditions and is often associated with the somatory sensations of tightness, itch, and pain [5].

Dry skin is one of the common problems due to defective stratum corneum. It is a condition featured by some subjective or objective denominators, including sensory characteristics with dry, uncomfortable, itchy, stinging, and tingling sensation; tactile characteristics with a rough, uneven, and sandlike feeling; and visible characteristics with redness, lackluster surface, dry, white patches, flaky appearance, cracks, and even fissures. In addition, several skin diseases are also featured by dry skin, including atopic dermatitis, ichthyosis, and the like. Moisturizers are agents designed to repair the damaged stratum corneum to make the stratum corneum softer and more pliant by increasing its hydration, resulting in smooth, more supple, and healthier looking skin. Moreover, moisturizers are also designed to act as adjuvant treatment option for some dermatologic diseases with feature of dry skin. From the view of safety, therapeutic moisturizers should be noncomedogenic, devoid of irritant ingredients, and compatible with many other therapeutic regimens [3].

Moisturizers have been traditionally used to alleviate dry skin. They can reduce transepidermal water loss by promoting barrier repair, soothe exposed dermal nerve endings by creating a temporary artificial barrier, and restore skin softness. Recently, moisturizers have been shown to prevent the induction of primary irritation and to accelerate the process by which the skin heals itself. This

is an important function, since a quality moisturizer formulation should not only reduce dry skin and irritation, but also prevent the return of these conditions, which can lead to skin disease [4].

The demand for effective non-prescription topical products to treat inflammatory diseases such as eczema, atopic dermatitis, seborrheic dermatitis, and even psoriasis has led to the introduction of products based on either novel synthetic chemicals or on botanical “actives” which claim to be effective anti-inflammatory compounds. Some of the many purported botanical anti-inflammatory “active” ingredients in cosmeceutical products include bee pollen, curry extract, jewelweed, green tea extract, aloe, bilberry, tea tree oil, lavender essential oil, *Boswellia*, and willow bark. Although there are a wide number of topical anti-inflammatories available as prescriptions which are effective in treating skin inflammation, all have some side effects that negatively impact their usefulness. Topical steroids are effective for treating many dermatologic diseases but can lower collagen production in dermal fibroblasts, reduce their proliferation, and cause skin thinning. Topical immunomodulators are immunosuppressive and can lead to increased risk for infection and even cancer. Clearly, there is a continued need for identifying newer anti-inflammatory technologies that effectively treat skin disorders without having such strong immunosuppressive effects. Botanically derived anti-inflammatory compounds as well as newer synthetic drugs, should help meet this need [6].

EXPERIMENTAL

Qualitative data of the skin barrier regenerating cream formulation is presented in Table 1.

Figure 2 shows by comparison, the composition of the studied cream. The different ratios between lipophilic and hydrophilic components are noticed.

Standards and Reagents

Sample preparation of the skin barrier regenerating cream

Phase A (SUCRAGEL AOF (Glycerin, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sucrose Laurate, Aqua), Cerasynt SD (Glyceryl Stearate), Lanette D (Cetearyl Alcohol), Shea butter (Butyrospermum Parkii), Cacao butter (Theobroma Cacao), Jojoba (Simmondsia Chinensis) Oil, Phytosqualan (Squalane), dermofeel® TOCO 70 non-GMO (Tocopherol, Helianthus Annuus (Sunflower) Seed Oil)) was melted on water bath at 75°C. Phase B (demineralized water, dermorganics® Glycerin (Glycerin),

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dermosoft® LP (Caprylyl Glycol, Glycerin, Glyceryl Caprylate, Phenylpropanol) was heated at 80°C. Phase A1 (xanthan gum) was dispersed in phase B. Phase A was emulsified with phase B under stirring and cooling down to 40°C was started under medium stirring. Phase C (GATULINE® SKIN-REPAIR BIO (Alcohol (and) Water (and) Onopordum Acanthium Flower/Leaf/Stem Extract) and Honey LG (Mel Extract) was added under stirring.

Table 1. Qualitative formulation Skin barrier regenerating cream

Phase	Ingredient	INCI designation	Function	Supplier
A	SUCRAGEL AOF	Glycerin, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sucrose Laurate, Aqua	emollient	AlfaCos
	Cerasynt SD	Glyceryl Stearate	emollient/emulsifying	ISP
	Lanette D	Cetearyl Alcohol	emollient/emulsifying/emulsion stabilising/opacifying/viscosity controlling	Cognis
	Karite CP	Butyrospermum Parkii Butter	skin conditioning/emollient	SOPHIM
	Cacao Butter	Theobroma Cacao Butter	emollient	Sophim
	Jjoba oil	Simmondsia Chinensis Oil	emollient	SOPHIM
	Phytosqualane	Squalane	emollient/skin conditioning	SOPHIM
	dermofeel® TOCO 70 non- GMO	Tocopherol, Helianthus Annuus (Sunflower) Seed Oil	antioxidant	Dr. Straetmans
A1	Keltrol RD	Xanthan Gum	binding/emulsion stabilising/viscosity controlling/gel forming	CP Kelco
B	Deionised Water	Aqua	solvent	/
	dermorganics® Glycerin	Glycerin	denaturant/humectant /solvent	Dr. Straetmans
	dermosoft® LP	Caprylyl Glycol, Glycerin, Glyceryl Caprylate, Phenylpropanol	preservative	Dr. Straetmans
C	GATULINE® SKIN-REPAIR BIO	Alcohol (and) Water (and) Onopordum Acanthium Flower/Leaf/Stem Extract	active ingredient	Gattefosse
	Honey LG	Mel Extract	active ingredient	Naturex

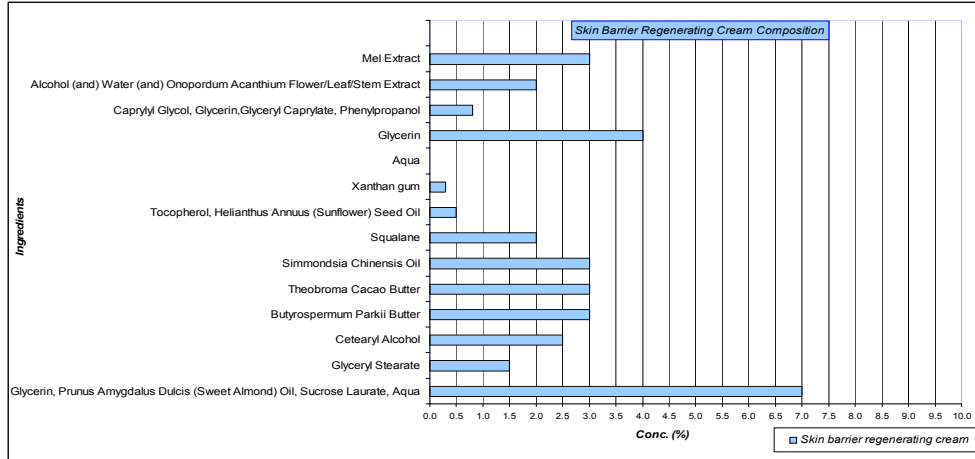


Fig. 2. The composition of the Skin barrier regenerating cream in a graphical representation

Physico-chemical characteristics of the developed Skin barrier regenerating cream- relevant characteristics, acceptance criteria, test methods

Quality control consisted of the following determinations:

Appearance

The appearance, color and odor were tested organoleptically.

pH determination

Was performed using a pH meter (Mettler Toledo (Schwerzenbach, Switzerland)).

Determination of the viscosity

Was performed using a HAAKE Viscotester VT550 (spindle R = 6, shear rate $D=5 \text{ s}^{-1}$, temperature $T=20^{\circ} \text{C}$).

Accelerated stability studies

The developed dermatocosmetic formulation was monitored under accelerated stability studies. Accelerated stability tests were performed over a period of 30 days while maintaining the product at 4, 20 and 40 ° C.

RESULTS AND DISCUSSION

Presentation report of the developed dermatocosmetic formulation

The Skin barrier regenerating cream is specially created as a dermatocosmetic

formulation and as contained active ingredients for sensitive skin, irritated, dry, with tendency of dehydration. The formulated cream associates a complex of emollients (Jojoba, Squalane, Shea butter) with role in restoring the hydro-lipid protective barrier of the skin, contributing to a good softening and moisturizing of the sensitive skin with innovative active ingredients with specific action- directly stimulates epidermal regeneration and promotes cutaneous repair (GATULINE® BIO SKIN-REPAIR (INCI name Alcohol (and) Water (and) Onopordum Acanthium Flower/Leaf/Stem Extract).

Phytosqualane has a geriatric type activity on wrinkled skin, reducing fine lines.

Shea butter is known for its excellent softening, moisturizing and nourishing properties with a good spreadability and leaving a non greasy feeling to the skin.

α -tocopheryl acetate (dermofeel® E 74 A) is an effective antioxidant, helping to combat skin aging processes caused by free radicals. It softens the skin and improves skin elasticity.

Honey extract tones and revitalizes, restores and nourishes the skin, restores altered connective tissue due to external factors.

Applied regularly, the developed dermatocosmetic cream means an ideal product for improving the appearance of sensitive, irritated and dehydrated skin. The cream prevents and alleviates skin irritation, restores the skin's water balance and ensures effective hydration throughout the day.

Physico-chemical characteristics of the developed Skin barrier regenerating cream

Quality control of the developed dermatocosmetic cream revealed: achieving an acceptable cosmetic preparation with elegant appearance and appropriate physico-chemical and pharmacotechnical (pH, viscosity) characteristics. The initial determination results are shown in Table 2.

Table 2. Initial physico-chemical determination of the cosmeceutical cream

<i>Nr.</i>	<i>Properties</i>	<i>Admissibility conditions</i>
1.	Appearance	- homogeneous emulsion
2.	Colour	- soft light white
3.	Odour	-characteristic
4.	pH	- 5,5
5.	Viscosity	-6.500 mPas.S

Accelerated stability studies performed over a period of 30 days, while maintaining the product at 4, 20 and 40°C, showed that the formulated and studied dermatocosmetic product is stable. The results are shown in Table 3.

Table 3. Physico-chemical determination of the cosmeceutical cream

<i>Test</i>	<i>Admissibility conditions (initial)</i>	<i>Admissibility conditions (after 30 days)</i>
Appearance	homogeneous emulsion	proper
Odour	characteristic	proper
Colour	soft light white	proper
pH	5,5	5,5
Viscosity	5.500 mPas.S	6.500 mPas.S

CONCLUSIONS

Cosmetics are commercially available products that are used to improve the appearance of the skin. Consumer demand for more effective products that more substantively beautify the appearance has resulted in increased basic science research and product development in the cosmetics industry. The result has been more ingredients that may actually improve not just the appearance of the skin, but the health of the skin as well. We now have products that renew, restore, and rejuvenate—not just cleanse, protect, and moisturize [7]. The latest innovation in the field of cosmetics is the development of active cosmetics.

Currently, cosmetics are not only intended for the improvement of the appearance or odor of the consumer, but are also intended for the benefit of their target, whether it is the skin, the hair, the mucous membrane, or the tooth. With this functional approach, products became diversified and started to claim a multitude of actions on the body. In order for cosmetic products to support these activities, raw materials became more efficacious, safe, bioavailable, and innovative, while remaining affordable. Subsequently, the cosmetic market greatly expanded, becoming accessible to millions of consumers worldwide [8].

The research presented in this paper had as main objective the development and formulation of a skin barrier regenerating dermatocosmetic. The developed dermatocosmetic formulation associates two valuable emulsifiers for effective support of the cosmetic cream- Shea butter, a known emollient in cosmetics for its regenerative and moisturizing effects and Sucragel AOF with strong moisturizing effects. The developed formulation incorporates a innovative active ingredient- GATULINE® BIO SKIN-REPAIR (Alcohol (and) Water (and) Onopordum Acanthium

Flower/Leaf/Stem Extract)- acting on keratinocyte differentiation, stimulating the optimal epidermal reconstruction of dry or damaged skin. The emollient raw materials, respectively Shea butter was added in a 5% concentration in the formulation and Sucragel AOF in 7%. The concentration of active ingredient has been introduced in the formulation at a concentration of 2%. The cream prevents and alleviates skin irritation, restores the skin's water balance and ensures effective hydration.

Quality control of the developed dermatocosmetic cream revealed: achieving an acceptable cosmetic preparation with elegant appearance and appropriate physico-chemical and pharmacotechnical (pH, viscosity) characteristics (after preparation and after 30 days of preparation).

Accelerated stability studies performed over a period of 30 days, while maintaining the product at 4, 20 and 40°C, showed that the formulated and studied dermatocosmetic product is stable.

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