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Test Method for Efficacy Measurement of Skin Whitening Cosmetic Products

化妆品祛斑美白功效测试方法

National Medical Products Administration

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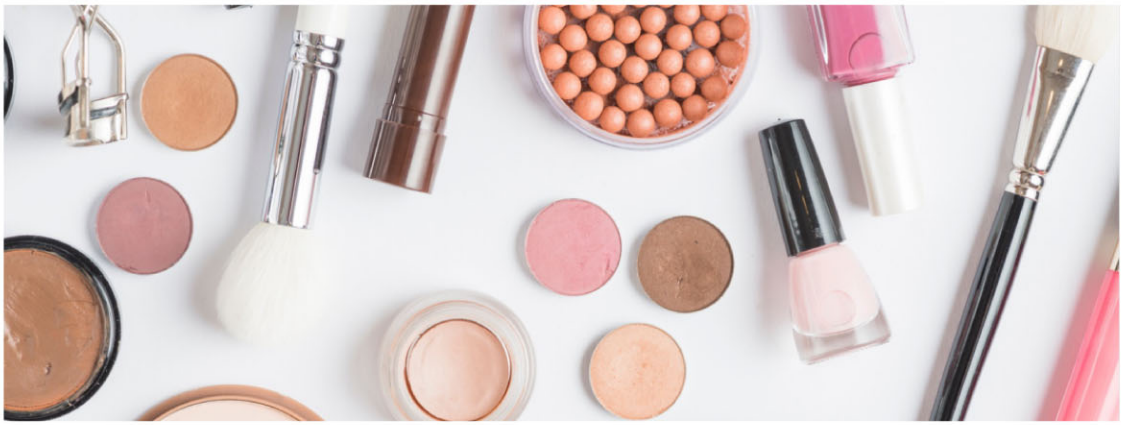

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Appendix 7

Test Method for Efficacy Measurement of Skin Whitening Cosmetic Products

Method I Test method for efficacy measurement of skin whitening cosmetic products through a pigmentation model induced by ultraviolet in human

1 Scope

This method specifies the test method for efficacy measurement of skin whitening cosmetic products through a pigmentation model induced by ultraviolet in human.

2 Definition

2.1 Minimal erythema dose (MED): It refers to the minimum dose (J/m^2) or the shortest time (s) of ultraviolet irradiation required by reaching most areas of the irradiation spot for scope, which can cause clearly visible erythemas on the skin.

2.2 Individual type angle (ITA°): It refers to the parameter used to characterize human skin color by measuring skin *L*a*b** color space data with skin colorimeter or reflectance spectrophotometer, and the calculation formula is as follows:

$$ITA° = \left\{ \arctan \frac{(L^* - 50)}{b^*} \right\} \frac{180}{\pi}$$

2.3 Melanin index (MI): It refers to the parameter used to characterize the melanin content in skin by measuring the absorption of spectrum with specific wavelength by the skin surface.

3 Test Method

3.1 Selection of subjects

The qualified subjects shall be selected according to the inclusion and exclusion criteria, to ensure that the number of effective cases completed in each test area is not less than 30.

3.1.1 Inclusion criteria

3.1.1.1 Healthy male or female, 18 ~ 60 years old;

3.1.1.2 The ones whose ITA° value of skin color at the tested part is 20°~41°;

3.1.1.3 Those who have no allergic diseases or allergic history of cosmetic products or other external preparations;

3.1.1.4 Those who have no history of photosensitivity diseases in the past and haven't taken drugs affecting photosensitivity recently;

3.1.1.5 There shall be no pigmentation, inflammation, cicatrix, pigmented nevus and hirsutism, *etc.* for the skin in the tested part;

3.1.1.6 Those who can accept the tanning of the skin in the tested part with artificial light source;

3.1.1.7 Those who can understand the test process, and voluntarily participate in the test and sign a written informed consent.

3.1.2 Exclusion criteria

3.1.2.1 Pregnant or lactating women, or those who prepare for pregnancy in the near future;

3.1.2.2 Those who have a dermatosis history such as psoriasis, eczema, atopic dermatitis and severe acne, *etc.*;

3.1.2.3 Those who have taken anti-inflammatory drugs such as corticosteroids orally or externally within the recent 1 month;

3.1.2.4 Those who have taken any products or drugs (such as hydroquinone preparations) that affect skin color orally or externally within the recent 2 months;

3.1.2.5 Those who have participated in similar tests within the recent 3 months or 3 months ago, but their skin pigmenting marks at the tested part have not been completely faded;

3.1.2.6 Those who have participated in other clinical tests within the recent 2 months;

3.1.2.7 Others that are considered to be not suitable to participate in the test by clinical assessment.

3.2 Test substance

3.2.1 Test product: skin whitening cosmetic products.

3.2.2 Negative control: blank control in pigmented area.

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附件 7

化妆品祛斑美白功效测试方法

Test Method for Efficacy Measurement of Skin Whitening Cosmetic Products

第一法 紫外线诱导人体皮肤黑化模型祛斑美白功效测试法

1 范围

本方法规定了通过紫外线诱导人体皮肤黑化模型对化妆品祛斑美白功效的测试方法。

2 定义

2.1 最小红斑量（Minimal erythema dose，MED）：引起皮肤清晰可见的红斑，其范围达到照射点大部分区域所需要的紫外线照射最低剂量（J/m^2）或最短时间（s）。

2.2 个体类型角（individual type angle，ITA°）：通过皮肤色度计或反射分光光度计测量皮肤 *L*a*b** 颜色空间数据来表征人体皮肤颜色的参数，计算公式如下：

$$ITA^{\circ} = \{\arctan\frac{(L^{*} - 50)}{b^{*}}\}\frac{180}{\pi}$$

2.3 黑素指数（melanin index，MI）：通过测定皮肤表面对特定波长光谱的吸收来表征皮肤中黑素含量的参数。

3 试验方法

3.1 受试者的选择

按入选和排除标准选择合格的受试者，确保各测试区最终完成有效例数均不低于30人。

3.1.1 入选标准

3.1.1.1 18~60 岁，健康男性或女性；

3.1.1.2 测试部位肤色 ITA°值在 20°~41°者；

3.1.1.3 无过敏性疾病，无化妆品或其它外用制剂过敏史；

3.1.1.4 既往无光感性疾病史，近期内未使用影响光感性的药物；

3.1.1.5 受试部位的皮肤应无色素沉着、炎症、瘢痕、色素痣、多毛等现象；

3.1.1.6　能够接受测试区域皮肤使用人工光源进行晒黑者；

3.1.1.7　能理解测试过程，自愿参加试验并签署书面知情同意书者。

3.1.2　排除标准

3.1.2.1　妊娠或哺乳期妇女，或近期有备孕计划者；

3.1.2.2　有银屑病、湿疹、异位性皮炎、严重痤疮等皮肤病史者；

3.1.2.3　近 1 个月内口服或外用过皮质类固醇激素等抗炎药物者；

3.1.2.4　近 2 个月内口服或外用过任何影响皮肤颜色的产品或药物（如氢醌类制剂）者；

3.1.2.5　近 3 个月内参加过同类试验或 3 个月前参加过同类试验，但试验部位皮肤黑化印迹没有完全褪去者；

3.1.2.6　近 2 个月内参加过其他临床试验者；

3.1.2.7　其他临床评估认为不适合参加试验者。

3.2 受试物

3.2.1　试验产品：祛斑美白化妆品。

3.2.2　阴性对照：黑化区空白对照。

3.2.3　阳性对照：按附录 I 配方配制的 7%抗坏血酸（维生素 C）制品（4℃冷藏、铝管避光保存）。

3.2.4　受试物涂抹

由工作人员按照随机表对应测试区进行受试物的涂抹，涂样面积应不小于 6cm^2，涂样量为 2.00±0.05mg/cm^2。每个测试区之间的间隔应不小于 1.0cm。产品使用频率应根据产品使用说明，如需每天多次涂抹，每次涂抹间隔时间不小于 4 小时。

3.3　试验部位：优先选择背部作为试验部位，也可选择大腿、上臂等非曝光部位。每个黑化测试区面积应不小于 0.5cm^2，并应位于每个涂样区域内。

3.4　试验仪器

3.4.1 日光模拟仪：采用具有连续性光谱辐射、能够产生 UVA+UVB 波长紫外线的氙弧灯日光模拟仪。290nm 以下的波长应用适当的过滤系统去除，输出波谱需经过计量检定或校准。

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