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Technical Guidelines for Preservative Challenge Testing and Assessment of Cosmetics

化妆品防腐挑战测试评估技术指南

National Institutes for Food and Drug Control

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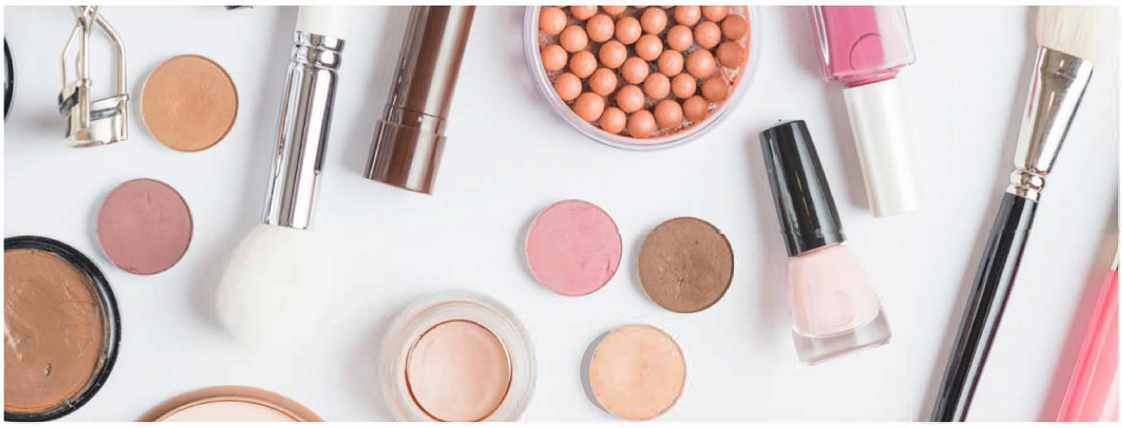

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Attachment 2

Technical Guidelines for Preservative Challenge Testing and Assessment of Cosmetics

National Institutes for Food and Drug Control

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1. Scope

This *Guidelines* specifies the method for evaluation of preservative efficacy of cosmetics.

This *Guidelines* is applicable to the evaluation of preservative system efficacy of cosmetics.

2. Terms and Definitions

2.1 Preservative Efficacy Evaluation Test

A test method for evaluating preservative system efficacy of cosmetics according to changes in viable microorganism amount that is tested at regular intervals under simulated possible contamination situations present in cosmetics which are achieved by artificially contaminating the cosmetics with a certain amount of microorganisms.

2.2 Neutralizer

A reagent that can be added to mixtures of cosmetics and microorganisms to eliminate the inhibiting or killing effects of antibacterial or germicidal components in the cosmetics on microorganisms.

3. Equipment and Materials

3.1 Type A2 biosafety cabinet.

3.2 High-pressure steam sterilizer.

3.3 Balance: with a sensitivity of 0.1 g.

3.4 Constant temperature incubator: 36 ℃±1 ℃, 28 ℃±2 ℃, and 25 ℃±2 ℃.

3.5 Homogenizer.

3.6 Sterile pipette: 1 mL (graduated in 0.01 mL division), 10 mL (graduated in 0.1 mL division), or micropipette and its tip.

3.7 Microscope.

3.8 pH Meter.

3.9 Vortex mixer.

3.10 Sterilized plate: with a diameter of 90 mm.

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附件 2

化妆品防腐挑战测试

评估技术指南

中国食品药品检定研究院

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目 录

1.范围

本指南规定了化妆品防腐效能的评价方法。

本指南适用于化妆品防腐体系效能评价。

2.术语和定义

2.1 防腐效能评价试验

将一定量的微生物人工污染到化妆品中，模拟化妆品可能出现的污染情况，每隔一定时间检测其中的存活菌量，根据存活菌量的变化评价化妆品防腐体系效能的试验方法。

2.2 中和剂

可添加至化妆品和微生物混和物中，消除化妆品中抑菌或杀菌成分对微生物抑制或杀灭作用的试剂。

3.设备和材料

3.1 A2 型生物安全柜。

3.2 高压蒸汽灭菌器。

3.3 天平：感量为 0.1g。

3.4 恒温培养箱：36℃±1℃、28℃±2℃、25℃±2℃。

3.5 均质器。

3.6 无菌吸管：1mL(具 0.01mL 刻度)、10mL(具 0.1mL 刻度)或微量移液器及吸头。

3.7 显微镜。

3.8 酸度计。

3.9 涡旋混匀器。

3.10 灭菌平皿：直径 90mm。

3.11 无菌玻璃棉。

4.培养基和试剂

4.1 0.85%生理盐水。

4.2 卵磷脂吐温 80 营养琼脂培养基，见附录 A.1。

4.3 虎红（孟加拉红）培养基，见附录 A.2。

4.4 含 0.05%(v/v)聚山梨酯 80 的生理盐水，见附录 A.3。

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