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General Guidelines for Microbiological Examination Methods in Cosmetics (Draft for Comments) and Explanatory Notes

《化妆品中微生物检验方法总则(征求意见稿)》及起草说明

National Institutes for Food and Drug Control

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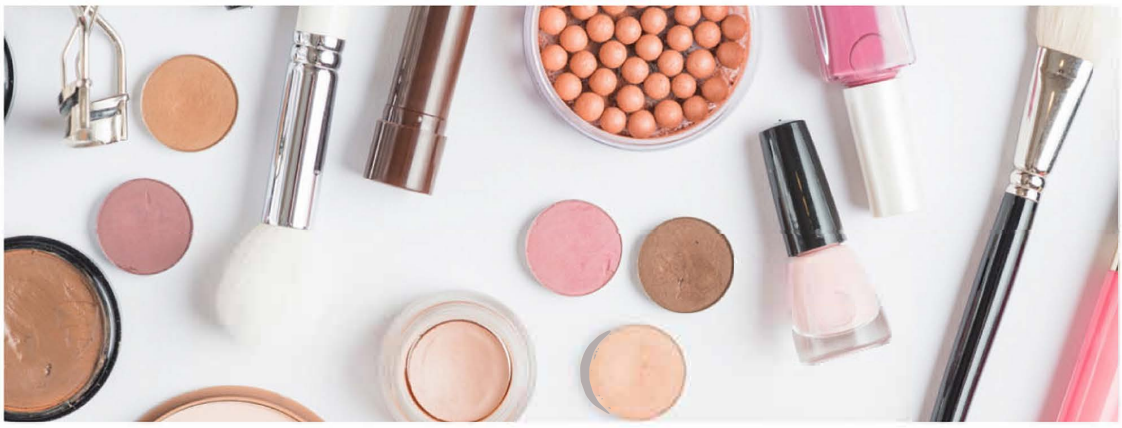

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Attachment 1

General Guidelines for Microbiological Examination Methods in Cosmetics (Draft for Comments)

1 Scope

This part specifies the basic requirements for microbiological examination in cosmetics.

This part applies to cosmetic sample collection, storage, preparation of test samples, and quality control.

2 Basic Laboratory Requirements

2.1 Environment

2.1.1 The laboratory environment shall not affect the accuracy of examination results.

2.1.2 The working zone of the laboratory shall be clearly separated from the office zone.

2.1.3 The working area and overall layout of the laboratory shall be capable of meeting the needs of conducting examination work.

2.1.4 The isolation and identification of pathogenic microorganisms shall be performed in a biosafety level 2 (BSL-2) laboratory, and the internal environment of the laboratory shall comply with the requirements for a BSL-2 laboratory.

2.2 Personnel

2.2.1 The examination personnel shall have relevant professional training experience in microorganisms, possess corresponding qualifications, and be able to understand and correctly perform examination.

2.2.2 The examination personnel shall master knowledge of laboratory biological examination safety operation and disinfection.

2.2.3 The examination personnel shall maintain personal cleanliness and hygiene during the examination process to prevent artificial contamination of the samples.

2.2.4 The examination personnel shall comply with the provisions of relevant preventive measures during the examination process to ensure their own safety.

2.2.5 The personnel with color vision impairment shall not perform experiments involving

color discrimination.

2.3 Apparatus and Equipment

The test equipment and apparatus shall be capable of meeting the needs of examination work.

2.3.1 Balance: 0–200 g, accurate to 0.1 g.

2.3.2 Autoclave.

2.3.3 Shaker.

2.3.4 Erlenmeyer flasks: 250 mL, 150 mL.

2.3.5 Glass beads.

2.3.6 Glass rods.

2.3.7 Sterile graduated pipettes: 10 mL, 1 mL.

2.3.8 Constant temperature water bath.

2.3.9 Homogenizer or mortar and pestle.

2.3.10 Sterile homogenization bags.

2.3.11 Constant temperature incubator.

2.3.12 Refrigerator.

2.3.13 Microscope.

2.4 Strains

2.4.1 Standard or reference strains that are preserved by recognized microbial culture collections or other peer-recognized institutions and are traceable shall be used.

2.4.2 When necessary, systematic and comprehensive records may be maintained for original (wild-type) strains isolated, purified and identified from cosmetics or the environment, which have not been registered with recognized microbial culture collections. Such records may include the isolation time, source, principal phenotypic characteristics, and other relevant information of the strains.

2.4.3 The laboratory shall maintain standard or reference strains sufficient to meet the testing requirements. Verification shall be performed upon receipt and during subculture and preservation.

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附件 1

化妆品中微生物检验方法总则（征求意见稿）

General Guidelines for Microbiological Examination Methods in Cosmetics (Draft for Comments)

1 范围

本部分规定了化妆品微生物学检验的基本要求。

本部分适用于化妆品样品的采集、保存、供检样品制备及质量控制。

2 实验室基本要求

2.1 环境

2.1.1 实验室环境应不影响检验结果的准确性。

2.1.2 实验室的工作区域应与办公室区域应明显分开。

2.1.3 实验室工作面积和总体布局应能满足从事检验工作的需要。

2.1.4 病原微生物分离鉴定工作应在二级生物安全实验室（Biosafety level 2, BSL-2）进行，实验室内环境应符合二级生物安全实验室的要求。

2.2 人员

2.2.1 检验人员应具有相应的微生物专业培训经历，具备相应的资质，能够理解并正确实施检验。

2.2.2 检验人员应掌握实验室生物检验安全操作知识和消毒知识。

2.2.3 检验人员应在检验过程中保持个人整洁与卫生，防止人为污染样品。

2.2.4 检验人员应在检验过程中遵守相关预防措施的规定，保证自身安全。

2.2.5 有颜色视觉障碍的人员不能执行涉及到辨色的实验。

2.3 仪器和设备

试验设备与仪器应能满足检验工作的需要。

2.3.1 天平：0~200g，精确至 0.1g。

2.3.2 高压灭菌器。

2.3.3 振荡器。

2.3.4 三角瓶：250mL、150mL。

2.3.5 玻璃珠。

2.3.6 玻璃棒。

2.3.7 灭菌刻度吸管：10mL、1mL。

2.3.8 恒温水浴箱。

2.3.9 均质器或研钵。

2.3.10 灭菌均质袋。

2.3.11 恒温培养箱。

2.3.12 冰箱。

2.3.13 显微镜。

2.4 菌株

2.4.1 应使用微生物菌种保藏专门机构或同行认可机构保存的、可溯源的标准或参考菌株。

2.4.2 必要时，可对从化妆品或环境分离、纯化、鉴定的，未在微生物菌种保藏专门机构登记注册的原始分离菌株（野生菌株）进行系统、完整的菌株信息记录，包括分离时间、来源和菌株的主要表型特征等信息。

2.4.3 实验室应保存能满足实验需要的标准或参考菌株，在购入和传代保藏过程中，应进行验证试验。

3 培养基及试剂的质量控制

化妆品微生物检验用培养基的质量评价项目包括促生长能力、抑制能力及生化特性，各培养基的检验项目及所用的菌株见表 1~4。表中菌株可采用其他等效菌株进行检测。

实验室应针对每批次使用的培养基开展质量控制和评价工作。若生产商能提供由具备相应检验能力且取得国家相关认证认可资质的检验机构出具的同批次产品检验报告，实验室可保留相关证明文件，并根据实际需求对该批次培养基的质量予以评估。对于表 2~4 中未包含的培养基和试剂，实验室可根据其性能，参考表 2~4 中建立的方法进行评价。

3.1 培养基的促生长能力

3.1.1 固体培养基

将表2中规定的试验菌株接种到非选择性肉汤（如TSB）培养基中，培养过夜或采用其他方法（如培养18~24 h），制备10倍系列稀释的菌悬液。进行生长率测试时，细菌和酵母菌每平板的接种水平为50~250 CFU，霉菌每平板的接种水平为30~150 CFU。

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