National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : FOOD AND DRUGS ADMINISTRATION LABORATORY, 341, BANDRA-KURLA COMPLEX, MUMBAI, MUMBAI SUBURBAN, MAHARASHTRA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-10534 **Page No** 1 of 4

Validity 20/04/2022 to 19/04/2024 **Last Amended on** 03/06/2022

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- DRUGS AND PHARMACEUTICALS	Calcium Gluconate Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 1459 (IP Volume I Page 28, Appendix 2.2.3)
2	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Ceftriaxone Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 1541 (IP Volume I Page 28, Appendix 2.2.3)
3	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Chlorpheniramine Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 1597 (IP Volume I Page 28, Appendix 2.2.3)
4	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Compound Sodium Lactate Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume III Page 3225 (IP Volume I Page 28, Appendix 2.2.3)
5	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Dexamethasone Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 1781 (IP Volume I Page 28, Appendix 2.2.3)
6	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Dextrose Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 1797 (IP Volume I Page 28, Appendix 2.2.3)
7	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Diazepam Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 1802 (IP Volume I Page 28, Appendix 2.2.3)
8	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Frusemide Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 2134 (IP Volume I Page 28, Appendix 2.2.3)
9	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Gentamicin Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 2168 (IP Volume I Page 28, Appendix 2.2.3)
10	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Mannitol Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 2499 (IP Volume I Page 28, Appendix 2.2.3)
11	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Meropenem Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 2535 (IP Volume I Page 28, Appendix 2.2.3)
12	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Metronidazole Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume II Page 2595 (IP Volume I Page 28, Appendix 2.2.3)
13	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Ondansetron Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume III Page 2788 (IP Volume I Page 28, Appendix 2.2.3)

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14	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Sodium Chloride and Dextrose Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume III Page 3210 (IP Volume I Page 28, Appendix 2.2.3)
15	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Sodium Chloride Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume III Page 3212 (IP Volume I Page 28, Appendix 2.2.3)
16	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Sterile Water for Injection I.P.	Bacterial Endotoxin Test (BET) Method A - Gel Clot Limit Test Method	IP Volume III Page 3518 (IP Volume I Page 28, Appendix 2.2.3)
17	CHEMICAL- DRUGS & PHARMACEUTICALS	Albendazole Tablets I.P.	Assay	IP Volume II, Page 1170
18	CHEMICAL- DRUGS & PHARMACEUTICALS	Albendazole Tablets I.P.	Identification	IP Volume II, Page 1170
19	CHEMICAL- DRUGS & PHARMACEUTICALS	Albendazole Tablets I.P.	Uniformity of Weight	IP Volume II, Page 1170
20	CHEMICAL- DRUGS & PHARMACEUTICALS	Amoxycillin Dispersible Tablets I.P.	Assay	IP Volume II, Page 1232
21	CHEMICAL- DRUGS & PHARMACEUTICALS	Amoxycillin Dispersible Tablets I.P.	Disintegration	IP Volume II, Page 1232
22	CHEMICAL- DRUGS & PHARMACEUTICALS	Amoxycillin Dispersible Tablets I.P.	Identification (by IR)	IP Volume II, Page 1232
23	CHEMICAL- DRUGS & PHARMACEUTICALS	Amoxycillin Dispersible Tablets I.P.	Uniformity of Dispersion	IP Volume II, Page 1232
24	CHEMICAL- DRUGS & PHARMACEUTICALS	Amoxycillin Dispersible Tablets I.P.	Uniformity of Weight	IP Volume II, Page 1232
25	CHEMICAL- DRUGS & PHARMACEUTICALS	Ascorbic Acid Tablets I.P.	Assay	IP Volume II, Page 1271
26	CHEMICAL- DRUGS & PHARMACEUTICALS	Ascorbic Acid Tablets I.P.	Disintegration	IP Volume II, Page 1271
27	CHEMICAL- DRUGS & PHARMACEUTICALS	Ascorbic Acid Tablets I.P.	Identification	IP Volume II, Page 1271
28	CHEMICAL- DRUGS & PHARMACEUTICALS	Ascorbic Acid Tablets I.P.	Uniformity of Weight	IP Volume II, Page 1271
29	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Tablets I.P.	Dissolution	IP Volume II, Page 1509
30	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Tablets I.P.	Identification	IP Volume II, Page 1509
31	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Tablets I.P.	Uniformity of Weight	IP Volume II, Page 1509

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32	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Tablets I.P.	Water	IP Volume II, Page 1509
33	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Oral Suspension I.P.	Assay	IP Volume II, Page 1507
34	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Oral Suspension I.P.	Identification	IP Volume II, Page 1507
35	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Oral Suspension I.P.	pH	IP Volume II, Page 1507
36	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Oral Suspension I.P.	Stability of Suspension	IP Volume II, Page 1507
37	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Oral Suspension I.P.	Uniformity of Weight or Volume	IP Volume II, Page 1507
38	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Oral Suspension I.P.	Water	IP Volume II, Page 1507
39	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefadroxil Tablets I.P.	Assay	IP Volume II, Page 1509
40	CHEMICAL- DRUGS & PHARMACEUTICALS	Paracetamol Paediatric Syrup I.P.	4-Aminophenol	IP Volume III, Page 2857
41	CHEMICAL- DRUGS & PHARMACEUTICALS	Paracetamol Paediatric Syrup I.P.	Assay	IP Volume III, Page 2857
42	CHEMICAL- DRUGS & PHARMACEUTICALS	Paracetamol Paediatric Syrup I.P.	Identification	IP Volume III, Page 2857
43	CHEMICAL- DRUGS & PHARMACEUTICALS	Paracetamol Paediatric Syrup I.P.	Uniformity of Weight/ Volume	IP Volume III, Page 2857
44	CHEMICAL- DRUGS & PHARMACEUTICALS	Pyrazinamide Tablets I.P.	Assay	IP Volume III, Page 3043
45	CHEMICAL- DRUGS & PHARMACEUTICALS	Pyrazinamide Tablets I.P.	Dissolution	IP Volume III, Page 3043
46	CHEMICAL- DRUGS & PHARMACEUTICALS	Pyrazinamide Tablets I.P.	Identification	IP Volume III, Page 3043
47	CHEMICAL- DRUGS & PHARMACEUTICALS	Pyrazinamide Tablets I.P.	Related Substances	IP Volume III, Page 3043
48	CHEMICAL- DRUGS & PHARMACEUTICALS	Pyrazinamide Tablets I.P.	Uniformity of Weight	IP Volume III, Page 3043
49	CHEMICAL- DRUGS & PHARMACEUTICALS	Trimethoprim and Sulphamethoxazole Oral Suspension I.P.	Assay (Sulphamethoxazole)	IP Volume III, Page 3441
50	CHEMICAL- DRUGS & PHARMACEUTICALS	Trimethoprim and Sulphamethoxazole Oral Suspension I.P.	Assay (Trimethoprim)	IP Volume III, Page 3441

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51	CHEMICAL- DRUGS & PHARMACEUTICALS	Trimethoprim and Sulphamethoxazole Oral Suspension I.P.	Identification	IP Volume III, Page 3441
52	CHEMICAL- DRUGS & PHARMACEUTICALS	Trimethoprim and Sulphamethoxazole Oral Suspension I.P.	pH	IP Volume III, Page 3441
53	CHEMICAL- DRUGS & PHARMACEUTICALS	Trimethoprim and Sulphamethoxazole Oral Suspension I.P.	Uniformity of Weight/ Volume	IP Volume III, Page 3441