



Technical Guidelines for Research on Efficacy-Related Ingredients of Anti-Hair Loss Cosmetics (Trial)

《防脱发化妆品功效相关原料研究技术指导原则（试行）》

National Institutes for Food and Drug Control

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Attachment 2

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Anti-Hair Loss Cosmetics
(Trial)**

National Institutes for Food and Drug Control

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Contents

I. Introduction	0
II. Application Scope	0
III. General Principles	0
IV. Research Methods for Efficacy-Related Ingredients	1
(I) Research with Reference to Regulation Documents or Technical Standards	1
(II) Analysis and Evaluation on Efficacy-Related Ingredients of Anti-Hair Loss Cosmetics	2
1. Research on Mechanism of Action	2
2. Efficacy Evaluation Research	2
3. Quality Control Research on Anti-Hair Loss Agents.....	4

I. Introduction

In accordance with the *Cosmetic Supervision and Administration Regulation* (CSAR), anti-hair loss cosmetics are classified as special cosmetics and subject to registration management. The basic materials for such cosmetics to exert an anti-hair loss efficacy are related ingredients in the formulas that have an anti-hair loss efficacy. Therefore, the selection and research of efficacy-related ingredients are the prerequisite for product formula design and research. For the purpose of standardizing and guiding the research on efficacy-related ingredients of anti-hair loss cosmetics, these guidelines are hereby formulated.

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

II. Application Scope

These guidelines apply to the research on anti-hair loss efficacy-related ingredients in anti-hair loss cosmetic formulas. Such ingredients fall into two categories: the first category includes single-component ingredients and components of non-single-component ingredients that have been shown to have an anti-hair loss effect through research, i.e., the “anti-hair loss agents” filled out in formulas; the second category refers to ingredients that play an auxiliary role in exerting the anti-hair loss effect, namely the “anti-hair loss adjuvants” filled out in formulas. In principle, it is not required to clarify the specific components of an anti-hair loss adjuvant in a non-single-component ingredient. Anti-hair loss adjuvants can be used alone or in combination with anti-hair loss agents in products.

Registrants shall apply 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 simultaneously.

III. General Principles

The research on anti-hair loss efficacy-related ingredients in cosmetics shall be conducted surrounding the definition of the anti-hair loss efficacy. Analysis and evaluation, or test research may be conducted on anti-hair loss efficacy-related ingredients used by referring to relevant regulation documents or technical standards published or approved by

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中国食品药品检定研究院

目 录

一、前言.....	1
二、适用范围	1
三、一般原则	1
四、功效相关原料研究方法	2
(一) 参考法规资料或技术标准开展研究	2
(二) 对防脱发化妆品功效相关原料开展分析评价	2
1. 作用机理研究.....	2
2. 功效评价研究.....	2
3. 防脱发剂质量控制研究	3

一、前言

根据《化妆品监督管理条例》，防脱发化妆品属于特殊化妆品，实行注册管理。化妆品发挥防脱发功效的物质基础为配方中具有防脱发功效的相关原料，因此功效相关原料的选择与研究是产品配方设计与研究的前提。为规范和指导防脱发化妆品功效相关原料的研究，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、标准的不断完善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

本指导原则适用于防脱发化妆品配方中防脱发功效相关原料的研究。防脱发功效相关原料包括两类，一是通过研究证明具有防脱发作用的单一原料或非单一原料中的组分，即配方中填报的“防脱发剂”；二是辅助发挥防脱发作用的原料，即配方中填报的“防脱发辅助剂”，原则上，非单一原料不要求明确防脱发辅助剂组分。防脱发辅助剂可以单独用于产品，也可与防脱发剂共同用于产品。

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

化妆品中防脱发功效相关原料的研究应围绕防脱发的功效释义。可参考国内外监管部门发布或批准的相关法规资料或技术标准，也可采用其他科学合理的方法对使用的防脱发功效相关原料开展分析评价或试验研究。此外，注册人应对防脱发功效相关原料开展安全评估，必要时开展毒理学试验研究，以确保其在化妆品中使用的安全性。

采用监管部门发布或批准的法规资料或技术标准，或者学术期刊公开发表的研究性文献资料时，应对资料进行分析，重点关注防脱发功效相关原料与资料中原料的一致性，如原料组成、质量规格、使用量、使用范围、其他限制条件等。

分析评价研究中，重点关注研究模型和试验方法，应有适当的试验模型和完整的试验方法，有明确的受试物、对照组、所用试剂、仪器设备、主要试验步骤、数据处理方法、研究结果与分析、研究结论等关键技术信息，必要时对相关背景资料、方法学资料进行收集分析，确保研究结果的科学性与可重复性。

开展试验研究时，其中的人体功效评价试验研究鼓励在取得化妆品领域的检验检测机构资质认定（CMA）或中国合格评定国家认可委员会（CNAS）认可，或符合药物临床试验质量管理规范（GCP）等资质认定或认可的机构完成。



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