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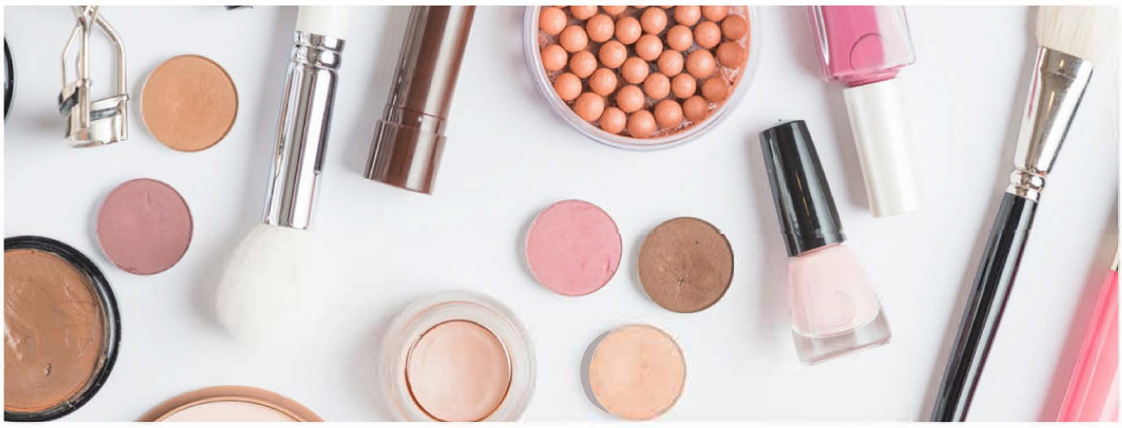
Q&A on Seven Test Methods, including the General Principles for Microbiological Examination in Cosmetics

关于《化妆品中微生物检验方法总则》等7项方法的问答

National Institutes for Drug Control

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Q&A on Seven Test Methods, including the *General Principles for Microbiological Examination in Cosmetics*

Following the recent issuance by the National Medical Products Administration (NMPA) of the *Announcement on Incorporating Seven Test Methods, Including the General Principles for Microbiological Examination in Cosmetics, into the Safety and Technical Standards for Cosmetics* (Announcement No. 105 of 2026), the National Institutes for Drug Control (NIDC) has prepared the following Q&A:

I. General Principles for Microbiological Examination in Cosmetics

(I) What promoted the revision of this standard?

In recent years, China's cosmetics industry has developed rapidly, with the market exceeding RMB 1 trillion for three consecutive years. Dosage forms have become increasingly diverse, and preservative systems increasingly complex. However, the General Principles for Microbiological Examination in the current *Safety and Technical Standards for Cosmetics 2015* (hereinafter referred to as "STSC 2015") did not include requirements for evaluating culture medium quality or testing the suitability of microbiological test methods. Consequently, the methods could not adequately account for the antimicrobial effects of preservatives in cosmetics, potentially resulting in false-negative results and allowing contaminated products to go undetected. To ensure the quality and safety of cosmetics, revision of the original test methods was therefore necessary.

This revision draws on international standards issued by organizations such as the International Organization for Standardization (ISO) and the United States Pharmacopeia (USP). It introduces quality control requirements for culture media and establishes procedures for microbiological test method suitability testing, thereby addressing gaps in technical controls and improving the reliability of test results. It also aligns the technical requirements with international standards, providing a sound technical basis for microbiological quality control in cosmetics.

(II) What are the main revisions to this standard?

Compared with the previous version of the General Principles for Microbiological

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关于《化妆品中微生物检验方法总则》等 7 项方法的问答

针对国家药监局近日发布的《国家药监局关于将〈化妆品中微生物检验方法总则〉等 7 项方法纳入化妆品安全技术规范的公告》（2026 年第 105 号），中国药品检定研究院起草相关问答，具体内容如下：

一、化妆品中微生物检验方法总则

（一）本标准的修订背景是什么？

近年来，我国化妆品产业快速发展，连续三年市场规模突破万亿元，产品剂型日益丰富，防腐体系日趋复杂。现行《化妆品安全技术规范（2015 年版）》（以下简称《规范》）中原微生物检验方法总则缺少培养基质量评价及方法适用性试验要求，无法有效评估化妆品中防腐成分的抑菌作用，易造成假阴性结果导致污染产品漏检。为保障化妆品质量安全，有必要对原检验方法进行修订。

此次修订参考了 ISO、USP 等国际标准，新增培养基的质量控制要求，建立微生物检验方法适用性试验程序，补齐技术管控短板，保障检验结果可靠性，实现技术要求与国际接轨，为化妆品微生物控制提供坚实技术支撑。

（二）本标准主要修订了哪些内容？

相较于原微生物检验方法总则，主要修订以下内容：

一是新增实验室基本要求（见“2 实验室基本要求”），从环境、人员、设备、检验用品、菌株管理五个方面进行系统规定，明确洁净区域、BSL-2 实验室及人员资质要求，从源头保障检验规范性。

二是新增培养基质量评价要求（见附录 D），规定每批次开展促生长能力、抑制能力和生化特性三项评价，建立参比培养基制度，解决培养基批间差异问题，保障结果可比性。

三是新增方法适用性试验要求（见“4.4 方法适用性试验”及附录 E），分别规定定量和定性检验的适用性试验方法，明确稀释、中和剂、薄膜过滤等抑菌成分消除途径，避免防腐剂导致假阴性。

四是新增生物安全与质量控制要求（见“6 生物安全与质量控制”），明确对照试验设置和人员考核要求，规范过程质量控制。



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