 **SRI LANKA ACCREDITATION BOARD**

 **for CONFORMITY ASSESSMENT**

**APPLICATION FORM**

***for* accreditation *of* TEST FACILITIES for GOOD LABORATORY PRACTICE**

***Instructions to the Applicant:***

1. Please submit the duly filled application along with all annexures and documents and records referred in the application and Self-Assessment Checklist (GLP-FM(P)-11).
2. Please read Rules and Procedures for Accreditation of TL/CL/ML/IB/PTP/RMP/GLP (AC-RG(P)-26), Terms and Conditions for Maintaining Accreditation of TL/CL/ML/IB/PTP/RMP/GLP (AC-RG(P)-08), Policy on governing the use of Accreditation Symbols (AC-RG(P)-01) and Specific criteria GLP Accreditation (GLP-RG(P) -04) before filling the application.

Director /CEO



Sri Lanka Accreditation Board for Conformity Assessment

No. 44, Dedicated Economic Centre

Kirimandala Mawatha

Narahenpita

**APPLICATION FOR ACCREDITATION of GOOD LABORATORY PRACTISE**

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| We apply for SLAB accreditation of **Good Laboratory Practice of our** **test facility** as per details given below: |
|  |  |  |  |  |
| First Accreditation  |  |  | 1. Scope Extensionin the existing accredited type of study
 |  |
|  |  |  |  |  |
| Renewal of Accreditation |  |  | 1. Scope extension in new field of study
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| 1. **1. Test Facility Details**
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|  |
|  | **Name of the Test Facility** |  |
| Address |  |
| Telephone |  | Fax No |  |
| e-mail |  |  |  |
|  |  |  |  |
| **1.2.** | **Name of Parent Organization (if part of an organization)** |  |
| Address |  |
| Telephone |  | Fax No |  |
| e-mail |  |  |  |
|  |  |  |  |
| **1.3.** | **Legal status and date of establishment**(Please provide copy of registration / Relevant section of act or regulation) |  |

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| **2.** | **Accreditation Details** |
|  |  |
| **2.1.** | **Type of Studies for which accreditation is sought** (Please tick the appropriate box, a separate application to be filled for each discipline)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Physical-chemical studies |  |  | Environment toxicity Studies |  |
| Toxicity studies |  |  | Ecosystems related Studies  |  |
| Residue studies |  |  | Safety studies |  |
| Analytical & Non-Clinical studies |  |  | Statistical Analysis of Data |  |
| Mutagenicity studies |  |  | Others (Please specify) |  |

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| **2.2.** | **If the Test Facility is already accredited for GLP, attach the Scope & Good Laboratory Practice for which** **accreditation has been granted**(Please attach the scope of accreditation)  |
| **2.3.****2.4** | * 1. **If the Laboratory is already accredited for ISO/IEC 17025/ ISO 15189, indicate the fields of testing and scope for which accreditation has been granted.**(Please attach the scope of accreditation)

**Scope of Accreditation**(Please indicate the Scope which accreditation is sought) ***–*** *Please attach Annexure 01*  |

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| **3.** | **Organization** |  |  |  |
|  |  |  |  |  |
| **3.1.** | **Senior Management** (Name, Designation) |
|  | 3.1.1. | Chief Executive of the Organization | **:** | **………………………………………………** |
|  | 3.1.2. | Person responsible for the test facility management | **:** | **………………………………………………** |
|  | 3.1.3. | Study Director | **:** | **………………………………………………** |
|  | 3.1.4. | Authorized Representative for SLAB | **:** | **………………………………………………** |
|  |  | Telephone: |  | Fax : |  | E-mail  |  |
|  |  | Mobile: |  |  |  |  |  |
|  |  |  |
|  |  |  |  |  |
|  | 3.1.5 | Information regarding any individual or organization that has provided consultancy or following assistance to towards SLAB accreditation; |
|  |  | Development of Quality Management System | **:** | **……………………………………………………** |
|  |  | Development of Technical Operations | **:** | **……………………………………………………** |
|  |  | Training | **:** | **……………………………………………………** |
|  |  | Conducting Internal Audits | **:** | **……………………………………………………** |
|  |  | Other | **:** | **……………………………………………………** |
|  |  |  |  |  |
|  | 3.1.7. | Any affiliation or relationships to SLAB | **:** | **……………………………………………………** |

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| **3.2.** | **Organization and Management Structure** |
|  | 3.2.1. | Indicate in an organization and management structure to the operating departments of the test facility for which accreditation is being sought (please append) |
|  | 3.2.2. | Indicate how the test facility is related to external organizations/sponsors or to its own parent organization (where applicable)  |
| **3.3.** | **Employees** |
|  | 3.3.1. | Total number in test facility for the scope applied: | ……………………………. |  |  |
|  | 3.3.2. | Details of staff – Please attach Annexure 03 |  |  |
|  | 3.3.3. | If Trainees or Contracted persons are employed, please indicate details of them |  |  |
|  |  | …………………………………………………………………………………..................................................………………………………………………………………………………….................................................. |

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| **4.** | **Equipment and Reference Materials** |
|  | 4.1. | Equipment List – Please attach Annexure 04 |  |  |
|  | 4.2. | List of reference materials – Please attach Annexure 05 |  |  |
|  |  |  |  |  |
| **5.** | **Internal and External Quality Assurance Programmes** Please attach Annexure 06 and Summary of recently participated Internal and External Quality Assurance Programmes related to the applied scope (Annexure 01). |
|  |  |  |  |  |
| **6.** | **Self-Assessment Checklist** – Please attach Annexure 07 |
|  |  |
| **7.**  | **Please attach the following documents / records** |
|  | 7.1. | Management System Documentation (GLP Manual, Management System Procedures) |
|  | 7.2. | A Sketch of the Test facility Layout |
|  | 7.3. | Sampling method including selection of samples or sites, the sampling plan and preparation treatment of samples |
|  | 7.4. | Study plan |
|  | 7.5. | Report of the last internal audit together with corrective action records. |
|  | 7.6. | Minutes of the last management review |
|  | 7.7. | Study report formats |
|  | 7.8. | Calibration certificates of key instruments |
|  | 7.9. | Standard Operating Procedures  |
|  | 7.10. | Whenever applicable, appropriate procedure or method for Validation and Verification of methods |
|  | 7.11 | Two signed copies of Terms and Conditions for maintaining laboratory accreditation (AC-RG(P)-08) |

**8. Willingness to undergo Assessment**

**We declare that**

* We are aware of and will abide by the Terms and Conditions for maintaining test facility accreditation TL/CL/ML/IB/PTP/RMP/GLP (AC-RG(P)-08) to be signed by both parties, which is enclosed.
* We agree to comply fully and continually fulfill the requirements of OECD Guidelines and SLAB requirements for the accreditation of test facility.
* We agree to comply with accreditation procedures and pay all costs for activities related to accreditation process as per Terms and Conditions for maintaining laboratory accreditation TL/CL/ML/IB/PTP/RMP/GLP (AC-RG(P)-08) & Fee Structure (GLP-RG(P)-01) available in SLAB website: [www.slab.lk](http://www.slab.lk).
* We agree to co-operate with the assessment team appointed by SLAB for assessment of all relevant documents by them and their visits to those parts of the test facility/site that are part of the scope of accreditation.
* We declare that all the information provided is true and accurate to the best of our knowledge. I’m aware that giving any fraudulent information will lead to termination of the accreditation process.

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| Signature of Chief Executive |  |
| Name & Designation |  |
| Date & Place |  |

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***For office use only***

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| A. | Check whether the following have been submitted | To be checked by the Management Assistant | To be checked by the Technical Manager |
|  | Annexure 01 - *Scope of Accreditation* |  |  |
|  | Annexure 02 - Authorized personnel for the study |  |  |
|  | Annexure 03 - Details of staff |  |  |
|  | Annexure 04 - Equipment List |  |  |
|  | Annexure 05 - List of reference materials |  |  |
|  | Annexure 06 - Internal and External Quality Assurance Programmes |  |  |
|  | Annexure 07 - Self-Assessment Checklist |  |  |
|  | Test methods/Standard Operating Procedures related to study |  |  |
|  | Organization and management structure |  |  |
|  | Summary of recently participated Internal and External Quality Assurance Programmes related to study |  |  |
|  | Management System Documentation |  |  |
|  | A Sketch of the Laboratory Layout |  |  |
|  | Sampling method including selection of samples or sites, the sampling plan and preparation treatment of samples |  |  |
|  | Study plan |  |  |
|  | Report of the last internal audit together with corrective action records. |  |  |
|  | Minutes of the last management review |  |  |
|  | Study report formats |  |  |
|  | Calibration certificates of key instruments |  |  |
|  | Whenever applicable, appropriate procedure or method for Validation and Verification of methods |  |  |
|  | Two Signed copies of Terms and Conditions for maintaining laboratory accreditation (AC-RG(P)-08) |  |  |
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| --- | --- | --- |
| ***Case file number:*** | *Assigned by* | *Verified by* |

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| To be filled by the Technical Manager / Deputy Technical Manager before assigning the application to Authorized officer

|  |  |  |  |
| --- | --- | --- | --- |
|  A. | Comments on the case file | : |  |
| B. | Allocation of Case file | : |  |
| C. | Document Review | : | Required/ Not Required |
| D. | Allocation for Document Review | : |  |

Date: …………………… Technical Manager/Deputy Technical Manager: ……………………. |

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| To be filled by the Authorized officer  |
| A. | Check whether the SLAB fulfills the following; |  |
|  Is the activity area of CAB under the purview of SLAB | Yes / No |
|  Can the initial assessment be performed in a timely manner | Yes / No |
|  If yes, state the duration | …………………………….. |
|  Has the SLAB Competence on accrediting the CAB | Yes / No |
| B. | Are all functions of CAB performed at one siteIf No, indicate the specific activities  | Yes / No |
|  |  |
| C. | Time estimation (Number of man days) for initial assessment | : ……………………………………………………. |
|  |  |  |  |
| D.  | Remarks of Authorized Officer | : ……………………………………………………………………………...……………………………………………………………………………….……………………………………………………………………………….……………………………………………………………………………….………………………………………………………………………………. |
|  | Date: …………………… Authorized Officer: …………………………….. |