

Laboratory **Chemo Test Laboratory, Pusalkar House, J.B. Road, Sewri (W),
Mumbai, Maharashtra**

Accreditation Standard **ISO/IEC 17025: 2005**

Certificate Number **TC-6453**

Page 1 of 8

Validity **30.10.2017 to 29.10.2019**

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.	Raw Materials (Powders/ Extract) (Pour Plate Method)	Microbial Limit Test		
		Total Bacterial Count (Total Aerobic Microbial Count)	IP'2014 Volume- I, Pg 42 BP'2017 Volume-V, App XVI (B) USP'40 (61), Pg 106	≥ 10 to 1000 cfu/gm
		Total Yeast & Mold count	IP'2014 Volume- I, Pg 42 BP'2017 Volume-V, App XVI (B) USP'40 (61), Pg 106	≥ 10 to 1000 cfu/gm
		E.coli	IP'2014, Volume- I, Pg 45 BP'2017 Volume-V, App XVI (B) USP'40 (62), Pg 112	Present/ Absent Per/gm
		Salmonella	IP'2014, Volume- I, Pg 45 BP'2017 Volume-V, App XVI (B) USP'40 (62),Pg 112	Present/ Absent Per/gm
		S.aureus	IP'2014, Volume- I, Pg 45 BP'2017 Volume-V, App XVI (B) USP'40 (62),Pg 112	Present/ Absent Per/gm
		P.aeruginosa	IP'2014, Volume- I, Pg 45 BP'2017 Volume-V, App XVI (B) USP'40 (62),Pg 112	Present/ Absent Per/gm
2.	Finish Product (Tablet/Capsule/ Cream) (Pour Plate Method)	Total Bacterial Count (Total Aerobic Microbial Count)	IP'2014 Volume- I, Pg 42 BP'2017 Volume-V, App XVI(B) USP'40 (61), Pg 57 (62), Pg 60	≥ 10 to 1000 cfu/gm

**Ashok Kumar
Convenor**

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Program Director**

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Page 2 of 8

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		Total yeast & mold count	IP'2014 Volume- I, Pg 42 BP'2017 Volume-V, App XVI(B) USP'40 (61), Pg 57 (62), Pg 60	≥ 10 to 1000 cfu/gm
		E.coli	IP'2014 Volume- I, Pg 45 BP'2017 Volume-V, App XVI(B) USP'40 (61),Pg 57 (62),Pg 62	Present/ Absent Per/gm
		Salmonella	IP'2014 Volume- I, Pg 45 BP'2017 Volume-V, App XVI(B) USP'40 (61), Pg 57 (62), Pg 62	Present/ Absent Per/gm
		S.aureus	IP'2014 Volume- I, Pg 45 BP'2017 Volume-V, App XVI(B) USP'40 (61), Pg 57 (62), Pg 62	Present/ Absent Per/gm
		P.aeruginosa	IP'2014 Volume- I, Pg 45 BP'2017 Volume-V, App XVI(B) USP'40 (61), Pg 57 (62), Pg 62	Present/ Absent Per/gm
3.	Finished Products (Injectable)	Bacterial Endotoxin Test (Gel Clot method)	IP'2014 Volume- I, Pg 28 BP'2017 Volume V 6.14,App XIV (c) USP'40 (85), Pg 92	Complies/ Does not comply
II.	COSMETICS			
1.	Skin Powder	Total Viable Count	IS 3959:2004	≥ 10 to 1000 cfu/gm
		Total Bacterial Count	Method IS 14648 – 2011	
		Total Fungal Count		
		E.Coli		Present/Absent/Per/gm

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Page 3 of 8

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2.	Skin Cream	Total Viable Count	IS 6608:2004	≥ 10 to 1000 cfu/gm
		Total Bacterial Count	Method IS 14648 – 2011	
		Total Fungal Count		
		E.Coli		Present/Absent/Per/gm
3.	Face Pack	Total Viable Count	Amendment – No.1 IS	≥ 10 to 1000 cfu/gm
		Total Bacterial Count	15153:2002	
		Total Fungal Count	Method IS 14648 – 2011	
		E.Coli		Present/Absent/Per/gm
4.	Moisturising Lotion	Total Viable Count	Method IS 14648 – 2011	≥ 10 to 1000 cfu/gm
		Total Bacterial Count		
		Total Fungal Count		
		E.Coli		Present/Absent/Per/gm

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Certificate Number TC-6453

Page 4 of 8

Validity 30.10.2017 to 29.10.2019

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CHEMICAL TESTING

I.	DRUGS & PHARMACEUTICAL			
1.	Raw Material			
a.	General Test	Loss on drying	IP'2014 App 2.4.19Pg. 162-163, BP' 2017 IX D USP'40<731>	0.05 % to 75 %
		Water by Karl Fischer	IP'2014 App 2.3.43 Pg. 113-114, BP' 2017 IX C USP' 40 <921>	0.1 % to 40 %
		Viscosity	IP'2014 App 2.4.28 Pg. 207-208, BP' 2017 V H USP'40 <912>	5 cps to 1,00,000 cps
		Melting Point/Range	IP'2014 App 2.4.21 Pg. 164-166, BP' 2017 V A USP' 40 <741>	-10 °C to 250 °C
		pH	IP'2014 App 2.4.24 Pg. 169-170, BP' 2017 V L, USP'40<791>	1 to 12
		Sulphated Ash	IP'2014 App 2.3.18 Pg. 98 BP' 2017 IX A, USP' 40 <281>	0.05 % to 35 %
		Loss on ignition	USP'40 <733>	0.05 % to 25 %
		Refractive Index	IP'2014 App 2.4.27 Pg. 203, BP' 2017 V E, USP'40 <831>	1.342 to 1.522

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Certificate Number TC-6453

Page 5 of 8

Validity 30.10.2017 to 29.10.2019

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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
		Weight/ml	IP'2014 App 2.4.29 Pg. 208-209, BP' 2017, V G USP'40 <841>	0.852 gm/ml to 1.45 gm/ml
		Specific optical rotation	IP'2014 App 2.4.22 Pg. 167-168, BP' 2017 V F USP' 40 <781>	± -10 ° to 360 °
		Heavy metals	IP'2014 App 2.3.13 Pg. 96-97, BP'2017 VII	Qualitative
		Arsenic	IP'2014 App 2.3.10 Pg. 96, USP'40 <211>	Qualitative
		Sulphate	IP'2014 App 2.3.18 Pg. 98 BP' 2017 VII, USP' 40 <221>	Qualitative
		Chloride	IP'2014 App 2.3.12 Pg. 96 BP' 2017 VII, USP' 40 <221>	Qualitative
		Iron	IP'2014 App 2.3.14 Pg. 97, USP' 40 <241>	Qualitative
		Boiling Range	IP'2014 App 2.4.8 Pg. 141-142, BP' 2017 V D	50 °C to 250 °C
		Residual solvents by GC		
		DCM	IP'2014 App 5.4. Pg. 854-864,	2.0 mg/kg to 600 mg/kg
		Methanol	BP' 2017 VIII L,	2.0 mg/kg to 3000 mg/kg
		Ethanol	USP' 40 <467>	2.0 mg/kg to 5000 mg/kg
		Chloroform		2.0 mg/kg to 600 mg/kg
		Ethyl acetate		2.0 mg/kg to 5000 mg/kg
		Acetone		2.0 mg/kg to 5000 mg/kg
		Identification by IR	IP'2014 App 3.1 337 BP' 2017 Appendix II A, USP' 40 <197>	Qualitative test

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Certificate Number **TC-6453**

Page 6 of 8

Validity **30.10.2017 to 29.10.2019**

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2.	API	Specific Test		
a.	Cyanocobalamin	Assay by UV	IP'2014, Pg. 1475 BP' 2017	80 % to 102 %
b.	Ampicillin trihydrate	Assay by HPLC	IP'2014, Pg.1070-1071	70 % to 101 %
c.	Atenolol	Assay by Titration	IP'2014, Pg.1097 BP' 2017	80 % to 101%
d.	Ascorbic Acid	Assay	IP'2014, Pg 1086 BP' 2017	80 % to 101 %
e.	Ibuprofen	Assay	IP'2014, Pg 1942-1943 BP' 2017	80 % to 102 %
f.	Miconazole Nitrate	Assay	IP'2014, Pg 2226-2227 BP' 2017	80 % to 102 %
g.	Paracetamol	Assay	IP'2014, Pg 2429-2430 BP' 2017	80 % to 102 %
h.	Trimethoprim	Assay	IP'2014, Pg 2922-2923 BP' 2017	80 % to 102 %
i.	Amoxicilin Trihydrate	Assay by HPLC	IP'2014, Pg 1055	80 % to 102 %
j.	Tramadol Hydrochloride	Assay	IP'2014, Pg 2898 BP' 2017	80 % to 102 %
k.	Metronidazole	Assay	IP'2014, Pg 2216 BP' 2017	80 % to 102 %
3.	Excipient	Specific Test		
a.	Stearic Acid	Assay by GC	IP'2014, Pg.2790 BP' 2017 Pg.1552	40 % to 100 %
b.	Magnesium Stearate	Fatty acid composition/content of stearic acid & palmitic acid	IP'2014, Pg.2144 BP' 2017 Pg.977	40 % to 100 %
c.	Menthol	Related substances by GC	IP'2014, Pg.2173	0.05 % to 5.00 %
d.	Disodium EDTA	Assay	IP'2014, Pg 1594-1595& 3843 BP' 2017	80 % to 102 %

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Certificate Number **TC-6453**

Page 7 of 8

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4.	Finished Products			
a.	General Test	Disintegration Time	IP'2014 App 2.5.1 Pg. 251-252, BP' 2017 XII A	30 sec to 3 hrs
b.	Formulation	Specific Test		
5.	Tablet			
a.	Metronidazole Tablets	Dissolution by UV	IP'2014, Pg. 2219-2220, BP'2017 USP' 40 Pg.5153	10 % to 120 %
		Assay	IP'2014, Pg 2219-2220, BP' 2017	80 % to 110 %
b.	Paracetamol Tablets	Assay by UV	IP'2014, Pg 2434, BP' 2017	80 % to 110 %
c.	Metformin Tablets	Dissolution by UV Assay by UV	IP'2014, Pg 2187 BP' 2017, USP' 40 Pg 5048	10 % to 102 % 80 % to 110 %
d.	Ibuprofen Tablets	1) Dissolution by UV	IP'2014, Pg 1945 USP' 40 Pg 4558	10 % to 102 %
e.	Ciprofloxacin Tablets	Dissolution by UV	IP'2014, Pg. 1403-1404, BP' 2017 USP' 40 Pg.3432	10 % to 102 %
f.	Formulation	Specific Test		
6.	Capsules			
a.	Amoxicillin Capsules	Dissolution by UV Assay by HPLC	IP'2014, Pg 1055-1056	20 % to 120 % 80 % to 110 %
II.	COSMETICS			
1.	Shampoo, Surfactant Based	pH Non Volatile Alcohol Soluble Matter	Annex C of IS 7884:2004 Annex B of IS 7884:2004	2 to 12 5 % to 15 %
2.	Skin Cream	pH Total Residue Total Fatty Substance Content	Annex B of IS 6608:2004 Annex D of IS 6608:2004 Annex C of IS 6608:2004	2 to 12 5 % to 50 % 5 % to 50 %
3.	Face Pack	pH Solid Content (Residue on evaporation)	Annex A of IS 15153:2002 Annex C of IS 15153:2002	2 to 12 5 % to 50 %

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Page 8 of 8

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4.	Skin Powders	pH of Aqueous suspension	Annex E of IS 3959:2004	2 to 12
		Moisture & Volatile Matter	Annex D of IS 3959:2004	1 % to 10 %
		Fineness:- Residue on 75 micron IS sieve	Annex C of IS 3959:2004	0.1 % to 5 %
		Residue on 150 micron IS sieve		0.1 % to 5 %
		Matter insoluble in boiling water	Annex B of IS 3959:2004	80 % to 99 %
5.	Toilet Soap	Total Fatty matter	CL 15 of IS 286:1978 (RA 2008)	30 % to 80 %