

Laboratory	SGS India Private Limited, AFL-Life Science, 2nd Floor, Tichel Bio Park Limited, CSIR Road, Taramani, Chennai, Tamil Nadu		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	09.12.2016
Certificate Number	T-1042	Valid Until	08.12.2018
Last Amended on	-	Page	1 of 2

S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I.	DRUG & PHAMACEUTICALS			
1.	Injectables & Sterile Products: 1. Eye/ Ear Drops	Sterility	IP 2014, volume I 2.2.11;56-63 BP 2015, Volume V, Appendix XVI A, V 475 – V 478 USP 39 (Chapter 71)	Qualitative
		Bacterial Endotoxin test (Gel Clot Limit Test)	IP 2014, volume I 2.2.3; 28-33 BP 2015, Volume V, Appendix XIV C, V 404—V 408 USP 39 (Chapter 85)	Qualitative
2.	Bulk Drugs, Intermediates,	Microbial Limit Tests Total Aerobic Microbial Count	IP 2014, volume I 2.2.9; 37-48,	<u>Pour Plate</u> Bacteria: 10-300 CFU/ml/g Fungi : 10-100 CFU/ml/g
		Total yeast and molds count	BP 2015, Volume V, Appendix XVIB, V 478- V 487	
		Escherichia coli, Salmonella spp, Pseudomonas aeruginosa, Staphylococcus aureus	USP 39 (Chapter 61-62)	Présent/Absent/gm or ml Présent/Absent/gm or ml Présent/Absent/gm or ml Présent/Absent/gm or ml
3.	Tablets & Capsules	Microbial Limit Tests Total Aerobic Microbial Count	IP 2014, volume I 2.2.9; 37-48,	<u>Pour Plate</u> Bacteria: 10-300 CFU/ml/g Fungi: 10-100CFU/ml/g
		Total yeast and molds count	BP 2015, Volume V, Appendix XVIB, V 478- V 487	
		Escherichia coli, Salmonella spp, Pseudomonas aeruginosa, Staphylococcus aureus	USP 39 (Chapter 61-62)	Présent/Absent/gm or ml Présent/Absent/gm or ml Présent/Absent/gm or ml Présent/Absent/gm or ml

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S.No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
4.	Creams / Ointments	Microbial Limit Tests Total Aerobic Microbial Count Total yeast and molds count Escherichia coli, Salmonella spp, Pseudomonas aeruginosa, Staphylococcus aureus	IP 2014, volume I 2.2.9; 37-48, BP 2015, Volume V, Appendix XVIB, V 478- V 487 USP 39<chapter 61-62>	<u>Pour Plate</u> Bacteria: 10 CFU/mg to 300 CFU/m/g Fungi: 10 CFU/ml/g to 100 CFU/ml/g Présent/Absent/gm or ml Présent/Absent/gm or ml Présent/Absent/gm or ml Présent/Absent/gm or ml
5.	Injectables, liquid products and Eye/Ear drops	Effectiveness of Antimicrobial Preservatives	IP 2014, volume I 2.2.11;56-63 BP 2015, Volume V, Appendix XVI A, V 475 – V 478 USP 39 (Chapter 71)	Bacteria: 3 log reduction Fungi: 2 log reduction
6.	Medical Devices (Catheters, Syringes with Needles, Tubular Rings, Sutures, Condoms, Copper-T, Intraocular Lenses, Surgical Gloves, Vascular Devices & I.V.Sets	Sterility Test Bacterial Endotoxin Test	IP 2014,2.2.11;56-63 volume I, BP 2015, Volume V, Appendix XVI, V 475&V 478 USP 39 (Chapter 71) IP2014, Volume I,2.2.3, 28-33, BP 2015, Volume V ,Appendix XIV C,A384-388 USP39 (Chapter 85)	Qualitative Qualitative

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