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Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices

化妆品生产质量管理规范检查要点及判定原则

National Medical Products Administration

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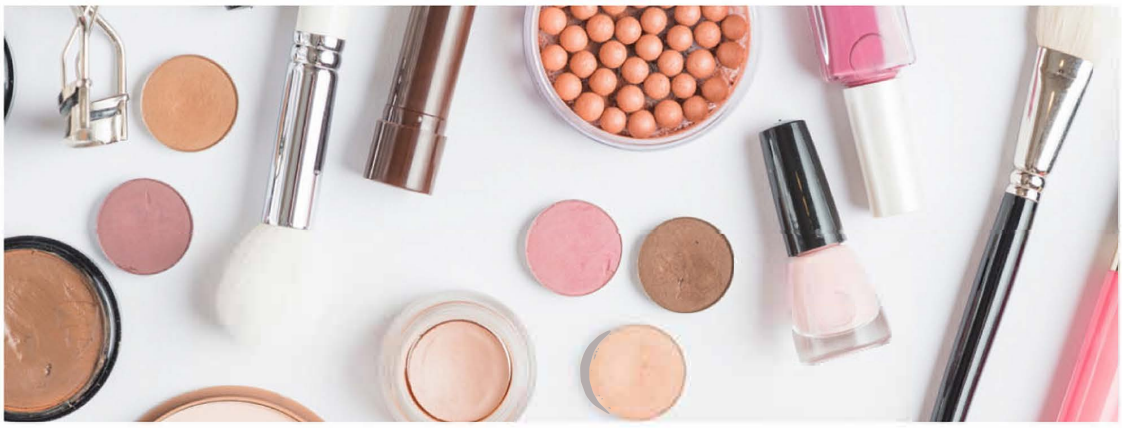

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Annex

Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices

In order to regulate the cosmetics production licensing, supervision and inspection work, guide the cosmetics registrants, notifiers and entrusted production enterprises to implement and carry out *Good Manufacturing Practices for Cosmetics* (the *Practices*), the National Medical Products Administration has organized and formulated the *Inspection Points and Judgment Principles of Cosmetic Good Manufacturing Practices* in accordance with the *Cosmetic Supervision and Administration Regulations* (CSAR), *Supervision and Administration Measures on Cosmetics Manufacture and Operation* and other laws and regulations.

I. Application Scope of Inspection Points of Cosmetic Good Manufacturing Practices

(I) Inspection of cosmetics registrants, notifiers and entrusted production enterprises engaged in cosmetics production activities in accordance with the “Inspection Points of Cosmetic Good Manufacturing Practices” (Actual Production, see Attachment 1). Attachment 1 lists 81 inspection items in total, covering 29 key items (including 3 critical items and 26 other key items) and 52 general items.

(II) Inspection of cosmetics registrants and notifiers entrusting production in accordance with the “Inspection Points of Cosmetic Good Manufacturing Practices” (Entrusted Production, see Attachment 2). Attachment 2 lists 24 inspection items in total, covering 9 key items (including 1 critical item and 8 other key items) and 15 general items.

(III) Separate inspection and judgement of cosmetics registrants and notifiers both engaged in cosmetics production activities and entrusting production respectively in accordance with the Attachments 1 and 2.

II. Inspection Classification and Judgment Principles of Cosmetic Good Manufacturing Practices

(I) On-site inspection of production license

Medical products administration departments of all provinces, autonomous regions and municipalities directly under the Central Government shall organize to conduct on-site inspection of production license for cosmetics production license applicants in accordance with Attachment 1.

1. If no any nonconforming item is found in terms of enterprise during on-site inspection, it shall be judged as “passed the on-site inspection”.

2. If any of the following circumstances is found in terms of enterprise during on-site

inspection, it shall be judged as “failed on-site inspection”:

(1) Having critical items not complying with the provisions;

(2) Having 6 or more defective critical items and other key items not complying with the provisions in total;

(3) Having 16 or more key items not complying with the provisions, defective key items, and general items not complying with the provisions in total.

3. If the enterprise is found to have items not complying with the provisions during the on-site inspection, but there is no such circumstance that shall be judged as “failed on-site inspection”, it shall be judged as “re-inspected after rectification”. Enterprises judged as “re-inspected after rectification” shall complete the rectification within the specified time and submit the rectification report to the medical products administration departments of province, autonomous region and municipality directly under the Central Government. After receiving rectification report, the said medical products administration departments can organize on-site re-inspection of enterprise according to the actual situation. After being confirmed that the rectification meets the requirements, it shall be judged as “passed on-site inspection”; if the rectification report is not submitted within the specified time limit or the rectified items still do not meet the requirements during re-inspection, it shall be judged as “failed on-site inspection”.

(II) On-site inspection after renewal of production license

Medical products administration departments of provinces, autonomous regions and municipalities directly under the Central Government shall, within 6 months from the date of re-issuing new cosmetics production license to the applicants for the renewal of cosmetics production license, supervise the applicant’s application documents and commitments for renewal of the license, and organize on-site inspection of such enterprises in accordance with Attachment 1. In case of compliance with the above-mentioned “failed on-site inspection” for inspection result, the medical products administration departments shall revoke the cosmetics production license thereof in accordance with the law. In case of compliance with the above-mentioned “re-inspect after rectification” for inspection result, and in case rectification report is not submitted within the specified time limit or the rectified items still do not meet the requirements during re-inspection, the medical products administration departments shall revoke the cosmetics production license thereof in accordance with the law.

(III) Daily supervision and inspection

1. Supervision and inspection of cosmetics registrants, notifiers and entrusted production enterprises engaged in cosmetics production activities

Medical products administration departments shall conduct supervision and inspection of all or part of the items in accordance with Attachment 1 regarding the implementation of the good manufacturing practices by the enterprises that have obtained cosmetics production licenses.

(1) If no any nonconforming items is found in terms of enterprise during on-site inspection, it shall be judged as “no defects in the production quality management system are found in the inspection”.

(2) If any of the following circumstances is found in terms of enterprise during on-site inspection, it shall be judged as “serious defects exist in the production quality management system”:

1) Having critical items not complying with the provisions;

2) Having 6 or more defective critical items and other key items not complying with the provisions in total;

3) Having 16 or more key items not complying with the provisions, defective key items, and general items not complying with the provisions in total.

(3) If the enterprise is found to have items not complying with the provisions during on-site inspection, but there is no such circumstance that shall be judged as “serious defects exist in the production quality management system”, it shall be judged as “defects exist in the production quality management system”.

2. Supervision and inspection of cosmetics registrants and notifiers entrusting production

Medical products administration departments shall conduct supervision and inspection of all or part of the items in accordance with Attachment 2 regarding the implementation of the good manufacturing practices by the cosmetics registrants and notifiers entrusting production.

(1) If no any nonconforming items is found in terms of enterprise during on-site inspection, it shall be judged as “no defects in the production quality management system are found in the inspection”.

(2) If any of the following circumstances is found in terms of enterprise during on-site inspection, it shall be judged as “serious defects exist in the production quality management system”:

1) Having critical items not complying with the provisions;

2) Having 4 or more defective critical items and other key items not complying with the provisions in total;

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附件

化妆品生产质量管理规范
检查要点及判定原则

为规范化妆品生产许可和监督检查工作，指导化妆品注册人、备案人、受托生产企业贯彻执行《化妆品生产质量管理规范》，根据《化妆品监督管理条例》《化妆品生产经营监督管理办法》等法规、规章，国家药监局组织制定了《化妆品生产质量管理规范检查要点及判定原则》。

一、化妆品生产质量管理规范检查要点适用范围

（一）对从事化妆品生产活动的化妆品注册人、备案人、受托生产企业，依据化妆品生产质量管理规范检查要点（实际生产版，见附 1）开展检查。附 1 共有检查项目 81 项，其中重点项目 29 项（重点项目包括关键项目 3 项，其他重点项目 26 项），一般项目 52 项。

（二）对委托生产的化妆品注册人、备案人，依据化妆品生产质量管理规范检查要点（委托生产版，见附 2）开展检查。附 2 共有检查项目 24 项，其中重点项目 9 项（重点项目包括关键项目 1 项，其他重点项目 8 项），一般项目 15 项。

（三）对既从事化妆品生产活动又委托生产的化妆品注册人、备案人，依据附 1 和附 2 分别开展检查并单独判定。

二、化妆品生产质量管理规范检查分类及判定原则

（一）生产许可现场核查

省、自治区、直辖市药品监督管理部门应当依据附 1 组织对化妆品生产许可申请人开展生产许可现场核查。

1.现场核查中未发现企业存在不符合规定项目的，应当判定为“现场核查通过”。

2.现场核查中发现企业存在以下情形之一的，应当判定为“现场核查不通过”：

（1）关键项目不符合规定；

（2）关键项目瑕疵数与其他重点项目不符合规定数总和大于 6 项（含）；

（3）重点项目不符合规定数、重点项目瑕疵数、一般项目不符合规定数总和大于 16 项（含）。

3.现场核查中发现企业存在不符合规定项目，但未存在上述应当判定为“现场核查

不通过”情形的，应当判定为“整改后复查”。判定为“整改后复查”的企业，应当在规定时间内完成整改，并向省、自治区、直辖市药品监督管理部门提交整改报告。省、自治区、直辖市药品监督管理部门收到整改报告后，可以根据实际情况对该企业组织现场复查，确认整改符合要求后，判定为“现场核查通过”；对于规定时限内未提交整改报告或者复查发现整改项目仍不符合规定的，应当判定为“现场核查不通过”。

（二）生产许可延续后现场核查

省、自治区、直辖市药品监督管理部门应当在其向化妆品生产许可延续申请人换发新化妆品生产许可证之日起 6 个月内，对申请人延续许可的申报资料和承诺进行监督，依据附 1 组织对该企业开展现场核查，核查结果为上述“现场核查不通过”的，应当依法撤销化妆品生产许可；核查结果为上述“整改后复查”，且在规定时限内未提交整改报告或者复查发现整改项目仍不符合规定的，应当依法撤销化妆品生产许可。

（三）日常监督检查

1.对从事化妆品生产活动的化妆品注册人、备案人、受托生产企业监督检查

负责药品监督管理的部门应当依据附 1 对已取得化妆品生产许可证的企业生产质量管理规范执行情况开展全部或者部分项目监督检查。

（1）现场检查中未发现企业存在不符合规定项目的，应当判定为“检查未发现生产质量管理体系存在缺陷”。

（2）现场检查中发现企业存在以下情形之一的，应当判定为“生产质量管理体系存在严重缺陷”：

1）关键项目不符合规定；

2）关键项目瑕疵数与其他重点项目不符合规定数总和大于 6 项（含）；

3）重点项目不符合规定数、重点项目瑕疵数、一般项目不符合规定数总和大于 16 项（含）。

（3）现场检查中发现企业存在不符合规定项目，但未存在上述应当判定为“生产质量管理体系存在严重缺陷”情形的，应当判定为“生产质量管理体系存在缺陷”。

2.对委托生产的化妆品注册人、备案人监督检查

负责药品监督管理的部门应当依据附 2 对委托生产的化妆品注册人、备案人生产质量管理规范执行情况开展全部或者部分项目监督检查。

（1）现场检查中未发现企业存在不符合规定项目的，应当判定为“检查未发现生产质量管理体系存在缺陷”。

（2）现场检查中发现企业存在以下情形之一的，应当判定为“生产质量管理体系存在严重缺陷”：

1）关键项目不符合规定；

2）关键项目瑕疵数和其他重点项目不符合规定数总和大于 4 项（含）；

3）重点项目不符合规定数、重点项目瑕疵数、一般项目不符合规定数总和大于 8 项（含）。

（3）现场检查中发现企业存在不符合规定项目，但未存在上述应当判定为“生产质量管理体系存在严重缺陷”情形的，应当判定为“生产质量管理体系存在缺陷”。

三、其他事项

省、自治区、直辖市药品监督管理部门可以结合实际，细化、补充制定本行政区域化妆品生产质量管理规范检查要点。

附：1. 化妆品生产质量管理规范检查要点（实际生产版）

2. 化妆品生产质量管理规范检查要点（委托生产版）

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