

Laboratory **Precise Analytics Lab. (A Division of Meyer Organics Pvt. Ltd.),
Plot No. B-22, Road No.16, Wagle Estate, Thane, Maharashtra**

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

Certificate Number **TC-7783**

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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
<u>BIOLOGICAL TESTING</u>				
I.	DRUGS AND PHARMACEUTICALS			
1.	Raw Materials	Total Bacterial count	IP 2018,2.2.9 ,Page.38-50 BP 2018 Appendix XVI B,Page.A509 USP 41 Chapter 61, Page.5965	10 cfu/g to 10 ³ cfu/g
		Total Fungal count	IP 2018, 2.2.9, Page.38-50 BP 2018 Appendix XVI B, Page.A509 USP 41 Chapter 61, Page.5965	10 cfu/g to 10 ² cfu/g
		Escherichia Coli	IP 2018,2.2.9, Page.38-50 BP 2018 Appendix XVI B, Page.A503 USP 41 Chapter 62, Page.5971	Qualitative (Present/Absent)/1g
		Salmonella	IP 2018,2.2.9, Page.38-50 BP 2018 Appendix XVI B, Page.A503 USP 41 Chapter 62, Page.5971	Qualitative (Present/Absent)/10g
		Pseudomonas aeruginosa	IP 2018,2.2.9, Page.38-50 BP 2018 Appendix XVI B, Page. A503 USP 41 Chapter 62, Page.5971	Qualitative (Present/Absent)/1g
		Staphylococcus aureus	IP 2018,2.2.9, Page.38-50 BP 2018 Appendix XVI B, Page. A503 USP 41 Chapter 62, Page.5971	Qualitative (Present/Absent)/1g
2.	Purified Water	Total Viable count (TVC)	Ph. Eur. Volume III Page.3935-3936	≥1 cfu/ml
		Total Viable count (TVC)	IP 2018, 2.2.9, Page.3516	≥1 cfu/ml
3.	Lactose anhydrous	Total Microbial Count (TMC)	IP 2018 (Page 2371-2372) & 2.2.9	10 cfu/g to 10 ³ cfu/g

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		E. Coli	IP 2018 (Page 2371-2372) & 2.2.9	Qualitative (Present/Absent)/1g
		Total Aerobic Microbial count (TAMC)	BP 2018 (Appendix XVI B, A509) / EP Vol.III, Page. 2864-2865,2.6.12	10 cfu/g to 10 ³ cfu/g
		E. Coli	BP 2018 (Appendix XVI B, A503) / EP Vol.III, Page. 2864-2865, 2.6.13	Qualitative (Present/Absent)/1g
4.	Lactose Monohydrate	Total Microbial Count (TMC)	IP 2018 (Page.2371) & 2.2.9	10 cfu/g to 10 ³ cfu/g
		E. Coli	IP 2018 (Page.2371) & 2.2.9	Qualitative (Present/Absent)/1g
		Salmonella	IP 2018 (Page.2371) & 2.2.9	Qualitative (Present/Absent)/10g
		Total Aerobic Microbial count (TAMC)	BP 2018 (Appendix XVI B, A509) / EP Vol.III, Page 2866,2.6.12	10 cfu/g to 10 ³ cfu/g
		E.coli	BP 2018 (Appendix XVI B, A503) / EP Vol.III, Page. 2866,2.6.13	Qualitative (Present/Absent)/1g
5.	Microcrystalline cellulose	Total Aerobic Microbial count (TAMC)	BP 2018 (Appendix XVI B, A509)	10 cfu/g to 10 ³ cfu/g
		Total Combined Yeast & Mould count (TYMC)	BP 2018 (Appendix XVI B, A509)	10 cfu/g to 10 ² cfu/g
		E. Coli	BP 2018 (Appendix XVI B, A503)	Qualitative (Present/Absent)/1g
		Salmonella	BP 2018 (Appendix XVI B, A503)	Qualitative (Present/Absent)/10 g
		Pseudomonas aeruginosa	BP 2018 (Appendix XVI B, A503)	Qualitative (Present/Absent)/1 g
		Staphylococcus aureus	BP 2018 (Appendix XVI B, A503)	Qualitative (Present/Absent)/1 g

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6.	Maize starch	E. Coli	IP 2018 (Page 3867-3868) & 2.2.9	Qualitative (Present/Absent)/1 g
		Salmonella	IP 2018 (Page 3867-3868) & 2.2.9	Qualitative (Present/Absent)/10 g
		Total Aerobic Microbial count(TAMC)	BP 2018 (Appendix XVI B, A509) / EP Vol.III, Page. 2969-2970, 2.6.12	10 cfu/g to 10 ³ cfu/g
		Total Combined Yeast & Mould count (TYMC)	BP 2018 (Appendix XVI B, A509) / EP Vol.III, Page. 2969-2970, 2.6.12	10 cfu/g to 10 ² cfu/g
		E. Coli	BP 2018 (Appendix XVI B, A503) / EP Vol.III, Page. 2969-2970, 2.6.13	Qualitative (Present/Absent)/1 g
B.	Pharmaceutical Dosage Forms / Non Sterile And Parental Preparations			
1.	Pharmaceutical non sterile preparation	Total Bacterial count (TBC)	IP 2018 (2.2.9) (Page 38-50)	10 cfu/g to 10 ³ cfu/g
		Total Fungal count (TFC)	IP 2018 (2.2.9) (Page 38-50)	10 cfu/g to 10 ² cfu/g
		Escherichia Coli	IP 2018 (2.2.9) (Page 38-50)	Qualitative (Present/Absent)/1g
		Salmonella	IP 2018 (2.2.9) (Page 38-50)	Qualitative (Present/Absent)/10g
		Pseudomonas aeruginosa	IP 2018 (2.2.9) (Page 38-50)	Qualitative (Present/Absent)/1g
		Staphylococcus aureus	IP 2018 (2.2.9) (Page 38-50)	Qualitative (Present/Absent)/1g
2.	Vitamin D3 with Calcium & minerals Tab. (Calcimax Forte + Tablets)	Total Bacterial count (TBC)	IP 2018 (2.2.9) (Page 38-50)	10 cfu/g to 10 ³ cfu/g
		Total Fungal count (TFC)	IP 2018 (2.2.9) (Page 38-50)	10 cfu/g to 10 ² cfu/g
		Escherichia Coli	IP 2018 (2.2.9) (Page 38-50)	Qualitative (Present/Absent)/1g

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			IP 2018 (Page 2595-2596) & 2.2.3	Qualitative (Complies/ Does not complies)
17.	Streptomycin Injection	Bacterial Endotoxins test (BET) (Gel clot method)	IP 2018 (Page 3267-3268) & 2.2.3	Qualitative (Complies/ Does not complies)
18.	Sterile water for Injection	Bacterial Endotoxins test (BET) (Gel clot method)	USP 41 (Page 4346-4347)	Qualitative (Complies/ Does not complies)
			IP 2018 (Page 3518-3519) & 2.2.3	Qualitative (Complies/ Does not complies)
19.	Ceftriaxone Sodium Injection	Bacterial Endotoxins test (BET) (Gel clot method)	IP 2018 (Page 1541-1542) & 2.2.3	Qualitative (Complies/ Does not complies)
20.	Dexamethasone sodium phosphate Injection	Bacterial Endotoxins test (BET) (Gel clot method)	IP 2018 (Page 1781-1782) & 2.2.3	Qualitative (Complies/ Does not complies)
21.	Doxorubicin Hydrochloride Injection	Bacterial Endotoxins test (BET) (Gel clot method)	IP 2018 (Page 1901-1902) & 2.2.3	Qualitative (Complies/ Does not complies)
II.	FOOD AND AGRICULTURE			
1.	Spices and Condiments (whole & ground)			
	<i>(Black Pepper, Fennel, Mustard Seed, Cardamom, Cumin, Coriander, Mace, Fenugreek, Cloves, Curry Powder)</i>	Salmonella spp.	IS 5887(Part 3)	Qualitative (Present/Absent)/25g

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2.	Milk and Dairy Products			
	(Skimmed Milk Powder, Ice cream Mix Powder)	Total Plate count	IS5402	≥10 cfu/g
		Coliform count	IS5401(Part 1)	≥10 cfu/g
		Escherichia Coli	IS 5887(Part 1)	Qualitative (Present/Absent)/1g
		Salmonella spp.	IS 5887 (Part 3)	Qualitative (Present/Absent)/25 g
		Staphylococcus aureus	IS 5887 (Part 2)	≥100 cfu/g
		Yeast and Mould count	IS 5403	≥10 cfu/g
3.	Nuts and nuts Products			
	(Pistachio nuts, Almond, Dates, Raisins, Walnuts)	Total Plate count	IS 5402	≥10 cfu/g
		Escherichia Coli	IS 5887 (Part 1)	Qualitative (Present/Absent)/1g
		Salmonella spp.	IS 5887 (Part 3)	Qualitative (Present/Absent)/25 g
		Staphylococcus aureus	IS 5887 (Part 2)	Qualitative (Present/Absent)/25 g
4.	Fruit and Vegetable products			
	(Jams, Juices, Concentrates and Sauces)	Staphylococcus aureus	IS 5887 (Part 2)	Qualitative (Present/Absent)/25 g
		Salmonella spp.	IS 5887 (Part 3)	Qualitative (Present/Absent)/25 g
	Tomato Ketchup /Sauce	Total Plate count	IS5402	≥10 cfu/g
	Other Fruits and Vegetable Products (Pickle, schezwan chutney)	Yeast and mould count	IS 5403	≥10 cfu/g

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<u>CHEMICAL TESTING</u>				
I.	DRUGS AND PHARMACEUTICALS			
1.	Pharmaceutical raw material	Description	IP 2018 Page No.14 USP 41 General Notices 5 (5.30)	Qualitative
		Solubility	IP 2018 Page No.220 BP 2018 General Notices (Part II) USP 41 General Notices 5 (5.30)	Qualitative
		Identification by IR	IP 2018 Page No.178 BP 2018 Appendix II A:A168 USP 41 Chapter 197K	Qualitative
		Identification by UV	IP 2018 Page No.183 BP 2018 Appendix II B:A174 USP 41 Chapter 197U	Qualitative
		Identification	IP 2018 Page No.129 BP 2018 As per individual Monograph USP 41 General Notices 5(5.40)	Qualitative
		Melting range	IP 2018 Page No.209 BP 2018 Appendix V A:A246 USP 41 Chapter 741	Ambient to 360 °C
		pH	IP 2018 Page No.215 BP 2018 Appendix V L:A259 USP 41 Chapter 791	1 to 14
		Refractive index	IP 2018 Page No.251 BP 2018 Appendix V E:A251 USP 41 Chapter 831	1.3 to 1.5
		Weight per ml	IP 2018 Page No.256 BP 2018 Appendix V G:A252	0.7 g/ml to 2.0 g/ml

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	Miconazole	Identification by IR	IP 2018 Page No. 2605 USP 41 Page no.2736	Qualitative
	Niacinamide IP	Identification by IR	IP 2018 Page No. 2724	Qualitative
	Thiamine Hydrochloride	Identification by IR	IP 2018 Page No. 3354 USP 41 Page no.4047	Qualitative
	Thiamine Nitrate	Identification by IR	IP 2018 Page No. 3356	Qualitative
	Propylene Glycol	Related Substance	IP 2018 Page No. 3026	Qualitative
	Glycerin IP	Ethylene Glycol, Diethylene Glycol And Related substances	IP 2018 Page No. 2184	NMT 0.05 % w/v
	Colloidal Silicon (Aerosil)	Loss on ignition	IP 2018 Page No. 3189	0.1% to 30.0%
	Lactose	Sulphated ash	IP 2018 Page No. 2372 BP 2018 Vol. II-66	0.01% to 10.0%
	L-lysine mono HCl USP	Iron	BP 2018 Vol. II -149 V-A283(2.4.9)	Qualitative
2.	Drugs and Pharmaceutical			
	Calcimax Forte + tablets	Assay Vitamin D3	MOA-596 Issue dated. 28.10.2017 Issue no. 02.	90% to 300%
		Assay of zinc by AAS	MOA-596 Issue dated. 28.10.2017 Issue no. 02.	90% to 110%
	Ugesic tablets	Assay of Piroxicam By HPLC	MOA-193 Issue dated. 15.09.2014 Issue 01.	90% to 110%
	Vitamin E acid succinate	Assay by GC	In house PA-07/2013-14	96% to 110%
	Vitamin E acetate	Assay by GC	BP 2018 Vol. II -1134	95% to 101%
	Imatinib capsule	Assay by HPLC	IP 2018 Page No. 2278	90% to 110%

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II.	FOOD AND AGRICULTURE			
1.	Cereal based products			
	Wheat Atta	Moisture	FSSAI lab manual for cereal and cereal product (clause 8.1)	0.1% to 25%
			IS 1155 Second revision. Appendix-A.	
		Total Ash	FSSAI lab manual for cereal and cereal product (clause 8.2)	0.1 % to 10.0%
			IS 1155 Second revision Appendix-B.	
		Acid insoluble ash	FSSAI lab manual for cereal and cereal product (clause 8.3)	0.025% to 5.0%
			IS 1155 Second revision Appendix-C.	
		Gluten	FSSAI lab manual for cereal and cereal product (clause 8.4)	1.0% to 25.0%
			IS 1155 Second revision Appendix-D.	
		Alcoholic acidity (as H ₂ SO ₄)	FSSAI lab manual for cereal and cereal product (clause 8.5)	0.025% to 10.0%
			IS 1155 Second revision Appendix-F.	
	Maida	Moisture	FSSAI lab manual for cereal and cereal product (clause 8.1)	0.1% to 25%
			IS 1009. Second revision Appendix-A	

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		Gluten	FSSAI lab manual for cereal and cereal product (clause 8.4)	1% to 25.0%
			IS 1010 First revision. Appendix-E.	
		Alcoholic acidity (as H ₂ SO ₄)	FSSAI lab manual for cereal and cereal product (clause 8.5)	0.025% to 5.0%
			IS 1010 First revision. Appendix-F.	
	Biscuit	Moisture	FSSAI lab manual for cereal and cereal product (clause 14.3)	0.1% to 25%
			IS 1011-2002. First revision. Appendix-B.	
		Acid insoluble ash	FSSAI lab manual for cereal and cereal product (clause 14.4)	0.025% to 2.0%
			IS 1011 First revision. Appendix-C.	
		Acidity of extracted fat (as oleic acid)	FSSAI lab manual for cereal and cereal product (clause 14.5)	0.1% to 5.0%
			IS 1011 First revision. Appendix-D.	
	Cereal & Pulses (Maize, Jawar, Bajra, rice, Masur whole, Mung whole, Chana whole, split pulses)	Moisture	FSSAI lab manual for cereal and cereal product (Clause 2.0)	0.1% to 25%
			IS 4333 (Part 2) First revision	
		Extraneous matter	FSSAI lab manual for cereal and cereal product (Clause 1.2)	0.1% to 50%
	IS 4333 (Part 1) Second revision. (Clause 6.2)			

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		Volatile oil content	FSSAI lab manual for spices and condiments (clause 6.0)	0.5 % to 25%
			IS 1797 Third revision (Clause 15.0)	
		Non volatile ether extract	FSSAI lab manual for spices and condiments (clause 9.0)	0.05 % to 20%
			IS 1797 Third revision (Clause 14.0)	
3.	Oils and Fats and related products			
	(Coconut oil, Ground nut oil, Mustard oil, Til oil, Refined vegetable oil, Palm oil, Palmolein, Sunflower oil, rice bran oil Hydrogenated vegetable oil).	Moisture	FSSAI lab Manual for oils and fats (Clause3.0)	0.05% to 5.0 %
			IS 548 (Part1) (Clause 5.0)	
		Refractive index	FSSAI lab Manual for oils and fats (Clause5.0)	1.3 to 1.5
			IS 548 (Part1) (Clause 10.0)	
		Saponification value	FSSAI lab Manual for oils and fats (Clause9.0)	70 to 300
			IS 548 (Part1) (Clause 15.0)	
		Unsaponifiable matter	FSSAI lab Manual for oils and fats (Clause 10.0)	0.1% to 10.0%
			IS 548 (Part1) (Clause 8.0)	
		Acid value	FSSAI lab Manual for oils and fats (Clause 11.0)	0.1 to 20
		IS 548 (Part1) (Clause 7.0)		
	Free fatty acid	FSSAI lab Manual for oils and fats (Clause 11.0)	0.05 to 10	
		IS 548 (Part1) (Clause 7.3.1)		
	Iodine value	FSSAI lab Manual for oils and fats (Clause 12.0)	1 to 300	
		IS 548 (Part 1) (Clause 14.0)		

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		Baudouin's Test	FSSAI lab Manual for oils and fats (Clause 5.0) IS 548 (Part 2) (Clause 6.0)	Qualitative
		Bellier Test	FSSAI lab Manual for oils and fats (Clause 14.0) IS 548 (Part 1 -2) (Clause 13.0)	0 to 60 °C
		Argemone oil test	FSSAI lab Manual for oils and fats (Clause 30.0) IS 548 (Part 2) (Clause 10.0)	Qualitative
		Cottonseed oil test	FSSAI lab Manual for oils and fats (Clause 16.0) IS 548-1(Part 2) (Clause 7.0)	Qualitative
		Mineral oil test	FSSAI lab Manual for oils and fats (Clause 28.0) IS 548 (Part 2) (Clause 12.0)	Qualitative
		Olive residue oil in olive oil	FSSAI lab Manual for oils and fats (Clause 25.0)	Qualitative
4.	Alcoholic beverages			
	Gin ,Beer, Whisky	Residue evaporation	IS 3752 Second Revision (Clause no 5.0)	0.05% to 30%
		Volatile acidity as acetic acid	IS 3752 Second Revision (Clause No 8.0)	1.0 g/l to 200 g/l
		pH	IS 3865 Third Revision Annex B.	1 to14
	Wine	Residue evaporation	IS 3752 Second Revision (Clause no 5.0)	0.05% to 30%
		Total acidity as tartaric acid	IS 7585. First Revision. (Clause No-5.2)	0.15 g/l to 25.0 g/l

