



**SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT**

**TERMS & CONDITIONS *for*
MAINTAINING
ACCREDITATION of
GOOD LABORATORY PRACTICE**



ACCREDITATION SCHEME FOR GOOD LABORATORY PRACTICE (GLP)

Terms & Conditions for maintaining accreditation of good laboratory practice

We the undersigned, on behalf the laboratory operates Good Laboratory Practice (*herein after referred to as Laboratory*)

(Name of the Laboratory)

understand the Rules & Procedures and Requirements of Accreditation Scheme for Good Laboratory Practice (GLP) and agree to fulfill and abide by the following terms and conditions adopted and implemented by the Sri Lanka Accreditation Board for Conformity Assessment (SLAB) for maintaining accreditation for GLP as given below.

(This document shall be signed by the Chief Executive or his Authorized Representative and submitted to SLAB in duplicate along with the application form. SLAB will return a copy after grant of accreditation by endorsing it. In case of changes, SLAB will make sure that the current document is signed by the laboratory, always.)

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Agreement

1. The laboratory shall carry out its activities in such a way as to meet the requirements of OECD Guidelines whichever is applicable and relevant to SLAB specific criteria for GLP (GLP-GL(P)-02) and Rules & Procedures for accreditation of GLP (GLP-RG (P)-02).
2. The accreditation shall be initially granted after a successful initial assessment for a period of three years, unless otherwise decided by the SLAB. Thereafter, shall be subject to on-site annual surveillance activities. These surveillance activities shall be conducted before the completion of each year for two years counting from the date of grant of accreditation.
3. Before expiry of the validity period, the accreditation granted shall be renewed by a re-assessment, for which the laboratory shall apply four months before the expiry of accreditation. Thereafter SLAB shall conduct re-assessment in every three years and annual surveillances.
4. In addition to planned surveillances, depending on the behavior of the laboratory or in response to complaints with regard to violation of rules and procedures of SLAB for accreditation, unannounced assessment or other surveillance activities may be arranged. The laboratory shall assist in the investigation and resolution of any accreditation related complaints about the laboratory referred to it by the SLAB.
5. When requested, the laboratory shall afford accommodation and co-operation to enable the SLAB to verify fulfillment of requirements for accreditation. These facilities shall be available at all premises where the conformity assessment is supposed to take place.
6. The laboratory shall offer SLAB access to laboratory personnel, locations, equipment and all relevant information including documents and records pertaining to accreditation that provide insight into the level of independence and impartiality of the laboratory from its related bodies, if applicable, to all relevant personnel and to all areas where GLP activities in the scope of accreditation are carried out in order to undertake any check to verify the capability of the laboratory, and to witness the activities are being performed relevant to accreditation.
7. The laboratory shall provide on request of SLAB, access to SLAB's assessment teams including observers, witnessing assessors and or any expert appoint on behalf of SLAB to assess the laboratory's performance or performance of SLAB's assessment team.
8. Laboratory shall provide personnel protective equipment (PPE) for assessment team when required.
9. The laboratory shall appoint competent personnel to perform and evaluate compliance against the applicable standard and the requirements of study.
10. On grant of accreditation, the laboratory shall claim accreditation in only those technical areas /study fields for which it has been accredited and as stated in the Certificate and Schedule of Accreditation.
11. The laboratory shall abide by the Policy governing the use of SLAB accreditation symbol (AC-RG (P)-01). The mark shall be used for the purpose of identifying correctly and unambiguously its study activities accredited by SLAB.
12. The laboratory shall not use study reports nor any part thereof in a misleading manner and not use the SLAB accreditation symbols or its accreditation symbol to imply a product, process, system or person is approved by the SLAB or/ and not state SLAB accreditation in a manner as to be considered misleading manner and not state its accreditation in a manner as to be considered misleading or unauthorized and bring disrepute on SLAB.

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13. The laboratory shall offer the SLAB or its representative cooperation in undertaking any check to verify studies and related records and documents of the laboratory, providing names of all authorized signatories/ Study Director who are responsible for authenticity and approval of study plans/ reports and issue of any statements related to studies covered under the scope of accreditation, offering access to relevant areas of the laboratory for witnessing studies carried out, examination of all relevant documentation and records and interaction with all relevant personnel of studies covered under scope of accreditation.

14. The laboratory shall pay fees for processing of application, fees for assessments; expenses towards travel, board & lodging for assessments and annual accreditation fees as determined from time to time by SLAB. In the event of withdrawal of accreditation, the laboratory shall settle the due payments if any.

15. The laboratory shall inform SLAB within 01 month of significant changes which affect the activities and operations of laboratory relevant to accreditation such as legal, commercial, ownership or organizational status, any suspension cancellation of registration status by regulatory bodies, organizational structure, top management & key personnel, main policies, resources and premises, scope of accreditation, work procedures and other such matter that may affect the ability of the laboratory to fulfill requirements of applicable accreditation criteria indicated in clause 01.

16. The accredited laboratory shall normally perform test which is covered under scope of accreditation by itself. Where a laboratory obtains tests/measurements services or part of the tests/measurements from external laboratories /facilities, this work shall be obtained only from another accredited laboratory as per ISO/IEC 17025/ISO 15189. If there are no accredited GLP facility, the laboratory may obtain services from non-accredited GLP facility having demonstrated competency through evaluation done by the laboratory as per the standard. The laboratory shall record and retain details of its investigation of the competence and compliance of its external services providers and maintain a register of all external service providers. The laboratory shall identify areas which require services of external parties and include into the study plan and obtain approval from relevant parties (Sponsors) involved in the study including Study Director.

17. The accredited/applicant laboratories shall regularly and satisfactorily participate in the External Quality Assurance Programmes covering its scope of accreditation as per SLAB Policy for Participation in External Quality Assurance Activities (AC-RG(P)-02).

18. The accredited laboratory shall respond promptly to the changes initiated by SLAB in its accreditation criteria, policies and procedures and for necessary change the laboratory will be given sufficient notice and time on the opinion of SLAB, as is found to be reasonable, to carry out adjustments in its system.

19. SLAB may at subsequent stage decide to suspend/reduce the scope of accreditation, granted initially, if significant deficiency/ies is/are observed during surveillance activity or re-assessment in the laboratory management system or technical competence, which is likely to adversely influence the study results or the laboratory is unable to complete corrective actions within agreed/ stipulated time of the surveillance activity/ re-assessment.

20. SLAB may suspend or withdraw accreditation of an accredited laboratory, on one or more of the following grounds and inform in writing:

- a. After undergoing a surveillance or re-assessment laboratory has not taken any corrective actions after getting sufficient time and notice from SLAB
- b. Non-payment of accreditation expenses
- c. Non-cooperation with SLAB.

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- d. Refusal to allow examination of documents and records by SLAB & its assessors.
- e. Denial of access to SLAB, its assessment team and/or peer evaluators to its laboratory areas.
- f. Wrong representation of scope of accreditation.
- g. Misuse of SLAB accreditation symbol or its use during and after expiry of accreditation.
- h. Activity bringing disrepute to SLAB.
- i. Result of complaint analysis or any other information which indicates that the laboratory no longer complies with requirements of SLAB.
- j. In the event of compromising impartiality of its laboratory's operations or violation of rules and procedures of SLAB.
- k. Evidence of fraudulent behavior, intentionally provides false or conceals information or reporting of facts.
- l. Non-adherence to significant changes as mentioned in section 15 of this document

21. The accredited laboratory upon suspension or withdrawal of its accreditation (however determined) or expiry of validity of accreditation shall forthwith discontinue its use of all advertising matter that contain any reference to the accreditation status and return the certificate and schedule/s of accreditation to SLAB.

22. Laboratory shall inform changes to studies cover under scope of accreditation. Such changes are assessed at the next surveillance/ re-assessment.

23. Laboratory is required to inform the SLAB in writing with justification, if any of the proposed assessor(s) happens to be their Consultant or associated with the laboratory in any other capacity, and SLAB shall not appoint these Consultants as team members.

24. SLAB absolves itself of any legal or financial liability arising out of any activities involving any accidental or consequential damages to personnel/ equipment/ products at any time. The laboratory shall carry out risk analysis and identify potential liabilities and make necessary arrangements (Insurance or reserve) to cover liabilities arisen from its study activities.

25. The Laboratory has the right to complaint on any dissatisfaction with SLAB accreditation process and all personnel involve in the accreditation as per the procedure for handling complaints (GN-PR(P)-08) or procedure for dealing with appeals complaints (GN-PR(P)-09).

26. All disputes, if any, arising out of SLAB decisions that remain unresolved through mechanism provided by SLAB are subject to the exclusive jurisdiction of the Courts in Sri Lanka and none other.

By signing this document, it is implied that a laboratory after accreditation implied agrees to comply at all times with all Terms and Conditions for Maintaining SLAB accreditation and legally enforceable agreement.

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Signature of Chief Executive or his Authorized Representative:

Name, Designation & Laboratory:

Date & Place:

Seal of the Laboratory, if any

Signature of Director/CEO, SLAB:

Name:

Date & Place:

Date of Receipt of Accredited Certificate:

Seal of SLAB

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