



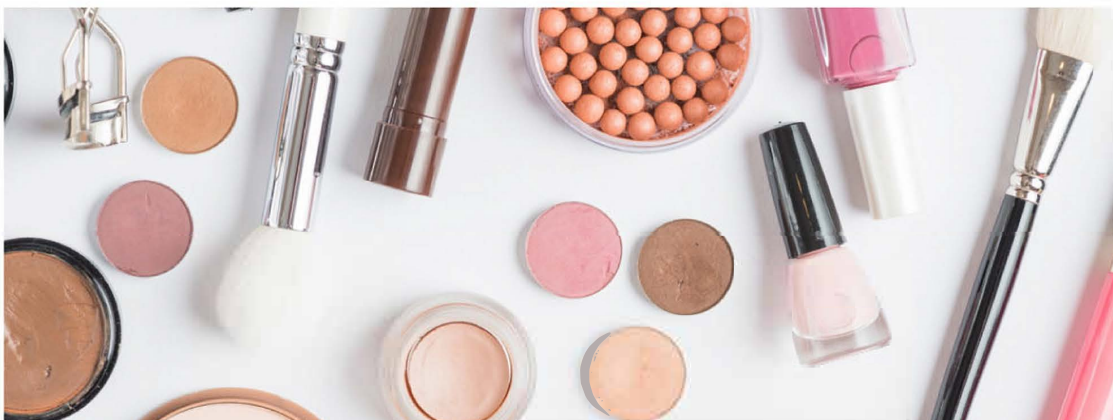
Technical Guidelines for Preservative Challenge Test of Cosmetics (Draft for Comments) and Drafting Explanation

化妆品防腐剂挑战试验技术指南(征求意见稿)
及起草说明

National Institutes for Food and Drug Control

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Attachment 2

Technical Guidelines for Preservative Challenge Test of Cosmetics (Draft for Comments)

1 Scope

This standard specifies an evaluation method for preservative effect of cosmetics.

This standard is applicable to the evaluation of preservative system effect of common cosmetics such as aqueous ($AW \geq 0.7$) emulsions and creams.

2 Terms and Definitions

2.1 Preservative effect evaluation test

A method of test for artificially contaminating cosmetics with a certain amount of microorganisms to simulate the possible contamination situations of cosmetics, and then counting living microorganisms at regular intervals, and evaluating the preservative system effect of cosmetics based on the changes in the living microorganism count.

2.2 Neutralizer

A reagent added to mixed cosmetics and microorganisms for eliminating the inhibiting or killing effects of cosmetics on microorganisms.

2.3 Rinse-off cosmetics

Cosmetics that are cleaned promptly after application on the human body (skin, hair, nails, lips, etc.).

2.4 Leave-on cosmetics

Cosmetics other than rinse-off products.

3 Equipment and Materials

3.1 Biosafety cabinet.

3.2 High-pressure steam sterilizer.

3.3 Balance: with a sensitivity of 0.1 g.

3.4 Constant temperature incubator: 36 °C $\pm$ 1 °C, 28 °C $\pm$ 2 °C.

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 tip.

3.7 Microscope.**3.8 pH Meter.****3.9 Sterilized plate: with a diameter of 90 mm.****4 Culture Mediums and Reagents****4.1 0.85% Normal saline.****4.2 Normal saline containing 0.05% (v/v) polysorbate 80, see Annex A.1.****4.3 Sterile sodium chloride-peptone buffer solution containing 0.05% (v/v) polysorbate 80 (pH=7.0), see Annex A.2.****4.4 Trypticase soy agar (TSA) medium, see Annex A.3.****4.5 Sabouraud's dextrose agar (SDA) medium, see Annex A.4.****4.6 SCDLP liquid medium, see Annex A.5.****4.7 Modified Eugon LT 100 broth, see Annex A.6.****4.8 D/E broth, see Annex A.7.****4.9 Modified Lethen broth, see Annex A.8.****5 Test Strains****5.1 Bacteria:**

Staphylococcus aureus CMCC (B) 26003

Escherichia coli CMCC (B) 44102

Pseudomonas aeruginosa CMCC (B) 10104

Staphylococcus epidermidis CMCC (B) 26629

5.2 Fungi:

Aspergillus niger CMCC (F) 98003

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- + INCI application

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附件 2

化妆品防腐剂挑战试验技术指南（征求意见稿）

1. 范围

本标准规定了化妆品防腐效能的评价方法。

本标准适用于含水的 ($AW \geq 0.7$) 乳液类和膏霜类等常见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，消除化妆品对微生物抑制或杀灭作用的试剂。

2.3 淋洗类化妆品

在人体表面（皮肤、毛发、甲、口唇等）使用后及时清洗的化妆品。

2.4 驻留类化妆品

除淋洗类产品外的化妆品。

3. 设备和材料

3.1 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： $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$ 、 $28^{\circ}\text{C} \pm 2^{\circ}\text{C}$ 。

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 灭菌平皿：直径 90mm。

4. 培养基和试剂

4.1 0.85%生理盐水。

4.2 含 0.05%(v/v)聚山梨酯 80 的生理盐水，见附录 A.1。

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4.3 含 0.05%(v/v)聚山梨酯 80 的 pH7.0 无菌氯化钠-蛋白胨缓冲液,见附录 A.2。

4.4 胰酪大豆胨琼脂培养基 (TSA) , 见附录 A.3。

4.5 沙氏葡萄糖琼脂培养基(SDA) , 见附录 A.4。

4.6 SCDLP 液体培养基, 见附录 A.5。

4.7 改良 Eugon LT 100 肉汤, 见附录 A.6。

4.8 D/E 肉汤, 见附录 A.7。

4.9 改良 Letheen 肉汤, 见附录 A.8。

5.实验菌株

5.1 细菌:

金黄色葡萄球菌 CMCC (B) 26003

大肠埃希氏菌 CMCC (B) 44102

铜绿假单胞菌 CMCC (B) 10104

表皮葡萄球菌 CMCC (B) 26629

5.2 真菌:

黑曲霉 CMCC (F) 98003

白色念珠菌 CMCC (F) 98001

在进行化妆品防腐效能评价试验时,可根据需要增加其他相关细菌或真菌作为测试菌株。如不采用本指南推荐的菌株,需说明菌株与指南中载明的菌株开展过验证,并且结果一致。

6.实验方法

6.1 供试品微生物检测

取不少于 2 份包装完好的供试化妆品样品,依据《化妆品安全技术规范》第五章微生物检验方法中菌落总数、霉菌和酵母菌检验方法对样品进行检测。供试品微生物检测的结果可记为 N_f 。

6.2 微生物悬液制备

6.2.1 细菌悬液制备

用接种环从菌种保存管中(或试管斜面上)取适量菌体,分区划线接种于 TSA 平板上, $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$, 培养 18 h~24 h。用接种环取第 1 代培养物,分区划线接种于 TSA 平板, $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$, 培养 18 h~24 h。挑取上述第 2 代培养物中典型菌落,分区划线接种于 TSA 平板, $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$, 培养 18 h~24 h, 即为第 3 代培养物。用无菌棉签取菌苔加入无菌生理盐水中,涡旋混匀。用无菌生理盐水将其稀释成约 1×10^7 CFU/mL ~



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