

SECTION IV
VOLUNTARY CERTIFICATION SCHEME FOR AYUSH PRODUCTS
Certification Process

1. SCOPE OF THIS DOCUMENT

This document explains the process of certification under the Voluntary Certification Scheme for AYUSH Products (hereinafter referred to as the Scheme) and the requirements that shall be followed in order to obtain, operate and maintain the Certification, and provide the basis to Ministry of AYUSH to grant Certificate of Pharmaceutical Products (CoPP) for AYUSH products.

2. OBJECTIVE

The objective of this document is to manage the operation of the Scheme and promote uniformity in its operation and the interaction between the Certification Bodies (from now on CBs), the manufacturing units seeking product certification and the Department of AYUSH.

3. SCOPE OF CERTIFICATION

3.1 The AYUSH Certification is awarded 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 the GMP Requirements based on WHO Guidelines for GMPs for Pharmaceutical Products or WHO Guidelines for GMP for Herbal medicines, as applicable, 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

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

Note

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

3.1.1 For any manufacturer to qualify for AYUSH Premium Mark certification, compliance to the domestic regulation and having in house testing facilities is a prerequisite.

- 3.2** The Voluntary Certification Scheme for AYUSH Products also provides the basis for grant of CoPP for AYUSH products to the manufacturing units certified for the AYUSH Premium Mark. AYUSH manufacturing units certified for AYUSH Premium Mark can approach the Ministry of AYUSH for grant of the CoPP for products and dosage forms included in the scope of certification of the AYUSH Premium Mark certificate.
- 3.3** The elements of the Certification process are:
- a) evaluation of the manufacturing facility and operations for manufacturing and hygiene processes and practices, and capability to manufacture AYUSH products of a desired quality on a continuous basis as per certification criteria,
 - b) verification if the specific products and dosage forms have been manufactured in accordance with data supplied by the manufacturing unit to the Licensing authority that formed the basis for their product approval;
 - c) evaluation of the quality of the AYUSH product(s) for compliance to relevant certification criteria through testing of products sampled from the manufacturing facility and the market or any other source.
- 3.4** The Scheme is open to any manufacturing unit in India.
- 3.5** The Ministry of AYUSH itself is not involved in the certification of AYUSH products. It is the mentor for the Certification Scheme, while the Scheme is managed and operated by QCI and certification is undertaken by independent product certification bodies duly accredited by NABCB and/or approved by QCI.
- 3.6** The process by which a manufacturing unit gains and maintains certification is summarized in the document “**Steps for obtaining Certification for AYUSH Products**”. The entire process of how to obtain certification of AYUSH products is also available on the website of Ministry of AYUSH (www....) as well as QCI (www.qcin.org).
- 3.7** The certification to the above mentioned criteria shall be carried out by the CBs duly accredited for the certification scheme as per ISO/IEC 17065 by NABCB and/or provisionally approved by QCI. To operate under the Scheme the CBs will require an extension of scope for Voluntary Certification Scheme for AYUSH Products within the accreditation for ISO/IEC 17065 and comply with the provisions of the document “Certification Process” and ‘Requirements for Certification Bodies’.

4. Requirements of Voluntary Certification Scheme for AYUSH Products

- 4.1** In addition to the requirements specified in the Certification criteria as relevant to the level applied/certified for, the following requirements specific to VCS for AYUSH Products shall also apply.
- 4.1.1 Internal Quality Assurance Protocol (IQAP)** – The Certification body shall develop an Internal Quality Assurance Protocol (IQAP), for describing the controls over the process and the product at various stages of production from raw materials, through processing and dispatch, the hygienic conditions, good manufacturing practices for ensuring the consistent production of AYUSH products that meet the specified certification criteria, based on a detailed assessment by the Certification Body’s Evaluation team, during stage 1 evaluation. While developing the IQAP, the certification body shall also consider the Master formulae and controls being exercised by the manufacturing unit for a specific product and dosage form submitted to the Licensing authority for product approval. The manufacturing unit shall be required to

comply with the same and the IQAP shall also become a part of the certification agreement. The essential elements that should be in the IQAP are given in Section IV IQAP document of this Scheme. The IQAP shall be maintained as a dynamic document and the CB shall review and amend the same if required, as and when the certification criteria undergoes modifications and revisions, whenever the manufacturing units processes and/or manufacturing facilities under go changes and the same have been approved by the Licensing authority. The manufacturing unit shall inform the certification body about changes in its processes, practices, operations, formulations and facilities and the approvals from the Licensing authority.

4.1.2 Availability of In-house testing facilities – Availability of in-house testing facilities for testing raw materials, finished products and conducting in-process testing required for ensuring appropriate process controls and as described in the agreed Internal Quality Assurance Protocol (IQAP), is a pre-requisite for obtaining AYUSH Premium mark certification. For tests for which inhouse testing facilities are not available, the manufacturing unit shall have an arrangement for testing the same in external test laboratories approved by the Department of AYUSH and/or accredited by NABL with the requisite scope. If the testing is done in NABL accredited test laboratories with requisite scope, these would be acceptable to certification bodies for the operation of the certification scheme .

4.1.3 Approval from the scheme owner for use of AYUSH Standard Mark and AYUSH Premium Mark - The “AYUSH Standard Mark” and the “AYUSH Premium Mark” for AYUSH Products are jointly owned by the Ministry of AYUSH and QCI, the joint Scheme Owners. The AYUSH manufacturing unit certified under this Scheme shall be required to obtain formal approval from the QCI for the use of the mark. Only Certification Bodies who are either approved by QCI or accredited by NABCB for this Scheme are permitted to evaluate and certify the AYUSH manufacturer units for the use of the AYUSH Mark on their products.

4.1.4 Certification Agreement – The certification agreements describes the terms and conditions which the AYUSH manufacturing unit is required to abide by after the grant of certification. The agreed IQAP shall also be part of the Certification agreement between the manufacturing unit and the Certification Body. Since the Scheme bestows self marking rights to the certified manufacturing unit, it is required to pledge its commitment to implement the agreed IQAP for ensuring conformity of products and processes to the Certification Criteria and the Scheme requirements on a continuing basis. The details of the requirements have been covered in the document “Section V Requirements for Certification Bodies”. The Certification Agreement shall also include requirements with respect to use of certificates and marks of conformity on the products by the certified manufacturing unit.

5. CERTIFICATION PROCESS

5.1 Registration of Application

5.1.1 The certification body shall provide the applicant manufacturing unit with an up-to-date detailed description of the evaluation and certification procedures, and the documents containing the requirements for certification, the applicants’ rights and the duties of suppliers of certified products (including fees to be paid by applicants and suppliers of certified products).

- 5.1.2** The above information along with the application format shall be made available on the CB's website.
- 5.1.3** The CB may design its own application format for the Voluntary Certification Scheme for AYUSH products, and while doing so shall ensure that as a minimum the following information is obtained.
- a) The general information about the manufacturing unit including its name and the address of its physical location; contact details; legal entity status; its functions and relationship in a larger organization, if any.
 - b) Details of the valid manufacturing licence, with validity dates and list of product(s) and their dosage form approved, issued by the licensing authority.
 - c) Dosage forms and names of product(s), from amongst those mentioned on the valid manufacturing licence for which certification is being sought with details in terms of Traditional medicines or proprietary product(s).
 - d) Ingredients in each product formulation;
 - e) The Level of Certification in terms of AYUSH Standard Mark / AYUSH Premium Mark and the Certification Criteria (as described in VCS for AYUSH Products - Certification criteria document) against which certification is being sought.
 - f) Information about judicial proceedings relating to its operations/product, any proceedings by any Regulatory body or suspension/cancellation/withdrawal of any relevant certifications/approvals under any Regulations.
 - g) General information about the applicant's activities, description of production processes, details of manufacturing facilities, technological context, facility layout, its human and technical resources (Internal as well as external, contracted, etc), number of shifts of operation, information on in-house laboratory, if any, accessibility to external testing facilities.
 - h) The controls exercised by the applicant for ensuring product conformity to the requirements described in the relevant certification criteria, including Internal Quality Assurance measures/plan.
 - i) Information concerning all processes outsourced, if any, by the applicant that have potential to affect conformity to requirements, with name(s) and address of the outsourced organization(s), the AYUSH manufacturing licence(s) with products approvals being held by them, the controls the manufacturing unit exercises for ensuring compliance to applicable certification criteria is required to be submitted at the application stage itself.
 - j) All other information considered essential for manday estimations and determining auditor competence.
- 5.1.4** The CB shall respond to all enquiries received from prospective applicants for AYUSH product certification with complete information for facilitating a registration of an applicant, within seven days of receipt of the query.
- 5.1.5** The AYUSH manufacturing unit shall apply to an approved Certification Body on the Application format prescribed by the CB.
- 5.1.6** The applicant must confirm that the manufacturing unit facility has been in production for at least one year, and that at least five commercial batches of one or more products within the dosage form for which certification is being sought, have been manufactured during the current licensed period. The applicant shall have evidence of having

manufactured all the products within a dosage form applied for, within a time period not exceeding the current licensing period and the previous licensing period.

5.1.7 The applicant manufacturing unit shall declare whether it has been an applicant/certified under this Scheme with or by any other certification body, and if yes then shall provide the previous evaluation reports to the new certification body. The certification body may verify the information provided by contacting the earlier certification body.

5.1.8 Certification is granted only against the current relevant certification criteria. The certification body shall review all applications for the above and ensure the same.

5.2 Application Review

5.2.1 A competent person of the CB shall undertake a review of the application received from the manufacturing unit, as per its documented procedure for ensuring the following ;

- a) the information about the manufacturing unit, the facilities and the product(s) to be certified is sufficient for the conduct of the application review and the subsequent certification process;
- b) any known difference in understanding between the certification body and the applicant is resolved, including agreement regarding certification criteria;
- c) the scope of certification sought is defined;
- d) the means are available to perform all evaluation activities;
- e) the certification body has the competence and capability to perform the certification activity.
- f) To determine the time required for conduct of the initial evaluation and surveillance evaluations. This shall be done in accordance with the CB's documented procedure for determination of evaluation time, which shall be established based on the requirements described in this document..
- g) To determine and nominate an evaluation team, evaluator and the technical reviewer competent for the certification scope applied for. This shall be done in accordance with the requirements specified in the document VCS for AYUSH Products – Requirements for Certification Bodies.

The procedure for conducting the application review, shall clearly describe the process for application review, responsibilities and the competence of personnel performing the application review.

5.2.2 Based on the review of applications for certification, deficiencies observed, if any, shall be informed to applicant within seven days of receipt of application. In case the information provided by the applicant is incomplete / insufficient for the purpose of conducting an application review, then the CB shall have procedure for obtaining additional information. The information thus received shall be recorded along with other information already received. Records of review shall be maintained.

5.2.3 Only applications found to be completely filled and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration shall be done within seven days of receipt of application or deficiencies communicated as per 5.2.2 above.

5.2.4 Antecedents of the applicants shall be checked in relation to the Scheme. If the manufacturing licence issued by Licensing authority has been suspended / cancelled

for a product or the factory during the last one year, the application from the same manufacturing unit shall not be entertained.

- 5.2.5** Applications from manufacturing units who have earlier either misused the AYUSH Certification Mark, or have been implicated / convicted by the court, or whose earlier certificate was cancelled because of violation of terms & conditions/misuse of certification mark shall not be registered within three years of conviction/strictures by the court/cancellation of the certificate by any CB.
- 5.2.6** Applications from manufacturing units found to be misusing the AYUSH Certification Mark while their application is being processed for grant if certificate, shall not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them shall be treated as per clause 5.2.5 given above.
- 5.2.7** Requests for grant of certificates from ex applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to subject to clauses 5.2.4, 5.2.5 and 5.2.6 above.
- 5.2.8** Certification Bodies shall reject or close all applications for certification under the following conditions;
- a) if Initial Evaluation is not carried out within six months of registration of application
 - b) if more than 20% of samples fail on factory testing during the Initial Evaluation and during the follow up Evaluation carried out after organization has confirmed necessary corrective actions.
 - c) If testing facilities are not completed within three months of Initial Evaluation, or else arrangements for testing for specified requirements in NABL accredited laboratories have not been made;
 - d) if during the Initial Evaluation it is observed that significant number of batches of the specific product and dosage form have not conformed to the Master Formula submitted to the Licensing authority and or have been subjected to corrections and rework
 - e) Non acceptance of internal quality assurance protocol within a month of Initial Evaluation;
 - f) Lack of competent personnel for production and testing,
 - g) If organizations shows no progress towards completion of corrective actions within three months of Initial Evaluation and six months of Registration of application.
 - h) Misuse of AYUSH Certification Mark
 - i) Evidence of malpractice
 - j) Voluntary withdrawal of application.
- 5.2.9** In the event of a closure/rejection of an Application, the application fee submitted with the application may be refunded as decided by the certification body.
- 5.3 Determination of evaluation time**
- 5.3.1** The certification body shall have documented procedures for determining time required for on site evaluation. The on site evaluation time determined for each client by the certification body, and the justification for the determination, shall be recorded. In determining the on site evaluation time, the certification body shall consider, among other things, the complexity of operations, the number of employees and the number of products offered for certification as given below;
- a) Basic on site evaluation time for Ayush Standard Mark - 1.5 mandays (in case the unit has a lab, time for its evaluation and testing of sample(s) to be added)
 - b) Basic on site evaluation time for Ayush Premium Mark - 2.5 mandays

- c) Evaluation time for each additional dosage form - Add 0.5 manday
- d) Number of employees - Add 0.5 manday each for employee strength more than 20 Full Time Equivalent, and for any multiples of 20 thereafter

5.3.2 The minimum evaluation time as above does not include the time spent either on preparation for the evaluation or for preparing the evaluation report.

5.3.3 The certification body shall not carry out any on site evaluation of duration lesser than as specified above, as testing for capability and verification of all production and testing records are an essential component of every on site evaluation. This includes all evaluations including those for surveillance, extension of scope etc.

5.4 Preparation and Planning for Initial Evaluation

5.4.1 Prior to undertaking the site visit, the certification body, through the members of its nominated evaluation team, shall undertake certain offsite activities as part of preparation and planning stage. These are:

- a) Study of all the information received and request for additional information, if required.
- b) Examination of the information on the scope of certification, level of certification, certification criteria, and shift operations for preparing a Stage 1 evaluation plan.
- c) Preparation of a checklist for requirements to be verified and evaluated during the onsite evaluation. If required, make modifications in generic GMP checklist developed by the Certification body for facilitating the evaluation. This modification can continue based on the observations made in stage 1 evaluation.

5.5 Initial Evaluation

5.5.1 Initial evaluation shall be carried out on site by a competent evaluation team in one stage for the AYUSH Standard Mark and two stages for the AYUSH Premium Mark.

5.5.2 The certification body shall communicate the composition of the evaluation team to the applicant manufacturing unit for identification of conflict of interest if any. If required sufficient background information in respect of the evaluation team members shall be provided to the applicant for this purpose. Any objections to the team by the applicant should be examined on merit.

5.5.3 Timings and date of Initial Evaluation shall be fixed in consultation with the organization ensuring that production processes representative of normal operations will be open for witnessing during the planned Evaluations. The duration and plan for Initial Evaluation shall be provided to the applicant.

5.5.4 Initial Evaluation of the product and the processes at the site of the applicant shall be conducted within one month of registration of application and or satisfactory fulfilment of all application requirements.

5.5.5 Initial evaluation for AYUSH Standard Mark

5.5.5.1 In the initial evaluation for AYUSH Standard Mark, the certification body shall list the applicable domestic regulatory requirements, and shall;

- a) verify compliance to the applicable certification criteria – applicable domestic regulatory requirements,
- b) witness the production processes covering as many products applied for as possible for verification of controls being exercised over manufacturing operations and practices
- c) evaluate the controls over incoming material, in process and finished products being implemented by the manufacturing unit are appropriate, adequate and being complied

with for ensuring continued conformity over the products characteristics/parameters as defined in the relevant Certification Criteria.

- d) verify adequacy of testing facilities in respect of the in-house tests carried out by the applicant, if any and or the arrangement with AYUSH approved laboratories or external NABL accredited laboratories.
- e) verify competence of testing personnel and testing facility by witnessing testing of representative number of sample(s) in the laboratory of the applicant manufacturing unit.
- f) draw samples for testing in an independent laboratory from each dosage form AYUSH product offered for certification, ensuring they are representative of normal production capability, as per sampling plan given below for testing in the factory as well for testing in an independent laboratory. They should be selected by the certification body from the factory (e.g. production, stock) in a manner that ensures that the impartiality of selection and the integrity of the sample is not compromised. While drawing sample from the factory, the certification body shall ensure that an appropriately packed and sealed counter sample from the same batch is left with the applicant unit.
- g) Based on information collected develop an Internal Quality Assurance Plan (IQAP) in discussion with the applicant (refer Clause 4.1.1 and Clause 5.5.11).

5.5.5.2 The evaluation team shall prepare an initial evaluation report

Deficiencies observed with respect to the certification criteria during the initial evaluation for AYUSH Standard Mark shall be informed in writing to the applicant

5.5.6 Initial evaluation for AYUSH Premium Mark

5.5.6.1 Stage 1 evaluation

5.5.6.1.1 During the Stage 1 evaluation for AYUSH Premium Mark, the certification body shall list the applicable regulatory requirements, and shall;

- a) Verify that the applicant has systems in place as per requirements of the certification criteria;
- b) Evaluate the status of GMPs for their appropriateness and adequacy on a continuous basis vis-à-vis the products, dosage forms and processes,
- c) Ascertain the availability of adequate equipment for production,
- d) Ascertain the availability of competent personnel for production and testing
- e) Ascertain availability of testing facilities in respect of the in-house tests carried out by the applicant, if any and or the arrangement with AYUSH approved laboratories or external NABL accredited laboratories
- f) Verify the availability of records required to be maintained as per certification criteria and
- g) evaluate the controls over incoming material, in process and finished products being implemented by the manufacturing unit are appropriate, adequate for ensuring continued conformity over the products characteristics/parameters as defined in the relevant Certification Criteria and develop an Internal Quality Assurance Plan (IQAP) in discussion with the applicant (refer Clause 5.5.11).
- h) the state of preparedness for the Stage 2 evaluation, and

5.5.6.1.2 Deficiencies observed with respect to the certification criteria during the Stage 1 evaluation shall be informed in writing to the applicant.

5.5.6.1.3 The evaluation team shall prepare a stage 1 evaluation report.

5.5.6.1.4 The Stage 2 evaluation by certification body shall take place only after necessary actions on the identified deficiencies have been taken and confirmed by applicant. The CB may seek documentary evidence or organize an onsite visit, if necessary, to verify the implementation of corrective actions.

5.5.6.2 Stage 2 evaluation

5.5.6.2.1 During the Stage 2 evaluation of the applicant, the team shall

- a) Verify and report compliance to the applicable certification criteria
- b) Witness the production processes covering as many products and dosage forms applied for as possible;
- c) Check for process controls being exercised for dosage forms and products under scope of certification for ensuring Product quality and conformance to regulatory requirements and undertake verification of all production and test records as per the requirements of the certification criteria. This would include review and verification of records from the receipt of raw materials, through formulation, processing, testing, storage, packaging and dispatch with details of Batch numbers and manufacturing dates, for all the products and dosage forms applied for in the scope of certification for compliance to WHO based (or stricter) GMPs and the data submitted with respect to the product and dosage form for product approval. Validation records, stability records for the product shall also be reviewed.
- d) If satisfied with above, draw samples of each dosage form AYUSH product offered for certification, ensuring they are representative of normal production capability, as per sampling plan given below for testing in the factory as well for testing in an independent laboratory (see clause 5.5.9); in case of Proprietary products, collect the product specifications that have been approved during the product approval by the Licensing authority, for ascertaining conformity of such products when sampled for independent testing.
- e) Witness the testing of at least one sample(s) of the product from one or more dosage forms for relevant important characteristics possible that can be tested in the factory testing laboratory for establishing its capability to test and for compliance to applicable certification criteria. If sample fails on factory testing, fresh sample to be drawn for factory and independent testing only after the organization has initiated a root cause analysis followed by corrective actions;
- f) Verify competence of testing personnel and the testing facility by witnessing testing of the sample in the laboratory of the organization.
- g) Confirm that the applicant manufacturing unit has manufactured and tested at least 5 commercial batches of one or more products within the dosage forms for which certification is being sought during the current licensed period, and relevant records as required by the certification criteria are available.

5.5.6.2.2 Any non conformities observed during Stage 2 evaluation with respect to the certification criteria shall be informed in writing to the applicant for taking necessary action.

5.5.6.2.3 The evaluation team shall prepare a stage 2 evaluation report.

5.5.7 Grading of Non Conformities

5.5.7.1 The non conformities observed during evaluations for AYUSH Standard Mark and AYUSH Premium Mark shall be classified as Major or Minor depending on their severity.

- a) A non conformity is classified as Major when it relates directly to the quality of the product and the manufacturing unit's capability to produce a product that would conform to the certification criteria. A number of minor NCs on the same aspect shall be clubbed together and raised as single major NC
- b) A non conformity is classified as Minor when it relates to other implementation issues which do not directly affect either the quality of the product or the manufacturing unit's capability to produce a product conforming to the certification criteria.

5.5.7.2 In case of major and minor NCs, the manufacturing unit shall carry out root cause analysis and inform the same along with correction and corrective actions, within a period of one month and 3 months respectively. All non-conformities are required to be closed before initial certification through verification of adequacy of the correction and corrective actions. All Major non-conformities, shall invariably require a follow-up audit.

5.5.8 The Evaluation report

5.5.8.1 The evaluation reports for initial evaluation for AYUSH Standard Mark and stage 1 and stage 2 for AYUSH Premium Mark shall clearly provide evidence and conclusions about the fulfilment of the evaluation objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria. The Certification Body shall develop appropriate report format(s) and report writing guidance document to ensure that the report provides, adequate and complete details for ensuring appropriate, evaluation, review and decision in respect of grant of certification.

5.5.9 Independent testing of samples

5.5.9.1 The manufacturing unit shall offer all products within a dosage form for which certification is being sought in batch sizes that are representative of their normal production. The certification body shall sample at least 25% of the products offered within the dosage form for independent testing. However if the manufacturing unit is testing its finished products in an NABL accredited laboratories, external or inhouse with due scope, and the test reports are available during the evaluation, only one product from each of the dosage forms shall be sampled for independent testing. In the latter case, if the sample fails on independent testing, fresh sampling will revert to the normal 25% of the products offered.

5.5.9.2 The samples drawn for independent testing, shall as far as possible not be from the same Batch as the sample drawn for factory testing.

5.5.9.3 The samples shall be drawn in a manner so as not to contaminate the product while sampling and packing.

5.5.9.4 The samples(s) shall be packed and sealed such that the product integrity is maintained for its intended shelf life.

5.5.9.5 The samples shall be clearly identified with their name, dosage form, batch identification and suitable identification to enable traceability to the applicant and the Initial Evaluation.

5.5.9.6 As far as feasible, the identity of the sample with respect to its Brand name, and the name of manufacturer as depicted on the original packing, shall be masked.

5.5.9.7 The samples shall be drawn in quantities adequate to facilitate their testing for all requirements specified in the Criteria.

5.5.9.8 If the product is affected by the conditions of temperature, handling and storage, then care shall be taken to ensure that the sample is drawn and maintained under those conditions for testing its conformity to specified criteria

5.5.9.9 The samples of AYUSH product(s) drawn for independent testing shall be forwarded to an NABL accredited testing laboratory for ascertaining conformance to specified criteria. The specified criteria shall be clearly mentioned and communicated to the testing laboratory. The samples(s) shall be duly coded and as far as possible, the identity of the manufacturer shall be hidden. The sample(s) shall be so despatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained.

5.5.10 Certification Body shall maintain records of all certification activities – application registration, documents provided by applicant, on site evaluation report including factory testing results, Test reports of sample sent for independent testing.

5.5.11 Internal Quality Assurance Protocol

5.5.11.1 An internal quality assurance protocol for controlling the quality of the AYUSH product(s) during various stages of production up to its despatch based on the general Internal Quality Assurance Protocol given under this scheme shall be developed by the CB in consultation with the applicant for each product and dosage form and given to the applicant. The applicants consent to comply with the same shall be obtained. This protocol advises the manufacturer on the protocol to be adopted for ensuring the quality of the AYUSH products. This protocol covers the following;

- a) Definition of a Batch ;
- b) The frequency of tests on the raw material, if necessary ,
- c) The controls at the intermediate stages of manufacture ,
- d) The parameters of quality and contaminants as specified in the applicable certification Criteria and product approval specification,
- e) Criteria for the conformity of the Batch to the various requirements of the applicable certification Criteria and product approval specification as applicable ,
- f) Sample size,
- g) Frequency of testing,
- h) Method of testing,
- i) List of instruments/equipments requiring periodic calibration,
- j) Compliance to Regulatory requirements,
- k) Records to be maintained.
- l) The format for maintaining test and other relevant records and
- m) Method of applying the AYUSH Mark of Conformity on the product including “ Not for Export” on all products intended for domestic market

5.5.11.2 The internal quality assurance protocol is a dynamic document and shall be reviewed and amended, if required, as when the certification criteria undergo modifications and revisions, when there are changes in the processes, manufacturing machinery, facility or otherwise. The applicant / certified unit under this Scheme shall inform the certification body about changes in its processes, manufacturing machineries, facilities and changes in the IQAP and the approval for the same received from the Licensing authority. The certification body shall review the modified IQAP, based on the information provided by the manufacturing unit or through a site evaluation. The date of implementation of the revised internal quality assurance

protocol shall be communicated to applicants and to the manufacturing unit that have been certified by the CB under this scheme.

5.5.12 A Brand Name declaration shall be obtained from the applicant indicating the Brand names the manufacturer intends to use on products covered under the AYUSH Certification Scheme. The applicant shall have to provide proof of ownership of the Brand name, and to facilitate any product recall if such a situation were ever to arise during the operation of the certification of scheme..

5.6 Final Evaluation

5.6.1 The purpose of this process step is conduct an evaluation of all the information gathered through the Initial Evaluation for Standard AYUSH Mark and Stage 1 and stage 2 evaluations for AYUSH Premium Mark, and the results of independent testing to ascertain if all the process steps as described in the certification process leading to grant of certificate have been fulfilled and if the evaluation confirms the capability of the applicant, for manufacturing the relevant AYUSH product (s) complying with the requirements described in the relevant certification criteria and the data submitted to the Licensing authority for product approval.

5.6.2 The final evaluation shall ensure the following:

- a) The availability of all relevant manufacturing and processing equipment required for the production/manufacture of the relevant AYUSH product.
- b) Availability of authorized and/or adequate power and water supplies, where such supplies are required for manufacturing and testing.
- c) Availability of adequate test facilities for conduct of tests as per the agreed IQAP and the requirements specified in the Certification criteria. The facilities may include in-house facilities and/or Ministry of AYUSH approved or NABL accredited external laboratory. In case, if the applicant is planning to get part/full parameters tested in an external laboratory then the applicant should be able to demonstrate that it will still be able to meet the requirements specified in agreed IQAP, with respect to frequency of testing and availability of external reports, where the tests results are necessary for approval of raw materials/intermediate materials and finished products, before they can be released for the next stage.
- d) Availability of Competent and qualified personnel for production and testing of AYUSH product(s) as relevant.
- e) Evaluation regarding compliance to applicable Certification Criteria including WHO based GMPs and the data submitted with respect to the product and dosage form for product approval.
- f) Evaluation regarding conformity of the product(s) and raw/intermediate material wherever specified, with parameters/ requirements of the certification criteria.
- g) Acceptance from the applicant for following the Internal Quality Assurance Protocol, for the products for which product certification is being sought.
- h) Necessary documentation for proof of legal entity and authentication of premises of manufacture where certification is being sought.
- i) The applicant's manufacturing unit having been in production for at least one year.
- j) The applicant manufacturing unit has manufactured at least five commercial batches of one or more products within the dosage form for which certification is being sought during the current licensed period.

- k) Acceptance from the applicant for other certification requirements like the fee, Brand name declaration, etc.
 - l) Verification of implementation of corrective actions and closure of all NCs raised.
 - m) Any other requirements prescribed by the Certification Body.
- 5.6.3** Based on the evaluation as above, recommendations for proceeding to next step of independent review and decision making shall be made. When the evaluation indicates that some requirements of the certification criteria or the certification scheme have not been met, then these requirements shall be completed and evaluated before proceeding to the next step.
- 5.6.4** The final evaluation shall be carried out by a competent personnel, duly authorised for this function. The team leader designated for the conduct of Initial Evaluation may also be authorised for this activity.
- 5.6.5** Records of final evaluation along with all supporting documents and reports shall be retained at least for the period of two certification cycles.
- 5.7 Review**
- 5.7.1** An independent review shall be carried out by person(s) or a committee having the relevant competence. The responsibility for review function, shall however be that of the certification body.
- 5.7.2** The Criteria for review shall be documented. It shall be based on the product requirements as specified in Certification Criteria and the certification scheme and process requirements as stated in this document.
- 5.7.3** Any information on which a review and decision is based which comes from any source other than the evaluation process, for example complaints, information received from regulators or Ministry of AYUSH, etc, should be made known to the applicant and given an opportunity to comment on it .
- 5.7.4** Nonconformities, which raise any doubt as to the conformity of the product must be corrected and the correction verified by the certification body (by site visit or other appropriate forms of verification) before certification is granted. The nonconformities and their resolution should be documented and made available for the purpose of review.
- 5.7.5** The records of review shall be retained and shall provide adequate confidence that all relevant aspects were examined prior to making recommendations.
- 5.7.6** The recommendation for certification decisions, whether positive or negative shall justify and document the basis for the same.
- 5.8 Certification Decision**
- 5.8.1** AYUSH Certification decision shall be the sole responsibility of the certification body and the decision shall be taken by its internal person(s) competent for the job provided they have not been involved in the process of evaluation of applicant manufacturing unit.
- 5.8.2** The person(s), who take(s) the decision on granting/withdrawing certification within the certification body shall have a level of knowledge and experience sufficient to evaluate the information obtained from the evaluation process and the review recommendations. Review and the certification decision may be completed concurrently by the same person (s).
- 5.8.3** Impartiality and absence of conflict of interest shall be ensured before entrusting the task of certification decision making.

5.8.4 The certification body shall grant certification for product(s) after ensuring complete compliance to the Certification Criteria and certification scheme requirements and all non conformances have been addressed. There shall be no conditional grant of certification.

5.8.5 In case based on the evaluation the Certification Body decides, not to grant certification to all product(s), few or any of the product(s) applied for, then it shall notify the applicant of the decision not to grant certification, and shall identify the reasons for the decision. If the applicant expresses interest in continuing the certification process, the certification body can resume the process for evaluation from the process as described above.

5.9 Certification Documentation

5.9.1 On grant of certification, the Certification body shall inform the organization and issue a Certificate, uniquely identified, with the following information;

- a) the name and address of the certification body;
- b) the name and address of the manufacturing unit and the address of the site certified;
- c) the effective date (the date on which certification is granted, which shall not precede the date on which the certification decision was completed) and the expiry date of certification. The date of granting, shall also include date of extending or renewing the certification, if applicable;
- d) the expiry date or recertification due date consistent with the recertification cycle;
- e) the certification criteria against which the certification has been awarded, complete with issue number and/or revision;
- f) the scope of certification with names of products and dosage forms aligned to the Licensed formulation as given on the manufacturing and product approval licences;
- g) Any other information required by the certification criteria used for certification;
- h) In the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents;
- i) The formal certification documentation shall include the signature of the individual(s) of the certification body assigned such responsibility.

5.9.2 Formal certification documentation shall only be issued after, or concurrent with, the following:

- a) the decision to grant or extend the scope of certification has been made;
- b) certification requirements have been fulfilled;
- c) the certification agreement has been completed/signed. The contents of the Certification agreements have been detailed in the document VCS for AYUSH Products – Requirements for Certification Bodies.

5.9.3 No Brand names of the AYUSH Products shall be mentioned on the Certificate document or any other document intimating grant of certification. Licensed formulation as given on the licences shall be mentioned on the certificate document or any other document intimating grant of certification.

5.9.4 The certificate for product certification shall be for a maximum period of 3 years from the date of decision to grant the product certification.

5.9.5 The certification decision shall clearly inform the manufacturing organization that they have to seek approval from QCI (representing the Ministry of AYUSH) for using the AYUSH Certification Mark on their products.

5.10 Directory of AYUSH manufacturing units and AYUSH products certified under this Scheme

5.10.1 The certification body shall maintain and make publicly available on its website, directory of valid certifications that as a minimum shall show the name, relevant certification criteria (normative document), scope of certification, geographical location (e.g. city and country) and validity of certification for each certified manufacturing unit. The information maintained by the Certification Body on its website shall also help the user to get readily the following information about the certified AYUSH products:

- a) identification of the AYUSH product and dosage form;
- b) the standard(s) and other normative document(s) to which conformity has been certified;
- c) identification of the certified manufacturing units and other details like address, etc.

5.10.2 The Certification Body shall also display suitably on its website the names of manufacturing units under suspension and those whose certificates have been cancelled.

5.10.3 Apart from the information made available on its website the Certification Body shall also have a provision and system for confirming validity of a certificate on request.

5.10.4 The Certification Body shall have a procedure for frequent updating of the information on its website.

5.11 Surveillance Evaluation

5.11.1 Surveillance evaluations of the certified sites during the first certification cycle shall be carried out at a frequency of at least once in twelve months, ensuring that the gap between two surveillance evaluations does not exceed twelve months. The Certification Body may allow a grace period of one month based on valid grounds beyond which delays shall lead to suspension of the certificate.

5.11.2 The mandays for surveillance assessment shall be determined as stated in this document.

5.11.3 The surveillance evaluation shall be carried out onsite at the certified premises. The objectives for this evaluation shall generally be the same as Stage 2 evaluation objectives.

5.11.4 An evaluation plan shall be prepared in advance and forwarded to the certified unit along with names of the evaluation team members, their role in the evaluation, duration of evaluation and evaluation dates.

5.11.5 The certification body shall ensure that critical steps in an operation or a combination of production operations on given days are witnessed and their controls verified, and witness testing of products in progress for assessing continued competence of testing personnel and testing capability. Planning for surveillance evaluations shall ensure this.

5.11.6 At least one sample of each product within each dosage form covered under scope of certification shall be sampled either from the factory or the market for independent testing in an NABL accredited laboratories, with a view to covering all the products an dosage form within a certification cycle. The certification body shall plan to ensure the same.

5.11.7 During the surveillance evaluation, the evaluation team shall as a minimum verify and report on the following;

- a) Compliance to the requirements of the certification criteria and other requirements of the certification process;
- b) Status of good manufacturing practices and hygienic conditions;
- c) Records required to be maintained as per GMP Requirements based on WHO Guidelines for GMPs for Pharmaceutical Products or WHO Guidelines for GMP for Herbal medicines, as applicable;
- d) Continued compliance of all products within a dosage form, in the scope of certification, manufactured since the last assessment to data submitted for each product and dosage form to the Licensing authority for product approval. Records from the receipt of raw materials, through formulation, processing, testing, storage, packaging and dispatch with details of Batch numbers and manufacturing dates, for all the products and dosage forms in the scope of certification shall be verified and reported. Validation records, stability records for the product shall also be verified;
- e) Compliance to the Internal quality assurance protocol;
- f) Handling and disposal of non-conforming products;
- g) Actions taken on discrepancies observed during the previous evaluation, failure of samples if any reported and informed to the manufacturing unit;
- h) Draw samples for factory testing and testing in independent laboratory;
- i) The continued availability of the manufacturing machinery and test equipment and changes since the previous evaluation. In the event of changes the evaluator shall ascertain if they are adequate for control of processes and testing of the products;
- j) Information on production of AYUSH products and the names of consignees to whom AYUSH marked products have been dispatched for the purpose of market sampling.

5.11.8 If any non-conformities are observed, the same shall be categorized as either a Major or a Minor as per description on non-conformity given in Clause 5.5.7 above. The non-conformity report shall be provided to the client in writing, generally on site, for correction and corrective action. Details of the same shall be reported in the Surveillance evaluation report.

5.11.9 If the surveillance evaluation results in an infructuous visit due to any reason, and neither the production and testing of products are witnessed nor products drawn for independent testing, the CB shall conduct another surveillance evaluation. Such additional evaluations may be charged to the certified unit as decided by the Certification Body.

5.12 Market samples

5.12.1 Samples of certified products shall be purchased from the market or procured from organized consumers and tested in NABL accredited laboratories for ascertaining compliance to requirements of the Certification Criteria.

5.12.2 The certification body shall draw a minimum of 2 samples from each dosage form certified from the market for each client in a year.

5.12.3 In case where the unit is certified to a number of products of different dosage forms under the same certificate, certification body shall attempt to draw the market samples in a manner so that all dosage forms and the entire range of products within each dosage form are covered in factory and market sampling for independent testing within a certification cycle.

5.12.4 Market samples shall be drawn in the original packaging and product integrity shall be ensured by the certification body.

5.13 Dealing with failure of samples reported in independent laboratory reports

5.13.1 Failure of sample of certified product, drawn from the factory or the market, to comply with the criteria shall be communicated to the certified manufacturing unit for investigation, root cause analysis and proposed corrective actions within 15 days of intimation. The CB shall respond to the proposed corrective actions within 5 days and the manufacturer shall implement the corrective actions within one month from acceptance of the corrective actions by the CB.

5.13.2 Depending on the nature of the failure reported, the CB shall decide on one or more of the following ;

- a) Draw additional samples of the product and dosage form manufactured around the same time from the market;
- b) Organize for an additional surveillance evaluation immediately
- c) Increase the frequency of surveillance evaluation
- d) Increase the number of market samples

The manufacturer shall be informed of the decision taken.

5.13.3 When the failure of the sample is in requirements relating to Contaminants the CB shall advise the manufacturer to;

- a) Stop despatches of the failing Batch if stocks are available either at the site or in their warehouses;
- b) Recall the failing Batch from the market;
- c) Identify all AYUSH products manufactured with same starting herbal material, or those manufactured during the same time under similar controls, and examine their Batch processing records and Batch packaging records and retest the Reference samples of these Batches in the custody of the Manufacturer; or
- d) Suspend the certification, till adequate and effective corrective actions are taken.

5.13.4 Based on the satisfactory demonstration of root cause analysis and corrective actions to prevent such recurrences in future, the decision to revert back to the normal operation of certification shall be taken by the Certification Body. Testing of fresh samples of the specific product and dosage form manufactured after implementation of corrective actions may be one of the mechanisms of satisfactory demonstration. Based on the root cause analysis, the CB may decide to increase the internal controls described in the IQAP. Evaluation of adequacy of the revision in IQAP and output of the relevant changes may be another means of satisfactory demonstration. Based on the specific situations the certification body shall decide the appropriate actions and record the justification for the same.

5.14 Suspension

5.14.1 The certification body shall issue instructions to the certified manufacturing units for suspension of certification when;

- a) any sample fails to conform to the requirements relating to Contaminants

- b) 2 consecutive samples, from the factory or market, as determined by date of manufacture, fail to conform to the requirements of the product requirements other than contaminants;
- c) Unsatisfactory performance during two consecutive Surveillance evaluations on account of any of these aspects is observed;
 - i) Unsatisfactory hygienic conditions
 - ii) Non implementation of Internal Quality Assurance Protocol
 - iii) Failure of sample on factory testing (in case of failure of contaminants 5.14.1 a) above applies)
 - iv) Important testing equipment not calibrated and no action taken by the certified unit
 - v) Testing equipment out of order and no alternate arrangements for testing
 - vi) Non availability of testing personnel and absence of alternate arrangements
 - vii) Repeated failure to take actions in respect of Major NCs, with in the time limit prescribed or Major raised on the same issue in 2 consecutive onsite evaluations
- d) Serious failures in compliance to GMP/GHP requirements during a surveillance.

5.14.2 The certification body shall issue due notice of at least one week for suspension of certification to the manufacturing unit. In case of serious failures mentioned at 5.14.1 a) and c) above, the notice may not be required.

5.14.3 On receipt of instructions for suspension of certification, the certified units shall suspend using AYUSH certification mark on AYUSH products being manufactured by them with immediate effect. The manufacturing unit shall be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.

5.14.4 While under suspension, the certification body shall ensure that despatches of certified AYUSH products to the market/customer are withheld until the product in stock has been reassessed for conformity to the criteria. The manufacturing unit shall reassess the quality of the products in stock and the CB shall verify this reassessed stock for conformity to the certification criteria before allowing its despatch.

5.14.5 When certification is suspended, the certification body shall require that, during the period of suspension, the certified unit makes no misleading claims and should advise relevant existing and potential purchasers regarding the status of certification, and ceases to use the certification mark on the products manufactured since the date of notification of suspension. The certification body shall ensure that the manufacturing unit has procedures in place to ensure that a non conforming certified AYUSH product that gave rise to suspension of certification is recalled.

5.14.6 The information about the suspension and withdrawal of certification shall be made publicly available by the Certification Body on its website

5.14.7 The certification body shall revoke suspension only when ;

- a) Corrective actions have been taken and verified by the certification body.
- b) Reports of Samples of AYUSH products manufactured after corrective actions, both during factory and independent testing confirm compliance to Criteria requirements.

5.14.8 Suspension shall not exceed a period of six months. The manufacturing unit's inability to resolve issues relating to suspension within this period shall lead to cancellation of certification.

5.15 Renewal

- 5.15.1** The certification body shall send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period.
- 5.15.2** The manufacturing unit shall apply for renewal in the prescribed format along with fee, if any prescribed by the CB at least 3 months before expiry of the certification.
- 5.15.3** The onsite recertification evaluation conducted towards the end of third year and before the expiration of the certificate shall be same as the initial evaluation (in case of AYUSH Premium Mark stage 2 evaluation) during which the certification body shall verify fulfilment of the entire requirements of certification criteria..
- 5.15.4** The certification body shall review the performance of the certified unit who has sought renewal of the Certificate, with respect to compliance to certification criteria during the entire certification cycle, prior to a decision on the renewal of the certificate.
- 5.15.5** The review shall be based on
- a) surveillance and renewal evaluation reports carried out during the certification cycle. The NCs raised and the satisfactory resolution of the issues raised and their effectiveness
 - b) Quantum of AYUSH products conforming to criteria expressed as percentage of quantity manufactured
 - c) Handling and disposition of non conforming products
 - d) Test reports for samples drawn from the factory and the market,
 - e) Any suspension of certificate during the previous validity period;
 - f) corrective actions taken
 - g) complaints if any received,
 - h) Adverse information, if any.
- 5.15.6** The review shall be conducted by competent person (s) designated for the function.
- 5.15.7** The decision for renewal of certificate shall be taken by the competent personnel authorised for the same, based on the satisfactory performance of the certified units as revealed through the review process.
- 5.15.8** The certification Body shall not renew certification with conditions for compliance to be verified subsequently. There shall be no conditional renewal of certification.
- 5.15.9** When performance of the certified units is not satisfactory, the certification body shall withhold the renewal of the certificate to the manufacturing organization clearly stating the reasons and give time for effecting corrective actions. The verification and decision on renewal should be taken within 3 months of the expiry date.
- 5.15.10** The corrective actions shall be verified generally on site unless the CB can verify the same off site prior to considering for renewal of certificate. The justification for off site review shall be recorded.
- 5.15.11** The renewal shall be effected from the date of the expiry of the previous certificate and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The manufacturing unit shall not claim certification or use the Certification Mark during this period.
- 5.15.12** In case the manufacturing unit does not complete satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.
- 5.15.13** When a certificate is not renewed, it shall expire at the end of validity period.
- 5.16 Cancellation**
- 5.16.1** Certification body shall cancel the certificate when ;

- a) Certified unit contravenes the terms and conditions of certification and provisions of AYUSH certification scheme like repeated failures of samples, suspension of certificate, inadequate corrective actions, lack of compliance to Internal quality protocol, misuse of AYUSH Certification Mark(s) etc
- b) AYUSH products are failing and not conforming to the requirements of the Certification Criteria repeatedly and the corrective actions taken are not ensuring compliance, or the proposed plan for corrective actions will take a considerable time beyond 6 months for implementation;

5.16.2 Certification body shall cancel the product certification certificate at the request of the certified unit, if the operation(s) in the certified units premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.

5.17 Changes affecting certification

5.17.1 When the certification scheme introduces new or revised requirements both in Certification criteria and Certification process requirements that affect the manufacturing unit, the certification body shall ensure these changes are communicated to all applicants and the certified units. The certification body shall verify the implementation of the changes by its applicants and certified units and shall take actions required by the scheme.

5.17.2 The contractual agreement with the certified unit shall have clearly defined clause which shall make it mandatory for the certified unit to agree to implement the changes in his processes and product, necessitated by the changes in above requirements.

5.17.3 Following decision on, and publication of, the changed requirements, the Certification Body shall verify that each certified unit makes necessary adjustments within such time as, in the opinion of the certification body, is reasonable, unless the Certification Scheme owner itself has decided the time lines. The verification may involve steps like onsite re-evaluation, testing of samples in an independent laboratory, evaluation, review and decision and issuance of revised formal certification documentation to extend or reduce the scope of certification, etc. In case the changes necessitate changes in IQAP, the certification body shall review and revise the IQAP and make necessary revision in the Certification agreement to reflect the revised IQAP. The records shall provide justification for choice of activities chosen for the purpose verification of changes.

5.17.4 The certified unit shall also be bound by the certification agreement to inform the Certification Body about changes initiated by it; including changes in process and product design, changes in technology of manufacturing, changes in IQAP, etc; which have the potential to affect the Product compliance to the certification criteria, and the approvals received from the Licensing authority. Based on the nature of changes informed, the Certification Body shall decide the verification activities, which may include the activities as stated in clauses 5.5 and all other process steps, as relevant.

5.18 Change of location/Ownership/Name

5.18.1 The certified manufacturing unit shall inform the CB of any change in the location of the manufacturing unit. On receipt of such information, the certification body shall issue instructions to the certified manufacturing units for suspension of certification with immediate effect and processed for cancellation of certification.

5.18.2 In the event of change of Ownership, the manufacturing unit shall provide necessary documentary evidence of having informed the change to the Licensing authority and its acceptance by the Licensing authority. The new management of the manufacturing unit shall submit its acceptance to the agreement for Certification with the CB, Internal Quality Assurance Protocol and payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

5.18.3 In case of change of Name, the manufacturer shall inform the change in the name to the CB supported with documentary evidence including a copy of the manufacturing licence issued by the Licensing authority, and if satisfied the CB shall endorse the Certificate in the new name.

5.19 Extension of scope

5.19.1 The certified unit shall be required to make a formal application for the purpose of inclusion of additional dosage forms and product(s) therein, and or additional products within dosage form(s) mentioned in the scope of certification, on a application form, prescribed if any, to the certification body.

5.19.2 The process steps of receipt of application information and application review, planning for evaluation, determination of competence of evaluators and others like for evaluation, review and decision making functions shall be the same as that for initial evaluation. The evaluation time shall be estimated as per details provided at CI 5.3 above.

5.19.3 Extension of scope of certificate for inclusion of additional dosage forms and products under the same certificate shall be done after:

- a) ascertaining that the certified organization has requisite resources required e.g. raw materials, process controls, manufacturing machinery, test facilities and technical skills .for dosage forms and products under extension of scope, through an on site evaluation,
- b) Verification if the specific additional products and dosage forms under extension of scope have been manufactured in accordance with data supplied by the manufacturing unit to the Licensing authority that formed the basis for their product approval, and
- c) Conformity of samples of products of the new dosage form, to requirements of the Certification Criteria when tested in an independent laboratory.

5.19.4 For extension of scope of certificate for inclusion of additional products within an existing dosage form of the AYUSH Product under the same certificate, the certification body shall ;

- a) Verify if the specific additional products within an existing dosage forms under extension of scope have been manufactured in accordance with data supplied by the manufacturing unit to Department of AYUSH that formed the basis for their product approval
- b) Draw samples of additional products as per sampling plan at CI 5.5.9 for independent testing.
- c) Process for extension of scope for the additional products on the basis of test reports of additional products in the same dosage form, provided by the manufacturer, subject to conformity of samples on independent testing mentioned at a) above.

5.19.5 The extension of scope shall be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation.

Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

5.20 Fee

5.20.1 A fee to be charged to the organization for various activities of the AYUSH Product certification scheme, without any discrimination between units, geographical location, size of the unit.

5.20.2 The CBs fee structure shall be publically accessible and also be provided on request.

5.20.3 CB shall notify and obtain consent to its fee structure from the manufacturing units prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the manufacturing units certified under this scheme of certification for their acceptance.

5.20.4 Records

5.20.4.1 The certification body shall have a documented policy and documented procedures in respect of the retention of records to demonstrate that all certification process requirements have been effectively fulfilled.

5.20.4.2 The certification related records shall be retained for two certification cycles. If required by law or any regulation relevant to the products certified, then the records shall be retained for longer period in accordance with the relevant regulation.

5.20.4.3 The certification body shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained.

5.20.4.4 If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and two more cycles. Otherwise, records shall be retained for a period defined by the certification body.

5.20.4.5 The certification records shall include records for all manufacturing units, which includes all organisations that submitted applications, and all organizations evaluated, certified, or with certifications suspended or withdrawn/ cancelled. The records of certification of units shall include the following:

- a) Application information and results of application review and mandays estimation and team competence records;
- b) Evaluation planning and preparation records, Evaluation plans and other related records;
- c) Justification of the methodology used for sampling and justification for evaluation time determination
- d) Records of initial evaluation reports for AYUSH Standard mark and Stage 1 and stage 2 evaluation reports and related records for AYUSH Premium mark; Test reports from independent laboratory;
- e) Initial and final evaluation records, Records of verification of correction and corrective actions;
- f) Records of review and certification decisions; committee deliberations and decisions, if applicable;
- g) Certification agreement;
- h) Certification Documentation (certificate, etc), including scope of certification and certification criteria;

- i) Records of complaints and appeals, and any subsequent correction or corrective actions;
- j) Related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors, technical experts, evaluators, review personnel, evaluators and decision makers, etc, as relevant;
- k) Any other records as relevant to the certification process, in order to provide confidence that the certification scheme requirements were complied with.

5.21 Complaints and appeals

- 5.21.1** The certification body shall have a documented procedure for handling of complaints and appeals.
- 5.21.2** The procedure for complaint handling shall include complaints from all stake holders, its certified manufacturing units as well as customers of its certified units.
- 5.21.3** The procedure for receipt and handling of complaints shall be made available to public on the CB's website and shall also be easily accessible on the website.
- 5.21.4** Upon receipt of a complaint or appeal, the certification body shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it. The certification body shall acknowledge receipt of a formal complaint or appeal.
- 5.21.5** The certification body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.
- 5.21.6** The procedure shall include the process steps for receiving and recording, evaluating and establishing validity of the same, investigating and make decisions on complaints and appeals. The process step shall also include the activities of root cause analysis, correction and corrective actions.
- 5.21.7** If the complaint relates to a certified unit and the certified product supplied by the certified unit, the examination and evaluation of the complaints shall take into consideration the effectiveness and implementation of the certified unit's certification system. The process of establishing validity of the certified product, should generally involve processes like conduct of additional surveillance activities – visit to certified unit's premises for special evaluation, testing and evaluation of certified product, against which the complaint had been received, etc. The decisions on complaint shall then be based on the result of additional surveillance activities.
- 5.21.8** The CB's complaint handling process shall document the actions to be taken by the CB as well as the certified unit, in case the certified product, against which the complaint was received was observed to be non-compliant with the specified requirements. Some of these actions/conditions shall also be included in the CB's legally enforceable contract with the certified unit.
- 5.21.9** The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them.
- 5.21.10** The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal. To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy for the manufacturing unit, or been employed by a manufacturing unit, shall not be used by the certification body to review or approve the resolution of a complaint or appeal for

that manufacturing unit within two years following the end of the consultancy or employment.

- 5.21.11** Whenever possible, the certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.
- 5.21.12** In respect of appeals the CB shall ensure that the individual(s)/committee entrusted with handling of appeal and its resolution decision shall be independent of the persons involved in certification related recommendations and decision and their position in the CB shall be such that it shall not be possible to influence their decisions with respect to the subject of the appeal.
- 5.21.13** The procedure shall also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions reached and also communicating to the appellant about the provision for giving an opportunity to formally present his case.
- 5.21.14** Based on the presentation made, the individual or a committee appointed for hearing the case shall take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process shall be given to the appellant.
- 5.21.15** The certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.
- 5.21.16** The certification body shall take any subsequent action needed to resolve the complaint or appeal.

Amendment Record Sheet				
Sl No	Date of Amendment	Description of Amendment	Incorporated by	Approved by
1	3rd Jan 2017	Clause 5.11.9 removed considering amendment in clause 5.11.1 of version 2 July 216	Sona Sharma(SS)	Anil Jauhri(AJ)
2	3rd Jan 2017	Clause 5.11.1, Version 2 July 2016 - Surveillance frequency changed from six month to once in twelve month.	SS	AJ