

VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS

SECTION III

Certification Criteria

1.1 This document describes the requirements against which certification can be obtained under the Voluntary Certification Scheme for AYUSH products. The certification is available at two levels:

- I. **AYUSH Standard Mark which** is based on compliance with the domestic regulatory requirements; herbal, Herbo-mineral and Mineral products (Schedule T GMP standards and supplementary guidelines) and
- II. **AYUSH Premium Mark which** is based on either or both of the following options;

**Option A:** Compliance with GMP Requirements based on WHO Guidelines for herbal products and Levels of contaminants as given in the Certification Criteria document.

*Note*

- i. The requirements of heavy metals shall not apply to AYUSH products having raw materials of metallic origin provided they are intended for the domestic market.*
- ii. For the time being this certification is available for Herbal products only.*

**Option B:** Compliance with regulatory requirements of any importing country provided they are more stringent than Option A above.

*Note*

- i. Currently, this certification is available for Herbal products*

### SECTION III: PADD: AYUSH MARK :CERTIFICATION CRITERIA

1.1.1 For any manufacturer to qualify for AYUSH Premium Mark certification, compliance with domestic regulation is a prerequisite.

1.2 The various criteria mentioned above are as follows:

- a) Drugs and Cosmetics Act, 1940 and Rules 1945 by the Drugs Controller General of India through the State Governments. Regulations for Ayurveda, Siddha and Unani (ASU) products is followed as per schedule T and Regulations for homeopathy products is followed as per schedule M1.
- b) GMP Requirements based on WHO Guidelines for AYUSH Premium Mark (Annex A)
- c) Permissible levels of contaminants for AYUSH Premium Mark (Annex B)
- d) Permissible levels of contaminants for AYUSH Standard Mark (Annex C)
- e) Regulations of importing countries – to be identified by the organization seeking Certification and provided to the Certification Body