Laboratory	**Pragya Research Laboratories Pvt. Ltd., H-165, Second Floor, Sector-63, Noida, Uttar Pradesh**		
Accreditation Standard	**ISO/IEC 17025: 2005**		
Certificate Number	**TC-7873**	**Page 1 of 6**	
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Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection

BIOLOGICAL TESTING

I	**DRUGS AND PHARMACEUTICALS**			
A.	**Antibiotics**			
1.	**Tablets**	Erythromycin Estolate	USP 41 (81)	70% to 150%
		Erythromycin Stearate	IP 2018,Vol. I 2.2.10 (cup-plate method)	70% to 150%
2.	**Injection**	Amikacin Sulphate	IP 2018,Vol. I 2.2.10 (cup-plate method)	70% to 150%
		Gentamicin Sulphate	IP 2018,Vol. I (cup-plate method) 2.2.10	70% to 150%
		Streptomycin Sulphate	IP 2018,Vol. I 2.2.10 (cup-plate method)	70% to 150%
B.	**Endotoxins**			
1.	**Parenteral Preparations Injection (small and Large volume parenteral)**	Bacterial endotoxin Test (Gel Clot Method)	IP 2018,Vol. I 2.2.3 USP 41(85)	Pass /Fail
2	**Surgical Devices, Transfusion, Infusion, Blood Bags and disposable, Blades, Syringes and needles**			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
C.	**Drug Substances (Active Pharmaceuticals Ingredients)**			
1.	**Solid Oral Dosages (Tablet and Capsules)**	Total Aerobic Microbial count / Total Aerobic viable count	IP 2018 Vol. I 2.2.9 USP 41 (61)	≥10cfu/g
		Total Fungal Count/Yeast and mould Count	IP 2018, Vol. I 2.2.9 USP 41 (61)	≥10cfu/g
		Escherichia Coli	IP 2018, Vol. I 2.2.9 USP 41 (62)	Present / Absent per g or10g
		Salmonella	IP 2018, Vol. I 2.2.9 USP 41 (62)	Present / Absent per g or 10g
		Staphylococcus aureus	IP 2018, Vol. I 2.2.9 USP 41 (62)	Present / Absent per g or 10g
		Shigella	IP 2018 ,Vol. I 2.2.9	Present / Absent per g or 10g
		Pseudomonas aeruginosa	IP 2018, Vol. I 2.2.9 USP 41 (62)	Present / Absent per g or 10g
		Candida albicans	IP 2018, Vol. I 2.2.9 USP 41 (62)	Present / Absent per g or 10g
		Clostridia	IP 2018, Vol. I 2.2.9 USP 41 (62)	Present / Absent per g
		Bile-Tolerant Gram-Negative Bacteria	IP 2018, Vol. I 2.2.9, USP 41 (62)	Present / Absent per g or 10g
2.	**Liquid Oral Dosages (Syrup)**	Total Aerobic Microbial count/ Total Aerobic viable count	IP 2018 2.2.9 USP 41 (61)	≥10 cfu/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Yeast and mould Count /Yeast and mould Count	IP 2018 2.2.9 USP 41 (61)	≥10 cfu/ml
		Escherichia Coli	IP 2018 2.2.9 USP 41 (62)	Present / Absent per g/ml or10g/ml
		Salmonella	IP 2018 2.2.9, USP 41 (62)	Present/Absent per g/ml or 10g/ml
		Staphylococcus aureus	IP 2018 2.2.9 USP 41 (62)	Present/Absent per g/ml or 10g/ml
		Shigella	IP 2018 2.2.9,	Present/Absent per g/ml or 10g/ml
		Pseudomonas aeruginosa	IP 2018 2.2.9, USP 41 (62)	Present/Absent per g/ml or 10g/ml
		Candida albicans	IP 2018 2.2.9, USP 41 (62)	Present/Absent per g/ml or 10g/ml
		Clostridia	IP 2014 Page No. 46 USP 41 (61& 62)	Present/Absent per g/ml or 10g/ml
		Bile-Tolerant Gram-Negative Bacteria	IP 2018 2.2.9 USP 41 (62)	Present/Absent per g/ml or 10g/ml

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CHEMICAL TESTING

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I.	**DRUGS& PHARMACEUTICALS**			
A.	**Raw material**			
	General Test	Identification By IR	IP 2018 Page No.178 - 183	Qualitative
		Specific Optical rotation/ optical Rotation	IP 2018 Page No.212 - 214	±0 to 360°
		Heavy metals	IP 2018 Page No.139 - 140	Qualitative
		Loss on Drying	IP 2018 Page No.208 -209	0.1% to 20% w/w
		Melting Point	IP 2018 Page No.209 - 212	Qualitative
		pH	IP 2018 Page No.215 - 216	1 to 14
		Water by KF	IP 2018 Page No.156	0.1 to 15%w/w
		Sulphates	IP 2018 Page No.140	Qualitative
B.	**Tablets and Capsules**			
1.	**General Test**	Disintegration	IP 2018 Page No.299 - 302	1 minute to 180 minutes
		Dissolution	IP 2018 Page No.302 to 308	50 % to 150 % of label claim
		Uniformity of weight	IP 2018 Page No. 1085 Page No. 308	0.06 g to 5.0 g
		Uniformity of content	IP 2018 Page No. 308 to 309	80 % to 150 % of average value
2.	**Acelofenac Tablet (IP)**	Identification (By HPLC)	IP 2018 Page No.1145	Qualitative
		Assay (By HPLC)	IP 2018 Page No.1145-1146	70 to 120 % of label claim
		Dissolution (By UV)	IP 2018 Page No.1145	50 to 120% of label claim
3.	**Atorvastatin Tablet IP**	Identification (By HPLC)	IP 2018 Page No.1287-1289	Qualitative
		Assay (By HPLC		70 % to 120 % of label claim

Suman Kharayat
Convenor

Jitendra B. Vispute
Program Manager

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Dissolution(by HPLC)		50 % to 120% of label claim
4.	**Cetirizine Tablets IP**	Identification (By HPLC)	IP 2018 Page No.1561-1562	Qualitative
		Assay (By HPLC)		70% to 120 % of label claim
		Dissolution (By UV)		50 % to 120% of label claim
5.	**Chlorpheniramine Tablets**	Identification (By TLC)	IP 2018 Page 1598	Qualitative
		Assay (By UV)		70% to 120 % of label claim
		Related Substances (By TLC)		Qualitative
6.	**Ofloxacin Tablet IP**	Identification (By HPLC)	IP 2018 Page No.2769-2770	Qualitative
		Assay (By HPLC)		70% to 120 % of label claim
		Dissolution (By UV)		50% to 120% of label claim
7.	**Paracetamol Tablet IP**	Identification (By IR)	IP 2018 Page No.2858	Qualitative
		Assay (By UV)		70 % to 120 % of label claim
		Dissolution (By UV)		50% to 120% of label claim
8.	**Ranitidine Tablet**	Identification (By IR)	IP 2018 Page No.3090	Qualitative
		Assay (By HPLC)		70% to 120 % of label claim
9.	**Sildenafil Citrate Tablet IP**	Identification (By HPLC)	IP 2018 Page No.3191	Qualitative
		Assay (By HPLC)		70% to 120 % of label claim

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Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Dissolution (By UV)		50% to 120% of label claim
C.	**INJECTION**			
1.	**Cyanocobalamin Injection**	Identification (By UV)	IP 2018 Page No.1772-1773	Qualitative
		Assay (By UV)		70% to 120% of label claim
		Related Substances(BY HPLC)		Qualitative

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