

Pharmaceutical Intermediates Catalogue 2024 1st Edition




Analytica Chemie Inc

www.analyticachemie.in



Your one stop Source for Pharmaceutical Impurities Reference Standards

Analytica Chemie Inc. offers over 8000 pharmaceutical impurities reference standards to support the Pharmaceutical industry worldwide

At Analytica Chemie,

- We deliver not only Impurities but also do reliable, high quality and cost-effective organic synthesis services.
- We provide analytical services and also undertake isolation, characterization and structural elucidation of unknown impurities.
- Rapid turnaround times on both the quotes and the delivery of the products.
- We listen carefully to the concerns and needs of customers, and address them promptly and efficiently.

Highlights of our Impurities

- Acknowledged by regulatory authorities worldwide.
- 8000+ impurities linked to official pharmacopoeia monographs.
- Customised pharmaceutical impurities synthesized on request
- Supply of mg to gm quantities.
- Each impurity is supported with detailed certificate of analysis.
- Additional documentation is provided on request
- Assistance in finding the right material to suit your analysis.



**4th Floor, Model Export Bhavan, 14th Cross, 2nd Stage, Peenya Industrial Area,
Bangalore - 560 058. India.**

Phone No. : +91 80 28363279 . Mobile : +91 9620240173

E-mail: in@analyticachemie.in | Web Site : www.analyticachemie.in

Certificate of Registration

This is to Certify that
Quality Management System of

ANALYTICA CHEMIE INC

MODEL EXPORT BHAVAN, 14TH CROSS , 2ND STAGE,
PEENYA INDUSTRIAL AREA, BANGALORE – 560058,
KARNATAKA, INDIA

has been assessed and found to conform to the requirements of
ISO 9001:2015
for the following scope :

DEVELOPMENT, MANUFACTURE AND SUPPLY OF CHEMICAL REFERENCE
MATERIALS AND ANALYTICAL TESTING SERVICES
IAF CODE : 12,34

Certificate No	: 22IQKP37/R1		
Initial Registration Date	: 30/06/2022	Issuance Date	: 10/01/2023
Date of Expiry	: 29/06/2025		
1st Surv. Due	: 30/05/2023	2nd Surv. Due	: 30/05/2024



Director



ACCREDITED
Management Systems
Certification Body
MSCB-119



AQG GLOBAL LLC

Head Office: Office No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE. e-mail: info@aqgworld.com.

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (In case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqgworld.com/activeclients.aspx> or www.aqgworld.com at Active Clients.

Certificate is the property of AQG Global LLC and shall be returned immediately when demanded.





National Accreditation Board for
Testing and Calibration Laboratories

CERTIFICATE OF ACCREDITATION

ANALYTICA CHEMIE INC.

has been assessed and accredited in accordance with the standard

ISO/IEC 17025:2017

**"General Requirements for the Competence of Testing &
Calibration Laboratories"**

for its facilities at

NO. 488B, 4TH FLOOR, MODEL EXPORT BHAVAN, 14TH CROSS, 2ND STAGE, PEENYA INDUSTRIAL
AREA, BENGALURU, KARNATAKA, INDIA

in the field of
TESTING

Certificate Number: TC-6013

Issue Date: 28/08/2024

Valid Until: 27/08/2026

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

Name of Legal Entity: Analytica Chemie Inc.

Signed for and on behalf of NABL



N. Venkateswaran
Chief Executive Officer

Analytica Chemie Inc., Bangalore, India

Analytica Chemie Inc. is a Contract Research Organization (CRO) with a proven track record of delivering various complex projects for the pharmaceutical industries.

Our services includes;

SYNTHETIC CHEMISTRY SERVICES

- Synthesis of impurity standards and reference standards
- Synthesis of metabolites and degradation impurities
- Synthesis of Genotoxic impurities
- Synthesis of API's and advanced intermediates (milligram to kilogram scale)
- Synthesis of stable isotope labelled compounds
- Process development
- Peptide synthesis



ANALYTICAL SERVICES

Analytica Chemie Inc. has GMP & GLP compliant, state-of-the-art analytical chemistry services laboratory, which is accredited by NABL (ISO/IEC 17025:2005), We offer analytical services to various pharmaceutical companies in India.

- Isolation and characterization of unknown Impurities
- Analytical testing services
- Analytical method development and method validation
- Extractable and leachable studies
- Stability studies
- Residual solvent method validation



IMPURITY SYNTHESIS LABORATORIES



QUALITY CONTROL & ANALYTICAL LABORATORIES

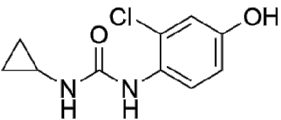
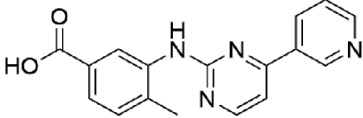
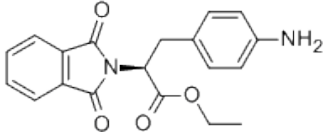
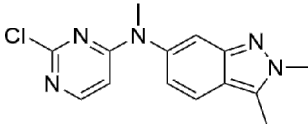
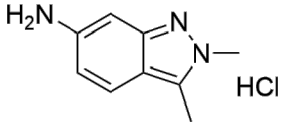
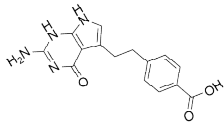
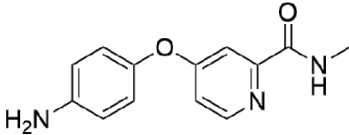
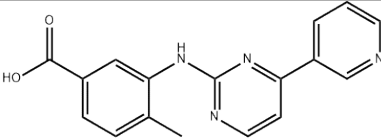


NMR FACILITY AND SCALE-UP LABORATORY



Code	Product Name	Structure	CAS No.
ACI-R02040	4-(Bromomethyl)-1-cyclohexyl-2-(trifluoromethyl)-benzene		800381-60-6
ACI-R05026	1-[3-Ethyl-4-(hydroxymethyl)phenyl] ethenone		1378888-43-7
ACI-R04058	1-(4,5-Diamino-10-aza-tricyclo[6.3.1.0]dodeca-2,4,6-trien-10-yl)-2,2,2-trifluoro-ethanone		230615-69-7
ACI-R04059	1-(9,10-Dihydro-6H-6,10-methano azepino[4,5-g]quinoxalin-8(7H)-yl)-2,2,2-trifluoroethanone		230615-70-0
ACI-R04060	1,6-di-(tert-butoxycarbonyl)-ergoline-8beta-carboxylic acid		1075250-76-8
ACI-R01040	6-Allyl-8-beta-carboxy-ergoline		81409-74-7
ACI-R19024	(S)-3-(4-(2-Chloro-5-iodobenzyl)phenoxy)tetrahydrofuran		915095-94-2
ACI-R19025	(3S)-3-[4-(5-Bromo-2-chlorobenzyl)phenoxy]tetrahydrofuran		915095-89-5
ACI-R03064	1-Chloro-2-(4-ethoxybenzyl)-4-iodobenzene		1103738-29-9

Code	Product Name	Structure	CAS No.
ACI-R03065	1-Chloro-2-(4-ethoxybenzyl)-4-bromobenzene		461432-23-5
ACI-R04061	DL-1,4-Dithiothreitol		3483-12-3
ACI-R02041	1-(8-(Benzyloxy)-2-hydroxyquinolin-5-yl)-2-bromoethanone		100331-89-3
ACI-R04062	5,6-Diethyl-2,3-dihydro-1H-inden-2-amine Hydrochloride		312753-53-0 HCl
ACI-R01041	2-(2-Aminopropan-2-yl)-N-[(4-fluorophenyl)methyl]-5-hydroxy-1-methyl-6-oxo-1,6-dihydro pyrimidine-4-carboxamide		51848-03-8
ACI-R04063	4-((6,7-dimethoxyquinolin-4-yl)oxy)aniline		190728-25-7
ACI-R01042	2-Amino-N-(2-chloro-6-methylphenyl)-5-thiazolecarboxamide		302964-24-5
ACI-R03066	2-(2-Aminopropan-2-yl)-N-[(4-fluorophenyl)methyl]-5-hydroxy-1-methyl-6-oxo-1,6-dihydro pyrimidine-4-carboxamide		302964-08-5
ACI-R02042	6,7-Bis-(2-methoxyethoxy)-4(3H)-quinazolinone		179688-29-0
ACI-R16052	(4-Phenoxy-phenyl)-1-piperidin-3-yl-1H-pyrazolo[3,4-d]pyrimidin-4-amine		1022150-12-4

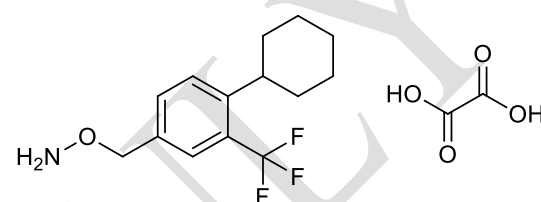
Code	Product Name	Structure	CAS No.
ACI-R03067	1-(2-chloro-4-hydroxyphenyl)-3-cyclopropylurea		796848-79-8
ACI-R13050	Methyl- (S)-N-Ethoxycarbonyl-4-Amino phenyl alaninate		169472-17-7
ACI-R01043	4-amino-L-phenyl-N-phthalylalanine ethyl ester		74743-23-0
ACI-R03068	N-(2-chloropyrimidin-4-yl)-N,2,3-trimethylindazol-6-amine		444731-75-3
ACI-R04064	2,3-Dimethyl-2H-Indazole-6-amine Hydrochloride		635702-60-2
ACI-R14048	-[2-(2-Amino-4,7-dihydro-4-oxo-1H-pymol[2,3- d]pyrimodin-5-yl)ethyl]benzoic acid		137281-39-1
ACI-R01044	4-(4-Aminophenoxy)-N-methylpyridine-2- carboxamide		284462-37-9
ACI-R13051	4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]benzoic acid		641569-94-0

Specification and Certificate of Analysis

Product Name: Siponimod Intermediate

Chemical Name: O-(4-cyclohexyl-3-(trifluoromethyl)benzyl)hydroxylamine oxalate

Product Information: Siponimod

Mol. Form.:	C ₁₆ H ₂₀ F ₃ NO ₅	Structure: 
Mol. Wt.:	363.13 g/mol	
CAS Number:	[800379-62-8]Free base	
Storage Condition:	Store in a tightly closed container at room temperature	

TEST	SPECIFICATION & ACCEPTANCE CRITERIA	RESULTS
Appearance	Off white to White colour powder	Off white colour powder
Solubility	Soluble in dimethyl sulfoxide	Complies
Identification by IR	The IR absorption spectrum of sample should conform to that of standard spectrum	Conforms
Identification by HPLC	Retention time of the sample should conform to that of standard in assay method	Conforms
Water content	NMT 1%	0.28%
Assay by HPLC (On anhydrous basis)	Not less than 97.0	99.6%
OXALIC ACID CONTENT (BY TITRIMETRY) (On anhydrous basis)	NLT 23.6 and NMT 26.0	24.5 %

*The assay/potency 'as is' is equivalent to the assay based of the not anhydrous and not dried substance respectively.

*NMT: Not More Than; NLT: Not Less Than.

Analytica Chemie Inc.

Chief Scientific Officer


Analytica Chemie
Cat. No.: ACI 010450
Trideuteriomethyl N-(5-pyrrolidinyl)acetamide
Reference substance

Analytica Chemie Inc
Lot. No.: 038011-1701
Clidinium Iodide-D3
[2-(4-chlorophenyl)acetyl]oxy-1-methyl-4-piperidyl octane-iodide d3
Reference substance for laboratory use only

Analytica Chemie Inc
Lot. No.: 121019-1600
Levonorgestrel Imp. S (EP)
13-methoxy-18,19-dinor-17 α -pregn-20-ene-20-one
Reference substance for laboratory use only

Analytica Chemie Inc
Cat. No.: ACI 045100
Lot. No.: 045100
Difluprednate
21-acetate
Reference substance

Analytica Chemie
Cat. No.: ACI 021100
Reference substance


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