

<b>Issue No: 01</b>	<b>Procedure for Conducting Conformance Assessments</b>		
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## 1.0 PURPOSE

- 1.1 To define the procedure for planning, conducting and reporting of Stage - 1 & 2 assessments carried out for FCI accreditations / **certification services** under Ayush product certification scheme.

## 2.0 SCOPE

- 2.1 This procedure applies to all conformance assessments conducted by FCI. The Ayush certification is awarded at two levels

- Ayush Standard Mark, which is based on compliance to the domestic regulatory requirements and
- Ayush Premium Mark, which is based on either or both of the following options **in addition to compliance with Domestic regulation requirement.**
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**Option A:** compliance to the GMP requirements based on W.H.O. guidelines and levels of contaminants as given in certification criteria document.

**Note:** 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.

For the time being the certification is available for herbal products only.

**Option B:** compliance to regulatory requirements of any importing countries provided these are more stringent than option A above.

**Note:** For the time being this certification is available for herbal products only.

For any manufacturer to qualify for Ayush Premium Mark Certification, compliance to the domestic regulation and having inhouse testing facilities **or sourcing of testing from independent lab** is a pre-requisite.

## 3.0 RESPONSIBILITIES

- 3.1 The Designated Person shall be responsible for ensuring that the audit is planned, managed and conducted in accordance with this procedure.

## 4.0 PROCEDURE

### 4.1 Audit Planning and Preparation

- 4.1.1 Assessments shall be carried out on site and other locations, where the scope of activity is carried on.

#### 4.1.2 Selection of assessment team under certification scheme for Ayush Products:

- 4.1.2.1 The assessment team selected for the scope shall have appropriate knowledge of the product, the applicable regulatory requirements, the process and GMP adopted and practiced in manufacturing of Ayush products of the organization to be evaluated and testing in case the unit has an in-house plant.

- 4.1.2.2 The assessment team can be supplemented by technical experts meeting the competency requirements mentioned under 4.1.2.12 of QMS/P-06.

- 4.1.2.3 Initially ISO 9001/ISO 22000 auditors or product certification assessors as assessors provided they have education and work experience as mentioned under 4.1.2.12.1 and 4.1.2.12.2 of QMS/P-06 and experience in GMP/GHP auditing/assessment in the areas of pharmaceuticals or food sector. Whenever these assessors are used, the assessment team shall be supplemented by a technical expert **whenever is needed.** All assessors deployed shall be either employed by FCI or contracted full time with FCI.

- 4.1.2.4 FCI shall identify and provide the competence needed to perform the initial assessment of the applicant at site.

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## 4.2 Assessment :

4.2.1 FCI shall reject or close all Application 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) Non acceptance of internal quality assurance protocol within a month of Initial Evaluation;
- e) Lack of competent personnel for production and testing,
- f) If organizations shows no progress towards completion of corrective actions within three months of Initial Evaluation
- g) Misuse of Ayush Certification Mark
- h) Evidence of malpractice
- i) Voluntary withdrawal of application.

4.2.2 In the event of a closure/rejection of an Application, the application fee submitted with the application shall not be refunded

## 4.3 Initial Evaluation

- 4.3.1 Initial evaluation shall be carried out by a competent evaluation team in one stage for the Ayush Standard Mark and two stages for the Ayush Premium Mark. In case the production facility is having inhouse lab for testing, then the assessment team is to be supported by a person having worked in a lab for a minimum period of 2 years working experience, in case the assessor doesn't have exposure to the lab. His mandays will not be counted for mandays calculation.
- 4.3.2 FCI shall communicate the composition of the teams to the applicant for identification of conflict of interest if any. Any objections to the team by the applicant should be examined on merit.
- 4.3.3 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.
- 4.3.4 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 fulfillment of all application requirements.
- 4.3.5 In the initial evaluation for Ayush Standard Mark:  
FCI shall list the applicable domestic regulatory requirements, verify compliance to the certification criteria and also verify competence of testing personnel and the testing facility by witnessing testing of sample(s) in the laboratory of the organization, if available.
- 4.3.6 During the Stage 1 evaluation for Ayush Premium Mark, the FCI shall list the applicable regulatory requirements, check the applicant's compliance to these requirements on a sampling basis, status of GMPs, availability of competent personnel and adequate equipment for production and testing, availability of production and test records, the validation records and the state of preparedness for the Stage 2 evaluation, and prepare a report.

The deficiencies observed during stage-1 evaluation shall be informed to the applicant through Non-conformance report (QMS F-19 Non Conformity Report)/Assessment (AY F-08)

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

*Note : The responses to the non-conformities raised during the Stage-1 audit are to be closed by the team leader before proceeding to stage-2. In determining the interval between Stage-1 and Stage-2 audit consideration shall be given to the needs of the client to resolve areas of concerns identified in Stage-1 audit. The time gap between stage-1 and stage-2 shall not be more than 6 (Six) months. In case if it is more than Six months Stage-1 process to be repeated.*

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4.3.8 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 applied for as possible;
- c) Check for process controls being exercised for dosage forms and products under certification for ensuring Product quality and conformance to regulatory requirements and undertake verification of all production and test records;
- d) If satisfied with b) above, draw sample the products offered for certification, ensuring, representative of normal production capability, as per sampling plan given below for testing in the factory as well for testing in an independent laboratory;
- e) Check the availability of testing facilities in the manufacturing facility for adequacy;
- f) Witness the testing of at least one sample(s) drawn for relevant important characteristics possible that can be tested in the factory testing laboratory 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;
- g) Verify competence of testing personnel and the testing facility by witnessing testing of the sample in the laboratory of the organization.
- h) Draw samples for independent testing, as far as possible not to be from the same Batch as the sample drawn for factory testing.
- i) Take care that Sample is drawn in such a manner so as not to contaminate the product while sampling and packing.
- j) Pack and seal the samples(s) such that the product integrity is maintained for its intended shelf life.
- k) Clearly identify the samples with their name and type, Batch identification and suitable identification to enable traceability to the applicant and the Initial Evaluation visit
- l) Mark the identity of the sample with respect to its Brand name, and the name of manufacturer as depicted on the original packing.
- m) Draw samples in quantities adequate to facilitate their testing for all requirements specified in the Criteria.
- n) Ensure that if the product is affected by the conditions of temperature, handling and storage, the sample is drawn and maintained under those conditions for testing its conformity to specified criteria.

4.3.9 FCI shall draw at least one sample of the product from one or more dosage forms for factory testing for establishing its capability to test, and sample at least 25% of the products offered within the dosage form for independent testing.

4.3.10 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. The non conformities shall be classified as Major or Minor depending on their severity.

4.3.11 A non conformity is classified as Major when it relates directly to the quality of the product and the manufacturing organizations capability to produce a product that would conform to the certification criteria.

4.3.12 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 organizations capability to produce a product conforming to the certification criteria.

4.3.13 Sample of each of the Ayush product drawn for independent testing shall be forwarded to an NABL accredited testing laboratory for ascertaining conformance to specified criteria. The specified criteria like Annex-B, Permissible level of contaminants for Ayush Premium Mark, Section-3 Certification Criteria and Annex-C, Permissible levels of Contaminants for Ayush Standard Mark, Section-3 Certification Criteria or regulatory requirement of an importing country in case of Ayush Premium Mark are forwarded and communicated to the testing laboratory under unique reference number (File No allotted by FCI followed by sample number in sequence for the same client and month & year).

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- 4.3.14 FCI 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.
- 4.3.15 Based on the Annex-A, Generic Internal Quality Assurance Protocol, FCI Shall develop an Internal Quality Assurance Protocol for each dosage form for every certified client, considering the clients operations with requisite controls that need to be exercised by the client at all stages of production for compliance to the criteria. Minimum consideration is to consider all requirements given in Annex-A forming part of the IQAP developed for the client. FCI shall provide this IQAP to the certified unit and obtain its consent for implementation. If amended subsequent to the certification, then the acceptance to abide by the same to be obtained from the client.

This protocol shall address 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,
  - e) Criteria for the conformity of the Batch to the various requirements of the applicable certification Criteria,
  - 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
- 4.3.16 The IQAP is a dynamic document and shall be reviewed and amended, if required, as when the certification criteria undergo modifications and revisions or otherwise. The date of implementation of the revised IQAP shall be communicated to applicants to the product certification scheme and to the manufacturing unit that have been certified by the CB under this scheme.
- 4.3.17 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 before the certification is granted. Proof of ownership of the Brand name if any, shall be obtained from the applicant before the certificate is granted and this will facilitate any product recall if such a situation were ever to arise during the operation of the certification of scheme.

#### **4.4 Grant of Certificate**

4.4.1 FCI shall ensure the following prior to processing the application for grant of certificate:

- a) The availability of all relevant manufacturing and processing equipment required for the production/manufacture of Ayush products.
- b) Availability of authorized and/or adequate power and water supplies, where such supplies are required for manufacturing and testing.
- c) A test laboratory fully equipped to check all quality characteristics and contaminants of the Ayush products strictly in accordance with the prescribed test procedure or an arrangement to have the same tested from an NABL accredited laboratory with the scope covering testing of Ayush products.
- d) Competent and qualified personnel for production and testing of Ayush product(s).
- e) Conformity of the product and raw material wherever specified, with parameters/requirements of the certification criteria;

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- f) Acceptance from the applicant for following the internal quality assurance protocol as communicated by FCI, for the products for which product certification is being sought;
- g) Necessary documentation for proof of legal entity and authentication of premises of manufacture where certification is being sought.
- h) Verification of the applicant's production facility having been in production for at least one year.
- i) Verification of the applicant having manufactured at least five commercial batches of the products of dosage form for which certification is being sought during the current licensed period.
- j) Acceptance from the applicant for other certification requirements like the fee, Brand name declaration, etc.
- k) Verification of implementation of corrective actions through a follow up evaluation on site in case of major non conformities,
- l) Verification of implementation of Corrective actions for the minor non conformities by off site review, and
- m) Any other requirements prescribed by the FCI.
- n) Applicant organizations found to be misusing the Ayush certification mark, while their application is processed for grant of certificate, shall not be processed any further and rejected after due notice of fifteen days and they shall be treated as fresh.

- 4.4.2 FCI shall grant certification after ensuring complete compliance to the Certification Criteria and certification scheme requirements and all non conformances have been addressed in accordance with Clause 4.3.1 above. There shall be no conditional grant of certification.
- 4.4.3 On grant of certification, FCI shall inform the organization and issue a Certificate, uniquely identified, to the organization indicating the names of the product(s) certified, the certification criteria against which the certification has been awarded, effective date, validity date, and the name and address of the organization site where certified as a minimum..
- 4.4.4 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.
- 4.4.5 Effective date of certification shall not be before the date of decision to grant the product certification to the organization.
- 4.4.6 The certificate for product certification shall be for a maximum period of 3 years from the date of decision to grant the product certification.
- 4.4.7 Certification decision shall clearly inform the manufacturing organization that they have to seek approval from QCI (representing the Department Ayush) for using the Ayush Certification Mark on their products.
- 4.4.8 FCI may attach technical experts to support their audit team who are selected basing on FCI Procedure.
- 4.4.9 Designated Person shall file the confirmation in the Client history file.
- 4.4.10 Audit team members will assemble an audit packet with downloaded documents and documents sent by the Designated Person. Any missing information should be requested from the Designated Person.
- 4.4.11 Prior to the audit or prior to the opening meeting during the scheduled assessor preparation time, the Team Leader will conduct a team briefing, if applicable. The team briefing will cover the following items as a minimum:
  - a. Introduce all audit team members.
  - b. Answer any questions the team members may have about conducting the audit.
  - c. Review the audit plan, scope and standard.
  - d. Review FCI definitions of minor and major nonconformances and potential registration recommendations.
  - e. Stress the importance of obtaining objective evidence.

#### 4.5 Opening Meeting

- 4.5.1 The Team Leader will be responsible for conducting the opening meeting and will:
  - a. Review the items on Opening Meeting as per AY G-01.
  - b. Have all present sign the opening/closing meeting attendance sheet
  - c. Giving the Client signed Confidentiality and Nondisclosure Statements

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- d. The Company Information Sheet should be reviewed, marked with any changes and signed by the Team Leader and Client before, during or immediately after the opening meeting. **In case of any increase in the Number of employees, then the increase in Mandays is possible. Please check with FCI office.**

4.5.2 The opening meeting should be brief in an attempt to hold to the established schedule.

4.5.3 Following the opening meeting the Team Leader may request, if applicable, a short plant tour to familiarize the audit team with the activities carried out within the Client's facility. The plant tour should be conducted per the audit schedule.

#### 4.6 The Conformance Audit

4.6.1 The Team Leader may convene with any or all assessors at any time during the audit to review their findings and determine any changes in planned activities and the audit plan.

- i. Individual assessors are responsible for documenting non-conformances and opportunities for improvement on the Non-conformance Report and submitting them to the Team Leader before the closing meeting.

4.6.2 Assessors identifying a possible "Major" nonconformance shall inform the Team Leader as soon as practical.

4.6.3 A nonconformance will only be sanctioned by the Team Leader if it is capable of being written in the words of the standard and/or documented system and is substantiated by objective evidence.

4.6.4 Assessors are encouraged to document opportunities for improvement to benefit the Client

- i. Non-conformances are categorized into two levels of severity: Major and minor. .  
ii. Clearly describe the nonconformance on Nonconformance Report. Only one nonconformance may be documented on each Nonconformance Report however, multiple situations of the same nonconformance type may be documented on the same form.

4.6.5 If the Client addresses a nonconformance to the assessor's satisfaction prior to the closing meeting, it may be "Approved" and "Verified" during the audit. Assessors are discouraged from this practice as it takes time from the audit and may not do justice to root cause analysis.

- i. The Team Leader shall approve all Nonconformance Reports  
ii. Audit Team will reconvene approximately **thirty (30) minutes** before each end-of-day meeting with the Client. They will then submit their findings to the Team Leader to determine whether non-conformances have been identified.  
iii. The Team Leader is responsible for obtaining the Client's Management Representative's signature on each Nonconformance Report.  
iv. The Team Leader will be responsible for conducting the "end-of-day" meetings, if applicable, with the Client's representatives. At these meetings the following items will be addressed as a minimum;

4.6.6 The findings to date, including any nonconformances identified.

4.6.7 Additional information required from the Client to plan the remainder of the audit.

4.6.8 Any questions the Client has regarding the progress of the audit.

4.6.9 A brief description of the audit activities planned for the following day.

- i. On the final day of the audit the Team will convene approximately **one (1) hour** before the closing meeting to finalize the non-conformances that have been identified.  
ii. The assessment team will then discuss the findings, agree on the severity of the nonconformances and agree upon one of the following recommendations;

#### A. Stage-1 Assessment in case of Ayush Premium Mark

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- Preparedness for proceeding to Stage-II Assessment or at this point of time, the organization is not ready to go for Stage-II assessment.

Stage-1 in case of Ayush standard mark or Stage-II or follow up audit or Surveillance.

B. Unable to recommend at this point of time because of open non-conformances if any and pending the testing of samples collected at NABL accredited lab as per parameters Annex-B or Annex-C as applicable. You are given 60 days time to respond with corrective actions, if required, these will be reviewed and verified at the site by one of the assessors.

In case of no NC's, wait till you hear from FCI about the results from Lab.

C. Recommendation not to maintain registration.(In case of surveillance)

a. The audit process identifies more than one Major non-conformance or 10 minor non-conformances and additionally lack of non-conformance resolution within the specified time frame will also result not to maintain registration.

Follow up audit incase of Stage-I of Ayush Standard Mark or Stage-II or Surveillance or Re-registration.

The audit team indentified more than one Major NCR or 10 Minor non-conformance or non-conformances are such that the responses to be verified at the site, follow up audit recommended.

#### 4.7 Closing Meeting

4.7.1 Team Leader is responsible for conducting the closing meeting and will address the following points as a minimum;

- a. Thank the Client for their assistance and hospitality
- b. Review the items on Closing Meeting as per AY G-02
- c. Have all present sign the opening/closing meeting attendance sheet

4.7.1 If the recommendation is "*Recommendation Not To Register*" the Team Leader must explain that the recommendation is subject to ratification by FCI and that it may be appealed by the Client.

4.7.2 The Team Leader is responsible for communicating this information clearly and concisely and ensuring that the closing meeting is not used to debate or negotiate the recommendation. The purpose of the closing meeting is to report the audit findings. Any challenge or dispute of the findings should be via the formal appeal process.

4.7.3 The Team Leader will leave a copy of the nonconformance reports with the Client at the conclusion of the audit and request the Client to respond to the Team Leader by the indicated date.

#### 4.8 Definitive Report of Operational Assessment

4.8.1 When the audit has been completed on the receipt of corrective actions from the client the Team Leader will produce an Assessment Report to FCI within 15 working days on closure of non-conformances. *The report is confidential to FCI and should under no circumstances be shown or issued to third parties other than the Accreditation body/legal requirements.*

#### 4.9 Audit Documentation

4.9.1 The Client can also forward corrective actions for all non-conformances to the FCI by the required "Corrective Action Response Date" and FCI will co-ordinate with the Team Leader.

4.9.2 Team Leader shall indicate acceptance and verification of implementation of all corrective actions on the nonconformance report. If the corrective action is unacceptable or additional information is needed for verification, the Client will be asked to resubmit.

4.9.3 The Designated Person or Team Leader will submit the report to FCI within 15 working days of the

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closure of non-conformance. Completed Nonconformance reports and Client corrective actions shall be included.

- 4.9.4 Window for submission of satisfactory corrective actions by the client in case of Stage-2 assessment/re-registration is 60 days from the date of audit and certification process will be completed in 90 days **from the date of audit**.

#### **4.10 Follow-up Audit**

- 4.10.1 If an on-site follow-up audit is necessary to verify corrective actions of nonconformances documented during the audit, then the auditor deputed will assess those evidences of conformity to NC's documented and submit his recommendation report to FCI while communicating the same to the auditee.
- 4.10.2 No more than 2 follow-up audits shall be conducted.

#### **4.11 Registration Decision**

- 4.11.1 The audit documentation is reviewed by FCI Management/designated reviewer.
- 4.11.2 All corrective actions must be closed with root cause analysis and corrective actions verified as complete before consideration by the Registration Committee.
- 4.11.3 A Registration Committee will convene with at least two members to review the audit documentation per the requirements of FCI Policy Manual & Procedures. **One of the committee members shall have exposure to Ayush Products.**
- 4.11.4 The Registration Committee shall review the audit documentation and record its registration decision on Recommendation Report. At a minimum they shall review;
- The Company Information Sheet and contract review
  - The Assessment Report
  - Nonconformance reports and associated Client corrective action responses.
  - The Recommendation Report;
  - Compliance with the requirements of Para 4.4 of this document
- 4.11.5 The Director FCI shall make the certification decision on the basis of the evaluation of audit findings and conclusions and any other relevant information provided by the registration committee.
- 4.11.6 The Designated Person shall notify the Client by letter of the decision and establish the tentative date for the first surveillance assessment if registration is granted. The three year certification cycle begins with the certification or recertification decision.
- 4.11.7 The Designated Person shall issue a registration packet, if registration is granted.
- 4.11.8 Should the Client appeal the decision, the Registration Committee will examine this appeal and adjudicate based upon the objective evidence submitted by both parties. If a dispute still exists upon further review, the issue will be resolved as defined in procedure Appeals.

### **5.0 RECORDS & Forms**

- 5.1. Conformance Audit History File section in Client History File

### **6.0 REVISIONS**

Original Issue, Rev.00, Dt: 01-10-2009

**Revision Issue, Rev.01, Dt: 25-05-2010**

**Revision Issue, Rev.02, Dt: 01-07-2010**