



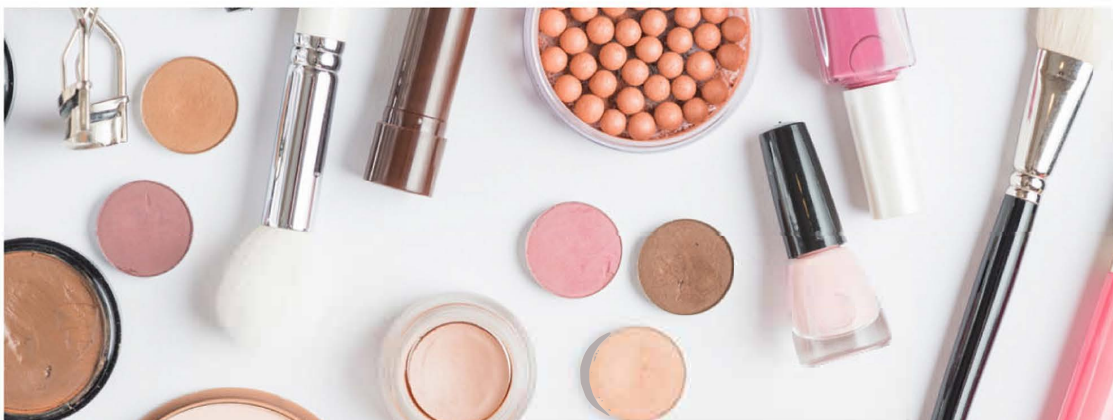
Technical Guidelines for Stability Evaluation of Cosmetics (Draft for Comments) and Drafting Explanation

《化妆品稳定性评价技术指南(征求意见稿)》
及起草说明

National Institutes for Food and Drug Control

Release Date: Apr 10, 2024
Implementation Date: /

Translated by ChemLinked



You can now catch up with the latest updates of China CSAR on ChemLinked:



Stay tuned for more translations:

We will provide English translations of CSAR and supporting rules.



Watch our webinars:

Interpretation of China's Cosmetic Supervision and Administration Regulation



Check out the breaking news:

China Finalises the Long-Awaited Cosmetic Supervision and Administration Regulation



Visit the featured page for more information:

Featured — China Cosmetic Regulatory Reform Tracking

Disclaimer

This is an unofficial document provided by **ChemLinked** (chemlinked.com), a platform of REACH24H Consulting Group, as an informational service to assist non-Chinese companies to better understand Asia Pacific especially China Chemical, Cosmetic, Food, Agrochemical and Drug regulatory issues.

This document should only be used as a reference and in case of any discrepancy between the English and original versions the original version shall prevail.

Nondisclosure:

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, you can read our [Privacy Policies](#) or contact us at cosmetic@chemlinked.com

Attachment 1

Technical Guidelines for Stability Evaluation of Cosmetics (Draft for Comments)

1 Scope

This document specifies the test requirements, test methods, and result evaluation for the stability evaluation of cosmetics.

2 Terms and Definitions

2.1 Influencing factor test

A test conducted under relatively extreme conditions for the purpose of finding the main factors that affect the quality stability of cosmetics and the quality changes that may occur, providing a reference for accelerated and long-term test conditions.

2.2 Accelerated test

A test conducted under temperature and humidity higher than that for long-term storage to investigate the stability of cosmetics, providing a basis for formula and technique design, as well as whether cosmetics can still maintain stable quality when deviating from actual storage conditions, and preliminarily predicting the quality trend of cosmetics under specified storage conditions.

2.3 Long-term test

A test conducted under set storage conditions to investigate the stability of cosmetics during transportation, storage, and use, providing a basis for confirming storage conditions and shelf life.

3 Test Requirements

Stability studies of cosmetics shall be designed reasonably based on the physicochemical properties of ingredients, product form, product formula, technique conditions, and packaging materials, etc. An influencing factor test, accelerated test, and long-term test can be conducted.

3.1 Test samples

The influencing factor test shall generally be conducted using one batch of samples, while the accelerated and long-term tests shall generally be conducted using three batches of

Make Sure Your Products Entering Global Market with Compliance

What we can do for you?



- + Responsible person (RP) service in China
- + Cosmetic formula and label compliance review
- + Product registration and notification
- + New cosmetic ingredient (NCI) registration and notification
- + Ingredient safety information submission
- + Cosmetic efficacy evaluation



- + Cosmetic formula and label compliance review
- + EDI Notification
- + Cosmetic QC test service
- + Functional cosmetic registration
- + Ingredients registration by ICID



- + Marketing license application
- + Cosmetics notification
- + Ingredients analysis and full ingredient list translation
- + Cosmetic test service
- + Label & advertisement review



- + Responsible Person (RP) service in the EU & UK
- + Cosmetic Product Notification Portal (CPNP)
- + Cosmetic Product Safety Report (CPSR)
- + 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

What makes us unique?

- ✓ Connect with officials and associations
- ✓ Flexible consulting service packages
- ✓ Team of qualified toxicology and regulatory experts

附件 1

化妆品稳定性评价技术指南（征求意见稿）

1 范围

本文件规定了化妆品稳定性评价的试验要求、试验方法和结果评价。

2 术语和释义

2.1 影响因素试验

影响因素试验是在较极端的条件下进行，以了解影响化妆品质量稳定性的主要因素及可能发生的质量变化情况，为加速试验和长期试验条件提供参考。

2.2 加速试验

加速试验是在高于长期贮存温度和湿度条件下，考察化妆品的稳定性，为配方和工艺设计、偏离实际贮存条件化妆品是否依旧能保持质量稳定提供依据，并初步预测化妆品在规定的贮存条件下的质量保持趋势。

2.3 长期试验

长期试验是在设定贮存条件下考察在运输、保存、使用过程中的化妆品稳定性，为确认贮存条件及保质期等提供依据。

3 试验要求

化妆品稳定性研究应结合原料的理化性质、产品形态、产品配方、工艺条件及包装材料等进行合理设计，可开展影响因素试验、加速试验和长期试验。

3.1 试验样品

影响因素试验一般应采用一批次样品进行，加速试验和长期试验一般应采用三批次样品进行。影响因素试验、加速试验用样品所用的产品配方、生产工艺、直接接触包装材料及封装条件等应与上市后的化妆品保持一致，长期试验用样品应与上市后的化妆品保持一致。

3.2 试验项目

稳定性研究可根据化妆品特点和质量控制要求，选择在保存期间易于变化、并可能影响化妆品质量稳定的项目，以及依据产品形态、使用方式及贮存过程中存在的主要风险等增加试验项目，以便客观、全面地反映化妆品的稳定性。



Free



Free trial



Standard



Corporate



Special

SUBSCRIBE TO CHEMLINKED NOW

REMOVE COSMETIC REGULATORY BARRIERS EXPEDITE ASIA MARKET ACCESS

- In-time regulatory information and market access requirements
- Supported by local and experienced technically adept technical team
- Strategic partnerships with competent authorities and industrial associations worldwide
- Customized consulting service for complete compliance solutions.

OUR SERVICES



Information & Knowledge

News, Reports, Expert Analysis
Pedia-articles



Databases

Regulatory Database, English Translations
Inventories/Lists



Solutions

Regulatory Compliance Service, On-demand
Translation, Advertisement Service, Tailor-made
Service, E-commerce Solution



Training

Webinars, Online Course
Offline Events