HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

JULY 2022

GUIDELINES FOR TESTING REQUIREMENTS OF HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

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
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1. Introduction

1.1 Dealers of Health Supplements (HS) and Traditional Medicines (TM) 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 and TM, to ensure that the products meet the expected safety and quality standards.

2. Safety and Quality Standards of Health Supplements and Traditional Medicines

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 refers 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 refers 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 and TM are specified in Table 1 and Table 2.

Table 1: Heavy Metals Limits

Heavy Metal	Quantity (by weight)
1. Arsenic	5 parts per million
2. Cadmium	0.3 parts per million
3. Lead	10 parts per million
4. 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, products derived from fermentation processes and topical products.

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 and TM 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 3 may be present in HS or TM 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 3: 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 have 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 4 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 4: Product Categories of Concern and Adulterants

Product Category	Specific medicinal substances to be included in the adulterant testing
Men's Sexual Health	- Androgenic Steroids - Erectogenic Agents
Pain Relief*	- Analgesics - Anti-inflammatory Agents
Slimming	- CNS Stimulants & Anorectics - Diuretics - Laxatives & Purgatives (including Sennosides) - Lipid Absorption Inhibitors - Thyroid Agents - Thyroid Extracts

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

3. Requirements for Test Report

3.1 Heavy metals, microbiological testing, poisons, and adulterants testing should be conducted on finished products. Product specification sheet or certificate of analysis on raw materials or intermediates may not be used to replace testing on the finished products.

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) Reference(s) to the relevant specifications and testing procedures
f) Test result(s), including limit(s) of detection*
g) Name and signature of analyst

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

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

4.3 Many national accreditation bodies are member 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 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 (Chapter 234) and Poisons Rules

HEALTH SCIENCES AUTHORITY

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