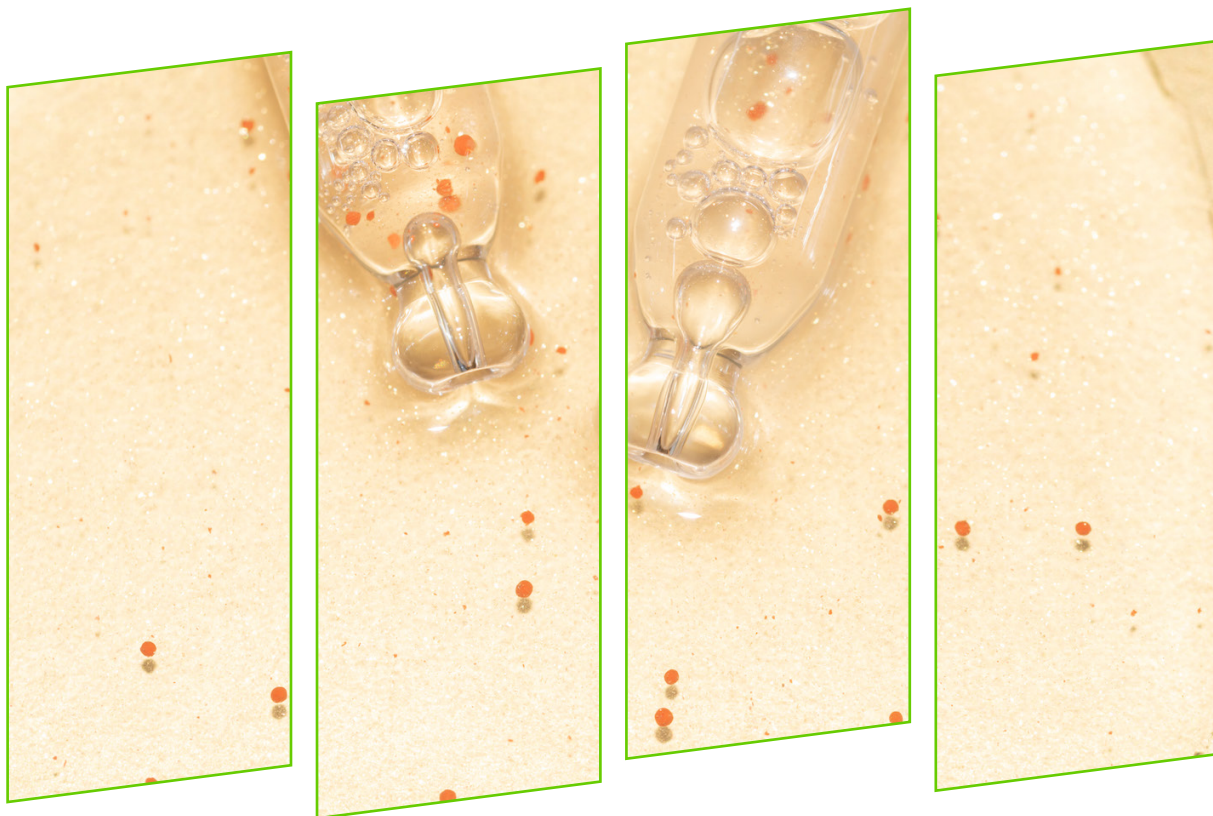




Cosmetic Ingredients-Acetyl Hexapeptide-8 《化妆品用原料 乙酰基六肽-8》

National Medical Products Administration

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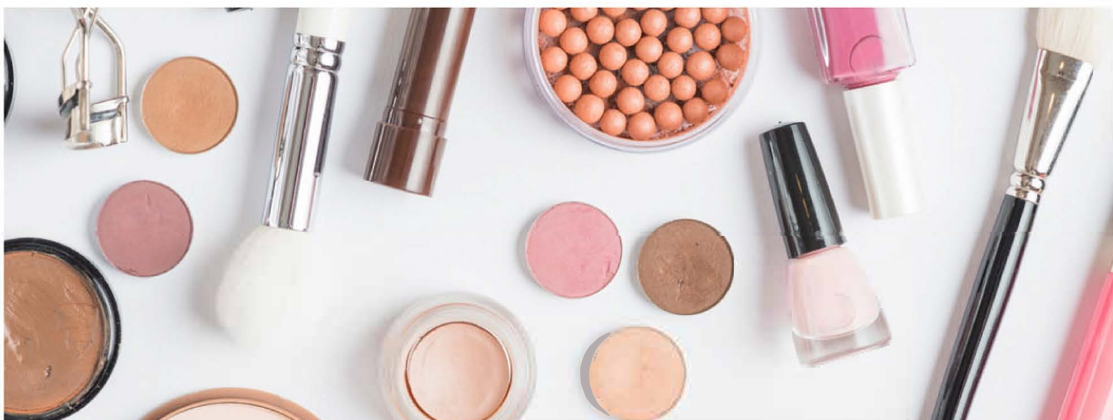
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Pharmaceutical Industry Standard of the People's Republic of China

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Cosmetic Ingredients—Acetyl Hexapeptide-8

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 *Directives for Standardization - Part 1: Rules for the Structure and Drafting of Standardizing Documents*.

Attention is drawn to the possibility that some of the contents of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This document was proposed by the National Medical Products Administration (NMPA).

This document is under the jurisdiction of the Sub-Technical Committee on Ingredients and Packaging Materials of the Technical Committee on Cosmetic Standardization under the NMPA.

The drafting units of this document are as follows: Zhejiang Institute for Food and Drug Control, Shandong Institute for Food and Drug Control, Shenzhen Institute for Drug Control, and Zhejiang Peptides Biotech Co., Ltd.

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Introduction

With the rapid development of the cosmetic industry and continuously increasing consumer requirements for product safety and efficacy, acetyl hexapeptide-8 has been increasingly widely used in cosmetics. At present, however, there are no national or industry standards for this ingredient, leading to inconsistent product quality on the market, prominent potential safety risks, and constraints on the healthy development of the industry. To strengthen the quality control of the cosmetic ingredient, ensure product safety and efficacy, and improve the overall technical level of the industry, it is of great significance to establish a unified, scientific, and practical standard for acetyl hexapeptide-8.

This document possesses the following technical characteristics and innovations: It systematically specifies, for the first time, comprehensive quality indicators for acetyl hexapeptide-8, covering sensory, physicochemical, microbiological, hazard substances and other related aspects. It establishes methods for identification, purity (area normalization method), and peptide content (external standard method) determination based on the high-performance liquid chromatography, and standardizes testing procedures for technique-related impurities, including acetic acid, trifluoroacetic acid, *etc.* This document will help unify the industry quality thresholds, promote the development of ingredient production towards higher standards and better quality, and provide a basis for quality control in cosmetic enterprises.

This document applies to acetyl hexapeptide-8 powder or loose bulk, in either acetate or salt-free form, prepared from glutamic acid, methionine, glutamine and arginine, as the starting ingredients through chemical synthesis, purification, and lyophilization. It does not apply to aqueous formulations, pre-dissolved forms, or analogues with other amino acid sequences. The technical requirements herein provide guidance for the quality control, product safety assessment, and quality and safety administration of the cosmetic ingredient.

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化妆品用原料 乙酰基六肽-8

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前 言

本文件按照GB/T1.1—2020《标准化工作导则 第1部分：标准化文件的结构和起草规则》的规定起草。

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本文件由国家药品监督管理局提出。

本文件由国家药品监督管理局化妆品标准化技术委员会原料和包装材料分技术委员会归口。

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引 言

随着化妆品产业的快速发展及消费者对产品安全与功效要求的不断提高，乙酰基六肽-8在化妆品中应用日益广泛。目前尚缺乏该原料的国家或行业标准，导致市场上产品质量不一，潜在安全风险突出，也制约了行业的健康发展。为加强化妆品原料质量控制，保障产品安全有效，提升行业整体技术水平，制定统一、科学、可操作的乙酰基六肽-8原料标准具有重要意义。

本文件在技术上具有以下特点与创新：首次系统规定了乙酰基六肽-8的感官、理化、微生物及有害物质等全维度质量指标。建立了基于高效液相色谱法的鉴别、纯度（面积归一化法）和肽含量（外标法）测定方法，并规范了乙酸、三氟乙酸等工艺相关杂质的检测流程。本文件将有助于统一行业质量门槛，推动原料生产向高标准、高质量方向发展，并为化妆品企业质量控制提供依据。

本文件适用于以谷氨酸、甲硫氨酸、谷氨酰胺和精氨酸为起始原料，经化学合成、纯化、冻干制得的乙酸盐或无盐形式的乙酰基六肽-8粉末或疏松块状物，不适用于水剂型、预溶解形式或其他氨基酸序列的类似物。本文件的技术要求在化妆品原料质量控制、产品安全评估及质量安全监管中具有指导作用。



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