

SECTION III
VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS
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:

- a) **Ayush Standard Mark** which is based on compliance to the domestic regulatory requirements; and
- b) **Ayush Premium Mark** which is based on either or both of the following options;

Option A: Compliance to GMP Requirements based on WHO Guidelines and Levels of contaminants as given in Certification Criteria document .

Note

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

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

Note

- i. For the time being this certification is available for Herbal products

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

1.2 The various criteria mentioned above are as follows:

- a) Domestic regulation means regulatory requirements prescribed under the Drugs and Cosmetics Act, 1940 for AYUSH products
- 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