



Technical Guidelines for Research on Quality Control Requirements for Hair Perm Cosmetics (Trial)

《烫发化妆品质量控制要求研究技术指导原则（试行）》

National Institutes for Food and Drug Control

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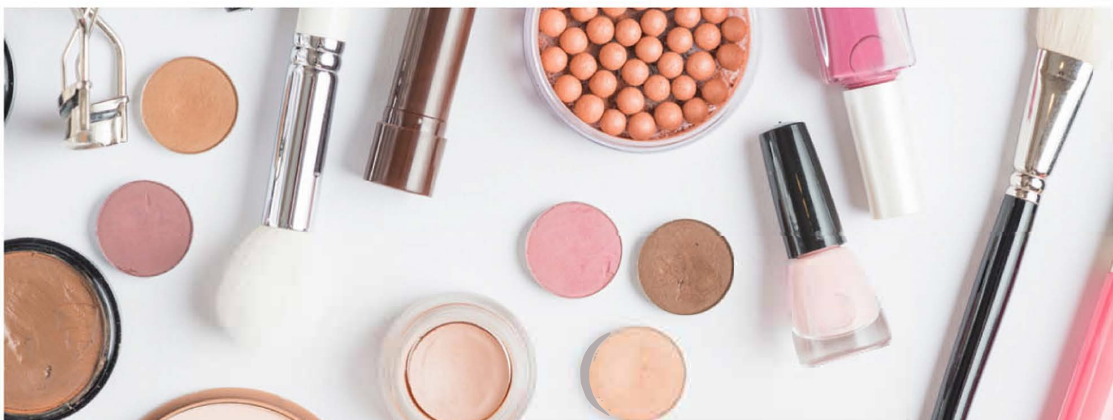
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Attachment 4

**Technical Guidelines for Research on Quality Control Requirements for
Hair Perm Cosmetics (Trial)**

National Institutes for Food and Drug Control

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I. Introduction

In accordance with the *Cosmetic Supervision and Administration Regulation* (CSAR), hair perm cosmetics are classified as special cosmetics, and subject to registration management. Registrants shall be responsible for the quality and safety of hair perm cosmetics. The CSAR has put forward higher requirements for the supervision, management, quality, and safety of cosmetics. Product executive standards aim to guide the cosmetic industry in implementing the principle of “one standard for one product”, and promote the improvement of product quality through standard management means. Quality control requirements constitute a crucial part of product executive standards. For the purpose of regulating and guiding the research on quality control requirements for hair perm cosmetics, these guidelines are hereby formulated.

These guidelines are formulated based on existing regulations and standards, as well as the current level of scientific cognition. Relevant contents will be adjusted in a timely manner with the update of regulations and standards, and the continuous development of science and technology.

II. Application Scope

These guidelines apply to the research on quality control requirements for hair perm cosmetics. The product quality control requirements mentioned herein refer to the “microbiological and physical and chemical indicators and their quality control measures” under the product executive standards in the registration dossiers, specifically including the testing items and indicators, quality management measures, and brief descriptions.

Registrants shall use these guidelines under the premise of complying with relevant existing laws, administrative regulations, mandatory national standards, and technical standards. If there are other applicable technical guidelines, the technical requirements in the corresponding guidelines shall also be referred to.

III. General Principles

The research on quality control requirements for hair perm cosmetics shall, on the basis of fully considering the impacts from the ingredient quality, formula composition, production techniques, product stability, circulation, use and other related links, determine targeted items and indicators that can effectively control product safety and quality, and reflect product characteristics. The quality control measures shall be operable, compatible with the production techniques, and capable of effectively controlling the stability and

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- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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附件 4

烫发化妆品质量控制要求研究 技术指导原则（试行）

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一、前言

根据《化妆品监督管理条例》（以下简称《条例》），烫发化妆品属于特殊化妆品，实行注册管理，注册人需对烫发化妆品的质量安全负责。《条例》对化妆品的监督管理和质量安全提出了更高要求。产品执行的标准旨在引导化妆品行业推行“一品一标”，运用标准管理的手段推动产品质量提升。质量控制要求是产品执行的标准中的重要内容，为规范和指导烫发化妆品的质量控制要求研究，制定本指导原则。

本指导原则是在现行法规、标准以及当前科学认知水平下制定的，随着法规、标准的调整以及科学技术的不断发展，相关内容将适时进行调整。

二、适用范围

本指导原则适用于烫发化妆品的质量控制要求研究。本指导原则所指产品质量控制要求是注册资料中的产品执行的标准“微生物指标和理化指标及其质量管理措施”，具体包括检验项目、指标、质量管理措施和简要说明。

注册人应在遵循现行相关法律、行政法规、强制性国家标准和技术规范的前提下使用本指导原则。如同时符合其他技术指导原则适用范围的，还应同时参考相应指导原则的技术要求。

三、一般原则

烫发化妆品的质量控制要求研究应在充分考虑原料质量、配方组成、生产工艺、产品稳定性、流通和使用各个环节影响的基础上，有针对性的确定能有效控制产品安全、质量和反映产品特征的项目和指标。质量控制措施应具有可操作性，与生产工艺相适应并能够有效控制产品批次间质量的稳定性和一致性，确保烫发化妆品的质量安全。

四、主要内容

烫发化妆品质量控制要求研究主要包括稳定性、质量控制项目和指标、质量管理措施等研究。

（一）稳定性研究

稳定性研究是产品质量安全研究的重要基础，可为产品使用期限和质量控制指标的设置提供依据。稳定性研究应结合产品特性选择在贮存期间易于变化，可能会影响产品质量安全、功效的项目，如产品性状、功效成分（烫发剂）含量等指标在温度、湿度等条件影响下随时间变化的规律。此外，还需充分考虑包装材料对产品质量的影响。



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