HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

SEPTEMBER 2024

GUIDELINES FOR MANUFACTURING STANDARDS OF HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

Guidelines Version 4

The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at www.hsa.gov.sg.

HSA Health Sciences Authority

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1. Introduction

1.1 Dealers of health Supplements (HS), traditional medicines (TM)*, medicated oils, balms (MOB) and medicated plasters are required to ensure that their products are manufactured in accordance with good manufacturing standards.

1.2 The objective of these guidelines is to provide guidance on the suitable manufacturing standards to ensure that these products are consistently produced to the quality standards appropriate for their intended use.

* Local Chinese Proprietary Medicines (CPM) manufacturers are subject to dealer licensing. For local CPM manufacturers, please refer to requirements for manufacturer's licence at: www.hsa.gov.sg/chinese-proprietary-medicines/dealers-licence/apply.

2. Acceptable Manufacturing Standards

2.1 The following manufacturing standards are considered acceptable:

- Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice for Medicinal Products
- World Health Organisation (WHO) Good Manufacturing Practices (GMP) for Pharmaceutical Products
- ASEAN Guidelines on Good Manufacturing Practice (GMP) for Health Supplements
- ASEAN Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines
- United States Food and Drug Administration (US FDA) Current Good Manufacturing Practice (cGMP) for Dietary Supplements
- International Organisation for Standardisation (ISO) - Food Safety Management (ISO 22000)*
- Food Safety System Certification (FSSC) 22000*
- Hazard Analysis Critical Control Point (HACCP) Systems*

* These are certification standards for food safety management systems which are considered suitable for HS and TM if the product is regulated under Food Laws in the country of manufacture. For manufacturers that are certified to HACCP standard, dealers should ensure that these manufacturers have proper procedures in place to manage feedback and recall activities.

2.2 If your manufacturer adopts a manufacturing standard not listed in paragraph 2.1, you are advised to check if it is equivalent to any of the standards listed in paragraph 2.1. You are strongly encouraged to engage a manufacturer that adopt a manufacturing standard that is equivalent to any of the listed standards.

2.3 The following documentation would demonstrate that the manufacturer complies with the manufacturing standards listed in paragraph 2.1. Dealers are recommended to ensure that the manufacturer has at least one of the following documents as evidence of the manufacturing standards for their HS, TM, MOB and medicated plasters. Dealers should hold evidence of the manufacturing standards adopted by the manufacturer.

- Manufacturer's licence issued by the regulatory authority responsible for the product type in the country of manufacture, whose manufacturing standards are acceptable; or

- Good Manufacturing Practice certification issued by the regulatory authorities that adopted acceptable manufacturing standards; or

- Third party certification (e.g. GMP certification, Food Safety Management certification) issued by certification bodies that are accredited by the Singapore Accreditation Council (SAC) or other accreditation bodies listed under the SAC's Mutual Recognition Agreement (MRA).

    - To search for the list of accredited certification bodies by SAC, please refer to https://sacinet2.enterprisesg.gov.sg/sacsearch/search
    - For the list of accredited bodies under SAC's MRA, please refer to https://iaf.nu/en/recognised-abs/

3 References

3.1 PIC/S Guide to Good Manufacturing Practice for Medicinal Products

3.2 WHO Good Manufacturing Practices for Pharmaceutical Products

3.3 ASEAN Guidelines on Good Manufacturing Practice for Health Supplements

3.4 ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines

3.5 USFDA Current Good Manufacturing Practice for dietary supplements (cGMP)

3.6 ISO 22000 Food Safety Management System

3.7 FSSC 22000 Food Safety Management System

3.8 HACCP Systems

Revision History

Version	Date of publication	Summary of changes*
1	March 2022	New document
2	July 2022	Editorial changes only
3	July 2023	Included medicated oils, balms and medicated plasters
4	September 2024	Updated the weblink to SAC's accredited certification bodies in Para 2.3.

*Editorial changes are not reflected

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