



Technical Guidelines for Research on Quality Control Standards of Sunscreen Cosmetics (Trial) (Draft for Comments)

防晒化妆品质量控制标准研究技术指导原则（试行）
（征求意见稿）

National Institutes for Food and Drug Control

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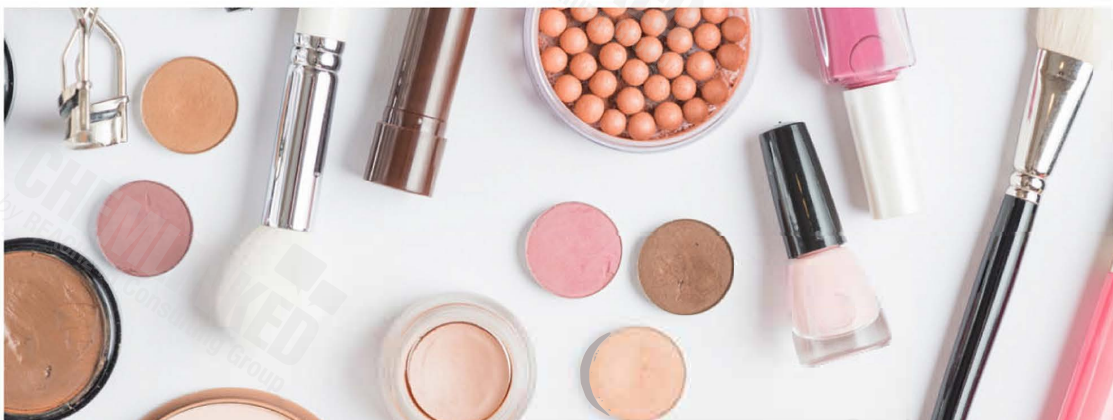
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Attachment 11

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Sunscreen Cosmetics (Trial)
(Draft for Comments)**

National Institutes for Food and Drug Control

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I. Introduction

In accordance with the *Cosmetic Supervision and Administration Regulations (CSAR)*, sunscreen cosmetics are classified as special cosmetics and subject to registration management, and registrants shall be responsible for the quality and safety of sunscreen cosmetics. Since the formal implementation of the CSAR on January 1, 2021, higher requirements have been put forward for the quality, safety, supervision, and management of cosmetics. As new requirements of the new cosmetic regulations, 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 measures. Quality control standards constitute a crucial part of product executive standards. To standardize and guide research on quality control standards for sunscreen cosmetics, these guidelines are hereby formulated.

These guidelines are formulated based on existing laws, administrative regulations, departmental rules, mandatory national standards, technical standards, and the current level of scientific cognition. Relevant content will be adjusted in a timely manner with the continuous improvement of regulations and standards, and the development of science and technology.

II. Application Scope

These guidelines apply to the research on quality control standards for sunscreen cosmetics. The product quality control standards 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, which specifically include testing items, indicators, quality management measures, and brief descriptions, among other contents.

Registrants shall apply these guidelines under the premise of complying with 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 standards for sunscreen cosmetics shall, on the basis of fully considering the impacts from various links such as ingredient quality, formula

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composition, production techniques, product stability, circulation, and use, formulate targeted items and indicators that can effectively control product quality and safety. The quality control measures shall be operable, compatible with production techniques, and capable of effectively controlling the stability and consistency of product quality among batches, so as to ensure the quality and safety of sunscreen cosmetics.

IV Main Content

The research on quality control standards for sunscreen cosmetics mainly includes stability, quality control indicators, and quality management measures *etc.*

(I) Stability Research

Stability research serves as a crucial foundation for product quality and safety research, providing a basis for determining the products' durability and setting quality control indicators. Items that are prone to changes during storage and may affect product quality, safety, or efficacy shall be selected as indicators for stability research. These include, but are not limited to, product traits (such as color), microorganisms, and concentrations of sunscreens (functional ingredients). The research involves observing how these indicators change over time under the influence of parameters like temperature, humidity, and light. Additionally, the effect of packaging materials on product quality needs to be fully considered.

(II) Research on Quality Control Items and Indicators

Based on stability research and in combination with product formulas, production techniques, and stability, scientific, reasonable, feasible items and control indicators that can reflect the products' safety and quality controllability shall be set under the "microbiological and physical and chemical indicators and their quality control measures" in the product executive standards.

Quality control items and indicators shall be clear and specific, and in principle, shall not be fewer than the testing items specified in the *Working Rules for Cosmetic Registration and Notification Testing* (hereinafter referred to as the *Testing Rules*). The quality control items and indicators for sunscreen cosmetics include hazard substances, microbiological indicators, and functional ingredient (sunscreen) indicators.

The control indicators of hazard substances and microorganisms shall comply with the limit requirements specified in the *Safety and Technical Standards for Cosmetics (STSC)*. It is encouraged to set control indicators stricter than the limit requirements in the *STSC* to

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