

Laboratory	Ozone Pharmaceuticals Ltd. (Analytical Lab), 639-640, MIE, Bahadurgarh, Haryana		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	26.06.2015
Certificate Number	T-1571	Valid Until	25.06.2017
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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
I.	DRUGS AND PHARMACEUTICALS			
A.	Drug Intermediate / Raw Materials / Finish Products	Total Microbial Count	IP 2014, Appendix 2.2.9 (Page no. 38-42)	≥ 1 CfU/ml or ≥ 10 CfU/g
		Salmonellae	IP 2014, Appendix 2.2.9 (Page no. 38-45)	Qualitative (Absent/present) 1 g or 1ml/10 g or 10 ml
		E. Coli	IP 2014, Appendix 2.2.9 (Page no. 38-45)	Qualitative (Absent/present) 1g or 1ml/10 g or 10 ml
		Pseudomonas Aeruginosa	IP 2014, Appendix 2.2.9 (Page no. 38-46)	Qualitative (Absent/present) 1g or 1ml/10 g or 10 ml
		Staphylococcus Aureus	IP 2014, Appendix 2.2.9 (Page no. 38-46)	Qualitative (Absent/present) 1g or 1ml/10 g or 10 ml
		Enterobacteria and Other Gram Negative Bacteria	IP 2014, Appendix 2.2.9 (Page no. 38-45)	Qualitative (Absent/present) 1g or 1ml/10 g or 10 ml
		Clostridia	IP 2014, Appendix 2.2.9 (Page no. 38-46)	Qualitative (Absent/present) (1gm or 1ml/10 gm. or 10 ml)
		Candida Albicans	IP 2014, Appendix 2.2.9 (Page no. 38-46)	Qualitative (Absent/present) 1g or 1ml/10 g or 10 ml

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1.	Gentamicin Sulphate (IP)	Assay	IP 2014, Appendix 2.2.10 (Page no. 1856 -1858)	450 mcg/mg to 750 mcg/mg
2.	Neomycin Sulphate (IP)	Assay	IP 2014, Appendix 2.2.10 (Page no. 2315-2316)	450 mcg/mg to 960 mcg/mg
3.	Amikacin Sulphate (IP)	Assay	OPLTP-69	450 mcg/mg to 950 mcg /mg
B. Pharmaceutical Dosage Forms/ Preparations				
1.	All Sterile Products (Parental Preparation , Ophthalmic and Non Parental Preparation , Surgical Dressing And Devices , Bulk Solids)	Sterility	IP2014, Appendix 2.2.11 (Page no. 59-66) USP 37 <71> (Page no. 71-76)	Qualitative
2.	All Sterile Products (Parental Preparations, Bulk Solids)	Bacterial Endotoxins	IP 2014 , Method A Appendix 2.2.3 (Page no.28-31) USP-37,Gel Clot technique <85> (Page no. 92-94)	Qualitative
3.	Gentamicin Injection (I.P.)	Assay	IP 2014 Appendix 2.2.10 (Page no.1859-1860)	10 mg/ml to 40 mg/ml
4.	Amikacin Sulphate Injection	Assay	OPLTP-69 (Issue no.01 & Date-01.04.2014)	10 mg/2 ml to 500 mg/2 ml

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5.	Cyanocobalamin (In Formulation)	Assay	OPLTP-66 (Issue no.01 & Date-01.04.2014)	0.50 mcg/ ml to 2000 mcg/ ml
6.	Methylcobalamin (In Formulation)	Assay	OPLTP-65 (Issue no.01 & Date-01.04.2014)	0.50 mcg/ ml to 2000 mcg/ ml
7.	Calcium Pantothenate (In Formulation)	Assay	USP 37, <91> (Page no. 101 to 108)	2 mg/ g to 50 mg/ g
C.	Ayurvedic Finished Products/ Raw Material	Total Microbial Count	API (Part 2), Volume-III: 2010 Appendix : 2.4 (Page no. 165-180)	1 cfu/ml or ≥10 Cfu /g
		Total Yeast and Mould Count	API (Part 2), Volume-III: 2010 Appendix : 2.4 (Page no. 165-180)	≥1 Cfu/ml or ≥10 Cfu /g
		E.Coli	API (Part 2), Volume-III: 2010 Appendix : 2.4 (Page no. 165-180)	Qualitative (Present/Absent)/g or /ml
		Salmonella	API (Part 2), Volume-III: 2010 Appendix : 2.4 (Page no. 165-180)	Qualitative (Present/Absent)/g or /ml
		Staphylococcus Aureus	API (Part 2), Volume-III: 2010 Appendix : 2.4 (Page no. 165-180)	Qualitative (Present/Absent)/g or /ml
		Pseudomonas Aeruginosa	API (Part 2), Volume-III: 2010 Appendix : 2.4 (Page no. 165-180)	Qualitative (Present/Absent)/g or /ml

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II. FOOD AND AGRICULTURAL PRODUCT				
1.	Animal Feed and Food Product (Semi Processed and Ready to Eat Food Products)	Total Plate Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g
		Yeast and Mould Count	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g
		Coliform	IS 5401 (Part 1): 2002	≥1 CfU/ml or ≥10 CfU /g
		E.Coli	IS 5887 (Part 1): 1976	≥1 CfU/ml or ≥10 CfU /g
2.	Processed Fruit and Vegetable Products	Total Plate Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g
		Yeast and Mould Count	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g
		Coliform	IS 5401 (Part 1): 2002	≥1 CfU/ml or ≥10 CfU /g
		E.Coli	IS 5887 (Part 1): 1976	Qualitative (Present/Absent)/ g/ml
3.	Spices & Condiments (Whole, Ground Mixed and Oleoresin)	Salmonella	IS 5887 (Part 3): 1999	Qualitative (Present/Absent)/ 25g /25ml
		Total Plate Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g
		Yeast and Mould Count	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g

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	Spices & Condiments (Whole, Ground Mixed and Oleoresin)	Coliform	IS 5401 (Part 1): 2002	≥1 CfU/ml or ≥10 CfU /g
		E.Coli	IS 5887 (Part 1): 1976	Qualitative (Present/Absent)/ g
		Bacillus Cereus	IS 5887 (Part 6): 2012	≥1 CfU/ml or ≥10 CfU /g
4.	Protein Rich Food Supplements For Infants & Preschool Children Processed Cereal Based Complementary Foods, Milk Cereal Based Complementary Foods & Infant Milk Substitutes Ready to Eat Protein Rich Extruded Food	Bacterial Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g
		Coliform	IS 5401 (Part 1): 2002	Qualitative (Present/Absent)/ g/ml
		Salmonella	IS 5887 (Part 3): 1999	Qualitative (Present/Absent)/25 g/ 25 ml
		Yeast and Mould	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g
		E.Coli	IS 5887 (Part 1) : 1976	Qualitative (Present/Absent)/ g/ml
		Staphylococcus Aureus	IS 5887(part 2): 1976	Qualitative (Present/Absent)/ g/ml
		Shigella	IS 5887 (Part 7): 1999	Qualitative (Present/Absent)/25 g/ 25 ml
5.	Pulses and Cereal	Total Plate Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g

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6.	Pulses and Cereal	Yeast and Mould Count	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g
		Coliform	IS 5401 (Part 1): 2002	≥1 CfU/ml or ≥10 CfU /g
		E.Coli	IS 5887 (Part 1):1976	Qualitative (Present/Absent)/ g/ml
		Total Plate Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g
		Yeast and Mould Count	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g
7.	Milk and Milk Products	Coliform	IS 5401 (Part 1): 2002	≥1 CfU/ml or ≥10 CfU /g
		E.Coli	IS 5887 (Part 1) : 1976	Qualitative (Present/Absent)/25 g or 25ml
		Salmonella	IS 5887 (Part 3):1999	Qualitative (Present/Absent)/25 g or 25ml
		Total Plate Count	IS 5402: 2012	≥1 CfU/ml or ≥10 CfU /g
		Yeast and Mould Count	IS 5403: 1999	≥1 CfU/ml or ≥10 CfU /g
7.	Processed Food Ready to Eat Canned Food	Coliform	IS 5401(Part 1) : 2002	≥1 CfU/ml or ≥10 CfU /g

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	Processed Food Ready to Eat Canned Food	E.Coli	IS 5887 (Part 1) : 1976	Qualitative (Present/Absent)/ g or ml
		Salmonella	IS 5887 (Part 3): 1999	Qualitative (Present/Absent)/ 25 g or 25ml
III.	WATER			
1.	Packaged Drinking Water & Natural Mineral Water	Aerobic Microbial Count at 22 °C	IS 5402: 2012	≥1 CfU/ ml
		Aerobic Microbial Count at 37 °C	IS 5402: 2012	≥1 CfU/ ml
		Yeast and Mould Count	IS 5403: 1999	Qualitative (Present/Absent)/250 ml
		Coliform	IS 5401 (Part 1) : 2002	Qualitative (Present/Absent)/250 ml
		E.Coli	IS 5877 (Part 1) : 1976	Qualitative (Present/Absent)/250 ml
2.	Drinking Water, Swimming Pool Water	Total Plate Count/ Standard Plant Count	IS 1622: 1981	≥1Cfu/ml
		Coliform	IS 1622: 1981 IS 5401 (Part 1) : 2002	MPN (index)/100ml Qualitative (Present/Absent)/250 ml
		E.Coli	IS 1622: 1981 IS 5887 (Part 1): 1976	Qualitative (Present/Absent)/100 ml (Present/Absent)/250 ml

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IV. COSMETICS AND ESSENTIAL OILS				
1.	Skin Cream	Total Viable Count	IS 14648: 2011	≥1 CfU/ml or ≥10 CfU /g
		Total Yeast & Mould Count	IS 14648: 2011	≥1 CfU/ml or ≥10 CfU /g
		Gram Negative Pathogens	IS 14648: 2011	Qualitative (Present/Absent)/g or ml
2.	Antibacterial Toilet Soap (Solid Cake)	Antibacterial Activity	IS 11479 (Part 1) : 2001	Qualitative
3.	Hair Cream	Total Viable Count	IS 14648: 2011	≥1 CfU/ml or ≥10 CfU /g
		Total Yeast & Mould Count	IS 14648: 2011	≥1 CfU/ml or ≥10 CfU /g
-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X				