AYUSH QUALITY MARK PROGRAMME

Additional Requirements for Ayush Product Testing Laboratories as per ISO/IEC 17025 *(Effective 1 Jan 2027)*

1. Introduction

1.1 This document prescribes the additional requirements to be followed by the Ayush products testing laboratories besides compliance to ISO/IEC 17025 for the purpose of obtaining recognition by the AYUSHEXCIL under the Ayush Quality Mark Programme of the Ministry of Ayush.

2. Additional requirements

The additional requirements are indicated by prefix A with the clause number of ISO/IEC 17025 for ease of understanding,

A1 Purpose

A1.1 This document specifies additional requirements for laboratories involved in testing of Ayush products under the Programme. These requirements are additional to the requirements specified vide ISO/IEC 17025 "*General requirements for competence of testing and calibration laboratories*", which the Ayush products testing laboratories are required to comply with and be accredited, in order to be recognized by the AYUSHEXCIL under the provisions of Ayush Quality Mark Programme.

A2. Scope

A2.1 This document specifies additional criteria for the competence of Ayush products testing laboratories. It specifies requirements for laboratories engaged in testing of various groups of Ayush tests as listed in Annex 1 to the document "System for Grant of Ayush Quality Mark to Ayush Product Testing Laboratories". It covers testing of parameters in broad groups, such as, General physical and chemical tests; Pharmacognosy/microscopy related tests, Identification; Assay/analysis and other phytochemical related tests; Residues and chemical contaminants tests, Microbial and biological tests, as applicable to Ayurvedic, Sidha, Homeopathic and Unani products/drugs.

NOTE: The term "shall" used throughout this document indicates those provisions which are mandatory in nature. The term "should" is used to indicate guidance which, although not mandatory, is provided as a means of meeting the requirements of the approval criteria. In case the laboratory uses an alternative means of meeting the requirements, they would have to provide suitable and adequate justification.

A2.2 It is also intended that these additional criteria shall be used by the accreditation bodies recognized under the programme for assessment of laboratories, engaged in testing of Ayush products, for the purpose of recognition by AYUSHEXCIL under the Programme.

A2.3 The structure of this document has been aligned with the structure of ISO/IEC 17025: 2017. Against each requirement in the standard (ISO /IEC 17025: 2017), additional requirements have been described, where applicable. These requirements shall be in addition to those specified in ISO/IEC 17025: 2017. In respect of all other elements the existing provisions shall apply.

A2.4 Scope of Testing of Laboratory for the purpose of recognition -The Laboratory seeking recognition under the Scheme, shall have the competence to test and be accredited for that scope by the accreditation body, for one or more of the following groups:

Groups/ description:

1. General Physical and chemical tests
2. Pharmacognosy/ microscopy related tests
3. Identification, assay/analysis and other phytochemical related tests
4. Residues and chemical contaminants
5. Microbial/biological tests

The details of tests/parameters under each group are given under Annex 1 of the document **"System for Grant of Ayush Quality Mark to Ayush Product Testing Laboratories".**

Note: If any laboratory wants to cover testing of one or more streams of Ayush such as Ayurveda, Homeopathy, then the laboratory may identify and apply for those specific tests and they shall cover all tests/parameters applicable to that stream.

A4 General requirements

A4.01 Integrity

The laboratory shall maintain integrity at all times. It shall implement systems and measures to require all its personnel, internal and external, to maintain integrity. The laboratory's system for maintaining integrity shall include measures like having a Code of Integrity and Conduct, which is required to be signed by all individuals (internal and external) involved in laboratory's activities, policy on gifts, guidelines for handling situations when offered inducement etc. should be developed and implemented.

Note 1 Integrity is defined as the quality of being honest and having a consistent

and uncompromising adherence to strong moral and ethical principles and values.

A4.02 Independence

The following situations may exist with respect to status of a laboratory.

a. The laboratory is a third party and independent organization, or
b. The laboratory is part of/is inhouse laboratory of a manufacturing unit, or is linked to a Ayush manufacturing organization.

In any of the situations as above, the laboratory shall clearly and accurately declare the status in all its documentation and the application for accreditation as well as application for recognition under Ayush mark scheme.

A4.1 Impartiality

A4.1.1 All provisions of clause 4.1.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A4.1.1.1 In respect of ensuring impartiality through organizational structure see additional requirements as described in clauses A5.5.1) and A5.5.2).

A4.1.2 All provisions of clause 4.1.2 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A4.1.2.1 One of the main means of demonstrating this is through documenting top management commitment to impartiality. The top management is a person or group of people who directs and controls the laboratory (organization) at the highest level.

A4.1.3 All provisions of clause 4.1.3 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A4.1.3.1 The laboratory's system for maintaining impartiality shall include measures like having a Code of Integrity and Conduct, which is required to be signed by all personnel involved in laboratory activities.

A4.1.4 All provisions of clause 4.1.4 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A4.1.4.1 The laboratory shall have a process to identify, analyze, evaluate, treat, monitor, and document on an ongoing basis the risks (actual and perceptive) to impartiality from its activities (other divisions under the legal entity, see clause 5.1), or from its relationships (see Note under clause 4.1.4), or from the relationships of its personnel (professional and personal relationships).

A4.1.5 All provisions of clause 4.1.5 of ISO/IEC 17025: 2017 shall apply. The laboratory shall document the process of eliminating or minimizing the identified

risks.

A4.2 All provisions of clause 4.2 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A4.2.1 The responsibility of the laboratory for managing the confidentiality through legally enforceable commitment shall be documented.

A5 Structural requirements

A5.1 All provisions of clause 5.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

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A5.1.1 It shall be a legal entity that can be held legally responsible for all its testing activities. It shall be registered under the applicable national law so that it can function legally, make decisions independently and may be sued in its own name.

A5.1.2 In India, following legal entities meet the definition of a legal entity requirements as described above and hence such organizations shall be considered as meeting the requirement.

a. One Person Company, OPC (Registration under The Companies Act, 2013;
b. Limited Liability Partnership, LLP (Registration under The Limited Liability Partnership Act, 2008);
c. Company, Private Limited/Limited (Registration certificate under The Companies Act, 1956 or 2013);
d. Society/ Trust (Registration under Societies Registration Act, 1860/ Registration under the Indian Trusts Act, 1882, Government (as per Gazette or Government Notification).

A5.4 All provisions of clause 5.4 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A5.4.1 The size, structure and composition of the laboratory, taken together should be suitable for the competent performance of the technical and administrative functions of the laboratory.

A5.5 All provisions of clause 5.5 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A5.5.1) A laboratory, that is part of an organization involved in functions other than testing, shall be separate and identifiable within that organization structure. The organization structure shall include the detailed structure of the legal entity (parent body) showing positions of all divisions involved in different activities, including the support functions and a detailed structure of the testing laboratory division, when laboratory is a defined part of a larger organization within the legal entity.

A5.5.2) If the testing laboratory is part of an organization performing activities other than testing, say for example, inspection, certification, manufacturing, design and developments, conducting studies, etc., then there shall be clear demarcation and separation between the laboratory organization performing testing and the organization performing other activities, as defined through the reporting structures and clearly defined responsibilities of key personnel in both the organizations, to avoid potential conflicts of interest, like influence on the testing activities of the laboratory. The personnel performing actual testing shall be separate from personnel performing other activities like inspection and/or certification, manufacturing, conducting studies, etc., as applicable.

A6 Resource requirements

A6.2 Personnel

A6.2.1 All provisions of clause 6.2.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A6.2.1.1 All internal and external personnel shall be required to sign an agreement to abide by the requirements of laboratory code of conduct clearly defining their agreement to the requirements as specified in clause 6.2.1 of this standard.

A6.2.1.2 The laboratory shall ensure availability of adequate number of personnel as appropriate to the accepted/actual level of workload and be able to demonstrate the same.

A6.2.1.3 If the testing laboratory has a system for employing operational personnel on contract, then they shall be appointed on long-term contract basis. The laboratory shall also ensure that such personnel are supervised and competent for the assigned activities. Through signing of individual contract, they shall be appointed at least for a period of one year; however, in case of freshers the minimum period of contract shall be three years. Such a contract shall be signed with the concerned personnel directly. They shall commit to work in accordance with the laboratory's established systems including that for integrity and impartiality.. Supervisory level personnel including authorized signatory shall be in-house full-time employee of the testing laboratory.

A6.2.2 All provisions of clause 6.2.2 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A6.2.2.1 The individuals involved in conducting tests for different groups of parameters shall have following qualification:

a. Chemical and Physical tests: B.Sc. Chemistry or equivalent with minimum experience of 4 years of carrying out tests or analysis as per the AYUSH Pharmacopoeias or M.Sc. Chemistry or equivalent with experience of 2 years of carrying tests as per AYUSH pharmacopoeias.

b. Pharmacognosy/Microscopy related tests: Degree in Botany or equivalent with minimum experience of 2 years of carrying tests as per AYUSH pharmacopoeias.

c. Identification, assay/analysis and other phytochemistry related tests: B.Sc. Chemistry/Ayush related graduate degree or equivalent with minimum experience of 4 years of carrying out tests or analysis as per the AYUSH Pharmacopoeias or M.Sc. Chemistry/Ayush related degree or equivalent with experience of 2 years of carrying tests as per AYUSH pharmacopoeias.

d. Residues and chemical contaminants tests: B.Sc. Chemistry/Ayush related graduate degree or equivalent with minimum experience of 4 years of carrying out tests or analysis as per the AYUSH Pharmacopoeias or M.Sc. Chemistry/Ayush related degree or equivalent with experience of 2 years of carrying tests as per AYUSH pharmacopoeias. The analyst shall have minimum 2 years' experience of testing using instrumental techniques such as GC MS, LC MS, AAS, ICP, ICP MS.

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e. Microbiology tests: B.Sc. Microbiology with minimum experience of 4 years of carrying out tests or analysis as per the AYUSH Pharmacopoeias or M.Sc. Microbiology with experience of 2 years of carrying tests as per AYUSH pharmacopoeias or equivalent.

f. **Supervisor:** The testing laboratory shall have at supervisory level having a degree in Ayush-related subjects, minimum of 10 years related experience, and knowledge of Ayush regulations and pharmacopoeias.

A6.2.5 All provisions of clause 6.2.5 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A6.2.5 a) Competence requirement requires defining the academic qualification and experience requirements as well as the knowledge and skills requirements for the activities to be performed.

A6.2.5 b) Selection process shall include evaluation of all competence requirements and the process for doing the evaluation.

A 6.2.5 c) The laboratory shall establish and document a system for initial and ongoing training of the individuals working in the laboratory, whose work has influence on quality of testing. The laboratory shall have documented procedure for identifying training needs and providing training to its personnel. The training programme shall be relevant to the current and anticipated tasks of the testing laboratory.

Internal training alone is not considered adequate to make the staff knowledgeable on the latest status of science and technology and for introducing specialized testing like residue testing, microbiological testing, etc. It should include specialized training in different fields of Ayush product testing such as general physical, chemical, contaminants (residue) and microbiological testing as

relevant to the Ayush products. The effectiveness of the training actions taken shall be evaluated. Evidence of effective training in specific field should be available in terms of examination performance evaluation through quality checks (clause 7.7) as relevant.

A6.2.5 d) The procedure for effective supervision of the testing activities should be applicable to individual analysts in different testing sections like physical and chemical tests, pharmacognosy, phytochemical, microbiology, residue, etc., as applicable. The supervision should be provided by persons having knowledge and skills and familiarity with the test methods and analysis work in the particular testing section.

A6.2.5 e) The authorization of personnel for different scopes of testing, as relevant, shall be based on performance evaluation through quality checks. Records demonstrating the same performance evaluation shall be maintained. In respect of specific Ayush related tests such as physical/ chemical tests, pharmacognosy (study and microscopic tests related to Herbs, crude drugs and others as applicable), phytochemistry related tests (identification, analysis, etc.), at least one person at supervisory level and as authorized signatory shall have a degree in Ayush related subjects and minimum 10 years knowledge/experience of Ayush regulations and pharmacopoeia

A6.2.6 All provisions of clause 6.2.6 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A6.2.6 a) Development, modification, verification and validation of test methods require higher level of competence. Persons responsible for these activities shall have additional minimum experience of 2 years in specific validation related activities. In respect of Ayush product testing the contamination/residue related activities and phytochemical tests for products beyond those given in Ayush pharmacopoeia as well as proprietary medicines shall require such competences.

A6.2.6 b) The laboratory shall have a system for authorising testing personnel for specific tests based on in-house, on-the-job training or external training and subsequent performance evaluation.

A6.2.6 c) Personnel responsible for report review and authorization of Ayush reports shall have a degree in Chemistry, Botany, Ayurveda, Siddha, Unani or Bachelor in Pharmacy from a recognized University or equivalent, with experience of 10 years for carrying out tests or analysis out of which 5 years shall be in Ayush Product Testing and 2 years in supervisory capacity.

A6.3 Facilities and environmental conditions

A6.3.1 All provisions of clause 6.3.1 of ISO 17025: 2017 shall apply in addition to the following:

A6.3.1.1 The equipment, the infrastructure and facilities and the environmental conditions shall be adequate and appropriate to the scope applied for. Air conditioning shall be ensured where required. The space provided in the laboratory shall be appropriate/ adequate for the scope applied for. Layout of the laboratory shall ensure effective separation of the incompatible activities.

A6.3.4 All provisions of clause 6.3.4 of ISO 17025: 2017 shall apply in addition to the following:

A6.3.4.1 Within the microbiology laboratory, effective separation of areas of activities such as storage, cleaning, sterilization, media preparation, plating and incubation shall be ensured, as applicable.

6.4 Equipment

A6.4.1 All provisions of clause 6.4.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A6.4.1.1 The laboratory shall possess adequate equipment essential for carrying out tests for identity, purity, quality and strength of Ayurvedic, Siddha, Unani and Homeopathy drugs as per the Pharmacopeial standards or other available standards. Please, also refer to the minimum lists provided in PART XVI (A) of the AYUSH regulation. The equipment, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus shall be adequate and appropriate to the scope applied for.

A6.4.2 The laboratory shall not use the equipment outside its permanent control.

A6.5 Metrological traceability

A6.5.1 All provisions of clause 6.5.1 of ISO 17025: 2017 shall apply.

A6.5.2 All provisions of clause 6.5.2 of ISO 17025: 2017 shall apply in addition to the following:

A6.5.2.1 Certified reference materials for residue analysis shall be purchased, generally, from sources such as National Metrology Institutes (NMIs) or ISO 17034 accredited Reference Material Producers. Marker compounds required for identification tests, assay/analysis, and phytochemical tests for Ayush drug substances, shall be purchased from authentic sources, such as sources identified in Ayush Pharmacopoeias, ISO 17034 accredited reference material producers or any other national/international reputed providers.

A6.5.2.2 Reference cultures, like ATCC, for Microbiological Tests: The laboratory shall establish and document system for handling and effective maintenance of cultures and their appropriate usage.

A6.5.2.3 The laboratory shall establish and implement system for handling, storage and maintenance of reference materials, their dilution and preparation of secondary

CRM's, their maintenance and retention and shall maintain appropriate records. Reference materials and chemical standards shall be clearly labeled so that they are unambiguously identified and referenced against accompanying certificates or other documentation. Information should be available indicating shelf-life, storage conditions, applicability, restrictions of use, etc.

A6.6 Externally provided products and services

A6.6.1 All provisions of clause 6.6.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A6.6.1.1 When a laboratory is required to subcontract testing work because of some temporary needs such as breakdown of equipment, etc. then the laboratory shall ensure that the testing work is subcontracted to a laboratory which complies with the requirements laid down in this document and is duly accredited for the relevant Ayush scope. Further in all such cases the test reports received from the subcontracted laboratory (external service provider) shall be forwarded to the customer without making any changes to the test report.

A7 Process requirements

A7.1 Review of requests, tenders and contracts

A7.1.1 All provisions of clause 7.1.1 of ISO 17025: 2017 shall apply in addition to the following:

A7.1.1.1 Based on the facilities available, the laboratory shall maintain detailed data on the types of tests that are required to be carried out for various Ayush products as per applicable regulatory requirements and the laboratory's competence to test them.

A7.1.1.2 The laboratory shall have a comprehensive system and procedure for understanding the requirements for testing in terms of Ayush products to be tested and the relevant tests to be performed. The requirements may as be prescribed in the relevant pharmacopoeia, WHO requirements, or defined in any certification scheme. The requirements may also stem from classical formulation not covered in pharmacopoeia, proprietary formulations or from importing country's requirements. In all these cases the testing laboratory shall ensure that tests to be performed are clearly described during review of request (contract review) and accordingly documented in the contract.

A7.1.7.1 In response to any specific requirements (from regulatory authorities, organizations granting recognition, etc), the laboratory shall be willing to participate in specific proficiency/inter-laboratory testing programs, as a demonstration of its competence. It shall also be willing to subject itself to any unannounced assessments or additional assessments by any entity that recognises it.

A7.2 Selection, verification, and validation of methods

A7.2.1 Selection and verification of methods

A7.2.1.5 All provisions of clause 7.2.1.5 of ISO/IEC 17025: 2017 shall apply in addition to the following.

A7.2.1.6 All provisions of clause 7.2.1.6 of ISO/IEC 17025: 2017 shall apply in addition to the following.

A7.2.1.6.1 Please see comments against clause A 7.2.2.1

A7.2.2 Validation of methods

A7.2.2.1 All provisions of clause 7.2.2.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A7.2.2.1.1 For specialized tests like residue testing (metallic contaminants, pesticide and Aflatoxin residues), where the requirements require very low detection limits (as per WHO requirements or importing countries requirements for AYUSH Products), the laboratory would generally require to use standard methods as specified in AOAC, Environment Protection Agency – USA (EPA), American Public Health Association (APHA), Pesticide Analytical Manual (PAM) or research papers published in standard journals or any other standard publication, modified to suit the sample matrices of Ayush products to be tested for specific residues and laboratory specific aspects like type of equipment used and their sensitivities, extraction technique used and competence and skill development of the testing personnel, in order to achieve the desired detection levels matching the MRL's. Consequently, the laboratory would require to validate the adapted/modified test methods. The validation of chemical (specifically residue) test methods should be carried out as per the guidance provide in ISO/IEC 17025 or any other methods as specified in EURACHEM Guide. Some of the relevant aspects to be complied with are given below.

a, A generic procedure for method validation defining different method performance parameters and also plan of action to cover validation of different residues and different Ayush products matrices.

b. Procedure for carrying out actual validation experiments – the number of replicates, number of data points for different types of method performance parameters like recovery, linearity, etc. The laboratory should also establish acceptance criteria.

c. Specific design of experiment for individual validation experiments as per the plan. The experiment data should clearly state the quantity of sample taken and the spike quantity. The output of the experiment, mainly the detection/quantification limits should be expressed in terms of the unit of sample matrix. Based on the validation results the lab should document SOP

(Standard Operating Procedure) for regular analysis, which should include aspects like system for repeating calibration curves, recovery data, etc.

d. Based on the above the laboratory shall establish and document the laboratory performance characteristics like Selectivity & specificity, Range, Linearity, Sensitivity, LOD, LOQ, Accuracy/recovery, repeatability, etc., for analysis of different residue parameters in different Ayush matrices.

A7.2.2.4 All provisions of clause 7.2.2.4 of ISO/IEC 17025: 2017 shall apply in addition to the following.

A7.2.2.4.1 Normally the standard methods shall not be deviated unless the deviations have been technically justified, validated, documented, and authorised. All modified, laboratory- developed or non-standard test methods used by the testing laboratory shall be validated before use. Where they are available, certified reference materials should be used to determine any systematic bias. If not able, or where this is not possible results shall be compared with other technique(s), preferably based on different principles of analysis.

A7.3 Sampling

A7.3.1 All provisions of clause 7.3.1 of ISO/IEC 17025: 2017 shall apply in addition to the following.

A7.3.1.1 Where sampling is carried out by the laboratory as per customer's requirements, these shall be carried out in accordance with the requirements of ISO/IEC 17025 and the additional provisions specified in relevant regulations, if any, shall also apply.

A7.3.1.2 Customers taking their own samples shall be made aware of proper storage, sampling, and transportation facilities, as applicable. Customers shall be notified if the sample received is too small for meaningful analysis.

A7.4 Handling of test or calibration items

A7.4.1 All provisions of clause 7.4.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A7.4.1.1 Laboratory shall document the sampling procedures for taking test portions from laboratory samples received for testing, especially in samples where the composition of the sample is not uniform or the distribution of the analyte is not uniform through the matrix. It shall include measures to ensure that the test portion is as representative of the sample as possible.

A7.4.4 All provisions of clause 7.4.4 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A7.4.4.1 The procedure for sample handling shall define the period for the

retention and disposal of the samples in the laboratory. Samples should be stored until the test results are obtained, or longer, in line with regulatory and/ or other laboratory user's requirements. Laboratory sample portions that are highly contaminated (especially microbiological) shall be decontaminated prior to being discarded.

7.9 Complaints

A7.9.7.1 If the subject of complaint is of serious nature, likely to affect reputation of lab, accreditation body, and/or the regulator, then the lab shall inform the accreditation body, regulatory body and/or any other organization recognizing the laboratory promptly.

A7.11.6 All provisions of clause 7.11.6 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A7.11.6.1 Automated systems, generally used with sophisticated equipment's like AAS, GC, etc., shall normally be validated by checking for satisfactory operation and establishing the reliability of the system before it is allowed to run unattended. Where possible the controlling software shall be tailored to identify and highlight any malfunctioning of the equipment and tag associated data. The use of quality control samples and standards run at periodic intervals in the sample batches shall then be sufficient to monitor correct performance of the automated equipment on a day-to-day basis. Calculation validity shall be checked by testing with known parameter values. Electronic transfer of data shall be checked to ensure that no loss and/or alteration of data has occurred during transmission. This can be achieved on the computer using verification files, but wherever practical the transmission shall be backed-up by a hard copy of the data.

A8. Management system requirements

A8.1 General All provisions of clause 8.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A8.1.1 In addition to meeting the requirements of Clauses 4 to 7, the testing laboratory shall implement a management system in accordance with Option A only.

A8.1.3 Option B Not Applicable.

8.8 Internal audits (Option A)

A8.8.1 All provisions of clause 8.8.1 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A8.8.1.1 The internal audits shall be carried out in accordance with a pre-

determined frequency, which shall not be less than once in twelve months. They shall cover all the activities of the laboratory under the Ayush and shall cover all accreditation requirements. It shall also include witnessing of tests on a sample basis by a competent internal auditor. The report shall record all objective evidence for the requirements noted in this clause and indicate the lack of compliance observed.

A8.8.2 All provisions of clause 8.8.2 of ISO/IEC 17025: 2017 shall apply in addition to the following:

A8.8.2.1 The internal audit shall be conducted by competent auditors, who may be internal personnel of the testing laboratory or externally hired personnel. The internal auditor and/or audit team shall collectively have knowledge of ISO/IEC 17025:2017 and all other accreditation and Ayush regulatory requirements concerning testing, auditing techniques and the Ayush testing activities covered in the scope of the testing laboratory.