

Laboratory Sreechem Analytical Services Pvt. Ltd., Plot No. 62, 2nd & 3rd Floor,
Ayyanna Commercial, Prasanthi Nagar, Kukatpally, Hyderabad,
Telangana

Accreditation Standard ISO/IEC 17025: 2005

Certificate Number TC-5501

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Validity 13.04.2017 to 12.04.2019

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
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BIOLOGICAL TESTING

I.	DRUGS & PHARMACEUTICALS			
1.	Microbial Limit Tests			
a.	Drug Substances (APIs), Pharmaceutical Formulations, Drug Intermediates, and Raw materials	Total Aerobic Microbial Count	IP 2014, 2.2.9; USP 39, <61>	≥ 10 CFU/g
		Total Yeast & Mold Count	IP 2014, 2.2.9; USP 39, <61>	≥ 10CFU/ml ≥ 10 CFU/g
II.	WATER			
1.	Water- Raw Water & Purified Water	Bacterial count	IS 5402: 2012 IP 2014, 2.2.9	≥1 CFU/ml

Sandeep Singh Tomar
Convenor

N. Venkateswaran
Program Director

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CHEMICAL TESTING

I. DRUGS AND PHARMACEUTICALS				
1.	Physical and Chemical Methods	Description	IP 2014	Qualitative
		Solubility	IP 2014 Page 174	Qualitative
		Average weight	IP 2014, page 256-257	0.05 g to 5.0 g
		Moisture content	IP 2014, Page 113	0.1% w/w to 50%w/w
		pH	IP 2014, Page 169	1 to 12
		Loss on drying	IP 2014 Page 162;	0.1 % w/w to 10%w/w
		Loss on ignition	IP 2014 Page 163,	0.1 % w/w to 10%w/w
2.	Drug Substance (API)			
a.	Omeprazole IP	Identification by IR	IP 2014, Page 2372.	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by HPLC	IP 2014, Page 2373	10 % w/w to 105%w/w
b.	Ciprofloxacin Hydrochloride IP	Identification by IR	IP 2014, page 1399	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by HPLC	IP 2014, page 1400	10 % w/w to 105%w/w
c.	Rabeprazole Sodium IP	Identification by IR	IP 2014, Page 2631	4000 - 600cm ⁻¹
		Assay by HPLC	IP 2014, Page 2631	10 % w/w to 105%w/w
d.	Pantoprazole Sodium IP	Identification by IR	IP 2014, Page 2426	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by HPLC	IP 2014, Page 2427	10 % w/w to 105%w/w
e.	Levocetirizine Dihydrochloride IP	Identification by IR	IP 2014, Page 2077	4000 cm ⁻¹ - 600cm ⁻¹
		Enantiomeric purity by HPLC	IP 2014, Page 2077 -2078	0.01% w/w to 99.0 % w/w
f.	Montelukast Sodium IP	Identification by IR	IP 2014, Page 2247	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by HPLC	IP 2014, Page 2247 to 2248	10 % w/w to 105%w/w
g.	Azithromycin IP	Identification by IR	IP 2014, Page 1117	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by HPLC	IP 2014, Page 1118	10 % w/w to 105%w/w
h.	Ivermectin IP	Identification by IR	IP 2014, Page 3532	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by HPLC	IP 2014, Page 3533	10 % w/w to 105%w/w
i.	Simethicone IP	Identification by IR	IP 2014, Page 1585	4000 cm ⁻¹ - 600cm ⁻¹
		Assay by IR	IP 2014, Page 1585 to 1586	10 % w/w to 105%w/w

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j.	Acetaminophen USP	Identification by IR	USP 39, Page 2294	4000 cm ⁻¹ - 600cm ⁻¹
		4-aminophenol by HPLC	USP 39, Page 2294 to 2295	0.0001% to 0.005%w/w
		Assay by HPLC	USP 39, page 2294	10 % w/w to 105 % w/w
k.	Povidone IP	1-Vinyl-2-Pyrrolididone by HPLC	IP 2014, Page 2549	0.0001 % to 0.001 % w/w
l.	Magnesium stearate IP	Stearic acid by GC	IP 2014, Page 2144	10 % w/w to 80 % w/w
		Palmitic acid by GC	IP 2014, Page 2144	10 % w/w to 80 % w/w
m.	Aluminium Hydroxide Paste IP	Aluminium –assay by Titrimetry	IP 2014, Page 1021	2.0 % w/w to 10% w/w
3.	Capsules			
a.	Omeprazole IP-Capsules	Assay (HPLC)	IP 2014, Page 2374	80 % w/w to 120 % w/w
4.	Tablets			
a.	Rabeprazole sodium IP-Tablets	Assay (HPLC)	IP 2014, Page 2632	80 % w/w to 120 % w/w
		Acid resistance – by UV	IP 2014, Page 2631 to 2632	0.1% w/w to 100 % w/w
		Dissolution by UV	IP 2014, Page 2632	50 % w/w to 120 % w/w
b.	Pantoprazole sodium IP - Tablets	Assay (HPLC)	IP 2014, Page 2428	80 % w/w to 120 % w/w
		Acid resistance by HPLC	IP 2014, Page 2428	0.1 % w/w to 10 % w/w
		Dissolution by UV	IP 2014, Page 2428	50 % w/w to 120 % w/w
II.	NUTRACEUTICALS AND FUNCTIONAL FOODS			
1.	Fortified Food			
a.	Riboflavin	Content by HPLC	IP2014, USP 39	0.5 mg/kg to 50 mg/kg
b.	Thiamine Hydrochloride	Content by HPLC	USP 39, Page 6108	0.4 mg/kg to 40 mg/kg
c.	Zinc	Assay (AAS)	IP2014, USP 39	100 mg/kg to 10000 mg/kg

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d.	Iron	Content by AAS	IP2014, USP 39	0.00005 % to 50 %
e.	Methyl Sulfonyl Methane	Identification by FT-IR	USP 39, Page 6759	4000 cm ⁻¹ to 600cm ⁻¹
		Assay by GC	USP 39, Page 6759 to 6760	80 % w/w to 120 % w/w
f.	Sucrose	Assay by HPLC	IP 2014, USP 39	60 % w/w to 110 % w/w

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