# National Accreditation Board for Testing and Calibration Laboratories

## SCOPE OF ACCREDITATION

**Laboratory Name :** SYNGENE INTERNATIONAL LIMITED - BIOANALYTICAL LABORATORY LARGE MOLECULE, SYNGENE INTERNATIONAL LIMITED, THIRD FLOOR, TOWER I, SEMICON PARK, ELECTRONICS CITY PHASE -II, BENGALURU, KARNATAKA, INDIA

**Accreditation Standard** ISO/IEC 17025:2017

**Certificate Number** TC-9900 **Page No** 1 of 1

**Validity** 24/09/2021 to 23/09/2023 **Last Amended on** -

| S.No | Discipline / Group | Materials or Products tested | Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed | Test Method Specification against which tests are performed and / or the techniques / equipment used |
|---|---|---|---|---|
| Permanent Facility | | | | |
| 1 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Cytokines (TNF alfa, IL2) | ELISA (Direct, Indirect, Sandwich, Bridge) - Immunoassay Pharmacokinetics Assessment | SOP-GLP-BAL-II-0117, SOP-GLP-BAL-II-0120 |
| 2 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Monoclonal Antibodies (Trastuzumab, Infliximab, Rituximab, Bevacizumab, Ranibizumab, Panitumumab, Adalimumab, Ustekinumab, Dengue mAb, Tocilizumab) | ELISA (Direct, Indirect, Sandwich, Bridge) - Immunoassay Pharmacokinetics Assessment | SOP-GLP-BAL-II-0117, SOP-GLP-BAL-II-0120 |
| 3 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Monoclonal Antibodies (Trastuzumab, Infliximab, Rituximab, Bevacizumab, Ranibizumab, Panitumumab, Adalimumab, Ustekinumab, Dengue mAb, Tocilizumab) | ELISA (Direct, Indirect, Sandwich, Bridge) - Immunoassay, Immunogenicity assessment ADA/Nab | SOP-GLP-BAL-II-0118 |
| 4 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Monoclonal Antibodies (Trastuzumab, Infliximab, Rituximab, Bevacizumab, Ranibizumab, Panitumumab, Adalimumab, Ustekinumab, Dengue mAb, Tociluzumab) | Binding Kinetics - Surface Plasmon Resonance | SOP-GLP-BAL-II-0119 |
| 5 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Recombinant Proteins (Insulin, Insulin analogues, GCSF, FSH, Darbepoetin alfa) | ELISA (Direct, Indirect, Sandwich, Bridge) - Immunoassay Pharmacokinetics Assessment | SOP-GLP-BAL-II-0117, SOP-GLP-BAL-II-0120 |
| 6 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Recombinant Proteins (Insulin, Insulin analogues, GCSF, FSH, Interferon, Darbepoetin alfa) | Binding Kinetics - Surface Plasmon Resonance | SOP-GLP-BAL-II-0119 |
| 7 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Recombinant Proteins (Insulin, Insulin analogues, GCSF, FSH, Interferon, Darbepoetin alfa) | ELISA (Direct, Indirect, Sandwich, Bridge)- Immunoassay, Immunogenicity assessment ADA/Nab | SOP-GLP-BAL-II-0118 |
| 8 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Vaccines (HPV, COVID-19, Malaria, Typhoid, TDAP, Pneumococcal, Dengue) | ELISA (Direct, Indirect, Sandwich, Bridge) - Immunoassay Pharmacokinetics Assessment | SOP-GLP-BAL-II-0117, SOP-GLP-BAL-II-0120 |
| 9 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Vaccines (HPV, COVID-19, Malaria, Typhoid, TDAP, Pneumococcal, Dengue) | ELISA (Direct, Indirect, Sandwich, Bridge) - Immunoassay, Immunogenicity assessment ADA/Nab | SOP-GLP-BAL-II-0118 |