

Title: CHALLENGE TEST ON OILY PRODUCTS - VALIDATION OF INOCULUM

Authors Manzano, T.S.P. ¹, Costa, C.C. ², Franzim, M.S. ², Rodriguez, D.D.P ¹

Institution ¹ Natura Inovação e Tecnologia de Produtos Ltda. (Via de Acesso KM 30,5, prédio A – Bairro Empresarial Itaim - Cajamar - SP CEP: 07790-190), ² Arch Química Brasil Ltda. (Avenida Brasília 1150, Bairro Buru - Cidade de Salto - SP CEP: 13327-901)

Abstrat:

The cosmetic segment has grown in Brazil and it's been accelerated in recent years, becoming an important market in the economy. It is a sector that requires constant innovation in the products development. To meet the consumer's needs new cosmetic formulations have been developed between them, Anhydrous and Oily, as the following example: single-phase oil and gloss. In order to ensure a product with microbiological quality it is necessary the addition of preservative to prevent the growth of microorganisms in the formulations since manufacturing until expiration date. This system has its effectiveness assessed by challenge test, consisting of deliberate inoculation of specific microorganisms in the product, which are dispersed in aqueous base solution (inoculum). In oily products, which are immiscible in water, it becomes impossible this inoculation. In this class of products the preservative used is more restrict, because its physicochemical characteristic prevents microbial growth, it does not have free water available. However, it's been found that some critical conditions of these products using, as on the bath or when used on the lips, can change the amount of free water, favoring the growth of microorganisms and consequently the need of using preservatives. This study objective was to validate a suitable inoculum that was miscible with oily products and to keep them viable microorganisms until the end of the challenge test (28 days). In this validation oily ingredients polysorbate 20 (tween) and glycerol were submitted to toxicity testing and the strongest performance continued. They were mixed with Nutrient broth for bacteria and Sabouraud broth into molds and yeasts and the inoculums were formed. For validation process the parameters described in USP methodology chapter 1223 Validation of Alternative Microbiological Methods were used: accuracy, precision, limit of quantification, linearity and reproducibility. It is noteworthy that for comparative purposes, we just used the traditional inoculum commonly used in challenge test (saline 0.85%). According to the parameters used in the method in question, it's been concluded that the inoculum validated for use in the challenge test oily product was 25% glycerol added 75% Nutrient broth for bacteria and 25% glycerol added 75% broth Sabouraud for yeasts and molds.

Keywords: cosmetic, oily product, challenge test, oily inoculum.