



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

《染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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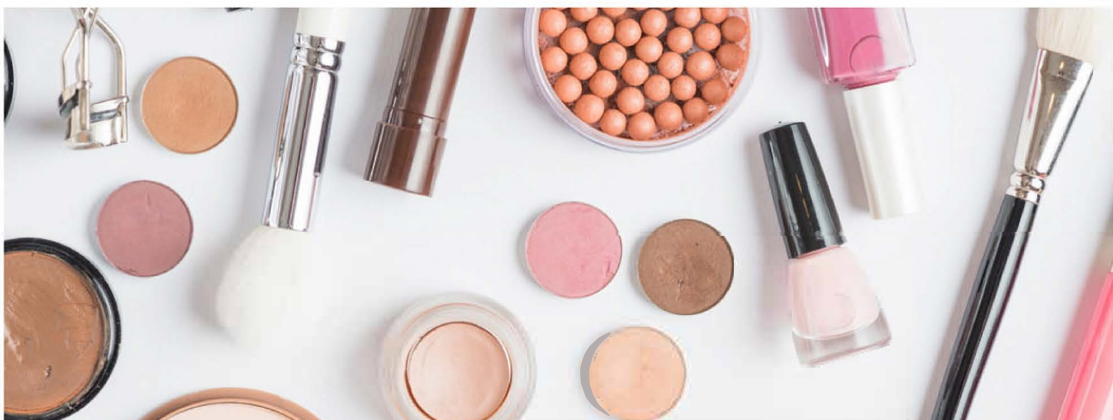
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Attachment 2

**Technical Guidelines for Research on Quality Control Requirements for
Hair Dye 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), cosmetics used for hair dyeing are classified as special cosmetics, and subject to registration management. Registrants shall be responsible for the quality and safety of hair dye cosmetics. Since the formal implementation of CSAR in 2021, higher requirements have been put forward for the quality, safety, supervision, and management of cosmetics. Product executive standards, as the new requirements of the new cosmetic regulations, 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 dye 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 dye cosmetics. The product quality control requirements mentioned herein, i.e., the “microbiological and physical and chemical indicators and their quality control measures” under the product executive standards in the registration dossiers, specifically include the testing items and indicators, quality management measures, and brief descriptions.

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

III. General Principles

Based on the product characteristics, the items and indicators that can effectively control product safety and quality and reflect product characteristics shall be established scientifically and rationally, with full consideration of potential impacts from the ingredient quality, formula composition, production technique, product stability, storage and use and other related links. The quality control measures shall be compatible with the production

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- + Preparation of Product Information File (PIF)



- + Cosmetic formula and label compliance review
- + FDA Voluntary Cosmetic Registration Program (VCRP)
- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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附件 2

染发化妆品质量控制要求研究 技术指导原则（试行）

中国食品药品检定研究院

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一、前言

根据《化妆品监督管理条例》（以下简称《条例》），用于染发的化妆品属于特殊化妆品，实行注册管理，注册人需对染发化妆品的质量安全负责。2021年，《条例》正式施行，对化妆品的质量安全和监督管理提出更高要求。作为化妆品新法规的新要求，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，为规范和指导染发化妆品质量控制要求的研究，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

本指导原则适用于染发化妆品的质量控制要求研究。本文所述产品质量控制要求，即注册资料中所涉及的产品执行的标准“微生物和理化指标及其质量控制措施”，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。如相关内容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

应基于产品特性，在充分考虑原料质量、配方组成、生产工艺、产品稳定性及贮存与使用等各个环节中可能产生影响的基础上，科学合理地设定可有效控制产品安全、质量和反映产品特性的项目与指标。质量控制措施应与生产工艺相适应，具有良好的可操作性和重现性，确保能有效控制产品批次间质量的稳定性和一致性，保障染发化妆品的质量安全。

四、主要内容

染发化妆品质量控制要求的研究主要包括稳定性、质量控制项目和指标、质量管理措施等内容。

（一）稳定性研究

稳定性研究是评估产品安全性和质量的重要基础，为确定产品使用期限及制定质量控制指标提供科学依据。研究应根据产品特性，选择在贮存期间易发生变化、可能会影响产品安全性、质量或功效的项目作为指标，如产品性状、功效成分含量等，考察这些指标



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