National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name : PSYCHOTROPICS INDIA LIMITED, UNIT-II, PLOT NO:-12 & 12A, INDUSTRIAL PARK-2, PHASE-1, SALEMPUR MEHMOOD-2, HARIDWAR, UTTARAKHAND, INDIA

Accreditation Standard ISO/IEC 17025:2017

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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
Permanent Facility				
1	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Parenteral Preparations Injection (Small Volume Parenteral)	Sterility	Section 2.2.11 of IP
2	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Small Volume Parenteral Injection	Bacterial Endotoxins Test (Method A, Gel-clot limit test method)	IP 2.2.3
3	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid oral dosage (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Escherichia coli	Section 2.2.9 of IP
4	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral Dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Total Fungal Count / Yeast and Mould Count	Section 2.2.9 of IP Vol. I 2.2.9 USP 41 (61)
5	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral Dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Total Aerobic Microbial Count/Total Aerobic viable count	Section 2.2.9 of IP Vol. I 2.2.9 USP 41 (61)
6	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral Dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Bile-Tolerant Gram Negative Bacteria	Section 2.2.9 of IP

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7	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral Dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Pseudomonas aeruginosa	Section 2.2.9 of IP
8	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral Dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Salmonella	Section 2.2.9 of IP
9	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral Dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Shigella	Section 2.2.9 of IP
10	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Solid Oral dosages (Metformin Hydrochloride Tablets IP, S - Amlodipine Tablets IP, Pantoprazole Gastro Resistant Tablet IP, Olmesartan Medoxomil Tablets IP, Telmisartan Tablets IP, Levocetirizine Tablets IP, Deflazacort Tablets, Metformin Hydrochloride Sustained Release Tablets IP, Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP, Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release), Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP & Capsules)	Staphylococcus aureus	Section 2.2.9 of IP
11	CHEMICAL- DRUGS & PHARMACEUTICALS	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release) Tablets	Assay Glimepiride (By HPLC)	In-House STP-S4/FGP/DOM/0528
12	CHEMICAL- DRUGS & PHARMACEUTICALS	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release) Tablets	Assay of Metformin Hydrochloride (By HPLC)	In-House STP-S4/FGP/DOM/0528
13	CHEMICAL- DRUGS & PHARMACEUTICALS	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release) Tablets	Assay Pioglitazone Hydrochloride (By HPLC)	In-House STP-S4/FGP/DOM/0528
14	CHEMICAL- DRUGS & PHARMACEUTICALS	Betahistine Tablet IP	Assay By HPLC	IP

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15	CHEMICAL- DRUGS & PHARMACEUTICALS	Betahistine Tablet IP	Dissolution By UV	IP
16	CHEMICAL- DRUGS & PHARMACEUTICALS	Betahistine Tablet IP	Identification By HPLC	IP
17	CHEMICAL- DRUGS & PHARMACEUTICALS	Betahistine Tablet IP	Identification by IR	IP
18	CHEMICAL- DRUGS & PHARMACEUTICALS	Betahistine Tablet IP	Related Substance by HPLC	IP
19	CHEMICAL- DRUGS & PHARMACEUTICALS	Deflazacort Tablet	Identification By HPLC	In House STP-S4/FGP/DOM/0523
20	CHEMICAL- DRUGS & PHARMACEUTICALS	Deflazacort Tablets	Assay By HPLC	In House STP-S4/FGP/DOM/0523
21	CHEMICAL- DRUGS & PHARMACEUTICALS	Dexamethasone Sodium Phosphate Injection	Assay (By HPLC)	BP
22	CHEMICAL- DRUGS & PHARMACEUTICALS	Dexamethasone Sodium Phosphate Injection	Free Dexamethasone By HPLC	IP
23	CHEMICAL- DRUGS & PHARMACEUTICALS	Dexamethasone Sodium Phosphate Injection	Identification (By HPLC)	BP
24	CHEMICAL- DRUGS & PHARMACEUTICALS	Drotaverine Injection	Assay (By HPLC)	In-House S4/FGP/IND/0330
25	CHEMICAL- DRUGS & PHARMACEUTICALS	Drotaverine Injection	Identification By HPCL	In-House S4/FGP/IND/0330
26	CHEMICAL- DRUGS & PHARMACEUTICALS	General Test	Identification By IR	IP
27	CHEMICAL- DRUGS & PHARMACEUTICALS	General Test	Identification Functional Group	IP
28	CHEMICAL- DRUGS & PHARMACEUTICALS	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release) Tablets	Dissolution of Metformin Hydrochloride	In-House STP-S4/FGP/DOM/0528
29	CHEMICAL- DRUGS & PHARMACEUTICALS	Glimepiride, Pioglitazone Hydrochloride & Metformin Hydrochloride (Extend Release) Tablets	Identification by HPLC	In House STP - S4/FGP/DOM/0528
30	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydrocortisone Sodium Succinate Injection	Assay by UV	IP
31	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydrocortisone Sodium Succinate Injection	Identification (By IR)	IP
32	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydrocortisone Sodium Succinate Injection	Identification (By TLC)	IP
33	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydrocortisone Sodium Succinate Injection	Related Substance By HPLC	IP

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34	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydroxyzine Tablet IP	Assay By HPLC	IP
35	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydroxyzine Tablet IP	Dissolution by UV	IP
36	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydroxyzine Tablet IP	Identification By HPLC	IP
37	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydroxyzine Tablet IP	Identification by TLC	IP
38	CHEMICAL- DRUGS & PHARMACEUTICALS	Hydroxyzine Tablet IP	Related Substance by HPLC	IP
39	CHEMICAL- DRUGS & PHARMACEUTICALS	Levocetirizine Tablets	Assay By HPLC	IP
40	CHEMICAL- DRUGS & PHARMACEUTICALS	Levocetirizine Tablets	Dissolution By HPLC	IP
41	CHEMICAL- DRUGS & PHARMACEUTICALS	Levocetirizine Tablets	Identification By HPLC	IP
42	CHEMICAL- DRUGS & PHARMACEUTICALS	Levocetirizine Tablets	Related Substance By HPLC	IP
43	CHEMICAL- DRUGS & PHARMACEUTICALS	Loratadine Tablet USP	Assay By HPLC	USP
44	CHEMICAL- DRUGS & PHARMACEUTICALS	Loratadine Tablet USP	Identification By HPLC	USP
45	CHEMICAL- DRUGS & PHARMACEUTICALS	Loratadine Tablet USP	Organic Impurities By HPLC	USP
46	CHEMICAL- DRUGS & PHARMACEUTICALS	Loratidine Tablet USP	Dissolution By HPLC	USP
47	CHEMICAL- DRUGS & PHARMACEUTICALS	Lorazepam Tablet	Assay by UV	IP
48	CHEMICAL- DRUGS & PHARMACEUTICALS	Lorazepam Tablet	Dissolution by UV	IP
49	CHEMICAL- DRUGS & PHARMACEUTICALS	Lorazepam Tablet	Identification by TLC	IP
50	CHEMICAL- DRUGS & PHARMACEUTICALS	Lorazepam Tablet	Identification By UV	IP
51	CHEMICAL- DRUGS & PHARMACEUTICALS	Lorazepam Tablet	Related Substance By TLC	IP
52	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin HCl Tablet	Assay by UV	IP

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53	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin HCl Tablet	Dissolution by UV	IP
54	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin HCl Tablet	Identification by IR	IP
55	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin HCl Tablet	Related Substance by HPLC	IP
56	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP	Assay of Glimepiride By HPLC	IP
57	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP	Assay of Metformin Hydrochloride By UV	IP
58	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP	Dissolution of Glimepiride By HPLC	IP
59	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP	Dissolution of Metformin Hydrochloride By UV	IP
60	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin Hydrochloride Sustained Release & Glimepiride Tablets IP	Identification By HPLC	IP
61	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin Hydrochloride Sustained Release and Glimepiride Tablets IP	Identification By UV	IP
62	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin hydrochloride sustained-release tablets	Assay By UV	IP
63	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin hydrochloride sustained-release tablets	Dissolution By UV	IP
64	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin hydrochloride sustained-release tablets	Identification By Chemical	IP
65	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin hydrochloride sustained-release tablets	Identification By IR	IP
66	CHEMICAL- DRUGS & PHARMACEUTICALS	Metformin hydrochloride sustained-release tablets	Related Substance By HPLC	IP
67	CHEMICAL- DRUGS & PHARMACEUTICALS	Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP	Assay of Levocetirizine Hydrochloride (By HPLC)	IP
68	CHEMICAL- DRUGS & PHARMACEUTICALS	Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP	Dissolution Levocetirizine Hydrochloride (By HPLC)	IP
69	CHEMICAL- DRUGS & PHARMACEUTICALS	Montelukast Sodium & Levocetirizine Hydrochloride Tablets IP	Related Substance (By HPLC)	IP
70	CHEMICAL- DRUGS & PHARMACEUTICALS	Montelukast Sodium &Levocetirizine Hydrochloride Tablets IP	Assay of Montelukast Sodium (By HPLC)	IP
71	CHEMICAL- DRUGS & PHARMACEUTICALS	Montelukast Sodium &Levocetirizine Hydrochloride Tablets IP	Dissolution of Montelukast Sodium (By HPLC)	IP

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72	CHEMICAL- DRUGS & PHARMACEUTICALS	Montelukast Sodium &Levocetirizine Hydrochloride Tablets IP	Identification (By HPLC)	IP
73	CHEMICAL- DRUGS & PHARMACEUTICALS	Olmesartan Medoxomil Tablet IP	Assay By HPLC	IP
74	CHEMICAL- DRUGS & PHARMACEUTICALS	Olmesartan Medoxomil Tablet IP	Related Substances By HPLC	IP
75	CHEMICAL- DRUGS & PHARMACEUTICALS	Olmesartan Medoxomil Tablets IP	Dissolution By HPLC	IP
76	CHEMICAL- DRUGS & PHARMACEUTICALS	Olmesartan Medoxomil Tablets IP	Identification By HPLC	IP
77	CHEMICAL- DRUGS & PHARMACEUTICALS	Ondansetron injection	Assay (By HPLC)	IP
78	CHEMICAL- DRUGS & PHARMACEUTICALS	Ondansetron injection	Identification (By HPLC)	IP
79	CHEMICAL- DRUGS & PHARMACEUTICALS	Ondansetron injection	Related Substance by HPLC	IP
80	CHEMICAL- DRUGS & PHARMACEUTICALS	Pantoprazole Gastro-resistant	Assay By HPLC	IP
81	CHEMICAL- DRUGS & PHARMACEUTICALS	Pantoprazole Gastro-resistant	Dissolution	IP
82	CHEMICAL- DRUGS & PHARMACEUTICALS	Pantoprazole Gastro-resistant	Identification by HPLC	IP
83	CHEMICAL- DRUGS & PHARMACEUTICALS	Pantoprazole Gastro-resistant	Identification By UV	IP
84	CHEMICAL- DRUGS & PHARMACEUTICALS	Pantoprazole Sodium for Injection BP	Assay (By HPLC)	BP
85	CHEMICAL- DRUGS & PHARMACEUTICALS	Pantoprazole Sodium for Injection BP	Identification (By IR)	BP
86	CHEMICAL- DRUGS & PHARMACEUTICALS	S-Amlodipine Tablet IP	Assay By HPLC	IP
87	CHEMICAL- DRUGS & PHARMACEUTICALS	S-Amlodipine Tablets	Dissolution by UV	IP
88	CHEMICAL- DRUGS & PHARMACEUTICALS	S-Amlodipine Tablets IP	Identification By HPLC	IP
89	CHEMICAL- DRUGS & PHARMACEUTICALS	Telmisartan tablets	Assay By HPLC	IP
90	CHEMICAL- DRUGS & PHARMACEUTICALS	Telmisartan tablets	Dissolution By UV	IP

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91	CHEMICAL- DRUGS & PHARMACEUTICALS	Telmisartan tablets	Identification By HPLC	IP
92	CHEMICAL- DRUGS & PHARMACEUTICALS	Telmisartan tablets	Related Substance By HPLC	IP
93	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride & Acetaminophen Tablets USP	Assay of Acetaminophen (By HPLC)	USP
94	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride & Acetaminophen Tablets USP	Assay of Tramadol Hydrochloride (By HPLC)	USP
95	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride & Acetaminophen Tablets USP	Dissolution of Acetaminophen (By HPLC)	USP
96	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride & Acetaminophen Tablets USP	Dissolution of Tramadol Hydrochloride (By HPLC)	USP
97	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride & Acetaminophen Tablets USP	Identification (By HPLC)	USP
98	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride & Acetaminophen Tablets USP	Organic Impurity (By HPLC)	USP-42
99	CHEMICAL- DRUGS & PHARMACEUTICALS	Tramadol Hydrochloride and Acetaminophen Tablet	4-Aminophenol in Acetaminophen Containing by Drug product by HPLC	USP-42
100	CHEMICAL- DRUGS & PHARMACEUTICALS	Ursodeoxycholic Acid Tablet IP	Assay By HPLC	IP
101	CHEMICAL- DRUGS & PHARMACEUTICALS	Ursodeoxycholic Acid Tablet IP	Dissolution By HPLC	IP
102	CHEMICAL- DRUGS & PHARMACEUTICALS	Ursodeoxycholic Acid Tablet IP	Identification By HPLC	IP
103	CHEMICAL- DRUGS & PHARMACEUTICALS	Ursodeoxycholic Acid Tablet IP	Identification By IR	IP
104	CHEMICAL- DRUGS & PHARMACEUTICALS	Ursodeoxycholic Acid Tablet IP	Related Substance By TLC	IP