Voluntary Cosmetics Good Manufacturing Practices

化粧品優良製造規範（台灣）

Taiwan Ministry of Economic Affairs(MOEA)
Ministry of Health and Welfare (MOHW)

Translated by Chemlinked

Release Date: 2014/06/09
Implementation Date: 2014/06/09

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Provisions of the Amended "Key points on the implementation of Voluntary Cosmetics Good Manufacturing Practices"

I. In order to guide the implementation of "Voluntary Cosmetics Good Manufacturing Practices" (hereinafter referred to as GMP) by the cosmetic industry and the establishment of verification mechanism for the implementation of GMP by the manufacturer, the "Key Points" are hereby formulated.

II. The GMP as mentioned in the "Key Points" refers to the "CNS 22716: Cosmetics – Good Manufacturing Practices (GMP) – Guideline on Good Manufacturing Practices" and acts as the basis for the verification of quality management system.

III. For any manufacturer applying for GMP verification in accordance with the "Key Points" (hereafter referred to as the applicant), his or her application for verification can only accepted when the production operations of all the products have been carried out in accordance with GMP for three months or based on a scale of more than three batches.

The applicant shall submit the evidentiary documents for factory registration or the evidentiary documents for exemption from carrying out factory registration as well as the application form on the verification of voluntary cosmetics good manufacturing practices (Attachment 1) and fill an application to the Industrial Development Bureau, MOEA (hereinafter referred to as the IDB-MOEA) for verification of all products in the dosage forms of various cosmetics (hereinafter referred to as Form A), or part of products in the dosage forms of various cosmetics (hereinafter referred to as Form B).

The scope of verification applied as referred to in the preceding paragraph includes that the manufacturer as mentioned in Form B must separately submit the list on application for verification of voluntary cosmetics good manufacturing practices and made-in-Taiwan cosmetics MIT smile logo products (Attachment 2) and evidentiary materials on products verified by voluntary cosmetics good manufacturing practices (Attachment 3).

IV. The IDB-MOEA shall complete a written-form inspection within twenty-one days since the date of completely receiving the application form and all other required documents.

In case that any additions or corrections are required to be made in the application for verification filed by the manufacturer, the IDB-MOEA shall notify the manufacturer in written form to make the additions or corrections within thirty days; For anyone who fails to or cannot make the required additions or corrections within the given time limit, his or her application shall be rejected.

Any applicant that passes the written-form inspection shall receive the on-site inspection.

V. The on-site inspection shall be executed out by the inspection team constituted by scholars & professionals brought together by MOEA and MHW and the IDB-MOEA shall act as its assistant & adviser. Before the inspection team executes the on-site inspection, the IDB-MOEA or the entrusted executive entity shall notify the applicant in written form about the date of the on-site inspection and the items regarding which coordination shall be provided. When the members of the inspection team execute the on-site inspection, the proof of identity shall be shown. During the on-site inspection, when it is necessary for the members of the inspection team to obtain or photocopy related documents, photos, audios or videos for storage, the consent of the applicant shall be obtained.

VI. When executing on-site inspection, the inspection team shall fill out the inspection form on verification of voluntary cosmetics good manufacturing practices (Attachment 4) and the non-conformity record form (Attachment 5), and take samples and submit them for testing.

The defect as recorded in the inspection form and the non-conformity record form as referred to in the preceding paragraph shall be signed off by the responsible person from both the inspection team and the applicant for confirmation, and the sheets shall be serve as a record for on-site inspection and be held by the inspection team and the applicant respectively.

VII. The defect as described in the preceding paragraph are divided into four levels including serious defect, major defect, minor defect and matters suggested for improvement and the defect at each level are defined as follows:

(I) Serious defect

1. Where any of the following misstatements is made or any of the following fraudulent behaviors is found with respect to products or related records & data:

(1) Falsely labelling of the date of manufacture

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