

Laboratory	Pharmaffiliates Analytics and Synthetics Pvt. Ltd., Plot No. 225, Industrial Area, Phase-II, Panchkula, Haryana		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	24.05.2016
Certificate Number	T-2267	Valid Until	23.05.2018
Last Amended on	06.09.2016	Page	1 of 4

S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I. DRUGS AND PHARMACEUTICALS				
1.	Raw Materials	Microbial enumeration tests / total aerobic viable count	IP 2105 addendum (Page. 3758)	10 cfu/ml to 1000 cfu/ml
		Total aerobic count / Total aerobic microbial count.	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38 <61> & <62> (Page. 112 to 120)	10 cfu/g to 1000 cfu/g
		Total fungal count/ Total combined yeast and mould count	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38 <61> & <62> (Page. 112 to 120)	10 cfu/ml to 100 cfu/ml 10 cfu/g to 100 cfu/g
		Tests for specified micro organisms		
		Staphylococcus aureus	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38 <61> & <62> (Page. 112 to 120)	Qualitative (Absent/Present)/ ml or g
		Pseudomonas	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38 <62> (Page. 115 to 116)	Qualitative (Absent/Present)/ ml or g

Laboratory	Pharmaffiliates Analytics and Synthetics Pvt. Ltd., Plot No. 225, Industrial Area, Phase-II, Panchkula, Haryana		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	24.05.2016
Certificate Number	T-2267	Valid Until	23.05.2018
Last Amended on	06.09.2016	Page	2 of 4

S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Raw Materials	E.coli	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP2015, Appendix. XVIB (Page. V478 to V493) USP 38, <62> (Page. 115)	Qualitative (Absent/Present)/ ml or g
		Salmonella	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP2015, Appendix. XVIB (Page. V478-V493) USP 38, <62> (Page. 115)	Qualitative (Absent/Present)/ ml or g
		Clostridia	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38, <62> (Page. 116)	Qualitative (Absent/Present)/ ml or g
		Shigella	IP 2014, Vol. I (2.2.9) (Page. 38 to 50)	Qualitative (Absent/Present)/ ml or g
2.	Finished Products (Solid Oral Dosages form)	Microbial enumeration tests / total aerobic viable count	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38 <61> & <62> (Page. 112 to 120)	10 cfu/ml to 1000 cfu/ml 10 cfu/g to 1000 cfu/g
		Total aerobic count / Total aerobic microbial count.		
		Total fungal count/ Total combined yeast and mould count	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP2015, Appendix. XVIB (Page. V478 to V493) USP38<61> & <62> (Page. 112 to 120)	10 cfu/ml to 100 cfu/ml 10 cfu/g to 100 cfu/g

Laboratory	Pharmaffiliates Analytics and Synthetics Pvt. Ltd., Plot No. 225, Industrial Area, Phase-II, Panchkula, Haryana		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	24.05.2016
Certificate Number	T-2267	Valid Until	23.05.2018
Last Amended on	06.09.2016	Page	3 of 4

S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Finished Products (Solid Oral Dosages form)	Tests for specified micro organisms		
		Staphylococcus aureus	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38 <62> (Page. 112 to 120)	Qualitative (Absent/Present)/ ml or g
		Pseudomonas	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38<62> (Page. 115 to 116)	Qualitative (Absent/Present)/ ml or g
		E.coli	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38, <62> (Page. 115)	Qualitative (Absent/Present)/ ml or g
		Salmonella	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38, <62> (Page. 115)	Qualitative (Absent/Present)/ ml or g

Laboratory	Pharmaffiliates Analytics and Synthetics Pvt. Ltd., Plot No. 225, Industrial Area, Phase-II, Panchkula, Haryana		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	24.05.2016
Certificate Number	T-2267	Valid Until	23.05.2018
Last Amended on	06.09.2016	Page	4 of 4

S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Finished Products (Solid Oral Dosages form)	Clostridia	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478 to V493) USP 38, <62> (Page. 116)	Qualitative (Absent/Present)/ ml or g
		Shigella	IP 2014, Vol. I (2.2.9) (Page. 38 to 50)	Qualitative (Absent/Present)/ ml or g
		Candida	IP 2014, Vol. I (2.2.9) (Page. 38 to 50) BP 2015, Appendix. XVIB (Page. V478-V493) USP 38, <62> (Page. 116)	Qualitative (Absent/Present)/ ml or g
II.	WATER			
1.	Water	Standard Plate count	IS 1622: 2003	≥ 1 cfu/ml
		Coliform count / MPN	IS 1622: 2003	< 2MPN/100 ml
		E.coli / MPN	IS 1622: 2003	< 2MPN/100 ml (Absent)

-X-X-X-X-X-X-X-X-X-X-X-X-