



# National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)



## SCOPE OF ACCREDITATION

Laboratory Name MEGSAN LABS PRIVATE LIMITED, # 3-31/33, PLOT NO.:33/PART, SY NO.S - 123,124,125 ,142, KOMPALLY, QUTHBULLAPUR, HYDERABAD, MEDCHAL MALKAJGIRI, TELANGANA , INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-5629 Page No. : 1 / 3

Validity 26/06/2019 to 25/06/2021 Last Amended on -

S.No	Discipline / Group	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing/ Limits of Detection
<b>Permanent Facility</b>					
1	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Antacid Suspensions	Antimicrobial Effectiveness testing	IP 2018, 2.2.2, B.P Appendix XVIC(EP 5.1.3) USP41 NF36:Chapter<51>: 2018	Qualitative()
2	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products	Candida albicans	IP 2018 2.2.9 B.P: Appendix XVIB,EP 2.6.13, USP41 NF36; Chapter <62> : 2018	Qualitative(Present / Absent/mL or g)
3	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products	Enterobacteriaceae& other gram negative bacteria	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.13 and USP 41 NF36: Chapter <62>: 2018	Qualitative(=10 cfu/ g)
4	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products	Escherichia coli	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.13 and USP 41 NF36: Chapter <62>: 2018	Qualitative(Present / Absent/mL or g)
5	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products	Pseudomonas aeruginosa	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.13 and USP 41 NF36: Chapter <62>: 2018	Qualitative(Present / Absent/mL or g)
6	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products	Salmonella	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.13 and USP 41 NF36: Chapter <62>: : 2018	Qualitative(Present / Absent/10ml or 10g)



# National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)



## SCOPE OF ACCREDITATION

Laboratory Name MEGSAN LABS PRIVATE LIMITED, # 3-31/33, PLOT NO.:33/PART, SY NO.S - 123,124,125 ,142, KOMPALLY, QUTHBULLAPUR, HYDERABAD, MEDCHAL MALKAJGIRI, TELANGANA , INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-5629 Page No. : 2 / 3

Validity 26/06/2019 to 25/06/2021 Last Amended on -

S.No	Discipline / Group	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing/ Limits of Detection
7	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products	Staphylococcus aureus	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.13 and USP 41 NF36: Chapter <62>: 2018	Qualitative(Present / Absent/mL or g)
8	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products /Capsules	Total aerobic microbial count	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.12 and USP 41 NF36: Chapter <61>: 2018	1.16 cfu/g to 1.61 cfu/g
9	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products/ tablets	Clostridia	IP 2018 2.2.9 B.P: Appendix XVIB,EP 2.6.13, USP41 NF36; Chapter <62> : 2018	Qualitative(Present / Absent/mL or g)
10	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products/Capsules	Total Yeast & Mold count	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.12 and USP 41 NF36: Chapter <61>: 2018	1.18 cfu/g to 1.6 cfu/g
11	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products/Syrup	Total aerobic microbial count	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.12 and USP 41 NF36: Chapter <61>: 2018	0.33 cfu/ml to 0.59 cfu/ml
12	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products/Syrup	Total Yeast & Mold count	IP:2018, 2.2.9:BP: Appendix XVIB,EP 2.6.12 and USP 41 NF36: Chapter <61>: 2018	0.15 cfu/ml to 0.7 cfu/ml



# National Accreditation Board for Testing and Calibration Laboratories

(A Constituent Board of Quality Council of India)



## SCOPE OF ACCREDITATION

Laboratory Name MEGSAN LABS PRIVATE LIMITED, # 3-31/33, PLOT NO.:33/PART, SY NO.S - 123,124,125 ,142, KOMPALLY, QUTHBULLAPUR, HYDERABAD, MEDCHAL MALKAJGIRI, TELANGANA , INDIA

Accreditation Standard ISO/IEC 17025:2017

Certificate Number TC-5629 Page No. : 3 / 3

Validity 26/06/2019 to 25/06/2021 Last Amended on -

S.No	Discipline / Group	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing/ Limits of Detection
13	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Finished products/Tablets	Bile tolerant gram negative bacteria	IP 2018,2.2.9 B.P,Appendix XIVB,EP 2.6.13, USP41NF36; Chapter <62> : 2018	Qualitative(Present / Absent/mL or g)
14	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Injections	Bacterial Endotoxins Test (Gel clot Method)	IP2018, 2.2.3 B.P Appendix XIVC EP 5.1.3, EP 2.6.14, USP41 NF36:Chapter <85>: 2018	Qualitative
15	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Sterility tests for Hospital ware, Surgical items, injectables	Sterility test	IP:2018: 2.2.11,B.P:Appendix XVIA, E.P.2.6.1,USP:41 NF36:Chapter <71>: 2018	Qualitative
16	CHEMICAL- DRUGS & PHARMACEUTICALS	Ibuprofen Tablet	Disintegration Test	IP2018 <2.5.1>: 2018	5 S to 30 Minutes
17	CHEMICAL- DRUGS & PHARMACEUTICALS	Lamivudine tablets	Assay by HPLC	IP 2018 <2.4.14>: 2018	80 % to 120 %
18	CHEMICAL- DRUGS & PHARMACEUTICALS	Sodium chloride & Dextrose injection	Appearance of solution	IP 2018 monograph: 2018	Qualitative(satisfactory)
19	CHEMICAL- DRUGS & PHARMACEUTICALS	Sodium chloride & Dextrose injection	Description	IP 2018 Monograph: 2018	Qualitative
20	CHEMICAL- DRUGS & PHARMACEUTICALS	Sodium chloride & Dextrose injection	pH	USP 41 NF 36 Monograph: 2018	1.68 to 12.45
21	CHEMICAL- DRUGS & PHARMACEUTICALS	Sodium chloride & Dextrose injection	Solubility	IP 2018 (2.4.26): 2018	Qualitative
22	CHEMICAL- DRUGS & PHARMACEUTICALS	Sodium chloride & Dextrose injections	Limit of 5-hydroxymethylfurfural and related substances by UV	USP41NF36 monograph: 2018	0.03 to 0.30