

METHODS AND COMPARISON. PRESERVATIVE EFFICACY IN COSMETICS



Antimicrobial efficacy is generally contributed by a number of factors, for example, concentration of preservatives, inherent characteristics of the formulation, design of the packaging and manufacturing process.

From the Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009, and provided by the Guidelines on Microbiological Quality of Finished Product in SCCS Notes of Guidance, preservation challenge test is necessary on cosmetic products, except those which are single-used, allow dosing without it coming in contact with the air, or are of low-risk (e.g. alcohol content > 20%, organic solvent-based, high/low-pH).

There are different widely and commonly adopted standard methods for preservative efficacy test. This article will focus on the methods and scopes of efficacy test (challenge test) in cosmetic products.

Cosmetic products are rich in nutrients, which provide a very favourable environment and condition for the growth of microorganisms. Controlling the growth of microorganisms during the use of products becomes very important. In most of the time, preservatives are added into the formulations to prevent and inhibit the microbial growth, so as to maintain the product safety within the shelf life in terms of microbiology.

Cosmetic Regulations of a number of countries always provide a positive list of preservatives for cosmetic use. However, in recent years, there is a trend of further tightening the use of preservatives, which reduces choice to the cosmetic industry.



TEST METHODS	ISO 11930	USP <51>	EUP Ch. 5.1.3	ASEAN ACM MAL 08
SCOPES	Designed specifically for cosmetic products	Designed specifically for pharmaceutical products	Designed specifically for pharmaceutical products	Designed specifically for cosmetic products
TEST MICROORGANISMS	Strains: <ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> • <i>Pseudomonas aeruginosa</i> • <i>Escherichia coli</i> • <i>Candida albicans</i> • <i>Aspergillus brasiliensis</i> 			Strains: <ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> • <i>Pseudomonas aeruginosa</i> • <i>Enterobacter aerogenes</i> • <i>Candida albicans</i> • <i>Aspergillus niger</i>
STUDY TIME POINTS	3 Time Points: <ul style="list-style-type: none"> • D7, D14, D28: Bacteria and Yeast • D14 and D28: Mold 	2 Time Points: <ul style="list-style-type: none"> • D14 and D28: Bacteria, Yeast and Mold 	4 Time Points: <ul style="list-style-type: none"> • D2, D7, D14, D28: Bacteria • D14 and D28: Yeast and Mold 	4 Time Points: <ul style="list-style-type: none"> • D7, D14, D21, D28: Bacteria, Yeast and Mold
CRITERIA	2 Criteria Criterion B is less stringent than Criterion A but only applies when there is other control factor, e.g. a package that can reduce the chance of microbial contamination after first use.	2 Criteria Criterion B is less stringent than Criterion A but only applies when it is considered that if higher concentration of preservative added to the product may poses hazard to health.	1 Criterion only	1 Criterion only



SGS Hong Kong can offer testing service to safeguard your products. For more information, please don't hesitate to contact SGS representatives, our experts will provide you professional technical and regulatory advice to safeguard your products.

FOR ENQUIRIES

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