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Technical Information Bulletin
Antimicrobial Preservative Effectiveness Testing Global Pharmacopoeia Standards for Topical Products

The following table is a summary of the different tests and specifications required by specific regions for Antimicrobial (Preservative) Effectiveness Testing (AET). The regions encompass Japan, Europe (including Great Britain), and the United States. In addition to the designated organisms, additional organisms can be used to challenge the product.

Important note: The Validation Test demonstrates the efficiency of the neutralizers used in the plate count method in inactivating the antimicrobial preservatives contained in the test sample. This is required by all compendial methods. Failure to properly neutralize the preservative system during testing can result in false negative results where lack of organism recovery may be due to inhibition of the organism.

	CTFA1		USP			JP		EP/BP				
Bacteria	Two from *Klebsiella pneumoniae, Enterobacter cloacae, Escherichia coli, Proteus species* or *Enterobacter gergoviae* One from *Staphylococcus aureus* or *Staphylococcus epidermidis* *Pseudomonas aeruginosa* and one from *P. cepacia, P. fluorescens, P putida, Flavobacterium sp* or *Acinetobacter sp.* *Bacillus subtilis* (Optional)		*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa*			*Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa*		*Staphylococcus aureus, Pseudomonas aeruginosa*				
Yeast	*Candida albicans* or *Candida parapsilosis*		*Candida albicans*			*Candida albicans*		*Candida albicans*				
Mold	*Aspergillus niger* or *Penicillium luteum*		*Aspergillus niger*			*Aspergillus niger*		*Aspergillus niger*				
Test Duration	28 or 56 days		28 days			28 days		28 days				
Sampling times in days For topical products	0, 2, 7, 14, 21 & 28		14 & 28			7, 14, 21 & 28		0, 2, 7, 14 & 28				
Types of Product	1. Water Miscible Cosmetics 2. Eye Area Cosmetics		1 Injections, 2 Topical, 3 Oral (non antacids) 4 Antacids			1A Injections, 1B Topical, 1C Oral 1D Antacids II Nonaqueous		C-1 Parenteral and Ophthalmic Preparations C-2 Oral Preparations C-3 Topical Preparations C-4 Ear Preparations				
Acceptance Criteria Cosmetics (Topical) 2	Log Reduction		Log Reduction			Log Reduction		Log Reduction3				
	7 d	14 and 28 d	7d	14d	28d	14d	28d		2d	7d	14d	28d
Bacteria	3	NI	-	2 from Initial	NI from 14 day	2	NI from initial	A B	2 -	3 -	- 3	NI NI
Fungi (yeast and mold)	1	NI	-	NI from Initial	NI from initial	NI from initial	NI from initial	A B	- -	- -	2 1	NI NI

NI : No Increase

Note:
The EP/BP criteria requires a reduction of bacteria at 2 days, this is the most stringent criteria for bacteria.
The CTFA criteria requires a reduction of fungi at day 7, this is the most stringent criteria for fungi.

1 The CTFA test allows the microorganisms to be pooled into groups of bacteria, fungi and mold. Additional organisms are listed in the procedure. In addition, at least one rechallenge is recommended for an additional 28 days.
2 The acceptance criteria listed above is only for topical products. The criteria will differ for other categories.
3 The EP/BP A criteria express the recommended efficacy to be achieved. In justified cases where the A criteria cannot be attained, for example, for reasons of an increased risk of adverse reactions, the B criteria must be satisfied.