National Accreditation Board for Testing and Calibration Laboratories

SCOPE OF ACCREDITATION

Laboratory Name :	CADILA HEALTHCARE LIMITED, ZYDUS RESEARCH CENTRE, BIOANALYTICAL LABORATORY, SURVEY NO. 396/403, SARKHEJ-BAVLA N.H. NO. 8 A, MORAIYA, AHMEDABAD, GUJARAT, INDIA
Accreditation Standard	ISO/IEC 17025:2017
Certificate Number	TC-9222
Page No	1 of 1
Validity	18/01/2021 to 17/01/2023
Last Amended on	22/07/2022

S.No	Discipline / Group	Materials or Products tested	Component, parameter or characteristic tested / Specific Test Performed / Tests or type of tests performed	Test Method Specification against which tests are performed and / or the techniques / equipment used
Permanent Facility				
1	BIOLOGICAL- BIOLOGICALS DERIVED PHARMACEUTICALS	Human Anti Trastuzumab antibody	Anti-Drug Antibody (ADA) Assessment in Serum by Immunoassay (ELISA)	SOP/BAL/001-01, MOA/TDM1/179-02
2	BIOLOGICAL- BIOLOGICALS DERIVED PHARMACEUTICALS	Trastuzumab emtansine	Pharmacokinetics (PK) Assessment in Serum by Immunoassay (ELISA)	SOP/BAL/009-01, MOA/TT/177-01
3	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Desidustat	Drug Estimation in Blood by LCMS	SOP/BAL/056-00, MOA/ZYAN/165-03
4	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Desidustat	Drug Estimation in Urine by LCMS	SOP/BAL/056-00, MOA/DESI+ZY-16894/182-00
5	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Drug Substance	Drug Estimation in Plasma by LCMS	SOP/BAL/056-00, MOA/ZY-19489/172-02
6	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Drug Substance	Drug Estimation in Plasma by LCMS	SOP/BAL/056-00, MOA/ZYBK2/178-01
7	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Drug Substance	Drug Estimation in Urine by LCMS	SOP/BP/061-21, MOA/ZY-19489/175-00, MOA/ZY-19489/175-01
8	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Drug Substance	Drug Estimation in Plasma by LCMS	SOP/BAL/056-00, SOP/BAL/056-01, MOA/ZYIL1/183-00
9	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Drug Substance	Drug Estimation in Urine by LCMS	SOP/BAL/056-00, SOP/BAL/056-01, MOA/ZYIL1/184-00
10	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Drug Substance	Drug Substance	SOP/BAL/056-00, MOA/ZYBK2/180-00
11	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Metabolite of Desidustat	Drug Estimation in Urine by LCMS	SOP/BAL/056-00, MOA/DESI+ZY-16894/182-00
12	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Metabolite of Drug Substance	Drug Estimation in Urine by LCMS	SOP/BP/061-21, MOA/ZY-19489/175-00, MOA/ZY-19489/175-01
13	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Metabolite of Drug Substance	Drug Estimation in Plasma by LCMS	SOP/BAL/056-00, MOA/ZY-19489/172-02
14	BIOLOGICAL- DRUGS AND PHARMACEUTICALS	Metabolite of Desidustat	Drug Estimation in Blood by LCMS	SOP/BAL/056-00, MOA/ZYAN/165-03