

CRITERIA FOR VARIOUS CATEGORIES

The criteria as finalized for various categories is summarized below:

1. Ayush Products

- b) Registered with a foreign regulator as Ayush medicine or Traditional Ayush Medicine or Natural Health Product or Complementary Medicine or any other international classification as per current regulations.
- c) Holding WHO-CoPP based on WHO GMP issued by CDSCO
- d) Certified for Ayush Premium Mark under the Voluntary Certification Scheme for Ayush Products managed by the Quality Council of India

2. Botanicals/Herbal Products Manufacturer

- a) Registered with foreign regulators as botanical drugs or herbal medicines or traditional herbal medicines
- b) Finished products complying with WHO-GMP along with product requirements as specified by WHO/importing country regulation
- c) Finished products complying with Codex GMP/HACCP through a recognized standard such as India HACCP certification scheme of QCI or ISO 22000 or any equivalent certification along with product requirements as specified in Codex standards/importing country regulations.
- d) Finished products complying with AYUSH Premium Mark along with product requirements as specified.

3. Medicinal Plants/Herbs/Botanicals as Raw/Starting Materials

- a) Compliance with any importing country regulations related to starting material of herbal origin/medicinal plants/ herbs/botanicals etc.
- b) Compliance with GAP and GFCP through NMPB-QCI voluntary certification scheme for medicinal plant produce (VCSMPP)
- c) WHO GACP guidelines along with limits of contaminants as prescribed by Ministry of Ayush or by any importing country.

- d) Compliance with organic standards like National Standard for Organic Production [NSOP] under National Programme for Organic Production [NPOP] of APEDA or equivalent

4. Hospitals/Day Care Centres/Clinics

- a) Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using ISQuaEEA accredited standards or equivalent, read with any additional requirements specified under this programme, for Ayush Hospitals / Day Care centres / Clinics
- b) Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using WHO EMRO Standards for Patient Safety Friendly Hospital Standards or equivalent standard, read with any additional requirements specified under this programme, for healthcare accreditation for Ayush Hospitals / Day Care centres / Clinics.
- c) Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using ISO 7101 or equivalent standard, read with any additional requirements specified under this programme, for healthcare accreditation.
- d) Certification to ISO 7101, read with any additional requirements specified under this programme for Ayush Hospitals / Day Care centres / Clinics, by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF)* for ISO 17021-1 until MLA for ISO 7101 is established.
- e) Certification to ISO 9001, read with any additional requirements specified under this programme for Ayush Hospitals / Day Care centres / Clinics, as applicable, by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF)* for ISO 17021-1/ISO 9001.

*IAF is transitioning to a new entity Global Accreditation Cooperation and the later shall apply when it starts functioning.

5. Ayush Wellness Centres

- a) Accreditation as per an ISQuaEEA endorsed or equivalent standard read with any additional requirements specified under this programme, as applicable, by an organization which is ISQuaEEA endorsed for healthcare accreditation.
- b) Accreditation as per ISO 7101 or equivalent standard, read with any additional requirements specified under this programme, as applicable, by an organization which is ISQuaEEA endorsed for healthcare accreditation.

- c) Accreditation as per ISO 21426 as modified to cover Ayush wellness centres under this programme by an organization which is ISQuaEEA endorsed for healthcare accreditation.
- d) Certification as per ISO 7101, read with any additional requirements specified under this programme, as applicable, by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF)* for ISO 17021-1 until MLA for ISO 7101 is established.
- e) Certification as per ISO 9001, read with any additional requirements specified under this programme, as applicable, by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF)* for ISO 17021-1/ISO 9001
- f) Certification as per ISO 21426 as modified to cover AYUSH wellness centres under this programme by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF)* for ISO 17065

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6. Medical Value Travel Facilitator

- a) Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using ISQuaEEA accredited standards or equivalent, read with any additional requirements specified under this programme, for MVTF
- b) Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using ISO 22525 or equivalent standard, read with any additional requirements specified under this programme for MVTF.
- c) Certification to ISO 22525, read with any additional requirements specified under this programme, by a certification body accredited by an accreditation body which is signatory to the Mutual Recognition Arrangement (MRA) of the International Accreditation Forum for ISO 17065

The MVTF shall ensure that the contracted healthcare providers meet any one of the following criteria to be eligible for recognition:

- i. Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using ISQuaEEA accredited standards or equivalent standards, read with any additional requirements specified under this programme, for healthcare accreditation.
- ii. Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using

- ISO 7101 or equivalent standard, read with any additional requirements specified under this programme, for healthcare accreditation.
- iii. Accreditation as Ayush wellness centre as per ISO 21426 as modified to cover AYUSH wellness centres under this programme by an organization which is ISQuaEEA endorsed for healthcare accreditation.
 - iv. Accreditation from an accreditation body accredited by the International Society for Quality in Health Care External Evaluation Association (ISQuaEEA) using WHO EMRO Standards for Patient Safety Friendly Hospital Standards or equivalent standard, read with any additional requirements specified under this programme, for healthcare accreditation
 - v. Certification to ISO 7101, read with any additional requirements specified under this programme, by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF) for ISO 17021-1 until MLA for ISO 7101 is established.
 - vi. Certification to ISO 9001, read with any additional requirements specified under this programme, as applicable, by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF) for ISO 17021-1/ISO 9001
 - vii. Certification to ISO 21426 as modified to cover AYUSH wellness centres under this programme by a certification body accredited by an accreditation body which is signatory to the Multilateral Recognition Arrangement (MLA) of the International Accreditation Forum (IAF) for ISO 17065

7. Product Testing Laboratories

The laboratory shall be accredited as per IS/ISO/IEC 17025 (latest version) as read with additional criteria/requirements (as applicable based on date of implementation) laid down by PO for Ayush laboratories through an accreditation body, that shall be a full member of International Laboratory Accreditation Cooperation (ILAC) and/or Asia Pacific Accreditation Co-operation (APAC) or any other regional accreditation cooperation body.