VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS

SECTION VI
Obtaining and Maintaining Certification

STEP I Planning for Product Certification

1. Obtaining certification against the Certification Criteria represents a challenge to manufacturers of AYUSH products.
2. It is therefore essential that the organizations interested in obtaining this certification consider carefully
   a) what AYUSH Certification they wish to achieve,
   b) identify the Criteria, and
   c) what needs to be achieved prior to applying for product certification.

STEP II Preparation

1. Obtain the relevant Certification Criteria documents namely the Domestic Regulations under the Drugs and Cosmetics Act, GMP Requirements based on WHO Guidelines, Levels of Contaminants, and Regulations of the importing country (if applicable);
2. Assess your process and product for compliance to relevant Certification Criteria.
3. Undertake preparations so as to ensure that the processes and the AYUSH product being manufactured would comply with the requirements of the relevant Certification Criteria.
4. Install in-house testing facilities if seeking certification for AYUSH Premium Mark.
5. Confirm that your production facility has been in production for at least one year.
6. Verify that five commercial batches of the products of dosage form for which certification is being planned to be sought, have been manufactured during the current licensed period.

STEP III Self assessment

1. Review your current systems and practices against the requirements of the latest relevant Certification Criteria.
2. Identify areas which need to be addressed and ascertain compliance prior to applying for product certification.
3. Please note that Certification Bodies are not permitted to provide consultancy although they can identify deviations from the relevant Certification Criteria requiring correction and/or corrective action.

STEP IV Select a Certification Body

1. Select an approved Product Certification Body to carry out the evaluation for Product certification at your site. Only Product Certification Bodies that are accredited by NABCB/authorized by QCI can certify for AYUSH Product certification.
2. In selecting a certification body, consider the range of products covered under the scope of accreditation of the Product Certification Body. Information on scope of accreditation is available on the websites of Ministry of AYUSH (https://ayush.gov.in/) and QCI (www.qcin.org) or can be obtained from the concerned certification body, either through correspondence or by visiting their website.
3. Certification Bodies will require details of your site, operations, products and relevant certification criteria on a prescribed Application form for registration of your Application

for grant of product certification. Obtain the prescribed application form from the selected Certification body.

4. Submit the application form duly filled to the selected certification body along with the following documents;
    a) Proof of being a legal entity
    b) Valid Manufacturing Licence ;
    c) Proof of Address of production site;
    d) List of installed manufacturing equipment;
    e) List of Testing facilities, if available;
    f) Copy of a test report covering all requirements of the relevant certification criteria for the product applied for; test report could be either from own laboratory or from an NABL accredited external laboratory,
    g) self evaluation checklist confirming that all requirements as prescribed in the relevant certification criteria are being complied with.

STEP V Registration and Evaluation by a Certification Body

1. The certification body will examine your application for completeness and adequacy, and deviations if any, will be informed to you for necessary correction and/or compliance. Once the application is found to be complete, it shall be registered by the Certification body.
2. The certification body will determine the duration of the evaluation at your site, on the basis of the number of products to be certified, the manpower, the complexity of operations and processes, and availability of lab and quote to you.
3. On acceptance of its quote, the Certification body shall in consultation with you finalize the dates for evaluation.
4. It is important that the facility is in production at the time of the Evaluation by the certification body otherwise another evaluation may have to be organized.
5. The certification body will carry out the evaluation in one stage for AYUSH Standard and in two stages for AYUSH Premium Mark. During the Stage 1 evaluation, your state of preparedness, status of GMPs and availability of competent personnel and equipment for production and testing will be assessed for their adequacy.
6. At the end of Stage 1 evaluation the Certification Body will inform the applicant in writing about the deficiencies observed, if any, with respect to the certification criteria.
7. Take necessary actions and inform the certification body as soon as possible but not later than 3 months of the Stage 1 Evaluation. Delays beyond this will lead to another Stage 1 evaluation of your facility by the certification body.
8. The certification Body will undertake the Stage 2 evaluation only after you have confirmed that necessary actions on the identified shortfalls have been taken.
9. For the stage 2 evaluation the certification body will visit the facility and evaluate the process and controls being implemented, the prevailing hygienic conditions, the testing facilities and the competence of the personnel for compliance to the certification criteria.
10. The certification body will draw samples of products from stocks that are representative of normal production capacities of the facility, and have the same tested in an independent laboratory accredited by NABL, for compliance to the certification criteria.

STEP VI Follow up and Corrective actions

1. At the end of Stage 2 evaluation the Certification Body will inform the applicant in writing of the deviations observed, if any, with respect to the certification criteria.
2. Take necessary actions and inform the certification body as soon as possible. If you do not show progress towards completion of corrective actions within three months of Initial Evaluation your application shall be closed.
3. If the corrective actions can be verified through documented evidence, you will be required to provide the same to the Certification Body for verification of corrective actions. However if verification of corrective action is to be undertaken at the manufacturing site or if a follow up evaluation is required is only possible at site, the Certification body evaluator visits the site for confirmation of the identified corrective action only or for follow up of non conformities identified during the previous evaluation.
4. If the sample drawn fails on independent testing, you will be informed of the same and advised to take necessary corrections for improving the product quality.
5. After taking the corrective actions, you must re-offer the products for sampling and testing by the certification body. The Certification body plans another visit to the site, verifies the corrective actions taken by the organization and draws the fresh sample from a stock of material that is representative of the normal production capacity of the organization.

STEP VII Certification decision

1. The Certification Body will review the onsite Stage 1 (if applicable) and Stage 2 evaluation reports, corrective action documentation provided by the applicant and verified if so required by the Evaluation team, and the independent test report(s) in order to make a certification decision.
2. Certificate shall be awarded to the manufacturer only for the range of products applied for and offered for evaluation and testing.
3. The decision for certification will be taken only when all requirements of the Scheme have been complied with.
4. The Certificate shall be awarded for fixed time tenure of 3 years, during which your operations and the products will be subjected to surveillance evaluations and testing, and beyond the 3 years period of validity the certificate will be renewed subject to ongoing compliance
5. The certification process should be completed within 12 months of the registration of the application failing which the certification body would reject your application.

STEP VIII Issue of a Certificate by Certification Body

1. The Certification Body issues a certificate to the manufacturer indicating that the requirements of the certification scheme have been met with and that the products conform to the relevant certification criteria. The name of the manufacturer with address of site, names of products, and the relevant certification criteria are clearly mentioned on the Certificate, along with effective date of certificate, validity of the certificate, name and address of the Certification Body and applicable logos.
2. The certificate should be issued within 7 days of the certification decision.
3. The Certification Body immediately informs the QCI about the grant of product certification.

STEP IX Agreement for usage of AYUSH Certification Mark(s)

1. The AYUSH Certification Mark(s) is not available for download from the AYUSH website/ any website.
2. Apply for authorization for affixing the applicable Certification Mark on AYUSH products for which you have been certified by the Certification body, on a prescribed format, which can be downloaded from the QCI website.
3. Submit the application form duly filled to the QCI secretariat .
4. Enter into a legally enforceable agreement with QCI authorizing you to affix the Certification Mark on the products for which you have been certified.
5. Based on this, the QCI website is updated with the name and address of the AYUSH manufacturer, the product covered in the scope of certification, the criteria against which certified, the Certification mark awarded, effective date of certificate and its validity.

STEP X Maintaining Certification

1. Ensure that production and testing facilities are maintained in working order and technical personnel are available at all times
2. Implement Internal Quality Assurance Protocol provided by the CB and maintain records
3. Inform production schedules to the CB when asked for
4. Ensure that the products certified under the Scheme comply with the Certification criteria – this will be checked by the CB through factory evaluation and market surveillance.

Using the AYUSH Certification Mark(s)

1. The AYUSH Certification Mark(s) is for use only by organisations that have achieved product certification.
2. The AYUSH Certification Mark(s) is to be affixed on the product and its packaging to depict product conformity to requirements of the AYUSH certification criteria.
3. The AYUSH Certification Mark(s) shall be affixed only on products conforming to relevant certification criteria, and non conforming products shall not to be marked with AYUSH Certification Mark(s).
4. The AYUSH Certification Mark(s) is owned by the Ministry of AYUSH and provided on its behalf to the certified unit. The AYUSH Certification Mark(s) can be used on all the manufacturing unit's communication tools such as company vehicles, letterheads, compliment slips, business cards, marketing collateral, advertising, exhibition graphics, electronic media.
5. Misuse of the AYUSH Certification Mark(s) would invite actions including rejection of application or suspension/cancellation of certification.

For any information, contact:

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