Evaluation of Preservatives for Cosmetic Formulations Using the Linear Regression Method

Authors: Ingrid Johanna Rojas G, M.Sc., Fabiola Echegaray M.Sc., Sonia Mayorga, Belcorp, Innovation and Research Laboratories, Cundinamarca, Colombia

Abstract

This study was performed to determine which of the preservative systems used in the formulation of body and facial creams is the most effective for the elimination of microbial contamination using the preservative challenge test and analysis by linear regression. These tests obtain results faster than CTFA and USP methods. For the microorganisms tested, *S.aureus* is the most difficult to eliminate by preservatives and *P.aeruginosa* is the most sensitive to the antimicrobial action of preservatives. To eliminate moulds and yeasts, the preservative system with Isothiazolinones and hydantoin is the most effective; however each formulator should be able to find the best combination of preservatives that can eliminate all kinds of microorganisms. Tests showed that parabens are the components that most effectively eliminate microbial contamination of products during use; however it is necessary to test new types of preservatives which are not considered to be a risk to human health.

Introduction

In recent years, the cosmetics and personal care products industry has had a sustainable growth in production and sales. New markets arising from globalisation mean being at the forefront of innovation and therefore the design and development of new products, increasing the demand for production processes to provide products with the best quality. To ensure that those products are safe from a microbiological point of view, it is important to perform microbiological analysis and evaluation of preservatives[2,10,12].

Preservative efficacy tests are designed to determine if a product can prevent microbial contamination due to the presence of a preservative system during use and lifetime, ensuring safe and reliable products[12]. This test is carried out using high contamination levels of microorganisms, as established by the CTFA (Cosmetic, Toiletry & Fragrance Association) and the USP (United States Pharmacopeia). The microorganisms most commonly used in preservative efficacy tests are *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans* and *Aspergillus brasiliensis*; they are used by inoculating the cosmetic product and tracking at a given time; the inoculated microorganisms must decrease during this time[1,15].

In the late 1970s, Donald Orth[7] proposed the linear regression method to evaluate the effectiveness of preservatives and the reduction of microorganisms added to the samples as a function of exposure time, thereby calculating the value D, which is the time required to reduce the number of viable organisms artificially added in 1.0-log or 90%. Thus, the system determines whether a cosmetic preservative is adequate to avoid possible microbial contamination, since preservatives are challenged against microorganisms artificially added to the test samples. This method gives results faster than provided by CTFA and USP because analyses are performed depending on the exposure time expressed in hours (for USP and CTFA, the exposure time is in days), thus determining the reduction of the microbial population. The linear regression method has been used in the formulation, design and development stages of cosmetic products as a quick way of obtaining results to evaluate the efficiency of preservatives, without eliminating the official methods established by CTFA and USP[1,15].

Acceptance criteria for the linear regression method are a value D ≤ 4h corresponding to a ≥ 6-log in 24h for pathogens, a D value of ≤ 28h corresponding to a ≥ 6-log in 7 days for nonpathogenic vegetative bacteria, yeasts and moulds. Proper preservation is indicated by a complete elimination of at least 106 cfu / g of pathogens in 24h and at least 106 cfu / g of non-pathogenic for 7 days[7,9].