HABILITATION THESIS

Current approaches to the formulation and evaluation of cosmetics and other health products

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ABSTRACT

The habilitation thesis entitled "*Current approaches to the formulation and evaluation of cosmetics and other health products*" represents a synthesis of the author's scientific, professional and academic activity, realised after the completion of her doctoral studies, with the public defense on 9th of September 2011. The research activity relied on the knowledge and expertise acquired during the doctoral studies, where the main concerns and interests were based on the characterization, analysis and evaluation of ingredients and cosmetic products. Subsequently, the activity has been directed towards two major directions in cosmetology, namely the formulation and evaluation of the safety and efficacy of ingredients and cosmetic products and other health products.

The rapid evolution of the cosmetics industry, and also the development and improvement of the legislation, designed to protect the consumer, has contributed to the increasing consumers credibility of cosmetology and cosmetic products. Whereas cosmetic products were recommended and used in the past mainly for beauty or hygienic purposes, nowadays they are used for more complex and demanding purposes, such as maintaining an optimum skin condition, performing an eutrophic function and finally performing an aesthetic criterion, while being safe and effective. Three main aspects are considered to be essential in relation to the formulation and development of cosmetic products - *quality*, *safety* and *efficacy*. In line with these legislative requirements, various studies on the safety, efficacy and analysis of cosmetic ingredients and formulations have been assessed.

The main objective of the research presented in the first chapter of the thesis represents the stability and microbiological evaluation through specific testing of cosmetic formulations with various ingredients, some of them restricted under current legislation (Regulation EU 1223/2009). One of the studies showed that a cosmetic formulation incorporating traditional preservatives (Phenoxyethanol/Paraben) can be preserved, by comperison with alternative preservatives in order to support the "paraben free" claim, demonstrating the possibility of replacing traditional preservatives with multifunctional additive complexes.

Another study referred to the formulation with different categories of emollients, comparing synthetic versus natural wax complexes and the study of some pharmacotechnical parameters and sensory evaluation of these formulations, aiming to highlight the sensory characteristics of the cosmetic formulation with a natural wax complex.

Another research underlines the benefits of innovative active ingredients, such as hyaluronic acid (HA) and its derivate, sodium hyaluronate, its application considering HA molecular weight, and the cosmetic effect, but also the combination with other active ingredients in cosmetic products, claiming additional benefits of the cosmetic product.

Biomimetic peptides, especially "botox-like" active ingredients, are an innovative strategy in cosmetology. Proteins and peptides from the venom of various species find their application in cosmetic formultions, in particular due to their anti-ageing effect or for the development of innovative active ingredients with similar effects. Natural venom is commercially available at a very high price, this beeing the reason of alternative active ingredients with similar effect, but at the same time more affordable. Regarding this, a study has been developed, based on the global cosmetic market analysis and cosmetics, which claim snake venom as an active ingredient in the INCI composition, concluding that the natural ingredient is predominantly replaced by the commercially available synthetic active - an active complex (INCI name Glycerin, Aqua, Dipeptide Diaminobutyroyl Benzylamide Diacetate), analogue of Waglerin-1, a disintegrin present in the venom of the *Tropidolaemus wagleri* species.

According to current legislative requirements, the safety of a cosmetic product refers to the composition, but also to the packaging, which comes into direct contact with the product. Thus, several studies have been assessed to evaluate the compatibility of some developed cosmetic formulations with various types of primary packaging (polyethylene (PE), polypropylene (PP) or glass vials with PP dispencer and cap), by monitoring quality parameters and stability of the formulation through accelerated stability tests.

The second chapter presents various studies describing some analytical methods, such as the application of gas or liquid chromatography methods for the quantitative determination of some active ingredients with antioxidant effect (α-tocopherol acetate, resveratrol, or coenzyme Q10) in cosmetic formulations and dietary supplements. A study has been developed to demonstrate the applicability of spectrophotometric methods for the determination of zinc in dietary supplements and another research concerned the quantification of dextromethorphan in syrup by liquid chromatography.

The use and application of nanoparticles present new opportunities in the formulation of a wide variety of products for human health, but also present some risks, due to certain properties, leading to innovative applications of nanomaterials, that may cause a potential hazard to human health. Considering this, some studies have been performed, describing the role, applications and benefits of active

substance delivery systems. A research highlights the most recent studies of polymer-drug conjugates containing natural polymers such as chitosan, hyaluronic acid, dextran, pullulan, silk fibroin, etc. Another study highlights the multiple applications of dendrimers, such as their use in antineoplastic therapy, in the delivery of non-steroidal anti-inflammatory drugs or antibiotics, in antiviral therapy or cardiovascular pathologies, or even in imaging and diagnostics. The aim of another study was to provide an overview of recent advances in the use of dendrimers as non-viral carriers in GDEPT (Gene-directed Enzyme Prodrug Therapy), as a promising strategy for prodrug delivery.

Another research direction relates to the adverse events of health products, i.e. cosmetics (cosmetovigilance), dietary supplements (nutrivigilance) or medical devices (materiovigilance), and as well to issues related to improving patients' quality of life.

Considering the didactic activity, the author aims first of all, in connection with the content of the lectures, to asses the improvement of the teaching materials based on theoretical and practical concepts, as well the development of scientific volumes as support materials, in order to achieve a professional teaching process. From the scientific and professional activity perspective, the research directions followed and developed previously, will be continued, but also innovative topics will be approached, such as the adjuvant topical treatment in the relief of skin disorders caused by chemo- and radiotherapy, studies on various active ingredients used in skin ageing prophylaxis, the development and evaluation of delivery systems of cosmetic active ingredients (liposomal or nanomaterials), cosmetovigilance issues and the applicability of *in silico* models for the evaluation of the risk assessment of cosmetic ingredients, in line with current legislative aspects.

Considering that ideally, the professional, scientific and academic activity should be perfectly balanced, it is proposed that these aspects will be achieved in the future, as they have been so far, on the principle of ethics and effective communication with collaborators and research groups members.