

Nitrosamine Impurities

Analytica Chemie Inc
Catalogue 2022

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.
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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, 4TH PHASE, PEENYA
INDUSTRIAL AREA, PEENYA, BANGALORE – 560058, INDIA

has been assessed and found to conform to the requirements of

ISO 9001:2015

for the following scope :

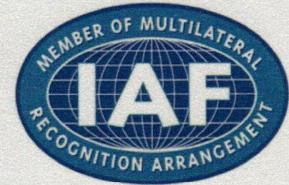
**DEVELOPMENT, MANUFACTURE AND SUPPLY OF CHEMICAL
REFERENCE MATERIALS AND ANALYTICAL TESTING SERVICES**

Certificate No	: 19IQCM50	Issuance Date	: 08/04/2019
Initial Registration Date	: 08/04/2019		
Date of Expiry*	: 07/04/2022		
1st Surve. Due	: 08/03/2020	2nd Surve. Due	: 08/03/2021


Director



ACCREDITED
Management Systems
Certification Body
MSCB-119



AQC MIDDLE EAST FZE.

Head Office: E1-1401 E Amber Gem Tower, Sheikh Khalifa Bin Zayed Road, 2, Ajman, UAE. e-mail : info@aqcworld.com.
Key Location: 403, Madhuban Building, 55, Nehru Place, New Delhi - 110019, 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.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.
Certificate is the property of AQC Middle East FZE 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: 28/08/2019

Valid Until:

27/08/2021*

*The validity is extended for one year up to 27.08.2022

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 Identity : 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



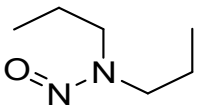
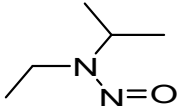
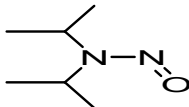
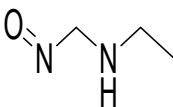
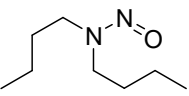
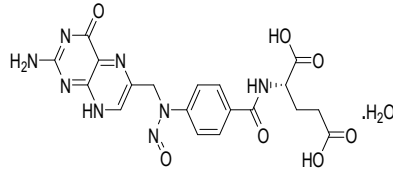
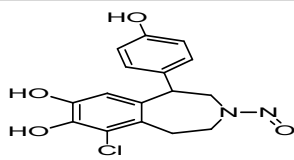
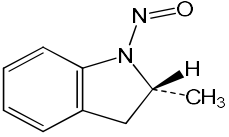
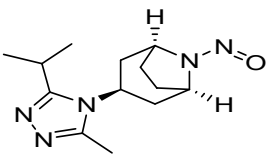
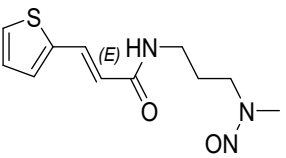
QUALITY CONTROL & ANALYTICAL LABORATORIES

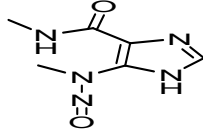
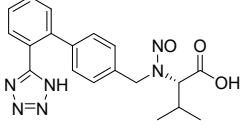
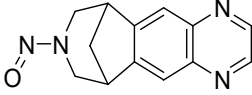
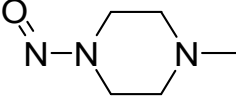
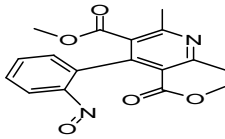
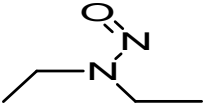
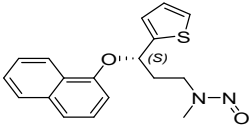
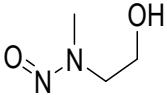
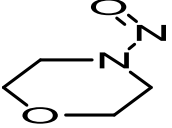
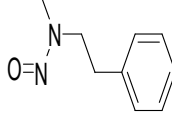
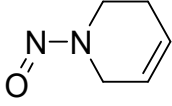


NMR FACILITY AND SCALE-UP LABORATORY



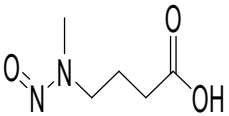
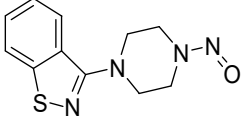
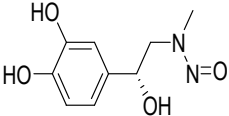
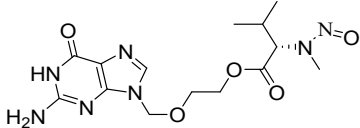
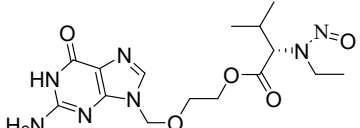
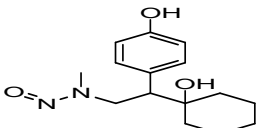
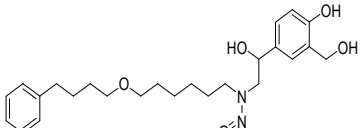
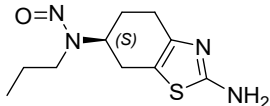
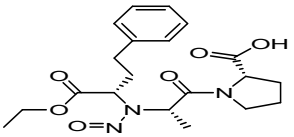
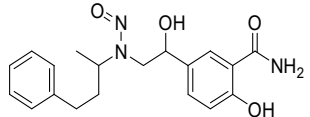
Code	Product Name	Structure	CAS No.
ACI-033715	N-Nitroso Ciprofloxacin: 1-Cyclopropyl-6-fluoro-1,4-dihydro-7-(4-nitroso-1-piperazinyl)-4-oxo-3-quinolinecarboxylic Acid		864443-44-7
ACI-R14014	1-Methyl-3-nitro-1-nitrosoguanidine: Methylnitronitrosoguanidine		70-25-7
ACI-031019	Nitroso Carvedilol: (S)-1-((2-(2-methoxyphenoxy)ethyl)amino)-3-((9-nitroso-9H-carbazol-4-yl)oxy)propan-2-ol		NA
ACI-130127	N-Nitrosometoprolol		138768-62-4
ACI-R14013	N-Nitrosopiperidine		100-75-4
ACI-020113	N-Nitroso Betahistine		32635-81-7
ACI-R14012	N-Nitrosodibenzylamine		5336-53-8
ACI-070402	N-Nitroso-3-azabicyclo[3.3.0]octane		54786-86-6
ACI-220416	N-Nitrosodimethylamine		62-75-9

Code	Product Name	Structure	CAS No.
ACI-220421	N-Nitrosodipropylamine (NPDA)		621-64-7
ACI-220417	N-Ethyl-N-nitroso-2-propanamine		16339-04-1
ACI-220418	N-Nitroso diisopropylamine		601-77-4
ACI-220419	N-Nitrosomethylethylamine (NMEDA)		10595-95-6
ACI-220422	N-Nitrosodibutylamine (NDBA)		924-16-3
ACI-060722	N-Nitroso-Folic acid		26360-21-4
ACI-064711	N-Nitroso Fenoldopam Impurity : 6-Chloro-1-(4-hydroxyphenyl)-3-nitroso-2,3,4,5-tetrahydro-1H-benzo[d]azepine-7,8-diol		NA
ACI-090701	Indapamide Imp. A (EP)		85440-79-5
ACI-137611	N-Nitroso Maraviroc Impurity		NA
ACI-148611	N-Nitroso Pyrantel pamoate impurity		NA

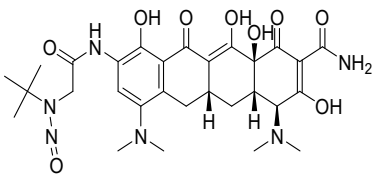
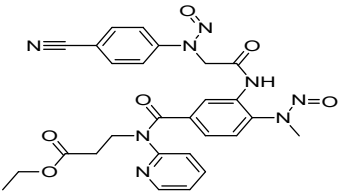
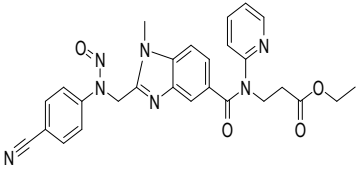
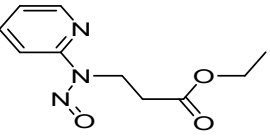
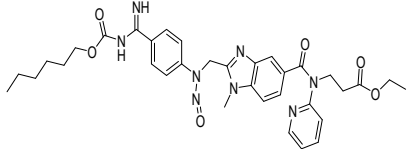
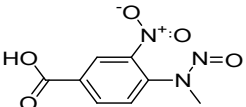
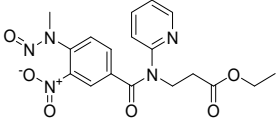
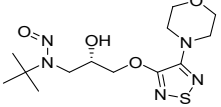
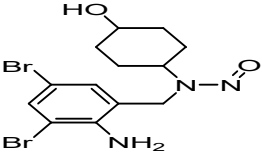
Code	Product Name	Structure	CAS No.
ACI-201614	Theophylline Impurity		NA
ACI-220426	Valsartan Nitrosamine Impurity		NA
ACI-221430	Varenicline Tartrate Impurity		NA
ACI-R13030	1-Methyl-4-nitrosopiperazine		16339-07-4
ACI-142002	Dehydronitrosonifedipine: 4-(2-Nitrosophenyl)-2,6-dimethyl-3,5-dimethoxycarbonylpyridine		50428-14-3
ACI-R14015	N-Nitrosodiethylamine(NDEA): N-Ethyl-N-nitrosoethanamine		55-18-5
ACI-043325	N-Nitroso Duloxetine		NA
ACI-R14016	N-(Nitrosomethyl)ethanolamine: 2-(Methylnitrosoamino)ethanol		26921-68-6
ACI R14017	N-Nitrosomorpholine: Nitrosomorpholine		59-89-2
ACI R14018	N-Nitroso N-Methyl-Phenethylamine: N-Methyl-N-nitrosobenzeneethanamine		13256-11-6
ACI R14019	N-Nitroso-1,2,3,6-Tetrahydropyridine: 1,2,3,6-Tetrahydro-1-nitrosopyridine		55556-92-8

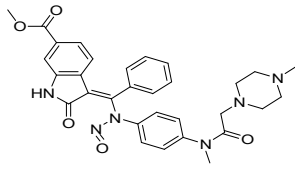
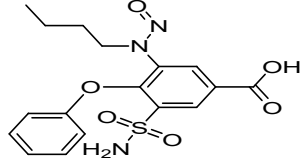
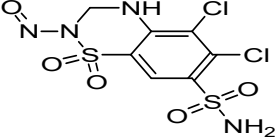
Code	Product Name	Structure	CAS No.
ACI-010125	N-Nitroso Atenolol: 4-[2-Hydroxy-3-[(1-methylethyl)nitrosoamino]propoxy]benzeneacetamide		134720-04-0
ACI R14020	2-[2-(4-Nitroso-1-piperazinyl)ethoxy]ethanol		73486-81-4
ACI-220427	Des(oxopentyl) N-Nitroso Valsartan: (2S)-3-Methyl-2-[nitroso[[2'-(2H-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]amino]butanoic acid		2254485-68-0
ACI-160425	N-Nitroso Phenylephrine: (R)-N-(2-Hydroxy-2-(3-hydroxyphenyl)ethyl)-N-methylnitrous Amide		78658-64-7
ACI R14021	4-Nitrosomethylaminopyridine: N-Methyl-N-nitroso-4-pyridinamine		16219-99-1
ACI-032725	N-Nitrosochloridiazepoxide: N-(7-chloro-4-oxido-5-phenyl-3H-1,4-benzodiazepin-4-ium-2-yl)-N-methylnitrous amide		51715-17-4
ACI -042025	Nitroso Desloratadine: 8-Chloro-11-(1-nitrosopiperidin-4-ylidene)-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine		1246819-22-6
ACI -040125	N-Nitroso Diclofenac: 2-[(2,6-Dichlorophenyl)nitrosoamino]benzeneacetic Acid		66505-80-4
ACI 190625	N-Nitroso Sotalol: N-[4-[1-Hydroxy-2-[(1-methylethyl)nitrosoamino]ethyl]phenyl]methanesulfonamide		134720-07-3
ACI R14026	N-Nitrosoamino-1-deoxy-1-N-Methyl-D-glucitol: 1-Deoxy-1-(methylnitrosoamino)-D-glucitol		10356-92-0
ACI R14022	N-Nitrosodiethanolamine: Nitrosobis(2-hydroxyethyl)amine		1116-54-7

Code	Product Name	Structure	CAS No.
ACI 080225	N-Nitroso Hydrochlorothiazide: 6-chloro-3,4-dihydro-4-nitroso-2H-1,2,4-Benzothiadiazine-7-sulfonamide 1,1-dioxide		63779-86-2
ACI 142525	N-Nitroso Nebivolol (Mixture of Diastereomers): N,N-Bis(2-(6-fluorochroman-2-yl)-2-hydroxyethyl)nitrous amide		1391051-68-5
ACI 033425	Clopidogrel nitroso impurity: 4,5,6,7-tetrahydro-5-nitroso-Thieno[3,2-c]pyridine		2460755-43-3
ACI-062825	N-Nitroso Fluoxetine: N-Methyl-N-nitroso-γ-[4-(trifluoromethyl)phenoxy]benzenepropanamine		150494-06-7
ACI 194425	N-Nitroso Safinamide: (S)-2-((4-((3-fluorobenzyl)oxy)benzyl)(nitroso)amino)propanamide		2657645-00-4
ACI R14023	N-Nitrosodiphenylamine: N,N-Diphenyl-N-nitrosoamine		86-30-6
ACI R14024	N-Nitrosopyrrolidine: 1-Nitrosopyrrolidine		930-55-2
ACI 165325	N-Nitrosopropranolol: 1-[(1-Methylethyl)nitrosoamino]-3-(1-naphthalenyloxy)-2-propanol		84418-35-9
ACI 132925	N-Nitroso Minocycline EP Impurity C: N-Nitroso-7-monomethylamino-6-deoxytetracycline		28698-93-3
ACI 133125	N-Nitroso Mefenamic acid: 2-[(2,3-Dimethylphenyl)nitrosoamino]benzoic acid		2114-63-8

Code	Product Name	Structure	CAS No.
ACI R14025	N-Nitroso-N-methyl-4-aminobutyric Acid(NMBA): 4-(Methylnitrosoamino)butanoic Acid		61445-55-4
ACI 124025	N-Nitroso Lurasidone Impurity: 3-(4-nitrosopiperazin-1-yl)benzo[d]isothiazole		NA
ACI-051325	N-Nitroso Epinephrine : 4-((R)-2-(N-methyl-N-nitrosoamino)-1-hydroxyethyl)benzene-1,2-diol		NA
ACI 220525	N-Nitroso Valaciclovir Impurity C: 2-((2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy)ethyl N-methyl-N-nitrosovalinate		NA
ACI 220526	N-Nitroso Valaciclovir Impurity D: 2-((2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy)ethyl N-ethyl-N-nitrosovalinate		NA
ACI 220125	N-Nitroso Venlafaxine Impurity : 1-[1-(4-methoxyphenyl)-2-(methylnitrosoamino)ethyl]-Cyclohexanol		2680662-11-5
ACI-190825	N-Nitroso salmeterol xinafoate impurity: 4-(2-(N-(6-(4-phenylbutoxy)hexyl)-N-nitrosoamino)-1-hydroxyethyl)-2-(hydroxymethyl)phenol		NA
ACI 161125	N-Nitroso Pramipexole: N-(2-amino-4,5,6,7-tetrahydrobenzo[d]thiazol-6-yl)-N-propylnitrous amide		NA
ACI 052725	N-Nitroso Enalapril: N-((S)-1-Ethoxy-1-oxo-4-phenylbutan-2-yl)-N-nitroso-L-alanylproline		NA
ACI-122825	N-Nitroso Labetalol: 2-hydroxy-5-(1-hydroxy-2-(nitroso(4-phenylbutan-2-yl)amino)ethyl)benzamide		NA

Code	Product Name	Structure	CAS No.
ACI 031825	N-Nitroso-N-Desmethyl cyamemazine: 10-(3-(N-methyl-N-nitrosoamino)-2-methylpropyl)-10H-phenothiazine-2-carbonitrile		NA
ACI 167925	N-Nitroso Palbociclib Impurity 2: N-(6-Acetyl-8-cyclopentyl-5-methyl-7-oxo-7,8-dihydropyrido[2,3-d]pyrimidin-2-yl)-N-(5-(4-nitrosopiperazin-1-yl)pyridin-2-yl)nitrous amide		NA
ACI 167926	N-Nitroso Palbociclib Impurity 3: 6-acetyl-8-cyclopentyl-5-methyl-2-((5-(4-nitrosopiperazin-1-yl)pyridin-2-yl)amino)pyrido[2,3-d]pyrimidin-7(8H)-one		NA
ACI 203525	N-Nitroso Tamsulosin: (R)-5-(2-((2-(2-ethoxyphenoxy)ethyl)(nitroso)amino)propyl)-2-methoxybenzenesulfonamide		NA
ACI 020225	N-Nitroso Bisoprolol: N-(2-Hydroxy-3-(4-((2-isopropoxyethoxy)methyl)phenoxy)propyl)-N-isopropyl nitrous amide		NA
ACI 181425	N-Nitroso Rizatriptan: 2-(5-((1H-1,2,4-triazol-1-yl)methyl)-1-nitroso-1H-indol-3-yl)-N,N-dimethylethan-1-amine		NA
ACI 170225	N-Nitroso Quinapril: (S)-2-(N-((S)-1-ethoxy-1-oxo-4-phenylbutan-2-yl)-N-nitroso-L-alanyl)-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid		NA
ACI 190525	N-Nitroso Sertraline: N-(4-(3,4-Dichlorophenyl)-1,2,3,4-tetrahydronaphthalen-1-yl)-N-methylnitrous amide		NA
ACI 071925	N-Nitroso Gefitinib: N-(3-Chloro-4-fluorophenyl)-N-(7-methoxy-6-(3-morpholinopropoxy)quinazolin-4-yl)nitrous amide		NA

Code	Product Name	Structure	CAS No.
ACI 204025	N-Nitroso Tigecycline: (4S,4aS,5aR,12aS)-9-(2-(tert-butyl(nitroso)amino)acetamido)-4,7-bis(dimethylamino)-3,10,12,12a-tetrahydroxy-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide		NA
ACI 043634	Dabigatran Dinitroso impurity: N,N'-dinitroso Dabigatran ethyl ester		NA
ACI 043633	Dabigatran Nitroso impurity: Ethyl 3-(2-(((4-cyanophenyl)(nitroso)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzodimidazole-5-carboxamido)propanoate		NA
ACI R14027	Ethyl 3-(Nitroso(pyridin-2-yl)amino) propanoate		NA
ACI 043631	N-Nitroso Dabigatran etexilate: Ethyl 3-(2-(((4-(N-(hexyloxy)carbonyl)carbamidoyl)phenyl)(nitroso)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzodimidazole-5-carboxamido)propanoate		NA
ACI R14028	4-(methyl(Nitroso)amino)-3-nitrobenzoic acid		NA
ACI 043632	Dabigatran Nitroso impurity: Ethyl 3-(4-(methyl(nitroso)amino)-3-nitro-N-(pyridin-2-yl)benzamido)propanoate		NA
ACI 201925	N-Nitroso Timolol: (S)-N-(Tert-butyl)-N-(2-hydroxy-3-((4-morpholino-1,2,5-thiadiazol-3-yl)oxy)propyl)nitrous amide		
ACI 010625	N-Nitroso Ambroxol: N-(2-Amino-3,5-dibromobenzyl)-N-((1r,4r)-4-hydroxycyclohexyl)nitrous amide		

Code	Product Name	Structure	CAS No.
ACI 152425	N-Nitroso Nintedanib: (Z)-methyl 3-(((4-(N-methyl-2-(4-methylpiperazin-1-yl)acetamido)phenyl)(nitroso)amino)(phenyl)methylene)-2-oxoindoline-6-carboxylate		NA
ACI 025125	N-Nitroso Bumetanide : 3-(Aminosulfonyl)-5-(butylnitrosoamino)-4-phenoxybenzoic acid		2490432-02-3
ACI 080226	N-Nitroso 5-Chloro Hydrochlorothiazide: 5,6-Dichloro-2-nitroso-3,4-dihydro-2H-benzo[e][1,2,4]thiadiazine-7-sulfonamide 1,1-dioxide		2490432-02-3

CERTIFICATE OF ANALYSIS

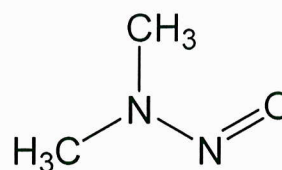
Reference Standard

Product Name: N-Nitrosodimethylamine

Product Information:

Product Code: ACI 220416
Lot No.: 220416-2002
Mol. Form.: C₂H₆N₂O
Mol. Wt.: 74.08 g/mol
CAS Number: [62-75-9]
QC Release Date: 18.12.2020
Recertified On: -
Retest due On: 17.12.2023

Chemical structure:




Long Term Storage: Store at -20°C. Protect from moisture and light.

Analytical Information:

Characteristics	Test results
Description	Colorless Liquid
IR	Complies
Mass Spectroscopy	m/z 74.8 [M] ⁺ Complies
¹ H NMR	Complies
Water content by KF	1.47%
Residual solvents by NMR	Nil
Purity by HPLC	99.98%
Total Impurities (HPLC)	0.02%
Assay / Potency 'as is'	98.5%

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

Analytica Chemie Inc.


 Dr. Malladi Srinivas
 Chief Scientific Officer
 Product Release



This Report was generated under a 21 CFR 11 Environment

System Information:

Sample ID: 220416-2002

System Status: Good

File Location: BLR-WS-0133\SQLEXPRESS\VAIMDB_Public(000)|Public Results\2020\Nove-2020\ 220416-2002_2020-12-16T16-56-30.a2r

PC/Workstation ID: FTIR- PC

Software Version: MicroLab PC(21CFR11): 5.3.1748.0

FW Version:1.96.00.0

Reporting Information:

Report Template: Spectrum.docx

Report Generated By: Group1\Project1\QC

Report Generation Date: 2020-12-16T16:56:30.645+05:30

Report Generation GMT Date:12-16-2020 11:26:36 AM

12/16/2020 4:56:36 PM

Data Information:

Method Name: Analytical Chemie

User: Group1\Project1\QC

Date/Time: 12-16-2020 4:56:30 PM

Instrument Model: Carry 630

Instrument S/N: MY16402006



Sample ID: 220416-2002

Method Name: Analytical Chemie

Sample Scans: 32

User: Group1\Project1\QC

Background Scans: 32

Date/Time: 12-16-2020 4:56:30 PM

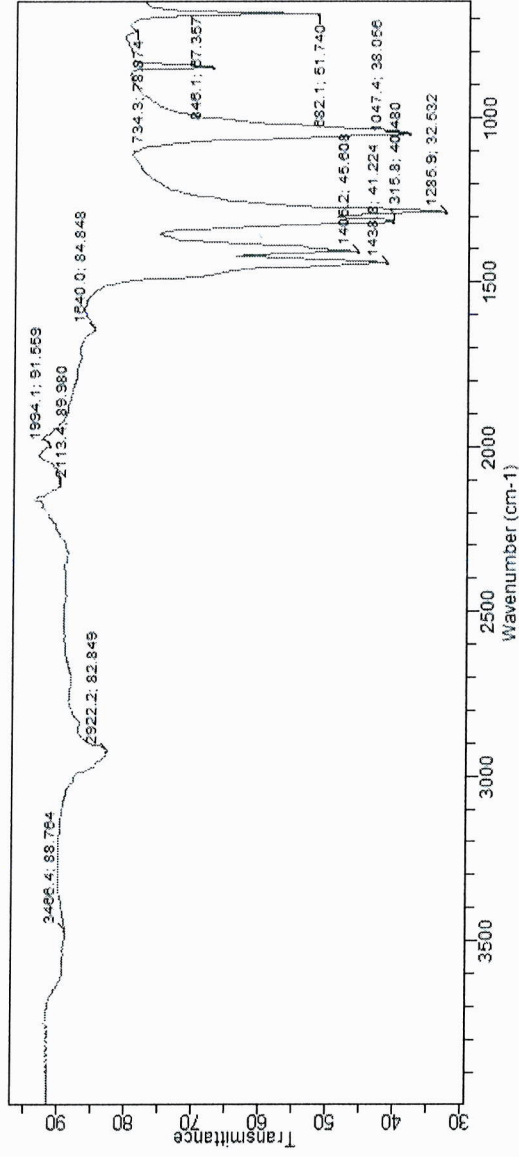
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Range: 4000 - 650

System Status: Good

Apodization: Happ-Genzel

File Location: BLR-WS-0133\SQLXPRESS\VAIMDB_Public(000)|Public Results\2020\Nove-2020\



E-SIGNATURES

Signature



Analysed by: *[Signature]*
16/12/2020

Checked by: *[Signature]*
16/12/2020

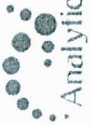
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Analysed by: *g-Ivan kury*
18/12/2020

Checked by: *A*
18/12/2020





Analytica Chemie Inc

220416-2002

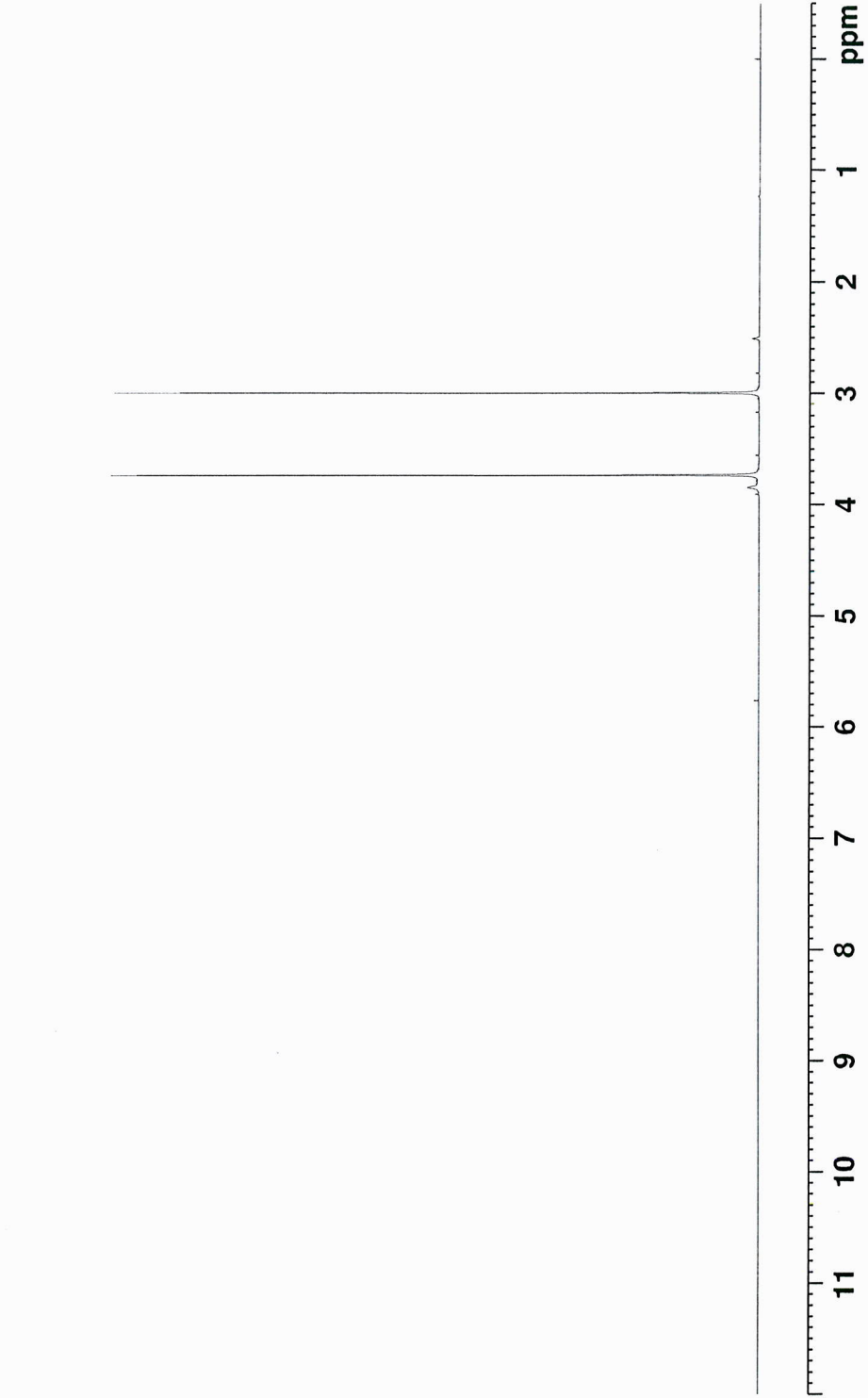
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2.50
2.03
2.01
2.00
1.99
1.97
1.91
1.48
1.47
1.46
1.24

Current Data Parameters
 NAME 220416-2002
 EXPNO 1
 PROCNO 1

F2 - Acquisition Parameters
 Date_ 20201217
 Time 12.53
 INSTRUM spect
 PROBHD 5 mm PABBO BB/
 PULPROG zg30
 TD 65536
 SOLVENT DMSO
 NS 32
 DS 2
 SWH 8012.820 Hz
 FIDRES 0.122266 Hz
 AQ 4.0894465 sec
 RG 101
 DW 62.400 usec
 DE 6.50 usec
 TE 294.1 K
 D1 1.00000000 sec
 TD0 1

==== CHANNEL f1 =====
 SFO1 400.1524711 MHz
 NUC1 1H
 P1 9.66 usec
 PLW1 9.10000038 W

F2 - Processing parameters
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 SF 400.1500004 MHz
 WDW EM
 SSB 0
 LB 0.30 Hz
 GB 0
 PC 1.00

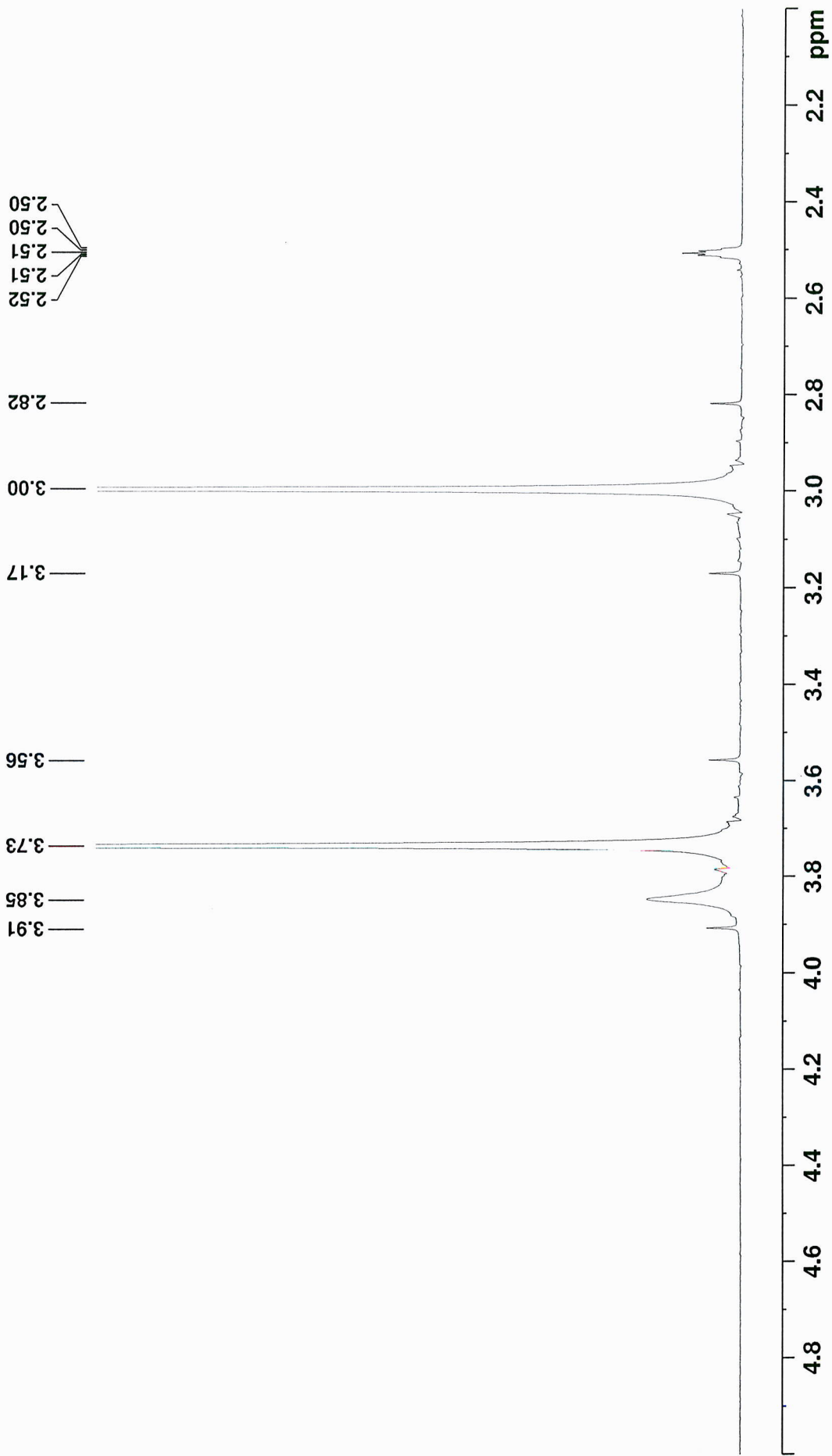


CHECKED BY: *[Signature]*

ANALYSED BY *g. Govan Kuruf* /17/12/2020

17/12/2020

220416-2002



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17/12/2020

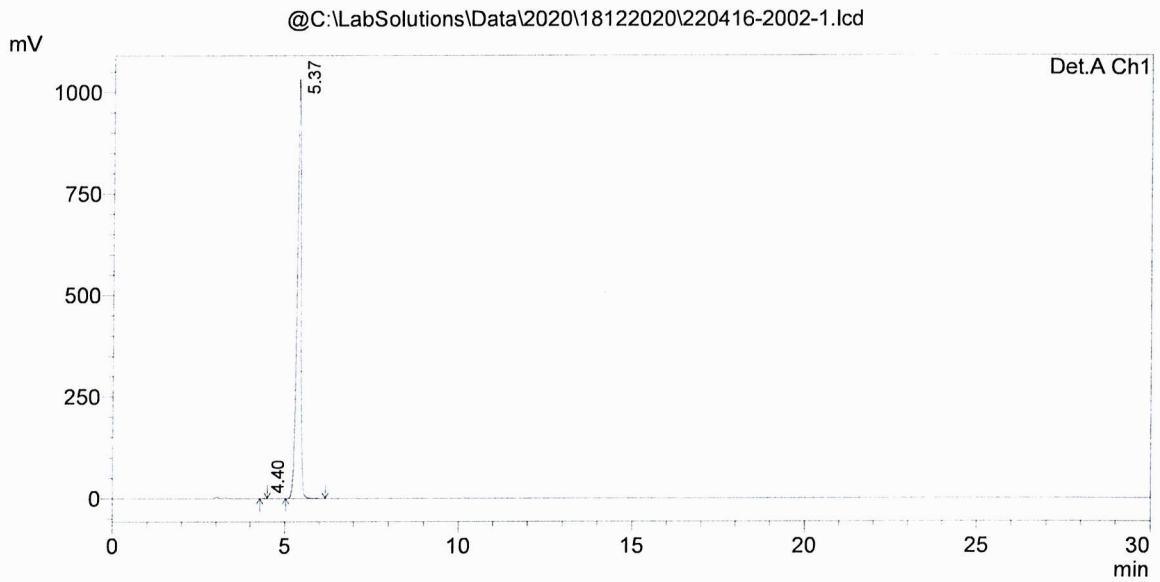
ANALYSED BY *[Signature]*
17/12/2020

==== Shimadzu LCsolution Analysis Report ====

@C:\LabSolutions\Data\2020\18122020\220416-2002-1.lcd

Injection Volume : 5 uL
Data File Name : 220416-2002-1.lcd
Data Acquired : 12/18/2020 3:25:43 PM
Data Processed : 12/18/2020 4:58:46 PM

Column : Puritas Eximius C18, 250 x 4.6mm,5µ
Mobile phase A: 0.05 M Sodium dihydrogen phosphate in water.
Mobile phase B:ACN
Pump mode:Isocratic , A:B::90:10v/v
Flow rate:1.0 ml/min



1 Det.A Ch1/225nm

Detector A Ch1 225nm

Peak#	Ret. Time	Area	Area %
1	4.40	1854	0.02
2	5.37	8062982	99.98
Total		8064835	100.00

Analyzed by:

[Signature]
18/12/2020



Checked by:

[Signature]
18/12/2020


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

Analytica Chemie Inc
Lot. No.: 038011-1701
Clidinium Iodide-D3
[2-(4-chlorophenylacetyl)oxy]-1-methyl-4-
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-one] Reference substance for laboratory use only

Analytica Chemie Inc
Cat. No.: ACI 045100
Lot. No.: 045100
Difluprednate
[11-decahydro-11-hydroxy-3,20-
-dioxo-1,4-dioxine] Reference substance for laboratory use only

Analytica Chemie
Cat. No.: ACI 021100
Reference substance


Analytica Chemie Inc

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Peenya Industrial Area, Bangalore - 560 058 India

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