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Test Method for Efficacy Measurement of Anti-hair Loss Cosmetic Products

化妆品防脱发功效测试方法

National Medical Products Administration

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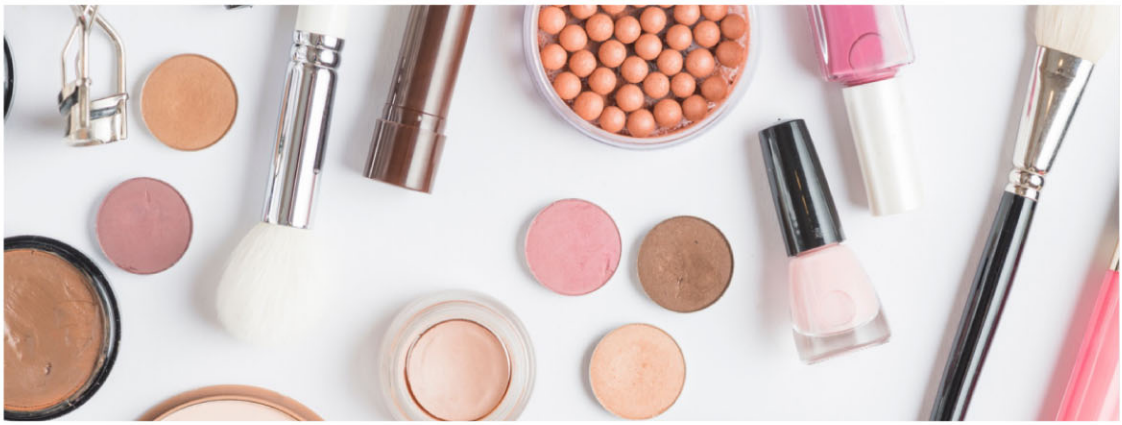

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Appendix 8

Test Method for Efficacy Measurement of Anti-hair Loss Cosmetic Products

1 Scope

This method specifies the test method for efficacy measurement of anti-hair loss cosmetic products.

2 Test Method

2.1 Selection of subjects

The qualified subjects shall be selected according to the inclusion and exclusion criteria, and divided into test group and control group according to the random table, so as to ensure that the number of effective cases completed is not less than 30 per group.

2.1.1 Inclusion criteria

2.1.1.1 Healthy male or female, 18 ~ 60 years old; the age and sex ratio of the subjects can be determined according to the consumption objects described in the specific test product instructions;

2.1.1.2 The ones whose hair length is 5~40 cm;

2.1.1.3 Those who suffer from excessive hair loss and slight hair thinning, with hair loss count greater than 10 by the 60-time combing method (see Annex I), and still greater than 10 after the 2-week washout period;

2.1.1.4 Those who have not received special hairdressing treatments such as hair dyeing, hair perming and hair styling in the past 1 month;

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

2.1.2 Exclusion criteria

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

2.1.2.2 Those who suffer from severe androgenetic alopecia, alopecia areata, cicatricial alopecia or the patients with other scalp/hair diseases;

2.1.2.3 Those who suffer from mental illness or psychological illness; or those with long-term sleep and emotional control disorders;

2.1.2.4 Those who have used anti-hair loss cosmetic products or other products with such efficacy or hair growth efficacy in the past 3 months;

2.1.2.5 Those who have taken or topically used any drugs that affect hair growth in the past 6 months;

2.1.2.6 Those who have received hair transplant treatment;

2.1.2.7 Those who have curly hair;

2.1.2.8 Those with high physical sensitivity;

2.1.2.9 Those who have participated in other clinical trials in the past 2 months;

2.1.2.10 Those that are considered to be not suitable to participate in the test by clinical assessment.

2.1.3 Restriction on subjects

2.1.3.1 During the screening and test period, the subjects could not wash their hair within 48±4 hours before each visit, and the time of not washing their hair before each visit shall be basically kept the same, and they could not comb hair by themselves on the day of the visit;

2.1.3.2 During the test period, no haircut within 2 weeks before each visit and assessment;

2.1.3.3 During the test period, no hair care and hairdressing measures can be taken, and no treatment for anti-hair loss and hair growth can be accepted;

2.1.3.4 During the test period, it is necessary to keep the original living habits and avoid major emotional fluctuation.

2.2 Test substance

2.2.1 Test product: Anti-hair loss cosmetics.

2.2.2 Control product: Products with substrate formulas of the corresponding test products and do not contain anti-hair loss functional ingredients. They shall be tested in parallel with the test products.

2.2.3 Product in the washout period: It is the same as the control product. Both the test

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附件 8

化妆品防脱发功效测试方法
Test Method for Efficacy Measurement of Anti-hair Loss Cosmetic Products

1 范围

本方法规定了对化妆品防脱发功效的测试方法。

2 试验方法

2.1 受试者的选择

按入选和排除标准选择合格的受试者，并按随机表分为试验组和对照组，确保最终完成有效例数不少于30人/组。

2.1.1 入选标准

2.1.1.1 18~60岁，健康男性或女性；受试者年龄和性别比例可根据具体试验产品使用说明所述消费对象相应确定；

2.1.1.2 头发长度在5~40cm之间；

2.1.1.3 有脱发多和头发轻度稀疏困扰，且按60次梳发法（见附录I）脱发计数大于10根、2周洗脱期后仍大于10根者；

2.1.1.4 近1个月内没有进行过染发、烫发、定型等特殊美发处理者；

2.1.1.5 能够理解试验过程，自愿参加试验并签署书面知情同意书者。

2.1.2 排除标准

2.1.2.1 妊娠或哺乳期妇女，或近期有备孕计划者；

2.1.2.2 重度雄激素源性脱发、斑秃、炎性瘢痕性脱发或其它患有头皮/毛发疾病患者；

2.1.2.3 患有精神类或心理疾病者；或者有长期睡眠、情绪控制障碍者；

2.1.2.4 近3个月内使用过具有防脱发功效的化妆品或其他具有此类功效或生发功效的产品者；

2.1.2.5 近6个月内服用过或局部使用过任何影响头发生长的药物者；

2.1.2.6　曾接受过头发移植治疗者；

2.1.2.7　头发卷曲者；

2.1.2.8　体质高度敏感者；

2.1.2.9　近2个月内参加过其他临床试验者；

2.1.2.10　临床评估认为不适合参加试验者。

2.1.3　受试者限制

2.1.3.1　受试者筛选和试验期间每次访视前48±4小时内不能洗头，且每次访视前不洗头发的时间基本保持一致，访视当天不能自行梳发；

2.1.3.2　试验期间每次访视评估前2周内不理发；

2.1.3.3　试验期间不能进行任何头发护理和美发处理措施，也不能接受任何防脱发、生发方面的治疗；

2.1.3.4　试验期间需保持原有的生活习惯，避免情绪波动大。

2.2　受试物

2.2.1　试验产品：防脱发化妆品。

2.2.2　对照产品：不含防脱发功效成分的相应试验产品基质配方产品，与试验产品平行测试。

2.2.3　洗脱期产品：同对照产品，洗脱期内试验组和对照组均使用对照产品。

2.2.4　使用方法：由工作人员按照随机表发放试验产品和对照产品，并根据使用说明对受试者进行产品使用指导，确保受试者在试验周期内正确使用受试物。受试物至少使用 12 周，试验期间要求受试者记录使用时间及使用过程中的任何不适感和不良反应症状。

2.3　试验器材

2.3.1　专业数码相机：像素不低于 1500 万，整个试验过程中包括光圈大小、感光度（ISO）及焦距等参数保持一致。

2.3.2　图像拍摄支架：能够固定受试者头部位置，使头顶与相机镜头保持垂直，配合专业数码相机以头顶为中心拍摄全部头发照片。

2.3.3　皮肤镜：LED 灯光源，波长 450~750nm，色温 6500~8000K，照度不低于 540 lx，放大倍数≥20 倍，检测直径不小于 1.0cm 或面积不少于 0.8cm^2。

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