

CDMO

ANALYTICAL SERVICES

Eurofins CDMO offers analytical services as part of API development as well as stand-alone analytical testing services for projects at various stages in the drug life cycle (pre-clinical to late phase). Our analytical scientists specialize in the development of analytical methods and phase appropriate specifications to ensure control of the synthetic process and quality of API throughout the program.

OUR SERVICES

METHOD DEVELOPMENT

QbD Method Development In-Process Controls Method Optimization Suitability Testing Starting Material, Intermediate & API Release Impurity Control & Characterization GTI Control Non-Chromophoric Detection Specification Development

1

2

3

4

5

METHOD QUALIFICATION/ VALIDATION

Method Establishment Method Transfer Phase Appropriate Method Qualification Method Verification Full Method Validation

STANDARD QUALIFICATIONS

Identification Standards Physical & Structure Characterization Reference Standards

LIFECYCLE OPTIMIZATION

DOE Studies CPP Assessment/Support Fate of Impurities Regulatory GAP Assessment CMC Support

STABILITY

Short Term Stability Studies ICH Stability Studies - I-IVa Photo Stability (ICH Q1B) Accelerated Stability Forced Degradation Studies Trending Studies and Reporting



CDMO

Analytical Services

Equipment Description	Manufacture	Model
Analytical Testing		
HPLC	Agilent, Waters	Various. Detectors: PDA, DAD, QDa, CAD, RI, ELSD
LCMS	Bruker	MicroTOF
UPLC	Waters	Acquity H-Class
FTIR	Perkin Elmer	PE Spectrum One
GC	Agilent	6890, 7890
GCMS	Agilent	5975
ICP-MS	Agilent	7700
UV-Vis	Agilent	8453 UV-Visible Spectroscopy System
Ion Chromatograph	Dionex	ICS-3000
KF Titrator	Mettler Toledo	T7 (Coulometric/ Volumetric)
Stability/Storage		
Stability Chambers	Caron/Fisher/Binder	Conditions: 25°C/60%RH, 30°C/65%RH, 40°C/75%RH
Photo Stability Chamber	Caron	7540-1
2-8 °C Refrigerator	Thermoscientific	TSX2305SA
-20 °C Freezer	Thermoscientific	TSX2305SA
-80 °C Freezer	Thermoscientific	U101-86
Software		
FUSION	SMatrix	UPLC Method Development
Empower 3	Waters	HPLC, GC, UPLC
Chemstation	Agilent	GCMS, UV (development only)
MassHunter	Agilent	ICPMS
Compass	Bruker	LCMS
Trios	TA Instruments	TGA
Integrity	TA Instruments	TGA/DSC
Chromeleon	Dionex/Thermofisher	IC
Spectrum	PerkinElmer	IR

Contact Us Eurofins CDMO Alphora Inc. 2395 Speakman Drive, Suite 2001 Mississauga, Ontario L5K 1B3 Canada

