

Issue No: 01	Procedure for Conducting Surveillance	
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1.0 PURPOSE

- 1.1 To define the procedure for planning, conducting and reporting of surveillance assessments carried out for FCI

2.0 SCOPE

- 2.1 This procedure applies to all surveillance assessments conducted by FCI at a client place on site visiting physical locations.

3.0 RESPONSIBILITIES

- 3.1 Designated Person shall be responsible for ensuring that the audit is planned, managed and conducted in accordance with this procedure.
Note: The Team Leader in this procedure refers to his role.

4.0 PROCEDURE

4.1 Audit Planning and Preparation

4.1.1 Surveillance Evaluation

- 4.1.1.1 Surveillance evaluations of the certified sites during the first certification cycle shall be carried out at a frequency of at least once in six months, ensuring that the gap between two surveillance valuations does not exceed six months. FCI may allow a grace period of one month based on valid grounds beyond which delays shall lead to suspension of the certificate.
- 4.1.1.2 FCI shall ensure that critical steps in an operation or a combination of production operations on a given days are witnessed, their controls verified, and samples drawn for testing both in the factory and for independent testing during the surveillance evaluation. Planning for surveillance evaluations shall ensure this.
- 4.1.1.3 In case where the unit is certified to a number of products of different dosage forms under the same certificate, FCI shall plan for surveillance evaluation with a view to covering all dosage forms, and as many Ayush products within each dosage form during the certification cycle through independent testing of factory samples and market samples. FCI shall draw more samples of products registering higher volumes in production.
- 4.1.1.4 For each dosage form certified, FCI shall ensure that as a minimum at least one sample of each dosage form from the factory and two from the market are drawn per annum for independent testing.
- 4.1.1.5 During the surveillance evaluation, the evaluators shall as a minimum check and report on the following;
- a) Compliance to the requirements of the certification criteria.
 - b) Status of hygienic conditions
 - c) Compliance to the Internal quality assurance protocol
 - d) Handling and disposal of non conforming products
 - e) Actions taken on discrepancies observed during the previous evaluation, failure of samples if any reported and informed to the manufacturing unit;
 - f) Draw samples for factory testing and testing in independent laboratory
 - g) 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.
 - h) 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.

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4.1.1.6 If any non conformities are observed, the same shall be categorized as either a Major or a Minor. 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.

4.1.1.7 FCI after completion of the first certification cycle may increase or decrease the frequency of surveillance evaluation based on the performance of the client not less than once in a year in any case.

4.1.1.8 The frequency of Surveillance Evaluation may be reduced to once in a year provided there have been no major non-conformities, failure of samples are complaints during the previous three years. FCI shall revert to the normal frequency immediately in case of any change in this situation occurs.

4.1.1.9 If the surveillance evaluation results in an infructuous visit due to any reason, and neither the production is witnessed nor products drawn for testing either in the factory or for independent testing, FCI shall conduct another surveillance evaluation. Such additional evaluations may be charged to the certified unit as decided by the FCI.

4.2 Market samples

4.2.1 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.

4.2.2 FCI shall draw a minimum of 2 samples from each dosage form product group certified from the market for each client in a year.

4.2.3 In case where the unit is certified to a number of products of different dosage forms under the same certificate, the planning of surveillance evaluation is to consider covering all dosage forms and as many Ayush products within each dosage form during the certification cycle through independent testing of factory samples and market samples. More samples of products registering higher volume in production to be drawn for sampling.

4.2.4 Market samples shall be drawn in the original packaging and product integrity shall be ensured by the FCI.

4.2.5 Failure of sample of certified product, drawn from the factory or the market, to comply to criteria requirements shall be communicated to the certified manufacturing unit for investigation, root cause analysis and proposed corrective actions within 15 days of intimation. The manufacturing unit 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.

4.2.6 Depending on the nature of the failure reported, the CB shall decide on one or any of the following;

- a) Draw additional samples of the product manufactured around the same time from the market;
- b) Organize for an additional surveillance evaluation immediately
- c) Ensure fresh sample is tested in the factory;
- d) Increase the frequency of surveillance evaluation
- e) Increase the number of market samples: the manufacturer shall be informed of the decision taken.

4.2.7 When the failure of the sample is in requirements relating to Contaminants the CB shall advise the manufacturer within 15 days 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.

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- 4.2.8 Designated person will agree upon and schedule the audit with the Client. The goal is to schedule the assessment requested by the Client as per the target date and conduct the audit on the target date. **The client to be informed atleast 30 days in advance of the due date of the surveillances.**
- 4.2.9 Designated Person will decide the composition of the audit team, ensuring that assessor qualifications match audit requirements as per scheme requirements. FCI may attach technical experts to support their audit team who are selected basing on FCI Procedure. The calculation of mandays is as per AY/P-04.
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 any of the assessment team members do not posses exposure to lab.** His mandays will not be counted for mandays calculation.
A brief description of each assessor's background and experience shall be provided upon request. In case of any objection to the composition of audit team by the Client the Designated Person will consult the Certification Manager and the decision will be informed to the Client. In case the Client disagrees with the decision, then the process will go through appeal procedure.
- 4.2.10 The Designated Person shall file the confirmation in the Client history file.
- 4.2.11 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.
- 4.2.12 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:
- Introduce all audit team members.
 - Answer any questions the team members may have about conducting the audit.
 - Review the audit plan, scope and standard.
 - Review FCI definitions of minor and major nonconformances and potential registration recommendations.
 - Stress the importance of obtaining objective evidence
- 4.3 Opening Meeting:**
- 4.3.1 The Team Leader will be responsible for conducting the opening meeting and will:
- Review the items on Opening Meeting as per FSMS/G-02.
 - Have all present sign the opening/closing meeting attendance sheet
 - Giving the Client signed Confidentiality and Nondisclosure Statements
 - 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. **If the Number of employees are different from the information given in the Client Information sheet then the lead assessor shall get in touch with the Certification Manager at FCI office and confirm the number of man days required for the audit. In case of change in the number of man days required for the audit, the Team Leader shall resolve this issue by discussing with the Client and FCI office before proceeding further with the audit.**
- 4.3.2 The opening meeting should be brief in an attempt to hold to the established schedule.
- 4.3.3 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.
- 4.3.4 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.

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- 4.3.5 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.
- Assessors identifying a possible major" nonconformance shall inform the Team Leader as soon as practical.
 - 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.
 - Assessors are encouraged to document opportunities for improvement to benefit the Client
- 4.3.6 Non-conformances are categorized into two levels of severity: , Major and minor.

4.4 Closing Meeting

- 4.4.1 The Team Leader is responsible for conducting the closing meeting and will address the following points as a minimum;
- Thank the Client for their assistance and hospitality
 - Review the items on Closing Meeting as per FSMS/G-03.
 - Have all present sign the opening/closing meeting attendance sheet.
- 4.4.2 If the recommendation is "*Recommendation Not To Maintain the Registration*" the Team Leader must explain that the recommendation is subject to ratification by FCI and that it may be appealed by the Client.
- 4.4.3 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.
- 4.4.4 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.

4.5 Reporting of Surveillance Assessments:

- 4.5.1 Audit team report all the non conformances and hand over to the company to initiate necessary corrective actions for the closure of the NCs.
- 4.5.2 After verification of the evidences submitted by the company for the non conformances of surveillance assessment and satisfactory closure of the NCs the report with recommendation is forwarded to FCI designated persons by the Team Leader.
- 4.5.3 Designated person submit the report to Registration Committee for decision on continuation of certification. The process of review and decision making is same as documented in the procedure for conformance assessment and the procedure for registration committee.

4.6 Follow-up Audit

- 4.6.1 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.
- 4.6.2 No more than 2 follow-up audits shall be conducted.
- 4.6.3 Followup audits shall be considered if greater than 1 Major and/or 10 Minor non-conformance have been identified. At the followup assessment, the team leader will make a registration recommendations.

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4.7 Decision for continuation of Registration:

- 4.7.1 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.
- 4.7.2 The audit documentation is reviewed by FCI Management/designated reviewer.
- 4.7.3 All corrective actions must be closed with root cause analysis and corrective actions verified as complete before consideration by the Registration Committee.
- 4.7.4 A Registration Committee will convene with at least two members to review the audit documentation per the requirements of FCI Policy Manual & Procedures.
- 4.7.5 The Registration Committee shall review the audit documentation and record its decision for continuation of registration on Recommendation Report. At a minimum they shall review;
 - a. The Company Information Sheet and contract review
 - b. The Assessment Report
 - c. Nonconformance reports and associated Client corrective action responses.
 - d. The Recommendation Report;
 - e. Compliance with requirements of 4.4 of this procedure
- 4.7.6 The Director FCI shall make the registration continuation decision on the basis of the evaluation of audit findings and conclusions and any other relevant information provided by the registration committee/FCI reviewer.
- 4.7.7 The Designated Person shall notify the Client by letter of the decision and establish the tentative date for the next surveillance assessment.
- 4.7.8 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.

4.8 Corrective Action Response Date

The window for submission of satisfactory corrective actions by the client is 60 days from the date of audit and the process of certification to be completed within 90 days from the date of audit.

4.12 Verification of Usage of Logo and Certification Mark.

5.0 RECORDS & Forms

5.1 Conformance Audit History File section in Client History File

6.0 REVISIONS

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

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