National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : MANKIND PHARMA LTD-CTL(MANKIND RESEARCH CENTRE), 191 E- SECTOR 4II-IMT, MANESAR, GURGAON, HARYANA, INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-5254 **Page No** 1 of 3

Validity 16/11/2022 to 15/11/2024 **Last Amended on** 07/02/2023

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	Gentamicin Injection	Assay by Cup-Plate Method	MK/STP/16002/02; Issue No: 01; Issue Date 06.01.2022
2	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Microbial Contamination in non sterile products	E.Coli, Salmonella, S. aureus, P. aeruginosa, Shigella, C. albicans & Clostridia	IP (Vol1, Pg No 45-46)
3	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Microbial Contamination in nonsterile products	Total aerobic viable count	IP (Vol 1,Pg No 38)
4	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Microbial Contamination in nonsterile products	Total yeast & mold count	IP (Vol 1,Pg No 38)
5	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Parenteral Preparations/ Water for Injection	Bacterial Endotoxin Test (By Gel clot Method)	IP (Vol 1,Pg No 28)
6	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Parenteral Preparations/Water for Injection	Sterility Testing	IP (Vol 1,Pg No: 59)
7	CHEMICAL- DRUGS & PHARMACEUTICALS	Amlodipine Tablets	Dissolution (by UV)	IP. Volume-II, Page No. 1220 & 1221
8	CHEMICAL- DRUGS & PHARMACEUTICALS	Atorvastatin Calcium	Identification (b)	IP. Volume-II, Page No. 1286 & 1287
9	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefixime Trihydrate	Assay	IP. Volume-II, Page No. 1523 & 1524
10	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefixime Trihydrate	Related Substances (Total Impurities)	IP. Volume-II, Page No. 1523 & 1524
11	CHEMICAL- DRUGS & PHARMACEUTICALS	Cefixime Trihydrate	Related Substances (Single Individual Impurity)	IP. Volume-II, Page No. 1523 & 1524
12	CHEMICAL- DRUGS & PHARMACEUTICALS	Ciprofloxacin HCl	Assay	IP. Volume-II, Page No. 1629 & 1630
13	CHEMICAL- DRUGS & PHARMACEUTICALS	Dicyclomine HCl	Assay (by Titration)	IP. Volume-II, Page No. 1815 & 1816
14	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Capsules)	Uniformity of Fill	IP. Volume –II, Chapter No. Capsules, Page No. 1085
15	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Average Weight	IP. Volume –II, Chapter No. Tablets, Page No.1119
16	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Average Weight	IP. Volume –II, Chapter No. Tablets, Page No.1119
17	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Disintegration Test	IP. Volume –I, Chapter No. 2.5.1, Page No. 299 to 302
18	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Friability	IP. Volume –I, Chapter No. 2.5.5, Page No. 309

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19	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Uniformity of Dispersion	IP. Volume -I, Chapter No. Tablets ,Page No. 1120
20	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Water	IP. Volume-I, Chapter No. 2.3.43, Page No. 156 to 158
21	CHEMICAL- DRUGS & PHARMACEUTICALS	Finish Products (Tablets)	Weigh Variation	IP. Volume –II, Chapter No. Tablets, Page No.1119
22	CHEMICAL- DRUGS & PHARMACEUTICALS	Guaiphenesin	Melting Point	IP. Volume-II ,Page No. 2197 & 2198
23	CHEMICAL- DRUGS & PHARMACEUTICALS	Injections/ Infusion	Extractable /Fill Volume	IP. Volume-I, Chapter No. Parental Preparations, Page No. 1113 to 1116
24	CHEMICAL- DRUGS & PHARMACEUTICALS	Injections/ Infusion	pH	IP. Volume-I, Chapter No. 2.4.24, Page No. 215 & 216
25	CHEMICAL- DRUGS & PHARMACEUTICALS	Isopropyl Alcohol	Benzene & Related Substances (Benzene)	IP. Addendum-II, Page No. 4663 & 4664
26	CHEMICAL- DRUGS & PHARMACEUTICALS	Oral Liquids (Syrup, Suspension, Dry Syrup)	Extractable/Fill Volume	IP, Volume-II, Chapter No. Oral Liquids, Page No. 1110 to 1113
27	CHEMICAL- DRUGS & PHARMACEUTICALS	Povidone	1-vinylpyrrolidone-2 one	IP. Volume –III, Page No. 2969 & 2970
28	CHEMICAL- DRUGS & PHARMACEUTICALS	Propranolol HCl	Assay (by Potentiometer)	IP. Volume-III, Page No. 3023 & 3024
29	CHEMICAL- DRUGS & PHARMACEUTICALS	Raw Materials	Loss on Drying	IP. Volume-I, Chapter No. 2.4.19, Page No. 208 & 209
30	CHEMICAL- DRUGS & PHARMACEUTICALS	Raw Materials	pH	IP. Volume-I, Chapter No. 2.4.24, Page No. 215 & 216
31	CHEMICAL- DRUGS & PHARMACEUTICALS	Raw Materials	Specific Optical Rotation	IP. Volume-I, Chapter No. 2.4.22, Page No. 212 to 214
32	CHEMICAL- DRUGS & PHARMACEUTICALS	Raw Materials	Sulphated Ash	IP. Volume-I, Chapter No. 2.3.18, Page No. 140
33	CHEMICAL- DRUGS & PHARMACEUTICALS	Raw Materials	Water	IP. Volume-I, Chapter No. 2.3.43, Page No. 156 to 158
34	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Total Ash	MK/STP/16006/03; Issue no:01; Issue date 06.01.2023
35	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Carbohydrate	MK/STP/16011/03; Issue No: 01; Issue Date 06.01.2023
36	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Energy	MK/STP/16012/03 ; Issue No:01; Issue Date 06.01.2023

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37	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Fat	MK/STP/16009/03; Issue No: 01; Issue Date 06.01.2023
38	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Loss on drying	MK/STP/16007/03; Issue no:01; Issue Date 06.01.2023
39	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Protein	MK/STP/16008/03; Issue no:01; Issue Date 06.01.2023
40	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Sachet (Powder)	Sugar	MK/STP/16009/03; Issue no:01; Issue Date 06.01.2023
41	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Average Weight	IP. Volume –I, Chapter No. 2.5.3, Page No.360
42	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Carbohydrate	MK/STP/16011/03; Issue no:01; Issue Date 06.01.2023
43	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Energy	MK/STP/16012/03; Issue no: 01; Issue Date 06.01.2023
44	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Fat	MK/STP/16009/03; Issue no:01; Issue Date 06.01.2023
45	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Loss on drying	MK/STP/16007/03; Issue no: 01 ; Issue Date 06.01.2023
46	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Protein	MK/STP/16008/03; Issue no: 01; Issue Date 06.01.2023
47	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Sugar	MK/STP/16010/03; Issue no: 01; Issue Date 06.01.2023
48	CHEMICAL- NUTRITIONAL SUPPLEMENTS	Tablets	Total Ash	MK/STP/16006/03; Issue no:01; Issue date 06.01.2023