# National Accreditation Board for Testing and Calibration Laboratories

## SCOPE OF ACCREDITATION

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|---|---|---|---|
| **Laboratory Name :** | NATIONAL INSTITUTE OF BIOLOGICALS, PLOT NO. A- 32, SECTOR 62, NOIDA, UTTAR PRADESH, INDIA | | |
| **Accreditation Standard** | ISO/IEC 17025:2017 | | |
| **Certificate Number** | TC-7725 | **Page No** | 1 of 30 |
| **Validity** | 16/08/2021 to 15/08/2023 | **Last Amended on** | 08/09/2021 |

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|---|---|---|---|---|
| Permanent Facility | | | | |
| 1 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | 1. Cell Culture Rabies vaccine 2. Live attenuated Measles Vaccine 3. Live attenuated Rubella Vaccine 4. Live attenuated MMR Vaccine 5. Live Attenuated Measles & Rubella Vaccine 6. Inactivated Polio vaccine 7. Rotavirus Vaccine Rotarix 8. Hepatitis A Inactivated Vaccine 9. Hepatitis B (rDNA) vaccine . 10. Haemophilus influenzae type b TT conjugate vaccine 11. Bacillus Calmette Guerin (BCG) vaccine 12. Bivalent Polio Myelitis Vaccine 13. Oral Cholera Vaccine | Sterility | NIB/STR/SOP/001/ R4 |
| 2 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Hepatitis B (rDNA) Vaccine | Identification and In-Virto potency assay by ELISA | NIB/VVL/SOP/060/R0 |
| 3 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Hepatitis B (rDNA) Vaccine | Identification and Potency assay | (ELISA)"NIB/VVL/SOP/59/R0 |
| 4 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Human Chorionic Gonadotropin Bulk/Inj. | Assay | (Weight gain method),NIB/EHL/SOP/40/R4 |
| 5 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | RT-LAMP | "Reactivity " | NIB/CKTL/SOP/013/R0 |
| 6 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | " 1. Cell Culture Rabies Vaccine 2. Inactivated Polio vaccine 3. Hepatitis A Inactivated Vaccine " | Bacterial Endotoxins | (Gel Clot method),NIB/EHL/SOP/28/R4 |
| 7 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | " 1. Human Coagulation Factor VIII Recombinant 2. Human Coagulation Factor IX Recombinant " | Bacterial Endotoxins | (Gel Clot method),NIB/EHL/SOP/28/R4 |
| 8 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | " 1. Rituximab 2. Adalimumab 3. Trastuzumab 4. Bevacizumab 5. Anti- D Immunoglobulin (Monoclonal) " | Bacterial Endotoxins | (Gel Clot method),NIB/EHL/SOP/28/R4 |
| 9 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | " Anti- D Immunoglobulin (Monoclonal)" | Abnormal Toxicity | NIB/AF/SOP/001/R4 |

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| 10 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | " 1. Soluble Insulin inj.2. Isophane Insulin inj.3. Biphasic Isophane Insulin (25/75)inj. 4. Biphasic Isophane Insulin (30/70)inj. 5. Biphasic Isophane Insulin (50/50) inj.6. Insulin Glargine inj. 7. Insulin Glulisine inj. 8. Insulin Lispro inj. 9. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) inj. 10. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) inj. 11. Insulin Aspart inj. 12. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) inj. 13. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) inj. 14. Insulin Detemir inj.15. Insulin Degludec inj. 16. Insulin Degludec/ Insulin Aspart inj.17. Exenatide inj. 18. Exenatide Once Weekely inj. 19. Liraglutide inj. 20. rh-erythropoietin 21. Filgrastim inj.22. Interferon Beta-1a inj. 23. Interferon Alpha-2b inj. 24. Peg-filgrastim inj. 25. peg-interferon Alpha-2b inj. 26. Teriparatide (rh-PTH) inj. 27. Peg Interferon Beta-1a inj. | Sterility | NIB/STR/SOP/001/ R4 |
| 11 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | " Peg- Filgrastim Inj." | Assay/ Potency | (Bio-assay) NIB/TMA/SOP/072/00 |
| 12 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Anti-Fya reagent 2. Anti-Jka reagent 3. Anti-K reagent 4. Anti-k reagent 5. Anti-Lea reagent 6. Anti-Leb reagent 7. Anti-Pi reagent 8. Anti-M reagent 9. Anti-N reagent 10. Anti-S reagent" | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/066/R2 |
| 13 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Anti-K reagent 2. Anti-Lea reagent 3. Anti-Leb reagent 4. Anti-Pi reagent 5. Anti- k reagent 6. Anti-Fya reagent 7. Anti-JKa reagent 8. Anti-M reagent 9. Anti-N reagent 10. Anti-S reagent " | Specificity | (Haemagglutination method),NIB/BRL/SOP/066/R2 |
| 14 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Cell Culture Rabies Vaccine 2. Hepatitis B (rDNA) Vaccine 3.Haemophilus influenzae type b TT conjugate vaccine " | Pyrogen | NIB/AF/SOP/002/R5 |
| 15 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Cell Culture Rabies Vaccine 2. Live Attenuated Measles Vaccine 3. Live Attenuated Rubella Vaccine 4. Live Attenuated MMR Vaccine 5. Live attenuated Measles & Rubella Vaccine 6. Inactivated Polio vaccine" | Bovine Serum Albumin content | (ELISA)"NIB/VVL/SOP/043/R1 |
| 16 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Human Albumin 2. Plasma Protein Fraction 3. Dried Human Anti hemophilic fraction (factor VIII) 4. Anti-D Immunoglobulin IM 5. Tetanus immunoglobulin IM 6. Human normal immunoglobulin IM 7. Hepatitis B Immunoglobulin IM 8. Rabies Immunoglobulin IM " | Abnormal Toxicity | NIB/AF/SOP/001/R4 |

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| 17 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Human Albumin 2. Plasma Protein Fraction 3. Human Normal Immunoglobulin IV 4. Human Normal Immunoglobulin IM 5. Anti D Immunoglobulin IM 6. Anti D Immunoglobulin IV 7. Tetanus Immunoglobulin 8. Dried Human Anti- hemophilic fraction (factor VIII) 9. Human Coagulation Factor IX 10. Anti-Thrombin III Concentrate 11. Human Fibrinogen 12. Hepatitis B Immunoglobulin IM 13. Hepatitis B Immunoglobulin IV 14. Rabies Immunoglobulin IM 15.Human Prothrombin Complex " | Pyrogen | NIB/AF/SOP/002/R5 |
| 18 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Human albumin 2. Human Plasma Protein Fraction 3. Human Normal Immunoglobulin IV 4. Human Normal Immunoglobulin IM 5. Anti-D Immunoglobulin IV 6. Anti-D Immunoglobulin IM 7. Human Tetanus immunoglobulin IM 8. Human Coagulation Factor VIII plasma derived 9. Human Coagulation Factor VIII recombinant 10. Human Coagulation Factor IX 11. Anti-inhibitor Coagulant complex 12. Fibrin sealant kit 13. Anti-thrombin III concentrate 14. Human Fibrinogen 15. Hepatitis Immunoglobulin IV 16. Hepatitis Immunoglobulin IM 17. Rabies Immunoglobulin IM 18. Human Prothrombin Complex 19. Human Coagulation Factor IX (r-DNA) 20. Human normal immunoglobulin IV (bulk) 21. human normal immunoglobulin IM (bulk) 22. human normal immunoglobulin (SC) 23. Hepatitits B immunoglobulin (SC) " | Sterility | NIB/STR/SOP/001/ R4 |
| 19 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Human Chorionic Gonadotropin Bulk/Inj. 2. Human Menopausal Gonadotropin Bulk " | Abnormal Toxicity | NIB/AF/SOP/001/R4 |
| 20 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Human Chorionic Gonadotropin Inj. 2. Menotropin (Human Menopausal Gonadotropin) Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Inj. 4. Recombinant Human Follicle Stimulating Hormone Inj. 5. Somatropin Inj. (Recombinant Human Growth Hormone) 6. Human Chorionic Gonadotropin Bulk 7.Menotropin ( Human Menopausal Gonadotropin) Bulk " | Sterility | NIB/STR/SOP/001/ R4 |
| 21 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Human Normal Immunoglobulin IV 2. Dried Human Anti-hemophilic fraction (factor VIII)" | Anti-A, Anti-B Haemagglutinin test | (Haem-agglutination method)," NIB/BPL/SOP/098/R0 |
| 22 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Live attenuated Measles Vaccine 2. Live attenuated Measles Mumps Rubella Vaccine 3. Cell culture Rabies Vaccine 4. Live attenuated Rubella Vaccine 5. Live attenuated Measles & Rubella Vaccine 6.Haemophilus influenzae type b TT conjugate vaccine " | Abnormal Toxicity | NIB/AF/SOP/001/R4 |
| 23 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Rituximab 2. Adalimumab 3. Trastuzumab 4. Bevacizumab 5. Anti- D Immunoglobulin (Monoclonal)" | Sterility | NIB/STR/SOP/001/ R4 |

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| 24 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Soluble Insulin inj. 2. Isophane Insulin inj. 3. Biphasic Isophane Insulin (25/75) inj. 4. Biphasic Isophane Insulin (30/70) inj. 5. Biphasic Isophane Insulin (50/50) inj. 6. rh-Insulin Bulk 7. Insulin Glargine inj. 8. Insulin Glulisine inj. 9. Insulin Aspart inj. 10. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) inj. 11. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) inj. 12. rh-Erythropoietin 13. Filgrastim inj. 14. Interferon Beta-1a inj. 15. Interferon Alpha-2b inj. 16. Peg- Filgrastim inj. 17. Peg-Interferon Alpha-2b inj. 18. Peg Interferon Beta-1a inj. 19.Exenatide inj." | Bacterial Endotoxins | (Gel Clot method),NIB/RPL/SOP/005/R4 |
| 25 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Streptokinase Bulk/Inj. 2. Recombinant Streptokinase Inj. 3. Urokinase Bulk/Inj. " | Abnormal Toxicity | NIB/AF/SOP/001/R4 |
| 26 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Streptokinase Inj. 2. Recombinant Streptokinase Inj. 3. Urokinase inj. 4. Heparin Sodium inj. 5.Streptokinase Bulk 6. Urokinase Bulk" | Sterility | NIB/STR/SOP/001/ R4 |
| 27 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Urofollitropin (Human follicle-stimulating Hormone) Bulk/Inj. 2. Recombinant Human Follicle Stimulating Hormone Inj." | Assay (FSH activity) | (Weight gain method),NIB/EHL/SOP/46/R3 |
| 28 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1. Urofollitropin (Human follicle-stimulating Hormone) Bulk/Inj. 2. Recombinant Human Follicle Stimulating Hormone Inj. " | Identification | (Weight gain method) ,"NIB/EHL/SOP/46/R3 |
| 29 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1.Human Chorionic Gonadotropin Bulk/ Inj. 2. Menotropin (Human Menopausal Gonadotropin) Bulk/Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Bulk/Inj. 4. Recombinant Human Follicle Stimulating Hormone Inj. 5. Somatropin Inj. (Recombinant Human Growth Hormone). " | Bacterial Endotoxins | (Gel Clot method),NIB/EHL/SOP/39/R3 |
| 30 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "1.Interferon Alpha-2b Inj. 2.Interferon Beta-1a Inj. 3.Peg Interferon Beta-1a Inj. 4.Peg-Interferon Alpha 2b Inj." | Identification | (CPER Assay) NIB/TMA /SOP/061/R1 |
| 31 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Anti- D Immunoglobulin (Monoclonal)" | Pyrogen | NIB/AF/SOP/002/R5 |
| 32 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Anti-A (Monoclonal) " | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method) NIB/BRL/SOP/018/R4 |
| 33 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Anti-A (Monoclonal) " | Avidity | (Haemagglutination method), NIB/BRL/SOP/018/R4 |
| 34 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Anti-A (Monoclonal) " | Identification | NIB/BRL/SOP/018/R4 |

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| 35 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Anti-A (Monoclonal) " | Specificity | (Haemagglutination method),NIB/BRL/SOP/018/R4 |
| 36 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Anti-D Immunoglobulin (Monoclonal)" | Assay/ Potency | (Flow Cytometry)," NIB/TMA/SOP/075/R1 |
| 37 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Enzymes & Hormones Blood Products Recombinant Product Vaccines" | Transmitted Transfusion infection Testing | NIB/IDL/SOP/33/R1 |
| 38 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "RNA Extraction (SARS-CoV-2) " | "Reactivity " | NIB/CKTL/SOP/007/R0 |
| 39 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Streptokinase Bulk " | Streptolysin activity | (UV Vis spectrophotometry),NIB/EHL/SOP/08/ R3 |
| 40 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | "Urokinase Inj." | Pyrogen | NIB/AF/SOP/002/R5 |
| 41 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | 1. Blood Donor Screening Multiplex (HBV, HCV & HIV) Test (Qualitative) 2. Infection Diagnostic Test for HIV-1 (Qualitative) 3. Infection Diagnostic Test for HCV (Qualitative) 4. Infection Diagnostic Test for HBV (Qualitative) | Sensitivity & Specificity | "NIB/MDL/SOP/43/R0 |
| 42 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | 1. HBV Viral Load Monitoring 2. HIV-1 Viral Load Monitoring 3. HCV Viral Load Monitoring | Accuracy | NIB/MDL/SOP/41/R0 |
| 43 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | 1. Insulin Lispro inj. 2. Insulin detemir inj. 3. Insulin degludec inj. 4.Liraglutide Inj. 5.Exenatide 6.Dulaglutide 7.Insulin Degludec/Liraglutide Inj. | Bacterial Endotoxin | (KCA Method) NIB/RPL/SOP/037/R3 |
| 44 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | 1. Interferon Alpha-2b Inj. 2. Interferon Beta-1a Inj. 3.Peg Interferon Beta-1a Inj. 4.Peg-Interferon Alpha 2b Inj. | Assay/ Potency | (CPER Assay) NIB/TMA /SOP/061/R1 |
| 45 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | 1. Streptokinase Bulk/Inj. 2. Recombinant Streptokinase Inj. 3. Urokinase Bulk/ Inj. 4.Heparin Sodium injection | Bacterial Endotoxin | (Gel Clot method),NIB/EHL/SOP/11/R3 |
| 46 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Adalimumab | Identification | (L929 Cytotoxicity inhibition bioassay),NIB/TMA/SOP/35/R1 |
| 47 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Adalimumab | "Assay/ Potency " | (L929 Cytotoxicity inhibition bioassay),"NIB/TMA/SOP/35/R1 |

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| 48 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti -B (Monoclonal) | Identification | NIB/BRL/SOP/019/R4 |
| 49 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti AB (Monoclonal) | Identification | NIB/BRL/SOP/020/R4 |
| 50 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti D Immunoglobulin IM/ IV | Potency | (Agglutination method),"NIB/BPL/SOP/60/R2 |
| 51 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A (Monoclonal) | Intensity | (Haemagglutination method)"NIB/BRL/SOP/018/R4" |
| 52 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A (Monoclonal) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/018/R4 |
| 53 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A, B (Monoclonal) | Specificity | (Haemagglutination method),NIB/BRL/SOP/020/R4 |
| 54 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A,B (Monoclonal) | Avidity | (Haemagglutination method),NIB/BRL/SOP/020/R4 |
| 55 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A,B (Monoclonal) | Intensity | (Haemagglutination method),NIB/BRL/SOP/020/R4 |
| 56 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A,B (Monoclonal) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/020/R4 |
| 57 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A1 (Lectin) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/024/R4 |
| 58 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A1 (Lectin) | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method),NIB/BRL/SOP/024/R4 |
| 59 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A1 (Lectin) | Specificity | (Haemagglutination method),NIB/BRL/SOP/024/R4 |
| 60 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-A1(Lectin) | Intensity | (Haemagglutination method),NIB/BRL/SOP/024/R4 |
| 61 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-AB (Monoclonal) | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method),NIB/BRL/SOP/020/R4 |

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| 62 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-B (Monoclonal) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/019/R4 |
| 63 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-B (Monoclonal) | Avidity | (Haemagglutination method),NIB/BRL/SOP/019/R4 |
| 64 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-B (Monoclonal) | Intensity | (Haemagglutination method),NIB/BRL/SOP/019/R4 |
| 65 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-B (Monoclonal) | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method),NIB/BRL/SOP/019/R4 |
| 66 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-B (Monoclonal) | Specificity | (Haemagglutination method),NIB/BRL/SOP/019/R4 |
| 67 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D (IgG)* (Monoclonal) | Reactivity Rouleaux/ Haemolysis/ Prozone* | (Haemagglutination method),NIB/BRL/SOP/21/R2 |
| 68 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D IgG (Monoclonal) | Specificity | (Haemagglutination method),NIB/BRL/SOP/21/R2 |
| 69 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D IgM (Monoclonal) | Specificity | (Haemagglutination method),NIB/BRL/SOP/022/R4 |
| 70 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D IgM +IgG (Monoclonal) | Specificity | (Haemagglutination method),NIB/BRL/SOP/23/R2 |
| 71 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgG) (Monoclonal) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/21/R2 |
| 72 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM + IgG) (Monoclonal) | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method),NIB/BRL/SOP/23/R2 |
| 73 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM) (Monoclonal) | Avidity | (Haemagglutination method),NIB/BRL/SOP/022/R4 |
| 74 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM) (Monoclonal) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/022/R4 |
| 75 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM) (Monoclonal) | Intensity | (Haemagglutination method),NIB/BRL/SOP/022/R4 |

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| 76 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM) (Monoclonal) | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method),NIB/BRL/SOP/022/R4 |
| 77 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM+IgG) (Monoclonal) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/23/R2 |
| 78 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM+IgG) (Monoclonal) | Avidity | (Haemagglutination method),NIB/BRL/SOP/23/R2 |
| 79 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-D(IgM+IgG) (Monoclonal) | Intensity | (Haemagglutination method),NIB/BRL/SOP/23/R2 |
| 80 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-H (Lectin) | Reactivity Rouleaux/ Haemolysis/ Prozone | (Haemagglutination method)NIB/BRL/SOP/025/R4 |
| 81 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-H (Lectin) | Potency (Titer) | (Haemagglutination),NIB/BRL/SOP/025/R4 |
| 82 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-H (Lectin) | Specificity | (Haemagglutination method),NIB/BRL/SOP/025/R4 |
| 83 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-H(Lectin) | Intensity | (Haemagglutination method),NIB/BRL/SOP/025/R4 |
| 84 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-HBc IgM ELISA | Sensitivity & Specificity | NIB/IDKL/SOP/29/R1 |
| 85 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-HBc Total ELISA | Sensitivity & Specificity | NIB/IDKL/SOP/28/R1 |
| 86 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Anti-HBs ELISA | Sensitivity & Specificity | NIB/IDKL/SOP/31/R1 |
| 87 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bacillus Calmette Guerin (BCG) vaccine | "Test for Assay/ Colony Forming Units (CFU) reactivity " | "NIB/BVL/SOP/15/R5 |
| 88 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bacillus Calmette Guerin (BCG) vaccine | Test for Excessive dermal reactivity | NIB/BVL/SOP/17/R5 |
| 89 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bacillus Calmette Guerin (BCG) vaccine | Test for Temperature Stability | NIB/BVL/SOP/19/R5 |

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| 90 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bacillus Calmette Guerin (BCG) vaccine | Test for Virulent mycobacteria | NIB/BVL/SOP/16/R5 |
| 91 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bevacizumab | " Assay/ Potency " | (Bioassay),"NIB/TMA/SOP/047/R1 |
| 92 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bevacizumab | Identification | (Binding Activity of VEGF by ELISA)"," NIB/TMA/SOP/45/R0 |
| 93 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bivalent Polio Myelitis Vaccine | Identification & Potency Assay | (in vitro cell culture method using Hep2C as indicator Cell Line),NIB/VVL/SOP/071/R1 |
| 94 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Bivalent Polio Myelitis Vaccine | Thermal Stability | NIB/VVL/SOP/071/R1 |
| 95 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Blood Glucose Test Strips for Glucometers | Accuracy/ Bias evaluation of blood glucose results from glucometers | (Method comparison),NIB/BKL/SOP/13/R3 |
| 96 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Blood Glucose Test Strips for Glucometers | Intermediate Precision evaluation of blood glucose results from glucometers | "NIB/BKL/SOP/014/R3 |
| 97 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Blood Glucose Test Strips for Glucometers | Repeatability Precision evaluation of blood glucose results from glucometers | "NIB/BKL/SOP/015/R3 |
| 98 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Cell Culture Rabies Vaccine | NIH Potency | NIB/VVL/SOP/054/R1 |
| 99 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Cell Culture Rabies Vaccine | NIH Potency | "NIB/VVL/SOP/007/R4 |
| 100 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Cell Culture Rabies Vaccine | Virus inactivation test | NIB/VVL/SOP/008/R3 |
| 101 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Filgrastim Inj. | " Identification & Assay/ Potency " | (Proliferation Bio-assay) NIB/TMA/SOP/060/00 |
| 102 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Fully Automated analyzer based Glucose Reagent | Linearity and Range evaluation of Glucose estimation | (Colorimetry),"NIB/BKL/SOP/08/R2 |
| 103 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Fully Automated analyzer based Glucose Reagent | TEa (Allowable Total Error limits) evaluation of Glucose estimation | (Colorimetry) "NIB/BKL/SOP/09/R2; 2017., NIB/BKL/SOP/010/R3 " |

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| 104 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Gel Card for forward grouping | Identification | NIB/BRL/SOP/55/R2 |
| 105 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Gel card for Forward grouping | Specificity | (Haemagglutination method),NIB/BRL/SOP/55/R2 |
| 106 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Glucometer Devices | Accuracy/ Bias evaluation of blood glucose results from glucometers by Method comparison | "NIB/BKL/SOP/027/R0 |
| 107 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Glucometer Devices | Intermediate Precision evaluation of blood glucose results from glucometers | "NIB/BKL/SOP/025/R0 |
| 108 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Glucometer Devices | Repeatability Precision evaluation of blood glucose results from glucometers | "NIB/BKL/SOP/026/R0 |
| 109 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HBe Ag/HBe Ag-Ab/Anti-Hbe ELISA | Sensitivity & Specificity | NIB/IDKL/SOP/30/R1 |
| 110 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HBsAg ELISA | Sensitivity & Specificity | NIB/IDL/SOP/18/R6 |
| 111 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HBsAg CLIA | Sensitivity & Specificity | NIB/IDL/SOP/038/R1 |
| 112 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HBsAg ELFA | Sensitivity & Specificity | NIB/IDKL/SOP/42/R0 |
| 113 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HBsAg RAPID | Sensitivity & Specificity | NIB/IDL/SOP/17/R6 |
| 114 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HBsAg/ HIV Neutralization | Sensitivity | NIB/IDL/SOP/61/R0 |
| 115 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HCV Antibody Confirmatory | Sensitivity & Specificity | NIB/IDL/SOP/66/R0 |
| 116 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HCV Antibody ELISA | Sensitivity & Specificity | NIB/IDL/SOP/16/R6 |

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| 117 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HCV Antibody RAPID | Sensitivity & Specificity | NIB/IDL/SOP/15/R6 |
| 118 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HCV CLIA | Sensitivity & Specificity | NIB/IDL/SOP/035/R1 |
| 119 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HCV ELFA | Sensitivity & Specificity | NIB/IDKL/SOP/40/R0 |
| 120 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Hepatitis A Inactivated Vaccine | Identification and assay | (ELISA)"NIB/VVL/SOP/58/R0 |
| 121 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HIV 1 & /2 Antibody Confirmatory | Sensitivity | NIB/IDL/SOP/14/R6, |
| 122 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HIV 1 & /2 Antibody, HIV Ag- Ab, HIV Ag CLIA | Sensitivity & Specificity | NIB/IDKL/SOP/36/R1 |
| 123 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HIV 1 & /2 Antibody, HIV Ag- Ab, HIV Ag ELFA | Sensitivity & Specificity | NIB/IDKL/SOP/41/R0 |
| 124 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HIV 1 & /2 Antibody, HIV Ag-Ab RAPID | Sensitivity & Specificity | NIB/IDKL/SOP/12/R6, |
| 125 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | HIV 1 & /2 Antibody/ HIV Ag-Ab ELISA | Sensitivity & Specificity | NIB/IDL/SOP/13/R6 |
| 126 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Human Chorionic Gonadotropin Bulk/Inj. | Identification | (Weight gain method) ,NIB/EHL/SOP/40/R4 |
| 127 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Human Normal Immunoglobulin I.V. | Anti-D antibodies | "NIB/BPL/SOP/074/R0 |
| 128 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Inactivated Polio vaccine | Identification, potency invitro | "NIB/VVL/SOP/53/R0 |
| 129 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Inactivated Polio vaccine | Potency assay in-vivo | "NIB/VVL/SOP/057/R0 |

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| 130 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated Measles & Rubella Vaccine | Identification, Potency & Thermal stability | ( in vitro cell culture method using VERO & RK-13 as indicator cell line),"NIB/VVL/SOP/050/R0; |
| 131 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated Measles Vaccine | Identification & Potency | (in vitro cell culture method using VERO as indicator cell line)"NIB/VVL/SOP/062/R0 |
| 132 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated Measles Vaccine | Thermal Stability using VERO as indicator Cell line | "NIB/VVL/SOP/062/R0 |
| 133 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated MMR Vaccine | Identification & Potency | (in vitro cell culture method using VERO & RK13 as indicator Cell Line)"NIB/VVL/SOP/063/R0 |
| 134 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated MMR Vaccine | Thermal Stability using VERO & RK 13 as indicator Cell line | "NIB/VVL/SOP/063/R0 |
| 135 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated Rubella Vaccine | Identification & Potency | (in vitro cell culture method using RK 13 as indicator cell line)"NIB/VVL/SOP/061/R0 |
| 136 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Live attenuated Rubella Vaccine | Thermal Stability using RK-13 as indicator Cell line | "NIB/VVL/SOP/061/R0 |
| 137 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Menotropin (Human Menopausal Gonadotropin) Bulk/Inj. | Assay (FSH activity) | (Weight gain method),NIB/EHL/SOP/44/R3 |
| 138 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Menotropin (Human Menopausal Gonadotropin) Bulk/Inj. | Assay (LH activity) | (Weight gain method),NIB/EHL/SOP/45/R3 |
| 139 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Menotropin (Human Menopausal Gonadotropin) Bulk/Inj. | Identification | (Weight gain method),NIB/EHL/SOP/44/R3 |
| 140 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Peg Interferon beta 1 a inj. | Bacterial Endotoxins | (KCA Method) NIB/RPL/SOP/37/R2 |
| 141 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Peg- Filgrastim Inj. | Identification | (Bio-assay) NIB/TMA/SOP/072/00 |
| 142 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Real-Time PCR Based SARS-CoV-2 Diagnostic | "Reactivity " | NIB/CKTL/SOP/013/R0 |

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|---|---|---|---|---|
| 143 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | rh - Erythropoietin | " Identification & Assay/ Potency " | (In vivo Bio-assay) NIB/RPL/SOP/32/R1 |
| 144 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | rh - Erythropoietin | Assay/Potency | (In-vitro Bio-assay) NIB/RPL/SOP/32/R1 |
| 145 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Rituximab | Assay/ Potency | (CDC Assay),"NIB/TMA/SOP/10/R2 |
| 146 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Rotavirus Vaccine Rotarix | Identification, potency & Thermal stability | ( immunofluorescence method, using MA 104 as indicator cell line)"NIB/VVL/SOP/048/R0 |
| 147 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Streptokinase Bulk (Conventional & Recombinant) | Identification | (Clot Lysis Method A),"NIB/EHL/SOP/04/R4 |
| 148 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Streptokinase Inj. | Streptolysin activity | (UV Vis spectrophotometry)" NIB/EHL/SOP/22/R3 |
| 149 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Streptokinase Inj.(Conventional & Recombinant) | Identification | (Clot Lysis Method A),NIB/EHL/SOP/18/R4 |
| 150 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Syphilis CLIA | Sensitivity & Specificity | NIB/IDL/SOP/037/R1 |
| 151 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Syphilis ELISA | Sensitivity & Specificity | NIB/IDL/SOP/32/R1 |
| 152 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Syphilis RAPID | Sensitivity & Specificity | NIB/IDL/SOP/027/R1 |
| 153 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Teriparatide (rh-PTH) Inj. | Assay/ Potency | (Bio-assay) NIB/TMA/SOP/073/R1 |
| 154 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Trastuzumab | Assay/ Potency " | (Inhibition of cell Proliferation assay)," NIB/TMA/SOP/40/R0 |
| 155 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Trastuzumab | " Assay/ Potency " | (HER2 Binding assay by flow cytometry),"NIB/TMA/SOP/39/R0 |
| 156 | BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS | Trastuzumab | " Identification " | (Anti-Id Ab ELISA)," NIB/TMA/SOP/37/R0 |

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| 157 | BIOLOGICAL- BIOLOGICALS DERIVED PHARMACEUTICALS | Urokinase Bulk /Inj. | Identification | (Clot Lysis Method A),NIB/EHL/SOP/30/R2 |
| 158 | BIOLOGICAL- BIOLOGICALS DERIVED PHARMACEUTICALS | Urokinase Bulk/Injection | Thromboplastic contaminants | NIB/EHL/SOP/082/00 |
| 159 | BIOLOGICAL- BIOLOGICALS DERIVED PHARMACEUTICALS | Viral Transport Medium (VTM) and Swabs | "Reactivity " | NIB/CKTL/SOP/014/R0 |
| 160 | CHEMICAL- DRUGS & PHARMACEUTICALS | Fibrin sealant kit | Stability | (Visual Observation),NIB/BPL/SOP/36/R3 |
| 161 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Aspart Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/51/R3 |
| 162 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Degludec Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/80/R0 |
| 163 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glargine Inj. | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/40/R5 |
| 164 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glulisine Inj. | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/102/R1 |
| 165 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glulisine Inj. | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC)NIB/RPL/SOP/103/R1 |
| 166 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glulisine Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/102/R1 |
| 167 | CHEMICAL- DRUGS & PHARMACEUTICALS | Liraglutide Inj. | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC) NIB/RPL/SOP/81/R0 |
| 168 | CHEMICAL- DRUGS & PHARMACEUTICALS | Teriparatide Inj. | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/90/R1 |
| 169 | CHEMICAL- DRUGS & PHARMACEUTICALS | " Exenatide Inj. Once Weekly " | Assay/ Potency | (SEC-HPLC) NIB/RPL/SOP/101/R1 |
| 170 | CHEMICAL- DRUGS & PHARMACEUTICALS | " Exenatide Inj." | Identification | (SEC-HPLC) NIB/RPL/SOP/67/R2 |
| 171 | CHEMICAL- DRUGS & PHARMACEUTICALS | " Insulin Degludec Inj. " | Related Proteins | (RP-HPLC) NIB/RPL/SOP/85/R0 |
| 172 | CHEMICAL- DRUGS & PHARMACEUTICALS | " Insulin Degludec/ Insulin Aspart Inj." | Identification | (RP-HPLC) NIB/RPL/SOP/97/R1 |
| 173 | CHEMICAL- DRUGS & PHARMACEUTICALS | " Insulin Lispro Inj." | Identification | (RP-HPLC) NIB/RPL/SOP/49/R3 |

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| 174 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1) Insulin Lispro Inj. 2) Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 3) Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj." | Related Proteins | (RP-HPLC) NIB/RPL/SOP/49/R3 |
| 175 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Anti-Lea reagent 2. Anti-Leb reagent 3. Anti-Pi reagent 4. Anti-M reagent 5. Anti-N reagent 6. Anti-S reagent" | Physical Appearance " | (Visual Observation),NIB/BRL/SOP/066/R2 |
| 176 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Biphasic Isophane Insulin (25/75) Inj. 2. Biphasic Isophane Insulin (30/70) Inj. 3. Biphasic Isophane Insulin (50/50) Inj." | Soluble human insulin content | (RP-HPLC) NIB/RPL/SOP/72/R2 |
| 177 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Cell Culture Rabies Vaccine 2. Hepatitis A Inactivated Vaccine 3. Hepatitis B (rDNA) Vaccine" | Aluminium Content | NIB/BVL/SOP/12/R2 |
| 178 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Exenatide Inj. 2. Interferon Beta-1a Inj. 3. Peg-Filgrastim Inj. 4. Peg Interferon beta 1a Inj." | Osmolality | (Osmometry) NIB/RPL/SOP/36/R0 |
| 179 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Fibrin sealant kit 2. Human Fibrinogen " | pH | (Potentiometry),NIB/BPL/SOP/35/R5 |
| 180 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Filgrastim Inj. 2. Teriparatide (rh-PTH) Inj." | Identification | (SDS-PAGE) NIB/RPL/SOP/47/R3 |
| 181 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Heparin sodium injection 2. Streptokinase inj. 3. Recombinant Streptokinase Inj. 4.Urokinase Injection" | Clarity | (Visual observation),NIB/EHL/SOP/16/R3 |
| 182 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Hepatitis A Inactivated Vaccine 2. Hepatitis B (rDNA) Vaccine" | Anti-microbial preservative test | "NIB/BVL/SOP/009/R5 |
| 183 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Hepatitis Immunoglobulin ( (IV/IM) 2. Hepatitis Immunoglobulin (SC) " | Potency | "NIB/BPL/SOP /61/R2 |
| 184 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Albumin 2. Plasma Protein Fraction 3. Human Coagulation factor VIII (plasma derived)" | Assay for Sodium | (Atomic Absorption Spectrophotometry (AAS))"NIB/BPL/SOP/09/R3; For factor VIII NIB/BPL/SOP/14/R1 |
| 185 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Albumin 2. Plasma Protein Fraction 3. Human Normal immunoglobulin (IV/IM) 4. Anti-D Immunoglobulin (IV/IM) 5. Tetanus immunoglobulin 6. Rabies Immunoglobulin 7. Hepatitis B Immunoglobulin (IV/IM) 8. Human Immunoglobulin Subcutaneous 9.Hepatitis B Immunoglobulin Subcutaneous 10.Human Immunoglobulin (Bulk) (IV/IM) 11.Human Tetanus Immunoglobulin (Bulk) " | Physical Characteristics & solubility | "NIB/BPL/SOP/76/R0 |
| 186 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Albumin 2. Plasma Protein Fraction | Identification & Purity | (SDS-PAGE),"NIB/BPL/SOP/12/R5 |
| 187 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Albumin 2. Plasma Protein Fraction" | Assay for Potassium | (Atomic Absorption Spectrophotometry (AAS))"NIB/BPL/SOP/10/R2; |

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|---|---|---|---|---|
| 188 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Chorionic Gonadotropin Inj. 2. Menotropin (Human Menopausal Gonadotropin) Inj. 3. Urofollitropin (Human follicle-stimulating Hormone) Inj. 4. Recombinant Human Follicle Stimulating Hormone Inj. 5. Somatropin Inj. (Recombinant Human Growth Hormone)." | Particulate Matter | (Visual Observation),NIB/EHL/SOP/49/R1 |
| 189 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Coagulation factor VIII (plasma derived) 2. Human Coagulation Factor VIII rDNA 3. Human Coagulation Factor IX 4. Anti-Thrombin III concentrate 5. Anti-inhibitor coagulant complex 6. Human Prothrombin Complex" | Osmolality | NIB/BPL/SOP/28/R4 |
| 190 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Coagulation factor VIII (plasma derived) 2.Human Coagulation Factor VIII (rDNA) 3.Human Coagulation Factor IX 4.Anti-Thrombin III concentrate 5.Anti-inhibitor coagulant complex 6.Human Coagulation Factor IX (rDNA) 7.Human Prothrombin complex " | Physical Characteristics & solubility | NIB/BPL/SOP/30/R3 |
| 191 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Human Normal immunoglobulin IV 2. Hepatitis Immunoglobulin IV 3. Anti-D Immunoglobulin IV 4.Human Immunoglobulin (Bulk) (IV)" | Osmolality | "NIB/BPL/SOP/27/R5 |
| 192 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Aspart Inj. 2. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 3. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj." | Assay/ Potency | (RP-HPLC)NIB/RPL/SOP/51/R3 |
| 193 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Aspart Inj. 2. Insulin Aspart & Insulin Aspart Protamine Inj. Suspension (30/70) Inj. 3. Insulin Aspart & Insulin Aspart Protamine Inj. Suspension (50/50) Inj." | Related Proteins | (RP-HPLC) NIB/RPL/SOP/51/R3 |
| 194 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Degludec Inj. 2. Insulin Degludec/ Insulin Aspart Inj." | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC)NIB/RPL/SOP/83/R0 |
| 195 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Degludec Inj. 2. Insulin Degludec/ Insulin Aspart Inj." | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/80/R0 |
| 196 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Degludec Inj. 2. Liraglutide Inj. 3. rh-Erythropoietin 4. Filgrastim Inj. 5. Interferon Alpha-2b Inj. 6. Peg- Filgrastim Inj. 7. Peg-Interferon Alpha-2b Inj. 8. Teriparatide (rh-PTH) 9. Interferon Beta-1a Inj. 10. Peg Interferon beta 1a Inj." | Dose accuracy/ Volume Tolerance | (Gravimetric) NIB/RPL/SOP/06/R4 |
| 197 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Lispro Inj. 2. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 3. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. 4. Insulin Aspart Inj. 5. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 6. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj. 7. Insulin Detemir Inj. 8. Isophane Insulin Inj. 9. Biphasic Isophane Insulin (25/75) Inj. 10. Biphasic Isophane Insulin (30/70) Inj. 11. Biphasic Isophane Insulin (50/50) Inj. 12 Soluble Insulin Inj." | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC) NIB/RPL/SOP/03/R5 |
| 198 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Insulin Lispro Inj. 2. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 3. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj." | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/49/R3 |

# SCOPE OF ACCREDITATION

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| **Accreditation Standard** | ISO/IEC 17025:2017 | | |
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| 199 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Interferon Alpha-2b Inj. 2. Interferon Beta-1a Inj." | Identification | (SDS-PAGE) NIB/RPL/SOP/79/R1 |
| 200 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Peg Interferon beta 1a (63µg/0.5ml) Inj. 2. Peg Interferon beta 1a(94µg/0.5ml) Inj." | Purity | (Oxidized content) NIB/RPL/SOP/28/R1 |
| 201 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Peg Interferon beta 1a Inj. 2. Peg Interferon beta 1a (63µg/0.5ml) Inj. 3. Peg Interferon beta 1a(94µg/0.5ml) Inj." | Impurity | (SEC – HPLC) NIB/RPL/SOP/77/R1 |
| 202 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. rh-Erythropoietin 2. Filgrastim" | Dissolution | NIB/RPL/SOP/25/R0 |
| 203 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin (25/75) Inj. 4. Biphasic Isophane Insulin (30/70) Inj. 5. Biphasic Isophane Insulin (50/50) Inj. 6. Insulin Glargine Inj. 7. Insulin Glulisine Inj. 8. Insulin Lispro Inj. 9. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 10. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. 11. Insulin Aspart Inj. 12. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 13. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj. 14. Insulin Detemir Inj. 15. Insulin Degludec Inj. 16. Insulin Degludec/ Insulin Aspart Inj. 17. Exenatide Inj. 18. Exenatide Once Weekly Inj. 19. Liraglutide Inj. 20. rh-Erythropoietin 21. Filgrastim Inj. 22. Interferon Beta-1a Inj. 23. Interferon Alpha-2b 24. Peg- Filgrastim Inj. 25. Peg-Interferon Alpha-2b Inj. 26. Teriparatide (rh-PTH) Inj. 27. Peg Interferon beta 1a Inj. 28. rh-Insulin bulk" | Color | (Visual Observation)NIB/RPL/SOP/06/R4 |
| 204 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin (25/75) Inj. 4. Biphasic Isophane Insulin (30/70) Inj. 5. Biphasic Isophane Insulin (50/50) Inj. 6. Insulin Glargine Inj. 7. Insulin Glulisine Inj. 8. Insulin Lispro Inj. 9. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 10. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. 11. Insulin Aspart Inj. 12. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 13. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj. 14. Insulin Detemir Inj. 15. Insulin Degludec Inj. 16. Insulin Degludec/ Insulin Aspart Inj. 17. Exenatide Inj. 18. Exenatide Inj. once weekly 19.Liraglutide Inj. 20.rh-Erythropoietin 21.Filgrastim Inj. 22.Interferon Beta-1a Inj. 23.Interferon Alpha-2b Inj. 24.Peg- Filgrastim Inj. 25.Peg-Interferon Alpha-2b Inj. 26.Teriparatide (rh-PTH) Inj. 27.Peg Interferon beta 1a Inj." | pH | NIB/RPL/SOP/06/R4 |
| 205 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin (25/75) Inj. 4. Biphasic Isophane Insulin (30/70) Inj. 5. Biphasic Isophane Insulin (50/50) Inj." | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/13/R6 |

# SCOPE OF ACCREDITATION

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| **Accreditation Standard** | ISO/IEC 17025:2017 | | |
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| 206 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin (25/75) Inj. 4. Biphasic Isophane Insulin (30/70) Inj. 5. Biphasic Isophane Insulin (50/50) Inj. 6. Insulin Lispro Inj. 7. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 8. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. 9. Insulin Aspart Inj. 10. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 11. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj. 12.Insulin Degludec 13.Insulin Degludec/ Insulin Aspart Inj. 14.Insulin Detemir Inj. 15.rh-Insulin Bulk, 16.Insulin Glargine Inj. 16. Liraglutide Inj." | Zinc metal ion estimation | (Atomic Absorption Spectrometry)NIB/RPL/SOP/04/R3 |
| 207 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin (25/75) Inj. 4. Biphasic Isophane Insulin (30/70) Inj. 5. Biphasic Isophane Insulin (50/50) Inj. 6. Insulin Glargine Inj. 7. Insulin Glulisine Inj. 8. Insulin Lispro Inj. 9. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 10. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. 11. Insulin Aspart Inj. 12. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 13. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj. 14. Insulin Detemir Inj. 15. Insulin Degludec Inj. 16. Insulin Degludec/ Insulin Aspart Inj. 17. Exenatide Inj. 18. Exenatide Once Weekly Inj. 19. Liraglutide Inj. 20. rh-Erythropoietin 21. Filgrastim Inj. 22. Interferon Beta-1a Inj. 23. Interferon Alpha-2b Inj. 24. Peg- Filgrastim Inj. 25. Peg-Interferon Alpha-2b Inj. 26. Teriparatide (rh-PTH) Inj. 27. Peg Interferon beta 1a Inj. 28. rh-Insulin bulk" | Clarity | (Visual Observation)NIB/RPL/SOP/06/R4 |
| 208 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin inj. 2. Isophane Insulin inj. 3. Biphasic Isophane Insulin (25/75) inj. 4. Biphasic Isophane Insulin (30/70) inj. 5. Biphasic Isophane Insulin (50/50) inj. 6. Insulin Glargine inj. 7. Insulin Glulisine inj. 8. Insulin Lispro inj. 9. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) inj. 10. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) inj. 11. Insulin Aspart inj. 12. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) inj. 13. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) inj. 14. Insulin Detemir inj. 15. Insulin Degludec inj. 16. Insulin Degludec/ Insulin Aspart inj. 17. Liraglutide inj." | Particulate Matter | (Sub Visible Observation),NIB/RPL/SOP/11/R4 |
| 209 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin (25/75) Inj. 4. Biphasic Isophane Insulin (30/70) Inj. 5. Biphasic Isophane Insulin (50/50) Inj. 6. rh-Insulin Bulk 7. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 8. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. 9. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 10. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj." | Identification | (RP-HPLC) NIB/RPL/SOP/54/R3 |

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| 210 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Soluble Insulin Inj. 2. Isophane Insulin Inj. 3. Biphasic Isophane Insulin(25/75) Inj. 4. Biphasic Isophane Insulin(30/70) Inj. 5. Biphasic Isophane Insulin(50/50) Inj. 6. rh-Insulin " | Related Proteins | (RP-HPLC) NIB/RPL/SOP/13/R6 |
| 211 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Streptokinase Bulk 2. Recombinant Streptokinase Bulk." | Assay/ Potency | (Chromogenic method),"NIB/EHL/SOP/10/R3 |
| 212 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Streptokinase Inj. 2. Recombinant Streptokinase Inj." | Assay/ Potency | (Chromogenic method), NIB/EHL/SOP/23/R3 |
| 213 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Tetanus immunoglobulin 2. Tetanus immunoglobulin (Bulk)" | Tetanus Potency | "NIB/BPL/SOP/64/R1 |
| 214 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Urokinase Bulk 2. HCG Bulk 3. Urofollitropin Bulk" | Appearance | "NIB/EHL/SOP/03/R4 |
| 215 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1. Urokinase Injection 2. Urofollitropin Bulk" | Solubility | "NIB/EHL/SOP/03/R4 |
| 216 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Anti-Fya reagent 2.Anti-Jka reagent 3.Anti-K reagent 4.Anti-k reagent 5.Anti-Lea reagent 6.Anti-Pi reagent 7.Anti-M reagent 8.Anti-N reagent 9.Anti-S reagent 10.Anti-Leb reagent" | Color | (Visual observation) , NIB/BRL/SOP/066/R2 |
| 217 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Bacillus Calmette Guerin (BCG) vaccine 2.Haemophilus influenzae type b TT conjugate vaccine 3.Live Attenuated Measles Vaccine 4.Live Attenuated Rubella Vaccine 5.Live Attenuated MMR Vaccine 6.Cell Culture Rabies Vaccine 7.Live Attenuated Measles & Rubella Vaccine " | Water Content/Moisture Content/ Residual Moisture | NIB/VVL/SOP/006/R3 |
| 218 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Exenatide Once Weekly inj. 2. rh-Erythropoietin 3.Filgrastim inj." | Water Content/Moisture Content/ Residual Moisture | NIB/VVL/SOP/006/R3 |
| 219 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Fibrin sealant kit " 2. Human Fibrinogen | Assay for Protein | (Clottable Protein: Kjeldahl method),NIB/BPL/SOP/51/R2 |
| 220 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Fibrin Sealant Kit" | Assay for Factor XIII | "NIB/BPL/SOP/85/R0 |
| 221 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Albumin 2.Plasma Protein Fraction" | Molecular size distribution | (HPLC),"NIB/BPL/SOP/11/R2 |
| 222 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Albumin 2.Plasma Protein Fraction 3.Human Normal immunoglobulin (IV/IM ) 4.Anti-D Immunoglobulin (IV/IM ) 5.Human Tetanus immunoglobulin 6.Rabies Immunoglobulin 7.Hepatitis B Immunoglobulin (IV/IM ) 8.Human Immunoglobulin (Bulk) (IV/IM) " | Assay for Protein | (Biuret method), NIB/BPL/SOP/007/R3; |

# SCOPE OF ACCREDITATION

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| 223 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Albumin 2.Plasma Protein Fraction 3.Human Normal immunoglobulin (IV/IM ) 4.Anti-D Immunoglobulin (IV/IM ) 5.Human Tetanus immunoglobulin 6.Rabies Immunoglobulin 7.Hepatitis B Immunoglobulin (IV/IM ) 8.Human Immunoglobulin (Bulk) (IV/IM) 9.Human Immunoglobulin Subcutaneous 10.Hepatitis B Immunoglobulin Subcutaneous 11.Human Tetanus Immunoglobulin (Bulk) " | Identification | (Double Immunodiffusion),"NIB/BPL/SOP /06/R4 |
| 224 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Albumin 2.Plasma Protein Fraction 3.Human Normal immunoglobulin (IV/IM ) 4.Anti-D Immunoglobulin (IV/IM ) 5.Human Tetanus immunoglobulin 6.Rabies Immunoglobulin 7.Hepatitis B Immunoglobulin (IV/IM ) 8.Human Immunoglobulin (Bulk) (IV/IM) 9.Human Immunoglobulin Subcutaneous 10.Hepatitis B Immunoglobulin Subcutaneous 11.Human Tetanus Immunoglobulin (Bulk) " | Identification | (Immuno-Electrophoresis),NIB/BPL/SOP /082/R1 |
| 225 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Albumin 2.Plasma Protein Fraction 3.Human Normal immunoglobulin (IV/IM ) 4.Anti-D Immunoglobulin (IV/IM ) 5.Human Tetanus immunoglobulin 6.Rabies Immunoglobulin 7.Hepatitis B Immunoglobulin (IV/IM ) 8.Human Immunoglobulin (Bulk) (IV/IM) 9.Human Immunoglobulin Subcutaneous 10.Hepatitis B Immunoglobulin Subcutaneous 11.Human Tetanus Immunoglobulin (Bulk) " | Protein Composition | (Zone electrophoresis),"NIB/BPL/SOP/ 52/R3" |
| 226 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Albumin 2.Plasma Protein Fraction | Assay for Protein | (Kjeldahl method)," NIB/BPL/SOP/08/R4 |
| 227 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Chorionic Gonadotropin Inj. 2. Menotropin (Human Menopausal Gonadotropin) Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Inj. 4. Recombinant Human Follicle Stimulating Hormone Inj. 5. Somatropin Inj. (Recombinant Human Growth Hormone)" | Clarity | (Visual observation)"NIB/EHL/SOP/50/R 1 |
| 228 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Coagulation Factor IX 2.Human Coagulation Factor IX (rDNA) 3.Human Prothrombin Complex" | Identification & Potency | NIB/BPL/SOP /54/R1 |
| 229 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Coagulation factor VIII (plasma derived) 2.Human Coagulation Factor VIII (rDNA) 3.Human Coagulation Factor IX 4.Anti-Thrombin III concentrate 5.Anti-inhibitor coagulant complex 6.Human Prothrombin complex" | pH | (Potentiometry),NIB/BPL/SOP/3 1/R3 |
| 230 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Coagulation factor VIII (plasma derived) 2.Human Coagulation Factor VIII (rDNA) | Identification & Potency | "NIB/BPL/SOP /53/R1 |
| 231 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Coagulation factor VIII (plasma derived) 2.Human Coagulation Factor VIII (rDNA) " | Identification & Potency | NIB/BPL/SOP/033/R3 |

# SCOPE OF ACCREDITATION

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|---|---|---|---|---|
| 232 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Coagulation factor VIII (plasma derived) 2.Human Coagulation Factor VIII Recombinant 3.Human Coagulation Factor IX 4.Fibrin sealant kit 5.Anti-inhibitor coagulant complex 6.Human Prothrombin Complex 7.Human Coagulation Factor IX (r-DNA) 8.Human Fibrinigen 9. Anti-D Immunoglobulin IM (Freez dried)" | Water Content/Moisture Content/ Residual Moisture | NIB/VV/SOP/006/R2 |
| 233 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IM ) 2.Anti-D Immunoglobulin (IM ) 3.Human Tetanus immunoglobulin 4.Rabies Immunoglobulin 5.Hepatitis B Immunoglobulin (IM ) 6.Human Immunoglobulin (Bulk) (IM) 7.Human Tetanus Immunoglobulin (Bulk) 8.Human Immunoglobulin Subcutaneous 9.Hepatitis B Immunoglobulin Subcutaneous " | Molecular size distribution | (HPLC), NIB/BPL/SOP/24/R3 |
| 234 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IV ) 2.Anti-D Immunoglobulin (IV ) 3.Hepatitis B Immunoglobulin (IV ) 4.Human Immunoglobulin (Bulk) (IV) | Molecular size distribution | (HPLC),NIB/BPL/SOP/23/R3 |
| 235 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IV) 2.Anti-D Immunoglobulin (IV) 3.Hepatitis B Immunoglobulin (IV) 4.Human Immunoglobulin (Bulk) (IV)" | Prekallikrein Activator Assay | NIB/BPL/SOP/026/R3 |
| 236 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IV/IM ) 2. Anti-D Immunoglobulin (IV/IM ) 3. Human Tetanus immunoglobulin 4. Rabies Immunoglobulin 5. Hepatitis B Immunoglobulin (IV/IM ) 6. Human Immunoglobulin (Bulk) (IV/IM)" | Identification & Purity | (SDS-PAGE),NIB/BPL/SOP/25/R6 |
| 237 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IV/IM ) 2.Anti-D Immunoglobulin (IV/IM ) 3.Human Tetanus immunoglobulin 4.Human Tetanus Immunoglobulin (Bulk) 5.Rabies Immunoglobulin 6.Hepatitis B Immunoglobulin (IV/IM ) 7.Human Immunoglobulin (Bulk) (IV/IM) 8.Human Immunoglobulin Subcutaneous 9.Hepatitis B Immunoglobulin Subcutaneous " | pH | (Potentiometry),NIB/BPL/SOP/19/R2 |
| 238 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IV/IM ) 2.Anti-D Immunoglobulin (IV/IM ) 3.Human Tetanus immunoglobulin 4.Human Tetanus Immunoglobulin (Bulk) 5.Rabies Immunoglobulin 6.Human Immunoglobulin (Bulk) (IV) 7.Human Immunoglobulin Subcutaneous 8. Human Normal immunoglobulin (IM) Bulk" | Antibody to Hepatitis B Surface Antigen | "NIB/BPL/SOP/061/R3 |
| 239 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Human Normal immunoglobulin (IV/IM ) 2.Anti-D Immunoglobulin (IV/IM ) 3.Human Tetanus immunoglobulin 4.Rabies Immunoglobulin 5.Hepatitis B Immunoglobulin (IV/IM ) 6.Human Immunoglobulin (Bulk) (IV/IM) 7.Human Immunoglobulin Subcutaneous 8.Hepatitis B Immunoglobulin Subcutaneous 9.Human Tetanus Immunoglobulin (Bulk) | Assay for Protein | (Kjeldahl method),NIB/BPL/SOP/22/R4 |
| 240 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Inactivated Polio Vaccine 2. Hepatitis A Inactivated Vaccine 3. Hepatitis B (rDNA) Vaccine" | Free formaldehyde | "NIB/BVL/SOP/34/R3 |

# SCOPE OF ACCREDITATION

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| **Laboratory Name :** | NATIONAL INSTITUTE OF BIOLOGICALS, PLOT NO. A- 32, SECTOR 62, NOIDA, UTTAR PRADESH, INDIA | | |
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| 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 |
|---|---|---|---|---|
| 241 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) Inj. 2.Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) Inj." | Insulin aspart in solution | (SEC-HPLC) NIB/RPL/SOP/51/R3 |
| 242 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Somatropin Inj. (Recombinant Human Growth Hormone) 2.Human Chorionic Gonadotropin Bulk 3. Menotropin ( Human Menopausal Gonadotropin) Bulk/Inj. 4. Urofollitropin Bulk" | Water Content/Moisture Content/ Residual Moisture | NIB/VV/SOP/006/R2 |
| 243 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Streptokinase Bulk/Inj. 2. Urokinase Bulk/Injection 3. HCG Bulk/Inj. 4. HMG Bulk/Inj. 5. Somatropin Injection" | Description | "NIB/EHL/SOP/03/R4 |
| 244 | CHEMICAL- DRUGS & PHARMACEUTICALS | "1.Streptokinase Inj. 2. Recombinant Streptokinase Inj. 3.Heparin Sodium injection" | Particulate Matter | (Visual Observation),NIB/EHL/SOP/17/R3 |
| 245 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Adalimumab" | Protein Content | NIB/TMA/SOP/006/R3 |
| 246 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Anti-D Immunoglobulin (Monoclonal)" | "Molecular Size Exclusion" | (SEC-HPLC),"NIB/TMA/SOP /070/R1 " |
| 247 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Anti-D Immunoglobulin (Monoclonal)" | Glycine Content | (Tirimetric),"NIB/TMA/SOP/071/ 00 " |
| 248 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Anti-D Immunoglobulin (Monoclonal)" | Physical Characteristics | "NIB/TMA/SOP/056/R2" |
| 249 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Anti-D Immunoglobulin (Monoclonal)" | Purity | (SDS-PAGE),NIB/TMA/SOP /068/R1 |
| 250 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Bacillus Calmette Guerin (BCG) Vaccine" | Test for Identification | (Immunochemical Assay ),"NIB/BVL/SOP/13/R5 |
| 251 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Bevacizumab " | Purity | (SDS-PAGE- Reducing/ Non Reducing),NIB/TMA/SOP/034/R1 |
| 252 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Bevacizumab" | Physical Characteristics | "NIB/TMA/SOP/056/R2" |
| 253 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Fibrin Sealant Kit" | Thrombin Assay | "NIB/BPL/SOP/75/R0 |
| 254 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Liraglutide Inj." | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/84/R0 |
| 255 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Recombinant Streptokinase Inj. " | Water Content/Moisture Content/ Residual Moisture | NIB/VVL/SOP/006/R3 |
| 256 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Rituximab | Identification | (CEX-HPLC),NIB/TMA/SOP/33/R2 |
| 257 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Rituximab" | Identification | (Capillary Zone Electrophoresis),NIB/TMA/SOP/043/R1 |

# SCOPE OF ACCREDITATION

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|---|---|---|---|---|
| 258 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Trastuzumab " | Physical Characteristics | "NIB/TMA/SOP/056/R2 " |
| 259 | CHEMICAL- DRUGS & PHARMACEUTICALS | "Trastuzumab" | Osmolality | NIB/TMA/SOP/004/R2 |
| 260 | CHEMICAL- DRUGS & PHARMACEUTICALS | 1. "Fibrin sealant kit " 2. Human Fibrinogen | Physical Characteristics & solubility | "NIB/BPL/SOP/36/R3 |
| 261 | CHEMICAL- DRUGS & PHARMACEUTICALS | 1. Streptokinase Bulk/Inj. 2. Recombinant Streptokinase Bulk/Inj. 3.Heparin Sodium injection 4.Urokinase Injection" | pH | NIB/EHL/SOP/06/R4 |
| 262 | CHEMICAL- DRUGS & PHARMACEUTICALS | 1.Human Chorionic Gonadotropin Inj. 2.Menotropin (Human Menopausal Gonadotropin) Inj. | pH | " NIB/EHL/SOP/06/R4 |
| 263 | CHEMICAL- DRUGS & PHARMACEUTICALS | 1.Insulin Lispro & Insulin Lispro Protamine Suspension (25/75) Inj. 2.Insulin Lispro & Insulin Lispro Protamine Suspension (50/50) Inj. | Soluble Insulin lispro content | (RP-HPLC) NIB/RPL/SOP/49/R3 |
| 264 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | Identification | (CEX-HPLC),"NIB/TMA/SOP/33/R2" |
| 265 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | Osmolality | NIB/TMA/SOP/004/R2 |
| 266 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | Physical Characteristics | "NIB/TMA/SOP/056/R2" |
| 267 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | Purity | (SDS-PAGE- Reducing/ Non Reducing),NIB/TMA/SOP/034/R1 |
| 268 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | Purity | (SEC-HPLC),NIB/TMA/SOP/020/R2 |
| 269 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | Identification | (SEC-HPLC),"NIB/TMA/SOP/020/R2" |
| 270 | CHEMICAL- DRUGS & PHARMACEUTICALS | Adalimumab | pH | "NIB/TMA/SOP/003/R2 " |
| 271 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti- A (Monoclonal) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/018/R4 |
| 272 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti- A (Monoclonal) | Color | (Visual observation) ,NIB/BRL/SOP/018/R4 |
| 273 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-A,B (Monoclonal) | Color | (Visual observation) ,NIB/BRL/SOP/020/R4 |
| 274 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-A,B (Monoclonal) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/020/R4 |
| 275 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-A1 (Lectin) | Color | (Visual observation) ,NIB/BRL/SOP/024/R4 |

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|---|---|---|---|---|
| 276 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-A1 (Lectin) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/024/R4 |
| 277 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-B (Monoclonal) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/019/R4 |
| 278 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-B (Monoclonal) | Color | (Visual observation) ,NIB/BRL/SOP/019/R4 |
| 279 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D (IgM +IgG) (Monoclonal) | Color | (Visual observation) ,NIB/BRL/SOP/23/R2 |
| 280 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D (IgM +IgG) (Monoclonal) | Physical Appearance | (Visual observation) , NIB/BRL/SOP/23/R2 |
| 281 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D (IgM) (Monoclonal) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/022/R4 |
| 282 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D (IgM) (Monoclonal) | Color | (Visual observation) ,NIB/BRL/SOP/022/R4 |
| 283 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D Immunoglobulin (Monoclonal) | Purity | (SDS-PAGE- Reducing/ Non Reducing),NIB/TMA/SOP/034/R1 |
| 284 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D Immunoglobulin (Monoclonal) | pH | "NIB/TMA/SOP/003/R2 " |
| 285 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D Immunoglobulin (Monoclonal) | Particulate Matter | (Sub Visible Observation),NIB/RPL/SOP/11/R 4 |
| 286 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D( IgG) (Monoclonal) | Color | (Visual observation) ,NIB/BRL/SOP/21/R2 |
| 287 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-D( IgG) (Monoclonal) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/21/R2 |
| 288 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-H (Lectin) | Color | (Visual observation) ,NIB/BRL/SOP/025/R4 |
| 289 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-H (Lectin) | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/025/R4 |
| 290 | CHEMICAL- DRUGS & PHARMACEUTICALS | Anti-inhibitor coagulant complex | Assay for Protein | (Clottable Protein: Kjeldahl method),NIB/BPL/SOP/090/00 |
| 291 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Identification | (SEC-HPLC),"NIB/TMA/SOP/020/R2" |
| 292 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | pH | "NIB/TMA/SOP/003/R2" |
| 293 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Purity | (CEX-HPLC),"NIB/TMA/SOP/046/R1" |

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|---|---|---|---|---|
| 294 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Purity | (SEC-HPLC),NIB/TMA/SOP/020/R2 |
| 295 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Protein Content | NIB/TMA/SOP/006/R3 |
| 296 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Identification | (Capillary Zone Electrophoresis),NIB/TMA/SOP/043/R1 |
| 297 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Identification | (CEX-HPLC),"NIB/TMA/SOP/046/R1" |
| 298 | CHEMICAL- DRUGS & PHARMACEUTICALS | Bevacizumab | Osmolality | NIB/TMA/SOP/004/R2 |
| 299 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. | Assay/ Potency | (SEC-HPLC) NIB/RPL/SOP/67/R2 |
| 300 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC) NIB/RPL/SOP/68/R2 |
| 301 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. | Product-Related Impurities | (Strong cation exchange-HPLC) NIB/RPL/SOP/69/R2 |
| 302 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. Once Weekly | "In vitro Complete Release " | (SEC-HPLC) NIB/RPL/SOP/99/R1 |
| 303 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. Once Weekly | "In vitro Initial Release" | (SEC-HPLC) NIB/RPL/SOP/98/R1 |
| 304 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. Once Weekly | Identification | (Strong Cation Exchange-HPLC) NIB/RPL/SOP/100/R1 |
| 305 | CHEMICAL- DRUGS & PHARMACEUTICALS | Exenatide Inj. Once Weekly | Purity | (Strong Cation Exchange-HPLC) NIB/RPL/SOP/100/R1 |
| 306 | CHEMICAL- DRUGS & PHARMACEUTICALS | Filgrastim Inj. | Higher Molecular Weight impurities | (SEC-HPLC) NIB/RPL/SOP/070/R4 |
| 307 | CHEMICAL- DRUGS & PHARMACEUTICALS | Filgrastim Inj. | Identification | (SEC-HPLC) NIB/RPL/SOP/070/R4 |
| 308 | CHEMICAL- DRUGS & PHARMACEUTICALS | G-CSF Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/71/R2 |
| 309 | CHEMICAL- DRUGS & PHARMACEUTICALS | G-CSF Inj. | Related Proteins | (SDS-PAGE) NIB/RPL/SOP/47/R3 |
| 310 | CHEMICAL- DRUGS & PHARMACEUTICALS | Gel card Forward grouping | Physical Appearance | (Visual observation) ,NIB/BRL/SOP/055/R2 |
| 311 | CHEMICAL- DRUGS & PHARMACEUTICALS | Haemophilus influenzae type b TT conjugate vaccine | pH | (Potentiometric Method),NIB/BVL/SOP/001/R6 |

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|---|---|---|---|---|
| 312 | CHEMICAL- DRUGS & PHARMACEUTICALS | Haemophilus influenzae type b TT conjugate vaccine | Free PRP | (Ribose Assay),"NIB/BVL/SOP/005/R2; |
| 313 | CHEMICAL- DRUGS & PHARMACEUTICALS | Haemophilus influenzae type b TT conjugate vaccine | PRP | (Ribose Assay),NIB/BVL/SOP/003/R2 |
| 314 | CHEMICAL- DRUGS & PHARMACEUTICALS | Haemophilus influenzae type b TT conjugate vaccine | Thiomersal content - Antimicrobial preservative | NIB/BVL/SOP/009/R5 |
| 315 | CHEMICAL- DRUGS & PHARMACEUTICALS | Haemophilus influenzae type b TT conjugate vaccine | Test for Identification | (Immunochemical Assay ),"NIB/BVL/SOP/002/R4 |
| 316 | CHEMICAL- DRUGS & PHARMACEUTICALS | Heparin Sodium injection | Assay/ Potency (Anti factor IIa activity) | (Chromogenic method)"NIB/EHL/SOP/48/R2 |
| 317 | CHEMICAL- DRUGS & PHARMACEUTICALS | Heparin Sodium injection | Identification | Method B-Reaction A of sodium Salt),"NIB/EHL/SOP/057/R1 |
| 318 | CHEMICAL- DRUGS & PHARMACEUTICALS | Human Albumin | Haem content | (UV-Vis spectrophotometry),"NIB/BPL/SOP/05/R2 |
| 319 | CHEMICAL- DRUGS & PHARMACEUTICALS | Human Albumin | pH | (Potentiometry),"NIB/BPL/SOP/04/R2 |
| 320 | CHEMICAL- DRUGS & PHARMACEUTICALS | Human Albumin | Prekallikrein Activator Assay | "NIB/BPL/SOP/56/R2 |
| 321 | CHEMICAL- DRUGS & PHARMACEUTICALS | Human Coagulation Factor IX (rDNA) | Molecular size distribution | (HPLC),NIB/BPL/SOP/078/R1 |
| 322 | CHEMICAL- DRUGS & PHARMACEUTICALS | Human Coagulation Factor IX rDNA | Identification & Purity | (SDS-PAGE),NIB/BPL/SOP/69/R1 |
| 323 | CHEMICAL- DRUGS & PHARMACEUTICALS | Human Coagulation Factor VIII rDNA | Identification & Purity | (SDS-PAGE),NIB/BPL/SOP/068/R0 |
| 324 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Degludec /Insulin Aspart Inj. | Related Proteins Aspart | (RP-HPLC),NIB/RPL/SOP/97/R1 |
| 325 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Degludec Inj. | "Related Proteins Degludec " | (RP-HPLC) NIB/RPL/SOP/85/R0; |
| 326 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Detemir Inj. | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/50/R3 |
| 327 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Detemir Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/50/R3 |
| 328 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Detemir Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/50/R3 |
| 329 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glargine Inj. | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC) NIB/RPL/SOP/43/R4 |

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| 330 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glargine Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/40/R5 |
| 331 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glargine Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/40/R5 |
| 332 | CHEMICAL- DRUGS & PHARMACEUTICALS | Insulin Glulisine Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/102/R1 |
| 333 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon alpha 2b Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/89/R1 |
| 334 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon Alpha-2b Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/89/R1 |
| 335 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon Alpha-2b Inj. | Impurity | (SDS-PAGE) NIB/RPL/SOP/79/R1 |
| 336 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon beta 1a Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/74/R1 |
| 337 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon Beta-1a Inj. | Dimer and related substances of higher molecular mass | (SEC- HPLC) NIB/RPL/SOP/77/R1 |
| 338 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon Beta-1a Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/74/R1 |
| 339 | CHEMICAL- DRUGS & PHARMACEUTICALS | Interferon Beta-1a Inj. | Protein Concentration | (RP-HPLC) NIB/RPL/SOP/74/R1 |
| 340 | CHEMICAL- DRUGS & PHARMACEUTICALS | Isophane Insulin Inj. | Insulin in the supernatant | (RP-HPLC) NIB/RPL/SOP/13/R6 |
| 341 | CHEMICAL- DRUGS & PHARMACEUTICALS | Liraglutide Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/84/R0 |
| 342 | CHEMICAL- DRUGS & PHARMACEUTICALS | Liraglutide Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/84/R0 |
| 343 | CHEMICAL- DRUGS & PHARMACEUTICALS | Oral Cholera Vaccine | Assay (Antigen content) | (Immunochemical Assay),"NIB/BVL/SOP/23/R0 |
| 344 | CHEMICAL- DRUGS & PHARMACEUTICALS | Oral Cholera Vaccine | Free formaldehyde | NIB/BVL/SOP/23/R0 |
| 345 | CHEMICAL- DRUGS & PHARMACEUTICALS | Oral Cholera Vaccine | pH | (Potentiometric Method)," NIB/BVL/SOP/23/R0 |
| 346 | CHEMICAL- DRUGS & PHARMACEUTICALS | Oral Cholera Vaccine | Test for Identification | (Immunochemical Assay ),"NIB/BVL/SOP/23/R0 |
| 347 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg Interferon beta 1a Inj. | Purity | (Oxidized content) NIB/RPL/SOP/28/R1 |
| 348 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg- Filgrastim Inj. | Identification | (SDS-PAGE, Non-Reducing) NIB/RPL/SOP/96/R1 |

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|---|---|---|---|---|
| 349 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg- Filgrastim Inj. | Identification | (SEC-HPLC) NIB/RPL/SOP/94/R1 |
| 350 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg- Filgrastim Inj. | Impurity | (SDS-PAGE, Non Reducing) NIB/RPL/SOP/96/R1 |
| 351 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg- Filgrastim Inj. | Impurity | (SEC-HPLC) NIB/RPL/SOP/94/R1 |
| 352 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg-Filgrastim Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/95/R1 |
| 353 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg-Filgratism Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/95/R1 |
| 354 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg-Interferon Alpha-2b Inj. | Identification | (SDS-PAGE) NIB/RPL/SOP/96/R1 |
| 355 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg-Interferon Alpha-2b Inj. | Purity | (SDS-PAGE) NIB/RPL/SOP/96/R1 |
| 356 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg-Interferon Alpha-2b Inj. | Purity | (SEC – HPLC) NIB/RPL/SOP/93/R1 |
| 357 | CHEMICAL- DRUGS & PHARMACEUTICALS | Peg-Interferon beta-1a Inj. | Identification | (Peptide mapping) NIB/RPL/SOP/28/R1 |
| 358 | CHEMICAL- DRUGS & PHARMACEUTICALS | Plasma Protein fraction | Haem content | (UV-Vis spectrophotometry),NIB/BPL/SOP/46/R2 |
| 359 | CHEMICAL- DRUGS & PHARMACEUTICALS | Plasma Protein Fraction | pH | (Potentiometry),NIB/BPL/SOP/45/R2 |
| 360 | CHEMICAL- DRUGS & PHARMACEUTICALS | rh-Erythropoietin | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC) NIB/RPL/SOP/66/R0 |
| 361 | CHEMICAL- DRUGS & PHARMACEUTICALS | rh-Erythropoietin | Identification | (SDS-PAGE followed by Immunoblotting) NIB/RPL/SOP/47/R3 |
| 362 | CHEMICAL- DRUGS & PHARMACEUTICALS | rh-Insulin Bulk | Assay/ Potency | (RP-HPLC) NIB/RPL/SOP/54/R3 |
| 363 | CHEMICAL- DRUGS & PHARMACEUTICALS | rh-Insulin Bulk | Higher Molecular Weight Proteins (HMWP) | (SEC-HPLC) NIB/RPL/SOP/46/R3 |
| 364 | CHEMICAL- DRUGS & PHARMACEUTICALS | rh-Insulin Bulk | Loss on Drying | (Gravimetric) NIB/RPL/SOP/42/R2 |
| 365 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Osmolality | NIB/TMA/SOP/004/R2 |
| 366 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Identification | (SDS-PAGE),"NIB/TMA/SOP/034/R1" |

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| 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 |
|---|---|---|---|---|
| 367 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Identification | (SEC-HPLC),NIB/TMA/SOP/020/R2 |
| 368 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | pH | NIB/TMA/SOP/003/R2 |
| 369 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Physical Characteristics | "NIB/TMA/SOP/056/R2 " |
| 370 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Purity | (SDS-PAGE- Reducing/ Non Reducing),NIB/TMA/SOP/034/R1 |
| 371 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Purity | (SEC-HPLC),NIB/TMA/SOP/020/R2 |
| 372 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rituximab | Protein Content | NIB/TMA/SOP/006/R3 |
| 373 | CHEMICAL- DRUGS & PHARMACEUTICALS | Rotavirus Live attenuated oral Vaccine (Rotarix ) | pH | (Potentiometric Method),NIB/VVL/SOP/047/R0 |
| 374 | CHEMICAL- DRUGS & PHARMACEUTICALS | Somatropin Inj. (Recombinant Human Growth Hormone) | "Identification" | (peptide mapping),"NIB/EHL/SOP/79/R00 |
| 375 | CHEMICAL- DRUGS & PHARMACEUTICALS | Somatropin Inj. (Recombinant Human Growth Hormone) | "Identification" | (RP- HPLC),NIB/EHL/SOP/58/R1 |
| 376 | CHEMICAL- DRUGS & PHARMACEUTICALS | Somatropin Inj. (Recombinant Human Growth Hormone) | "Identification" | (SE- HPLC),"NIB/EHL/SOP/56/R2 |
| 377 | CHEMICAL- DRUGS & PHARMACEUTICALS | Somatropin Inj. (Recombinant Human Growth Hormone) | Assay | (SE- HPLC),"NIB/EHL/SOP/56/R2 |
| 378 | CHEMICAL- DRUGS & PHARMACEUTICALS | Somatropin Inj. (Recombinant Human Growth Hormone) | Related Protein | (RP- HPLC),"NIB/EHL/SOP/58/R1 |
| 379 | CHEMICAL- DRUGS & PHARMACEUTICALS | Somatropin Inj. (Recombinant Human Growth Hormone) | Dimer and related substances of higher molecular weight | (SE-HPLC),"NIB/EHL/SOP/56/R2 |
| 380 | CHEMICAL- DRUGS & PHARMACEUTICALS | Streptokinase Bulk/Inj. | Streptodornase activity | (UV Vis Spectrophotometry),"NIB/EHL/SOP/07/R4 |
| 381 | CHEMICAL- DRUGS & PHARMACEUTICALS | Teriparatide (rh-PTH) Inj. | Identification | (RP-HPLC) NIB/RPL/SOP/90/R1 |
| 382 | CHEMICAL- DRUGS & PHARMACEUTICALS | Teriparatide (rh-PTH) Inj. | Related Proteins | (RP-HPLC) NIB/RPL/SOP/91/R2 |
| 383 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Purity | (CE-SDS under Reducing & Non-reducing conditions),"NIB/TMA/SOP/16/R2 " |
| 384 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Purity | (CEX-HPLC),"NIB/TMA/SOP/046/R1 " |

# SCOPE OF ACCREDITATION

**Laboratory Name :** NATIONAL INSTITUTE OF BIOLOGICALS, PLOT NO. A- 32, SECTOR 62, NOIDA, UTTAR PRADESH, INDIA

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

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|---|---|---|---|---|
| 385 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Purity | (SEC-HPLC),NIB/TMA/SOP/020/R2 |
| 386 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Water Content/Moisture Content/ Residual Moisture | NIB/VVL/SOP/006/R3 |
| 387 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Identification | (Capillary Zone Electrophoresis),NIB/TMA/SOP/043/R1 |
| 388 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Identification | (CEX-HPLC) "NIB/TMA/SOP/046/R1" |
| 389 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | pH | "NIB/TMA/SOP/003/R2" |
| 390 | CHEMICAL- DRUGS & PHARMACEUTICALS | Trastuzumab | Protein Content | NIB/TMA/SOP/006/R3 |