National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : SYNCBIO RESEARCH PRIVATE LIMITED, TESTING FACILITY, OFFICE-1, MARUTINANDAN ESTATE, CHANGODAR GIDC, TAJPUR ROAD, AHMEDABAD, GUJARAT, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-11202 **Page No** 1 of 2

Validity 08/12/2022 to 07/12/2024 **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	Follicle - Stimulating Hormone	Bioassay (In-Vivo)	IP 8th Edition, Volume-III, Page No. 3999
2	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Human Albumin / Plasma Protein Fraction / Human Normal Immunoglobulin IV / Human Normal Immunoglobulin IM / Anti D Immunoglobulin IM / Anti D Immunoglobulin IV / Tetanus Immunoglobulin / Dried Human Anti- Hemophilic Fraction (Factor VIII) / Human Coagulation Factor IX / Anti-Thrombin III Concentrate / Human Fibrinogen / Hepatitis B Immunoglobulin IM / Hepatitis B Immunoglobulin IV / Rabies Immunoglobulin IM / Rabies Vaccine / Hepatitis B Vaccine	Abnormal Toxicity	IP 8th Edition, Volume-I, Appendix 2.2.1, Page No. 27
3	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Human Albumin / Plasma Protein Fraction / Human Normal Immunoglobulin IV / Human Normal Immunoglobulin IM / Anti D Immunoglobulin IM / Anti D Immunoglobulin IV / Tetanus Immunoglobulin / Dried Human Anti- Hemophilic Fraction (Factor VIII) / Human Coagulation Factor IX / Anti-Thrombin III Concentrate / Human Fibrinogen / Hepatitis B Immunoglobulin IM / Hepatitis B Immunoglobulin IV / Rabies Immunoglobulin IM / Rabies Vaccine / Hepatitis B Vaccine	Pyrogen	IP 8th Edition, Volume-I, Appendix 2.2.8, Page No. 36
4	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Human Albumin / Plasma Protein Fraction / Human Normal Immunoglobulin IV / Human Normal Immunoglobulin IM / Anti D Immunoglobulin IM / Anti D Immunoglobulin IV / Tetanus Immunoglobulin / Dried Human Anti-Hemophilic Fraction (Factor VIII) / Human Coagulation Factor IX / Anti-Thrombin III Concentrate / Human Fibrinogen / Hepatitis B Immunoglobulin IM / Hepatitis B Immunoglobulin IV / Rabies Immunoglobulin IM / Rabies Vaccine / Hepatitis B Vaccine	Pyrogen	BP 9th Edition, Volume-V, Method 2.6.8, Page No. A447
5	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Human Chorionic Gonadotropin	Bioassay (In-Vivo)	BP 9th Edition, Volume-I, Page No. I-567
6	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Human Chorionic Gonadotropin	Bioassay (In-Vivo)	IP 8th Edition, Volume-II, Page No. 1610
7	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Human Chorionic Gonadotropin / Human Menopausal Gonadotropin Bulk	Abnormal Toxicity	IP 8th Edition, Volume-I, Chapter 2.2.1, Page No. 27
8	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Menotropin (Human Menopausal Gonadotropin)	Bioassay (In-Vivo)	BP 9th Edition, Volume-II, Page No. 228-229
9	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Menotropin (Human Menopausal Gonadotropin)	Bioassay (In-Vivo)	IP 8th Edition, Volume-III, Page No. 2524

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10	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Urofollitropin (Human Follicle-Stimulating Hormone)	Bioassay (In-Vivo)	BP 9th Edition, Volume-II, Page No. 1239-1240
11	BIOLOGICAL-BIOLOGICALS DERIVED PHARMACEUTICALS	Urofollitropin (Human Follicle-Stimulating Hormone)	Bioassay (In-Vivo) (Residual Luteinizing Activity)	BP 9th Edition, Volume-II, Page No. 1239-1240
12	BIOLOGICAL-TOXICOLOGY	Medical Devices (Including Aspiration Needle and Injection Needle, Billiary Stone Retrieval Balloon, Biopsy Forcep, Biopsy Needle Kit, Closed Wound Drainage Tube, Dialysis Tubing & Accessories, Catheters, Stent, Dolphin Suture, Double Lumen Hemodialysis Kit, Endoscopy Ligation Device, Endoscopy Mucosal Ressection, Endotracheal Tube, Infant Feeding Tube, IP Needle Diamond Tip, IV Canula with Safety Clip, Internal Prosthetic Replacements, Orthopaedic Screws / Small Joints / Wires / Nails / Pin, Ryles Tube, Wound Protector, Y Connector Arterial Cannula)	Pyrogen Test	ISO 10993 (Part 11)