Navi Mumbai, Maharashtra

Accreditation Standard ISO/IEC 17025: 2005

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į.	Product / Material	Specific Test Performed	•		
	of Test		against which tests are performed	Limits of Detection	

CHEMICAL TESTING

I.	DRUGS & PHARMACEUTICALS			
		General Test		
1.	Raw Material (Drug Substances (API))	Loss on drying	IP App 2.4.19Pg. 208 BP Appendix IX D USP <731>Pg.No.565	0.05 % to 60 % w/w
		Melting Point/Range	IP App 2.4.21Pg209 BPAppendix V A USP<741>Pg.No.576	30°C to 300°C
		рН	IP App 2.4.24Pg. 215 BPAppendix V L USP<791>Pg.No.614	1 to 14
		Sulphated Ash/ Residue on ignition	IP App 2.3.18Pg. 140 BP Appendix IX A USP<281>Pg.No.286	0.05% to 20% w/w
		Loss on ignition	IP App 2.4.20Pg. 209 USP<733>Pg.No.566	0.05% to 25% w/w
		Refractive Index	IP App 2.4.27Pg. 251 BP Appendix V E USP <831>Pg.No.695	1.342 to 1.522
		Relative Density/ Weight/ml/ Specific Gravity	IP App 2.4.29 Pg. 256 BP Appendix V G USP <841>Pg.No.695	0.852g/ml to 1.300 g/ml
		Water by Karl fisher	IP App 2.3.43 Pg 156 BP Appendix IX C USP <921>Pg.No.750	0.1% to 30 %w/w
		Arsenic	IP App 2.3.10 Pg. 138 BP Appendix VII USP <211>Pg.No.248	Qualitative
		Sulphate	IP App 2.3.17 Pg. 140 BP Appendix VII	Qualitative

Ajay Kumar Sharma Convenor Venugopal C Program Manager

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SI.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Chloride	IP App 2.3.12 Pg. 138 BP Appendix VII	Qualitative
		Iron	IP App 2.3.14 Pg. 139 BP Appendix VII	Qualitative
		Boiling Range	IP App 2.4.8 Pg. 185 BP Appendix V D	30°C to 300°C
		Identification by IR	IP App 2.4.6 178 BP Appendix II A	Qualitative
2.	API	Specific Test		
A.	Domperidone	Assay by Titration	IP Pg.No.1877 BP Pg.No.0559	90% to 105%w/w
B.	Sodium Saccharine	Assay by Titration	IP Pg.No.3158 BP Pg.No.1427 USP Pg.No.5773	90% to 105%w/w
C.	Paracetamol	Related substances by HPLC 4-chloroacetanilide - 4- aminophenol- 4-Nitrophenol- Any other impurity - Total Unknown impurity	IP Pg.no 2853 BP Pg.No.1208	0.1mg/kg to 100mg/kg, 0.1mg/kg to 100 mg/kg 0.0001% to 0.02%w/w 0.0001% to 1%w/w 0.01% to 1%w/w
D.	Sildenafil Citrate	Assay by HPLC	IP Pg.No.3189 USP Pg.No.5840	90% to 105%w/w
3.	Excipient	Specific Test		
A.	Stearic Acid	Assay by GC	IP Pg.No.3259 BP Pg. No. 1552	Stearic Acid 40% to 100% w/w, Sum of Stearic Acid & Palmitic Acid 90 to 100%w/w
B.	Magnesium Stearate	Fatty Acid composition/content of Stearic acid & Palmitic acid	IP Pg.No.2489 BP Pg.No. 0977	Stearic Acid 40% to 100% w/w, Sum of Stearic Acid & Palmitic Acid 90 to 100%w/w

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C.	Menthol	Related substances by GC	IP Pg.No.2528	0.01% to 5.00%w/w
		General Test		
		Disintegration Time (using Apparatus A)	IP App 2.5.1 Pg. 251-252 BP Appendix XII A USP <701> Pg.No.537	1 seconds to 180 minutes
4.	Formulation			
		Specific Test		
Α.	Metformin Tablets	Dissolution by UV	IP Pg.No. 2548 BP Pg.No. 800	60% to 120%w/w of label claim
		Assay by UV	IP Pg.No. 2548 BP Pg.No. 800	80% to 120%w/w of label claim
B.	Paracetamol Tablets	Related Substances By HPLC	IP Pg.No. 2858 BP Pg.No. 958	
		4-Chloroacetanilide- 4-Aminophenol- Any Other Impurity		0.1 mg / kg to 100 mg/kg 0.0005% to 1%w/w 0.0005% to 2.5%w/w
		Assay by UV		80% to 120%w/w of label claim
C.	Loperamide Capsules	Dissolution by HPLC	IP Pg.No. 2454- BP Pg.No. 4595	60% to 120%w/w of label claim
D.	Oral Liquid			
E.	Albendazole Suspension	Assay by HPLC	IP Pg. No. 1169-1170 USP Pg.No46	80% to 120%w/w of label claim
•••••		Residual solvents by GC	SOP No. QC/GEN/018	
		Betamethasone Dipropionate		
		Dichloromethane		1 mg/lit to 5000 mg/lit
		Methanol		1 mg/lit to 3000 mg/lit
		Ethanol		1 mg/lit to 5000 mg/lit
		Chloroform		1 mg/lit to 600 mg/lit
		Ethyl acetate		1 mg/lit to 5000 mg/lit
		Acetone		1 mg/lit to 5000 mg/lit

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II.	COSMETICS & ESS	SENTIAL OIL		
1.	Shampoo	pH at 25°c	IS 7884-2004	1 to 14
			(Amendment 2008 & 2012) SOP No.(QC/GEN/016)	
		Non Volatile Alcohol	IS 7884-2004	1% to 30% w/w
		Soluble Matter	(Amendment 2008 & 2012) SOP No.(QC/GEN/016)	1,70 to 00,70 til, 11
2.	Skin Cream	pH at 25°C	IS 6608-2004	1 to 14
			SOP No.(QC/GEN/015)	
		Total Residue	IS 6608-2004 SOP No.(QC/GEN/015)	1% to 50% w/w
		Total Fatty Substances	IS 6608-2004	1% to 50% w/w
		Content	SOP No.(QC/GEN/015)	
3.	Face Pack	Type-1 pH at 25°c,	IS 15153-2002	1 to 14
		Solid Content	(Type 1-Paste/	1% to 50% w/w
		Type-2 pH at 25°c,	Type 2-Powder)	
·	Claire Describer	Solid Content	SOP No.(QC/GEN/012)	
Α.	Skin Powder		10.0050.0004	4.1-44
1.	Body Powder	pH of Aqueous	IS 3959-2004	1 to 14
		suspension at 25°c Moisture & Volatile	SOP No.(QC/GEN/014) IS 3959-2004	0.01% to 20% w/w
		Matter	SOP No.(QC/GEN/014)	U.U 1 70 LU ZU70 W/W
		Residue on 75 micron Is	IS 3959-2004	0.01% to 20% w/w
		sieve	SOP No.(QC/GEN/014)	0.01/0 tO 20/0 W/W
	1	Residue on 150 micron is	IS 3959-2004	0.01% to 20% w/w
		sieve	SOP No.(QC/GEN/014)	5.5176 to 2076 ti/14
		Matter insoluble in boiling	IS 3959-2004	1% to 100% w/w
		water	SOP No.(QC/GEN/014)	
2.	Face powder	pH of Aqueous	IS 3959-2004	1 to 14
		suspension at 25°c	SOP No.(QC/GEN/014)	_
		Moisture & Volatile Matter	IS 3959-2004 SOP No.(QC/GEN/014)	0.01% to 20% w/w

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		Residue on 75 micron Is sieve	IS 3959-2004 SOP No.(QC/GEN/014)	0.01% to 20% w/w
		Residue on 150 micron is sieve	IS 3959-2004 SOP No.(QC/GEN/014)	0.01% to 20% w/w
		Matter insoluble in boiling water	IS 3959-2004 SOP No.(QC/GEN/014)	1% to 100% w/w
III.	SOAP DETERGENT	& TOILETRIES		
1.	Soap	Total Fatty matter	IS 286-1978 (R1991) Amendment 5 2011 SOP No.(QC/GEN/013)	1% to 100% w/w

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