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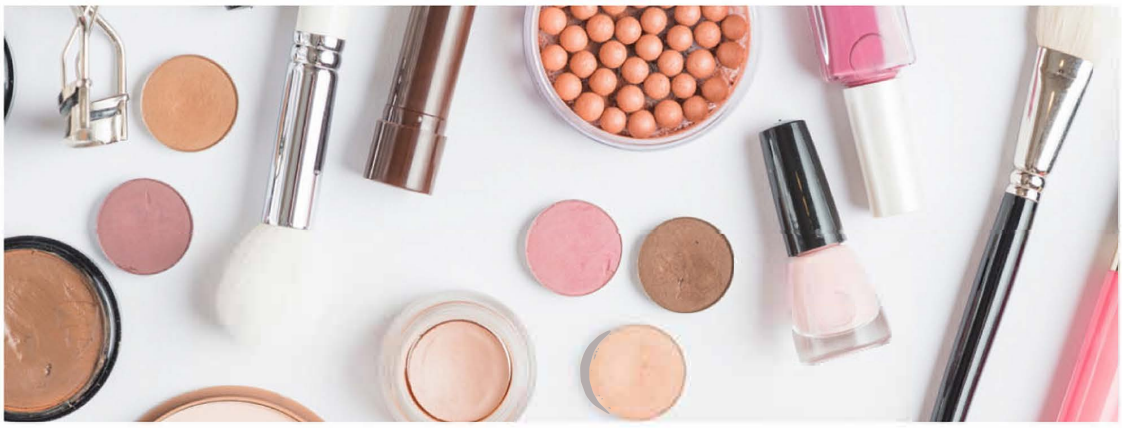
General Principles for Microbiological Examination in Cosmetics

化妆品中微生物检验方法总则

National Medical Products Administration

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Annex 2

General Principles for Microbiological Examination in Cosmetics

1 Scope

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

This part applies to microbiological examination in cosmetics.

2 General Requirements for Laboratories

2.1 Laboratory Environment

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

2.1.2 Laboratory work areas shall be clearly separated from office areas.

2.1.3 The size and overall layout of the laboratory shall be suitable for the testing activities to be performed. A unidirectional workflow is recommended to prevent cross-contamination.

2.1.4 Cosmetic samples shall be tested in designated clean areas, which shall be clearly marked.

2.1.5 The laboratory's ambient temperature, humidity, cleanliness, lighting, noise levels, and other environmental conditions shall meet the requirements of the testing activities.

2.1.6 The isolation and identification of pathogenic microorganisms shall be performed in a laboratory whose layout and safety measures meet the requirements for Biosafety Level 2 (BSL-2) laboratories.

2.2 Personnel

2.2.1 Testing personnel shall have an appropriate educational background or training in microbiology, possess the relevant professional knowledge, and be able to

understand and correctly perform the testing procedures.

2.2.2 Testing personnel shall be familiar with biosafety practices for laboratory testing, as well as procedures for disinfection and sterilization.

2.2.3 Testing personnel shall maintain personal cleanliness and hygiene during testing to prevent contamination of samples by personnel.

2.2.4 Testing personnel shall observe the applicable safety precautions during testing to ensure their own safety.

2.2.5 Personnel with color vision deficiencies shall not perform tests that require color discrimination.

2.3 Laboratory Equipment

2.3.1 Laboratory equipment shall be suitable for the testing activities to be performed. A list of commonly used laboratory equipment is provided in A.1.

2.3.2 Laboratory equipment shall be stored under appropriate environmental conditions that facilitate maintenance, cleaning, disinfection, and calibration. The equipment shall be kept clean and in good working order.

2.3.3 Laboratory equipment shall be regularly inspected and/or subjected to metrological verification, with appropriate labels affixed, and shall undergo regular maintenance and servicing to ensure proper performance and safe operation.

2.3.4 Records of routine monitoring or equipment use shall be maintained.

2.4 Testing Materials

2.4.1 Testing materials shall be suitable for microbiological testing. Commonly used testing materials are listed in A.2.

2.4.2 Testing materials shall be clean and/or sterile before use.

2.4.3 Testing materials to be sterilized shall be placed in designated containers, wrapped in suitable materials (such as sterilization wrapping paper or aluminum foil), or fitted with appropriate stoppers or caps. The effectiveness of sterilization shall be ensured.

2.4.4 Testing materials shall be stored in a clean and dry environment. Sterilized and

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附件 2

化妆品中微生物检验方法总则

General Principles for Microbiological Examination in Cosmetics

1 范围

本部分规定了化妆品微生物学检验的基本原则和要求。

本部分适用于化妆品的微生物学检验。

2 实验室基本要求

2.1 环境

2.1.1 实验室环境不应影响检验结果的准确性。

2.1.2 实验室的工作区域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,实验室布局宜采用单方向工作流程，避免交叉污染。

2.1.4 化妆品样品检验应在洁净区域进行，洁净区域应有明显标识。

2.1.5 实验室内环境的温度、湿度、洁净度及照度、噪声等应符合工作要求。

2.1.6 病原微生物分离鉴定工作应在符合二级生物安全实验室（Biosafety level 2, BSL-2）要求的布局环境、安全防护等条件下进行。

2.2 人员

2.2.1 检验人员应具有相应的微生物专业教育或培训经历，具备相关专业知识，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灭菌知识。

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辨色的实验。

2.3 实验设备

2.3.1 实验设备应能满足检验工作的需要，常用实验设备见 A.1。

2.3.2 实验设备应放置于适宜的环境条件下，便于维护、清洁、消毒与校准，并保持整洁与良好的工作状态。

2.3.3 实验设备应定期进行检查和/或检定（加贴标识）、维护和保养，以确保工作性能和操作安全。

2.3.4 实验设备应有日常监控记录或使用记录。

2.4 检验用品

2.4.1 检验用品应满足微生物检验工作的需求，常用检验用品见 A.2。

2.4.2 检验用品在使用前应保持清洁和/或无菌。

2.4.3 需要灭菌的检验用品应放置在特定容器内或用合适的材料（如专用包装纸、铝箔纸等）包裹或加塞，应保证灭菌效果。

2.4.4 检验用品的储存环境应保持干燥和清洁，已灭菌与未灭菌的用品应分开存放并明确标识。

2.4.5 灭菌检验用品应记录灭菌温度、灭菌时长及有效使用期限。

2.5 菌株

2.5.1 实验室应保存能满足实验需要的标准菌株。

2.5.2 应使用国内或国外微生物菌种保藏机构保存的可溯源标准菌株，或使用与标准菌株所有相关特性等效的可以溯源的商业派生菌株。推荐性菌株名称及编号见附录 B。

2.5.3 实验室应建立菌种管理的文件和记录。

2.5.4 对实验室分离菌株（野生菌株），经过鉴定后，可作为实验室内部质量控制的菌株。

2.6 培养基和试剂

部分培养基和试剂的配制方法见附录 C。

培养基和试剂的质量要求按照附录 D 的规定执行。

3 样品的采集及注意事项

3.1 采样过程遵循无菌操作程序，防止一切可能的外来污染。

3.2 所采集的样品，应遵循随机性、代表性的原则，并根据每批化妆品的生产总量及



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