HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

NOVEMBER 2024

GUIDELINES FOR TESTING REQUIREMENTS OF HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

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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 (importers, manufacturers, wholesale dealers) and sellers of health supplements (HS), traditional medicines (TM), medicated oils, balms (MOB) and medicated plasters are required to ensure that their products are safe, and that they conform with the applicable safety and quality standards.

1.2 The objective of these guidelines is to provide guidance on testing requirements for HS, TM, MOB and medicated plasters, to ensure that the products meet the expected safety and quality standards.

2. Safety and Quality Standards

2.1 Routine testing on the finished products should be performed to ensure that they meet the expected safety and quality standards.

2.2 All testings should preferably be performed by accredited laboratories[1].

2.3 Manufacturer's in-house testing laboratory, if used, should meet the following conditions:

a. Test methods are validated or referenced to a recognised pharmacopoeia[2] method; and
b. Manufacturer's in-house laboratory is audited as part of an independent GMP plant audit.

[1]Accredited laboratories refer to laboratories that have been accredited by the respective national accreditation body in the country of origin to conduct testing services in conformance to required standards.

[2]Recognised pharmacopoieas refer to any of the following:

a. British Pharmacopeia (BP)
b. Chinese Pharmacopeia (ChP)
c. European Pharmacopeia (EP)
d. Japanese Pharmacopeia (JP)
e. United States Pharmacopeia (USP)

A) HEAVY METALS AND MICROBIAL LIMITS

2.4 The applicable heavy metals and microbial limits for HS, TM, MOB and medicated plasters are specified in **Tables 1, 2 and 3**.

Table 1: Heavy Metals Limits

Heavy Metal	Quantity (by weight)
Arsenic	5 parts per million
Cadmium	0.3 parts per million
Lead	10 parts per million
Mercury	0.5 parts per million

Table 2: Microbial Limits

Microbe	Quantity (colony-forming units (CFU)) per g or ml of product
Total aerobic microbial count	Not more than 10^5
Yeast and mould count	Not more than 5×10^2
Escherichia coli, Salmonellae and *Staphylococcus aureus*	Absent

The above microbial limits may not be applicable to certain products such as probiotics and products derived from fermentation processes.

Table 3: Microbial Limits for Topical Use Products

Microbe	Quantity (colony-forming units (CFU)) per g or ml of product
Total aerobic microbial count	Not more than 10^4
Yeast and mould count	Not more than 5×10^2
Pseudomonas aeruginosa and *Staphylococcus aureus*	Absent

2.5 Notwithstanding the limits stated above, it is the responsibility of the dealers and sellers to ensure that the limits of microbial content of their products are appropriate and safe when used according to the recommended conditions and target users.

2.6 A set of guidelines has been developed by the ASEAN Traditional Medicines and Health Supplements Product Working Group for harmonising the technical standards applicable to these products to ensure these products' safety and quality. These Guidelines form part of the ASEAN Agreements on the Regulatory Framework for HS and TM, which are currently pending signing by all ASEAN member states. Once the Agreements are signed by all ASEAN member states, the ASEAN standards are to be implemented by ASEAN member states within the agreed timeframe. Dealers are encouraged to take into consideration the ASEAN Guidelines on Limit of Contaminants for HS and ASEAN Guidelines on Limit of Contaminants for TM when reviewing the microbial limits for their products. The ASEAN technical guidelines can be accessed at: https://asean.org/our-communities/economic-community/standard-and-conformance/.

B) INGREDIENTS WITH "POISONS"

2.7 Generally, HS, TM, MOB and medicated plasters are not allowed to contain substances that are controlled as "poisons" under Poisons Act. These "poisons" are potent medicinal substances that may pose public safety concerns when used without medical supervision.

2.8 However, traditionally used ingredients as specified in **Table 4** may be present in the products as applicable, subject to restrictions. Dealers and sellers are required to ensure that naturally occurring poison contents in such products are within the limits of use.

Table 4: Ingredients with Restricted Use

Ingredient	Constituent of concern	Restrictions
1. *Herba Ephedrae*	Ephedra alkaloids	- For traditional medicines: containing less than 1% of Ephedra alkaloids. - Not to be used in health supplements.
2. *Monascus purpureus* (Red Yeast Rice)	Lovastatin	- Containing less than 1% of lovastatin.

C) TESTING FOR ADULTERANTS FOR SOME PRODUCT CATEGORIES

2.9 HSA and other overseas regulatory agencies had reported adulteration of health products with potent chemical pharmaceutical substances. Their presence can pose health risks to unsuspecting consumers.

2.10 Some product categories, such as those specified below in **Table 5** have been implicated frequently in adulteration cases.

2.11 In order to ensure that such products do not contain hidden risk to unsuspecting consumers, testing for adulterants at accredited laboratories should be performed on every batch of product, prior to being marketed on the local market.

Table 5: Product Categories of Concern and Adulterants

Product Category	Specific medicinal substances to be included in the adulterant testing
Male Vitality Enhancement	- Androgenic Steroids - Erectogenic Agents
Pain Relief*	- Analgesics - Anti-inflammatory Agents
Weight Loss	- CNS Stimulants & Anorectics - Diuretics - Laxatives & Purgatives (including Sennosides) - Lipid Absorption Inhibitors - Thyroid Agents - Thyroid Extracts

*Pain relief claims are only allowed for TM. For more information, please refer to the Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines.

D) TESTING FOR DIETHYLENE GLYCOL (DEG) AND ETHYLENE GLYCOL (EG) IN ORAL LIQUID PRODUCTS

2.12 DEG and EG are toxic substances used as industrial solvents that can be fatal, even when taken in small amounts, especially for children.

2.13 Oral liquid products should be tested for compliance with the limits of DEG and EG, as specified in **Table 6**.

Table 6: Diethylene Glycol and Ethylene Glycol Limits

Substance	Quantity (by weight)
Diethylene glycol	1000 parts per million
Ethylene glycol	1000 parts per million

2.14 The above limits are applicable to oral liquid products.

2.15 Manufacturers of oral liquid products containing starting materials which are at risk of contamination by DEG or EG (e.g., glycerin (also known as glycerol), propylene glycol, sorbitol solution) should perform routine testing on the starting material or finished product for DEG and EG.

E) PHYSICAL TEST PARAMETERS FOR DIFFERENT DOSAGE FORMS

2.16 To ensure that the finished products consistently meet the required quality standards, it is important to test the physical quality attributes of the different dosage forms. Please refer to the Guidelines on Physical Test Parameters for Dosage Forms of Health Supplements and Traditional Medicines for more information on the physical quality attributes.

3. Requirements for Test Report

3.1 Heavy metals, microbiological testing, poisons, and adulterants testing should be conducted on finished products. DEG and EG testing should be conducted on the starting material or finished product, as feasible.

3.2 The test report should minimally contain the following information:

a) Date of report
b) Brand name (if applicable) and product name
c) Batch number
d) Name of substance(s) tested
e) Test result(s), including limit(s) of detection*
f) Name and signature of analyst or person responsible

*Test result should be reported quantitatively (e.g., Arsenic 0.05ppm). For test result that is reported as not detected or ND, the limit of detection must be stated on the test report.

4. Accredited Laboratories

4.1 A list of laboratories accredited for testing in Singapore can be found here.

4.2 Accredited analytical testing laboratories in Singapore can be found in SAC-SINGLAS' website https://www.sac-accreditation.gov.sg/.

4.3 For overseas analytical testing laboratories, please ensure that these laboratories are accredited by the respective national accreditation body in the country of origin.

4.4 Many national accreditation bodies are members of international organisations for accreditation bodies such as ILAC (https://ilac.org). For the detailed description of the overseas laboratories' scope of accreditation, please visit the respective national accreditation body's website listed in ILAC.

5. References

5.1 ASEAN Guidelines on Limits of Contaminants for Health Supplements

5.2 ASEAN Guidelines on Limits of Contaminants for Traditional Medicines

5.3 Poisons Act 1938 and Poisons Rules

5.4 The International Pharmacopoeia

5.5 United States Pharmacopoeia

Revision History

Version	Date of publication	Summary of changes*
1	March 2022	New document
2	July 2022	Added clarification that pain relief claims are only allowed for traditional medicines.
3	July 2023	• Included medicated oils, balms and medicated plasters • Added section 2.D on Physical Test Parameters for Different Dosage Forms • Added Table 3: Microbial Limits for Topical Use Products • Updated test report requirements
4	November 2024	Added diethylene glycol and ethylene glycol limits

*Editorial changes are not reflected

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