

# AYUSH QUALITY MARK PROGRAMME

## System for Grant of Ayush Quality Mark to Ayush Product Testing Laboratories

### Introduction

The Ministry of Ayush has instituted a system to recognize and grant **Ayush Quality Mark** to Ayush products and services for demonstrating adherence to globally recognized standards under the aegis of the AYUSHEXCIL. Ayush product and services have been identified along with applicable globally recognized standards, criteria and process for grant of **Ayush Quality Mark**.

**1. Scope:** This document describes the system including the criteria and the process for grant of **Ayush Quality Mark** to Ayush product testing laboratories.

**2. Criteria:** The laboratories shall meet the following criteria:

- a) The laboratory shall be accredited as per ISO/IEC 17025 as read with additional requirements (as applicable based on date of implementation) laid down by AYUSHEXCIL for Ayush Product testing 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.

\*or its successor Global Accreditation Cooperation Inc

- b) The scope of accreditation as per ISO/IEC 17025 shall cover all the tests/parameters of at least one group as given in **Annex 1**. The Ayush Quality Mark shall be granted only for such groups for which all the test/parameters are covered in the scope of accreditation.

Note: If any lab seeks to be considered for any one or more streams of Ayush (e.g. Ayurveda, Homeopathy, Unani etc.), then the laboratory may identify and apply for those specific tests but shall cover all tests/parameters applicable to that stream.

- c) In case of manufacturer's in-house laboratory, all tests within a group applicable to all its products shall be covered under the scope of accreditation. However, if the manufacturer is also engaged in external testing, then b), as above, shall apply.

### 3. Procedure

3.1 Any laboratory fulfilling the criteria as above shall apply to AYUSHEXCIL with the following:

3.1.1 Application form as at **Annex 2** along with the documents, including certificate issued by the accreditation body, as indicated in the application form.

3.1.2 Two copies of the agreement as at **Annex 3** duly signed by the authorized

signatory of the laboratory.

### 3.1.3 Applicable application fee.

3.2 AYUSHEXCIL shall verify the application for its completeness

3.3 If the check reveals any deficiency in documents, the applicant shall be informed within one week and the applicant shall provide the required information or documents within one week.

3.4 Once the application is found complete, then it shall be assigned a unique ID number which shall be used for all future correspondence between the laboratory and AYUSHEXCIL.

3.5 The application shall be reviewed by AYUSHEXCIL within one month. If the review indicates need for further information/documents/clarification, the applicant shall be informed, to submit the same within 2 weeks.

3.6 AYUSHEXCIL reserves the right to undertake a visit/assessment at the applicant's premises as part of the process on random basis or for specific reasons.

3.7 In case the applicant is found to meet the requirements prescribed under this programme, the applicant shall be informed of the intent to grant the **Ayush Quality Mark for the group(s) and stream(s)** with a request to pay the fee, as applicable, within one week.

3.8 In case the applicant is found to not meet the requirements, the applicant shall be given a 14 day notice enumerating the reasons for rejection. The applicant's response shall be duly considered and if the application is rejected, the applicant shall be informed of the decision with the reasons for rejection. The applicant may apply afresh at any time after rejection.

3.9 On receipt of fee, AYUSHEXCIL shall issue a certificate for the grant of **Ayush Quality Mark** along with a copy of the agreement duly countersigned by AYUSHEXCIL.

3.10 The grant of **Ayush Quality Mark** shall be effective from the date of issue of the certificate. The recognition granted to the laboratory shall remain valid concurrent with the validity of its accreditation.

3.11 AYUSHEXCIL reserves the right to undertake any visit/assessment as a part of its oversight over those granted **Ayush Quality Mark**. These visits/assessments may be announced or over a short notice or unannounced and the laboratory shall provide unrestricted access to the assessment team deputed by AYUSHEXCIL.

3.12 In case of any change in the information on the certificate issued by the accreditation body in respect of activity covered in this Programme, the recognised laboratory shall promptly inform AYUSHEXCIL within 3 working days. On receipt of the information AYUSHEXCIL shall decide on issuing a modified certificate, if needed. AYUSHEXCIL may decide to undertake an onsite assessment for the purpose, the reasons for which shall be duly communicated.

3.13 The grant of **Ayush Quality Mark** shall be valid until the accreditation, based on which it was granted, is valid and will be automatically suspended or withdrawn from the same date on which the accreditation is suspended or withdrawn or expires. The laboratory shall inform AYUSHEXCIL regarding any suspension or withdrawal / expiry within 3 days and shall not use **Ayush Quality Mark** during the period of suspension or after withdrawal/expiry.

3.14. If at any time during the recognition, AYUSHEXCIL finds the recognised laboratory is not in compliance with the criteria or the terms of agreement, it may suspend or withdraw partially or fully the recognition and the use of **Ayush Quality Mark** after serving a due notice and providing an opportunity to the laboratory to respond within 14 working days. The concerned accreditation body shall also be informed of the decision.

3.15 The laboratory may at any point of time voluntarily suspend or withdraw (fully or partially) the use of Ayush Quality Mark under intimation to AYUSHEXCIL. They shall immediately inform AYUSHEXCIL about the same. AYUSHEXCIL shall issue a revised certificate if necessary or take any other action deemed appropriate.

3.16 If there is any evidence of fraudulent behaviour or submission of false information or concealment of information AYUSHEXCIL shall proceed for withdrawal of recognition with due notice.

3.17 The aggrieved laboratory may prefer an appeal to the appellate authority as laid down in the Appeal Procedure within 30 working days of the adverse decision.

3.18 Before completion of one year from the grant of Ayush Quality Mark, the recognized laboratory shall pay Annual Fee for continuation of recognition. The recognized laboratory will have the option to pay the Annual Fee in advance for a maximum of 5 years.

#### **4. Fee Structure**

4.1 The following fee shall apply:

- a) Application Fee Rs. 10000/- + applicable GST (non-refundable)
- b) Annual Fee payable initially at the time of grant of **Ayush Quality Mark**

and subsequently annually in advance. Rs. 40,000/- + applicable GST.

- c) Manday charges in case of any visit / assessment by AYUSHEXCIL Rs. 10,000/- + applicable GST.
- d) Travel, boarding, lodging and local conveyance as per rules of AYUSHEXCIL

4.2 The fee is liable to change as per the decision of AYUSHEXCIL