

AYUSH QUALITY MARK PROGRAMME

System for Grant of Ayush Quality Mark to Ayush Medicinal Products Manufacturers

0. 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 products 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 Medicinal Product Manufacturers
2. **CRITERIA:** The Ayush Medicinal Product Manufacturer shall meet any of the following criteria to be eligible for recognition and grant of **Ayush Quality Mark**:

- a) Registration of Ayush Medicinal Products 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.
- b) Holding WHO-CoPP based on WHO GMP guidelines issued by CDSCO for identified Ayush Medicinal Products
- c) Holding Ayush Premium Mark Certification for Ayush Medicinal Products under the Voluntary Certification Scheme for Ayush Products managed by Quality Council of India

3. PROCEDURE

- 3.1 The Ayush Medicinal Product Manufacturer holding a valid certificate as per the criteria prescribed above shall apply to AYUSHEXCIL with the following:
 - a) Application Form as at **Annex 1** along with the documents, including copies of the certificate(s) issued by the relevant body, as indicated in the Application Form
 - b) Two copies of the “Agreement between AYUSHEXCIL and Medicinal Products Manufacturers” as at **Annex 2**, duly signed by the authorized signatory of the Ayush Products Manufacturer.
 - c) Applicable Application Fee
- 3.2. The AYUSHEXCIL shall review the application for completeness of documents. 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.

- 3.3. In case an Medicinal Product Manufacturer has more than one location where manufacturing activities are carried out and are covered by more than one certificate under the respective schemes mentioned in Item 2 above and which are proposed to be covered under the Ayush Quality Mark, then separate applications need to be submitted for each such location.
- 3.4. AYUSHEXCIL shall assign unique ID. to the application found complete with all documents. The receipt of application shall be acknowledged to the applicant conveying the ID which would be used for all future correspondence between the applicant and AYUSHEXCIL.
- 3.5. The AYUSHEXCIL shall review the application, within one month of its submission, as complete with all documents.
- 3.6. If the review indicates need for further information/documents/clarification, the applicant shall be informed of the same for submitting the same within 2 weeks.
- 3.7. The 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.
- 3.8. In case the applicant is found to meet the requirements prescribed under this programme, the applicant will be informed of the intent to grant the **Ayush Quality Mark** with the request to pay the Initial Recognition Fee as per the Fee Structure. The applicant shall pay the fee within one week.
- 3.9. In case the applicant is found not meeting the requirements, the applicant shall be given a 14 days' 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.
- 3.10. On receipt of fee for the applicants meeting the requirements, the AYUSHEXCIL shall issue a Certificate for the grant of **Ayush Quality Mark** along with a copy of the Agreement, duly countersigned by the PO.
- 3.11. The grant of **Ayush Quality Mark** shall be effective from the date of issue of the certificate.
- 3.12. Scope of certification under the **Ayush Quality Mark** shall be all such products which are covered under the documents related to eligibility criteria.
- 3.13. Validity of the Certificate shall be concurrent with validity of the registration/certification through which the Ayush Medicinal Products Manufacturer had met the eligibility criteria.
- 3.14. AYUSHEXCIL reserves the right to undertake any visit/assessment as part of its oversight over the certificates granted for use of **Ayush Quality Mark**. These visits/assessments may be announced or short notice or unannounced and the Ayush Medicinal Product Manufacturer shall provide unrestricted access to the visiting team deputed by AYUSHEXCIL.
- 3.15. AYUSHEXCIL also reserves the right to undertake market surveillance of the Ayush Medicinal

Products supplied by the recognized Ayush Medicinal Product Manufacturer. Such surveillance shall be carried out in a manner as deemed appropriate, on merit for specific case.

- 3.16. Before completion of one year from the grant of **Ayush Quality Mark**, the recognized Ayush Medicinal Products Manufacturer shall pay Annual Fee for continuation of recognition. The recognized Ayush Medicinal Products Manufacturer will have the option to pay the Annual Fee in advance for a maximum of 5 years.
- 3.17. In case of any change in the information related to the registration/certificate of the eligibility criteria in respect of products covered under the **Ayush Quality Mark**, the Ayush Medicinal Products Manufacturer shall promptly inform the AYUSHEXCIL within 3 days. On receipt of such information, AYUSHEXCIL shall decide on issuing a modified certificate, if needed.
- 3.18. AYUSHEXCIL may decide to undertake onsite assessment for the purpose of deciding modifications in the certificate, the reasons for which shall be duly communicated to the Ayush Medicinal Product Manufacturer.
- 3.19. The certification for **Ayush Quality Mark** shall be automatically suspended or withdrawn from the same date on which the registration/certification of the eligibility criteria is suspended or withdrawn or expires. The Ayush Medicinal Products Manufacturer shall inform the AYUSHEXCIL regarding any suspension or withdrawal or expiry within 3 days and shall not use the **Ayush Quality Mark** during the period of suspension or after withdrawal/expiry.
- 3.20. Revocation of suspension of certificate could be considered by AYUSHEXCIL depending upon the actions taken by the Ayush Medicinal Products Manufacturer leading to restoration of registration/certification meeting the eligibility criteria.
- 3.21. Certificate for **Ayush Quality Mark** once withdrawn cannot be revived. The Ayush Medicinal Products Manufacturer shall have to apply afresh, if desirous of seeking recognition under this programme.
- 3.22. If at any time during the recognition, AYUSHEXCIL finds that the Ayush Medicinal Products Manufacturer is not in compliance with the criteria or the terms of agreement, it may suspend or withdraw the recognition for the use of **Ayush Quality Mark** after serving a due notice and providing an opportunity to the Ayush Medicinal Products Manufacturer to respond, including personal hearing, if so desired.
- 3.23. The Ayush Medicinal Products Manufacturer, if aggrieved by any decision of the AYUSHEXCIL, may prefer an appeal to the Appellate Authority as laid down in the Appeal Procedure within 30 days of the adverse decision.

4. FEE STRUCTURE

4.1 The following fee shall apply:

- a) Application Fee Rs. 10,000/- + applicable GST [non-refundable].
- b) Initial Recognition Fee Rs. 50,000/-+ applicable GST, payable initially at the time of grant of **Ayush Quality Mark** (valid for first year)

- c) Annual Fee Rs. 50,000/-+ applicable GST, payable every year in advance.
- d) Manday charges in case of any visit / assessment by AYUSHEXCIL Rs. 15,000/+ applicable GST -
- e) Travel, boarding, lodging and local conveyance as per rules of AYUSHEXCIL.

4.2 Fee Structure is subject to change as per the decision of AYUSHEXCIL.