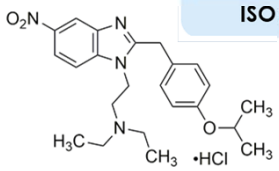
Certified Reference Material - Certificate of Analysis

Isotonitazene, Primary Measurement Standard

N,N-Diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1H-benzimidazole-1-ethanamine HCl

Product No.:	I-055-1ML
Lot No.:	FE04142124
Description of CRM:	Isotonitazene HCl in Methanol (Solution) Nominal concentration is adjusted for HCl content.
Retest Date:	June 2022 See Stability Section
Storage:	Store unopened in freezer (-10 °C to -25 °C).
Shipping:	Ambient. See Stability Section
Chemical formula:	$C_{23}H_{30}N_4O_3$ • HCl
CAS No.:	119276-00-5
Regulatory:	USDEA Exempt | Canadian TK # 061-1834

Cerilliant Quality
ISO 17034
ISO/IEC 17025
ISO 14001
ISO 9001



Analyte	Certified Concentration ± associated uncertainty U, $u = k * u$ ($k = 2$)
Isotonitazene	**1.000 ± 0.006 mg/mL**

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. See "Details on metrological traceability“ on page 3.

Measurement method: The certified value is calculated from high precision weighing of thoroughly characterized starting material. See “Details about certification process” on page 3.

Intended use: This Certified Reference Material is suitable for the in vitro identification, calibration, and quantification of the analyte(s) in analytical and R&D applications. Not suitable for human or animal consumption.

Minimum sample size: 1 µL for quantitative applications

Instructions for handling and correct use: Concentration is corrected for chromatographic purity, residual water, residual solvents, and residual inorganics. No adjustment required before use.

Users should quantitatively transfer desired volume using established good laboratory practices to spike into matrix or to dilute to the desired concentration. Each ampoule is intended for one-time use.

Nominal concentration is adjusted for HCl content. No adjustment required before use.

Health and safety information: Danger. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Accreditation: Cerilliant Corp. is accredited by the US accreditation authority ANAB as registered reference material producer AR-1353 in accordance with ISO 17034 and registered testing laboratory AT-1352 according to ISO/IEC 17025.

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

Darron Ellsworth, Quality Assurance Manager

June 16, 2021
Issue Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock, TX 78665, USA, Tel: 800-848-7837 / 512-238-9974

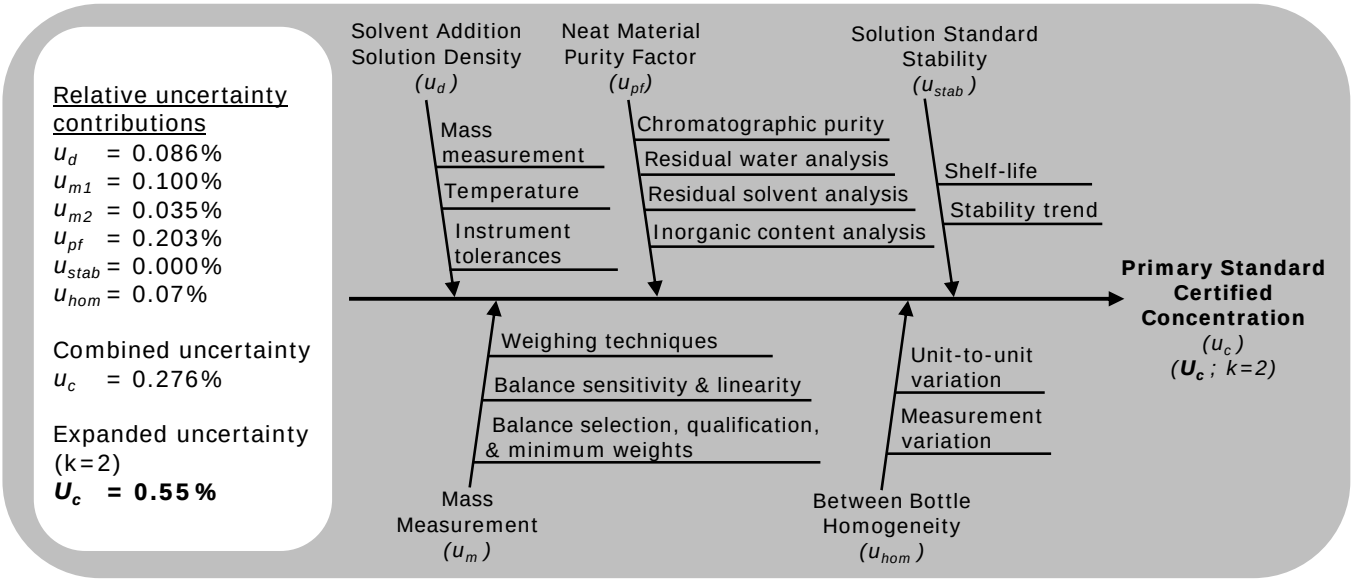
Packaging: 2 mL amber USP Type 1 glass ampoule containing not less than 1 mL of certified solution. Ampoules are overfilled to ensure a minimum of 1 mL volume can be transferred when using a 1mL Class A volumetric pipette.

Details on starting materials: Each raw material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques and is assigned a Mass Balance Purity Factor. Spectral data is provided on subsequent pages of this CoA.

Certificate of Origin: Cerilliant Corporation certifies no material of animal origin (BSE/TSE) was used in the preparation of this product. This material is a product of USA.

Associated uncertainty:

The uncertainty has been calculated by statistical analysis of all aspects of our production system and incorporated uncertainty of the mass balance purity factor, material density, balance, weighing technique, and homogeneity. Uncertainty components of the gravimetrically prepared Primary Standard concentration are shown in the figure below. Uncertainty is expressed as an expanded uncertainty in accordance with ISO 17034 at the approximate 95% confidence interval using a coverage factor of k=2. Uncertainty contribution from neat material homogeneity was established to be negligible through establishment of process controls and verification of the control process. Stability uncertainty was determined to be negligible by regression analysis.



Details on metrological traceability:

- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.

- Fill volume to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.

- The density and material Mass Balance Purity Factor of each raw material is traceable to the SI and higher order reference materials through mass measurement and instrument qualification and calibrations.

Details about certification process:

This standard has been prepared and certified under the ISO 17034, ISO/IEC 17025, and ISO 9001 standards. This standard meets the requirements of a Certified Reference Material and a Primary Standard as defined by ISO and is traceable to the SI and higher order standards through an unbroken chain of comparisons.

- Nominal concentration is calculated based on: the actual mass; Mass balance purity factor of the analyte(s); measured mass of the solution; and the density of the pure diluent at 20°C.

- Fill volume is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.

- Concentration is verified against an independently prepared calibration solution gravimetrically prepared.

- Additional certification information available upon request.

Solution Standard Verification

Concentration accuracy and within- and between-bottle homogeneity are analytically verified against an independently prepared calibration solution.

Standard Solution Assay Parameters		**Calibration Curve**	
Analysis Method:	HPLC/UV	**Calibration Curve:**	Linear Regression
Column:	Ascentis Express C18, 2.7 µm, 3.0 x 100 mm	**Number of Points:**	4
Mobile Phase:	Acetonitrile:0.1% Phosphoric acid in Water (35:65)	**Linearity (r) :**	1.000
Flow Rate:	1.2 mL/min		
Wavelength:	240 nm		

		Verified Concentration (mg/mL)	**%RSD - Homogeneity**
Standard Solution	**Lot Number**	**Actual Results**	**Actual Results**
New Lot	FE04142124	1.018	1.8

- Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.
- Within-sample and between-sample homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. Multiple samples pulled from across the lot using a random stratified sampling plan were analyzed to verify homogeneity. % RSD results shown above for the New Lot demonstrate ampoule-to-ampoule homogeneity.

Analyte Certification - Mass Balance Purity Factor

Each analyte is thoroughly identified and characterized using an orthogonal approach. A mass balance purity factor is assigned incorporating chromatographic purity and residual impurities. The mass balance purity factor and salt adjustment are utilized to calculate the weighing adjustment necessary to ensure accuracy of the solution standard concentration.

Material Name:	Isotonitazene HCl	**Molecular Weight (base):**	410.51
Material Lot:	FC11112007	**Molecular Weight (salt):**	446.97
Chemical Formula:	$C_{23}H_{30}N_4O_3$ • HCl	**Salt Adjustment:**	1.089
CAS Number:	119276-00-5		

Material Characterization Summary

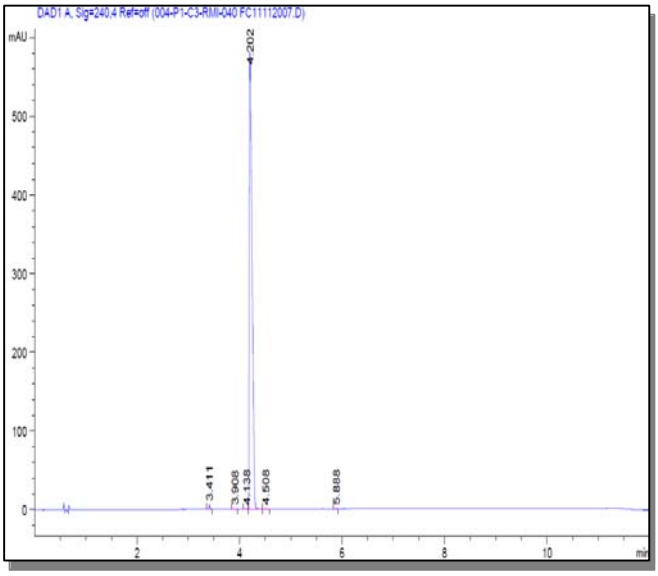
Analytical Test	Method	Results
Primary Chromatographic Purity by HPLC/UV Analysis	20384348	99.5%
Secondary Chromatographic Purity by GC/FID Analysis	20384346	99.1%
Identity by LC/MS Analysis	20384217	Consistent with Structure
Identity by ^{1}H-NMR Analysis	20384224	Consistent with Structure
Residual Solvent Analysis by GC/FID Headspace	20397799 [1]	0.15%
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	1.11%
Inorganic Content by Microash Analysis	20384350	Below Quantitation Limit
Mass Balance Purity Factor		98.26%

[1] Validated analytical method

- The primary chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- The primary purity method was selected to optimize resolution of impurities while minimizing degradation of the analyte. Secondary purity methods with orthogonal detector capabilities from the primary purity method are used as controls to confirm an accurate purity value.
- The primary chromatographic purity value is used to calculate the Mass Balance Purity Factor.
- A secondary chromatographic purity method is utilized as a control.
- Mass Balance Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- Mass Balance Purity Factor does not include adjustment for chiral and/or isotopic purity.

Spectral and Physical Data

HPLC / UV



Column: Ascentis Express C18, 2.7 µm, 3.0 x 100 mm

Mobile Phase: A: Acetonitrile
B: 0.1% Phosphoric acid in Water

Gradient:

Time (min)	% A	% B
0.0	15	85
8.0	80	20
10.0	80	20
10.1	15	85

Flow Rate: 0.7 mL/min

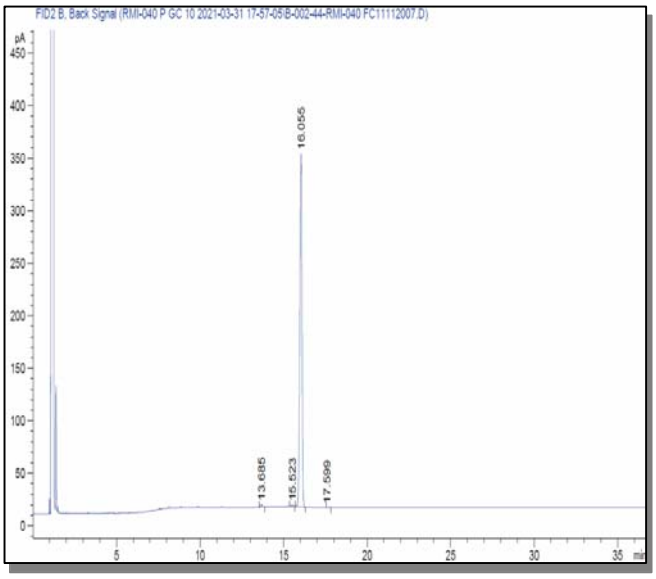
Wavelength: 240 nm

Sample Name: FC11112007

Acquired: March 27, 2021

Peak #	Ret Time	Area %
1	3.41	0.39
2	3.91	0.02
3	4.14	0.03
4	4.20	99.51
5	4.51	0.04
6	5.89	0.01

GC / FID



Column: DB-35ms, 30 m x 0.53 mm ID, 1.0 µm film thickness

Temp Program: 40°C to 310°C at 40°C/min hold 30 min

Injector Temp: Cool-on-Column

Detector Temp: 325°C

Sample Name: FC11112007

Acquired: March 31, 2021

Peak #	Ret Time	Area %
1	13.69	0.55
2	15.52	0.34
3	16.06	99.07
4	17.60	0.03

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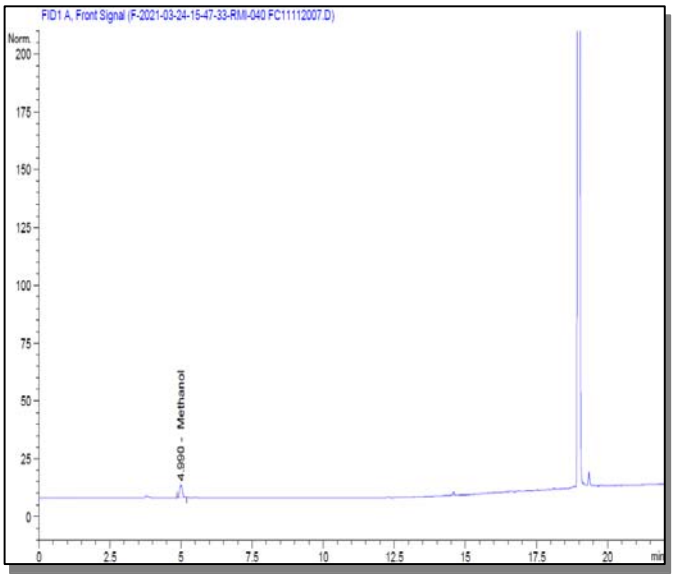
Spectral and Physical Data (cont.)

Residual Solvent Analysis by GC/FID Headspace

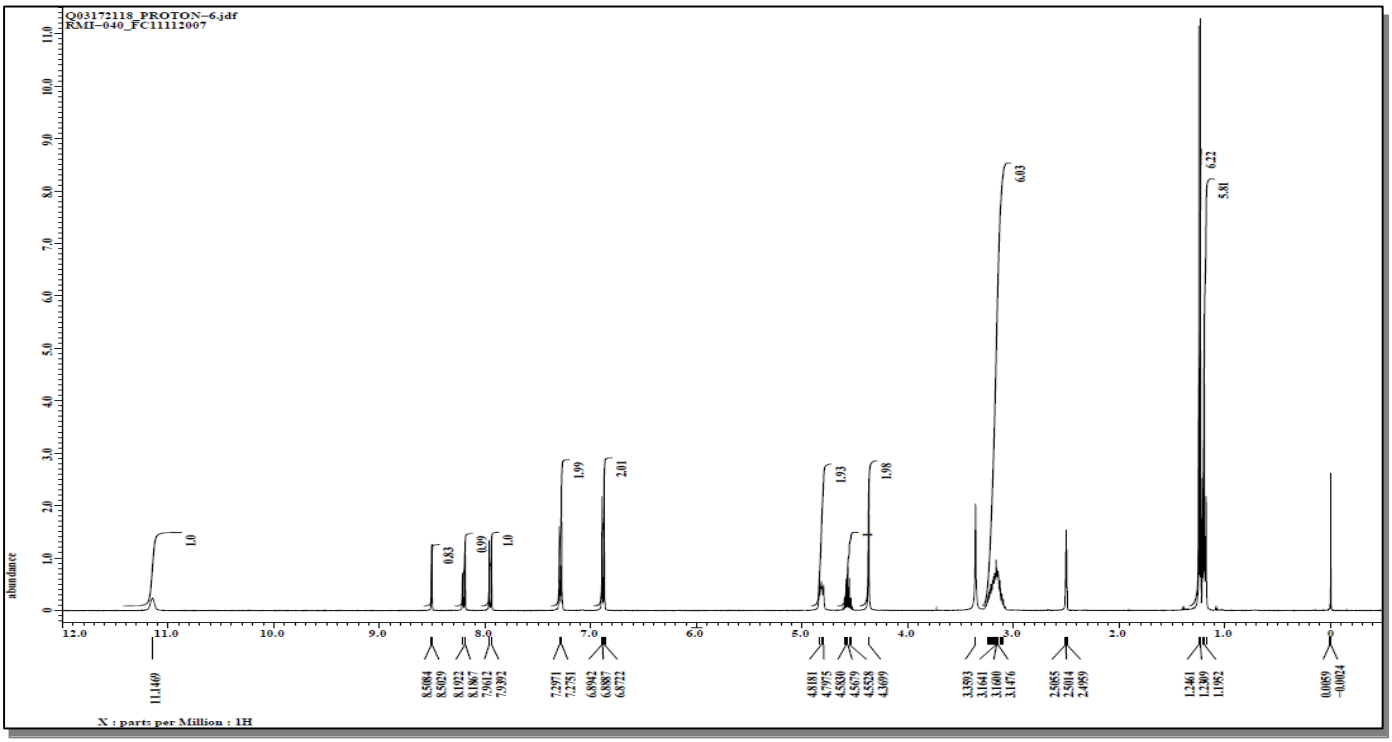


Column:	DB-ALC1 30 m x 0.53 mm, 3 µm film thickness
Temp Program:	40°C hold 12 min to 220°C at 40°C/min hold 5.5 min
Carrier Gas:	Helium
Flow Rate:	2.0 mL/min
Detector Heater Temp:	250°C
Injector:	Headspace Sampler
HS Oven Temp:	60°C
Vial Equilibration:	10 minutes
Sample Name:	FC11112007
Acquired:	March 24, 2021

Peak	Compound	Area	Weight %
1	Methanol	38.12	0.15
2	NMP	NA	NA
Total			**0.15**

^{1}H NMR

Instrument:	JEOL ECS 400
Solvent:	DMSO-D_6



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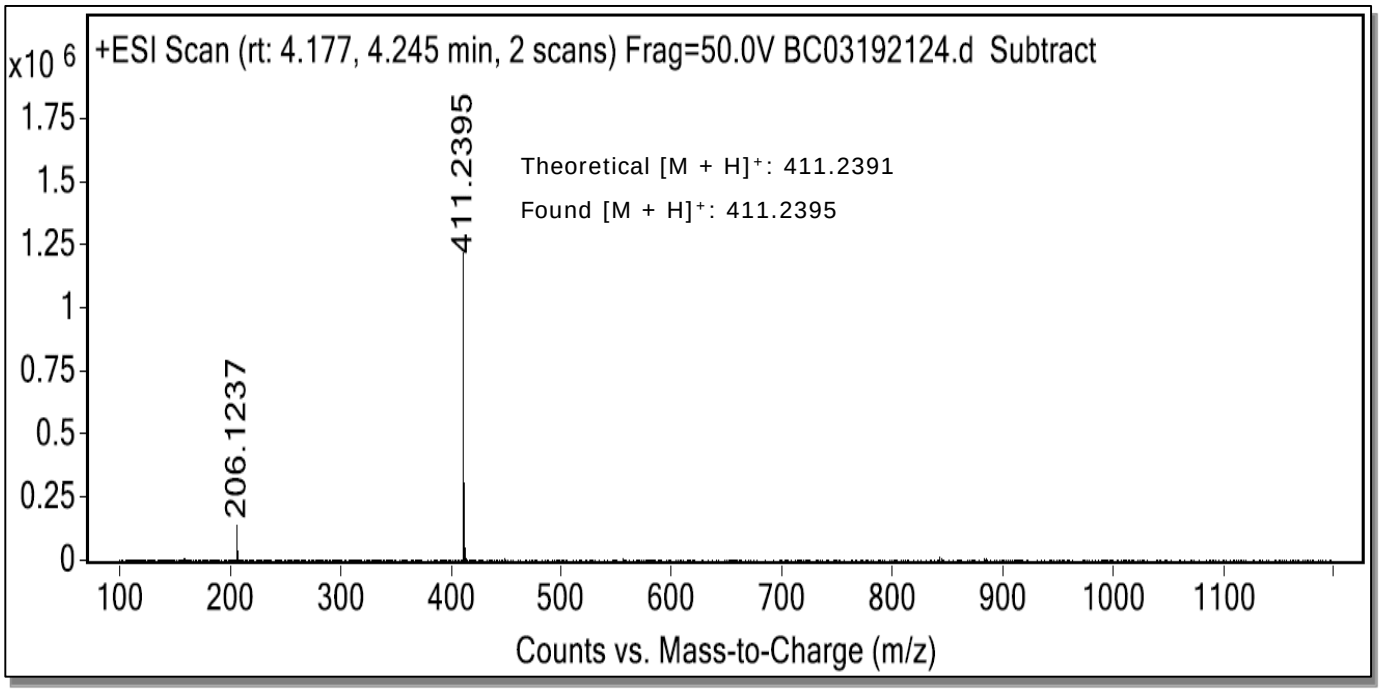
Spectral and Physical Data (cont.)

LC/MS

Column:	Ascentis Express C18, 2.7 µm, 3.0 x 50 mm	**Flow Rate:**	0.4 mL/min
Mobile Phase:	A: 0.1% Formic acid B: Acetonitrile	**Scan Range:**	100-1200 amu
		Ionization:	Electrospray, Positive Ion
		Instrument:	Agilent 6545XT QTOF
Gradient:		**Acquired:**	March 19, 2021

Time (min)	% A	% B
0.0	90	10
0.5	90	10
4.0	50	50
5.8	50	50
6.0	90	10
8.0	90	10



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Stability

Short term stability studies have been performed in multiple storage conditions for a period of up to four weeks. Short term data is utilized to support transport conditions and normal laboratory use. Real-time stability studies are performed at the recommended storage conditions over the life of the product.

Short Term Stability: *A summary of stability findings for this product is listed below.*

Storage Condition	Targeted Mean Kinetic Temperature (MKT)	Time Period/Result
Freezer	-20°C	No decrease in purity was noted after four weeks.
Refrigerator	5°C	
Room Temperature	20°C	
40°C	40°C	

Transport/Shipping: *Stability studies support the transport of this product at ambient conditions.*

Commutability

This standard is a solution of a pure substance in an organic solvent and is a Primary Standard. This Primary Standard is suitable for use in the preparation of calibrators and/or controls in any biological matrix. This standard is not in a biological matrix and therefore commutability to methods or standards in biological matrices does not apply.

COA Revision History

Revision No.	Date	Reason for Revision
00	June 16, 2021	Initial version.

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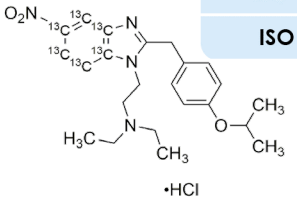
Certified Reference Material - Certificate of Analysis

Isotonitazene-$^{13}C_6$, Primary Measurement Standard

N,N-Diethyl-2-[[4-(1-methylethoxy)phenyl-$^{13}C_6$]methyl]-5-nitro-1H-benzimidazole-1-ethanamine HCl

Product No.: I-057-1ML
Lot No.: FE04142125
Description of CRM: Isotonitazene-$^{13}C_6$ HCl in Methanol (Solution)
Nominal concentration is adjusted for HCl content.
Retest Date: June 2022 See Stability Section
Storage: Store unopened in freezer (-10 °C to -25 °C).
Shipping: Ambient. See Stability Section
Chemical formula: $C_{17}{}^{13}C_6H_{30}N_4O_3$ • HCl
CAS No.: NA
Regulatory: USDEA Exempt | Canadian TK # 061-1836

Cerilliant Quality
ISO 17034
ISO/IEC 17025
ISO 14001
ISO 9001



Analyte	Certified Concentration ± associated uncertainty U, $u = k * u$ $(k = 2)$
Isotonitazene-$^{13}C_6$	**1.000 ± 0.006 mg/mL**

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. See "Details on metrological traceability" on page 3.

Measurement method: The certified value is calculated from high precision weighing of thoroughly characterized starting material. See "Details about certification process" on page 3.

Intended use: This Certified Reference Material is suitable for the in vitro identification, calibration, and quantification of the analyte(s) in analytical and R&D applications. Not suitable for human or animal consumption.

Minimum sample size: 1 µL for quantitative applications

Instructions for handling and correct use: Concentration is corrected for chromatographic purity, residual water, residual solvents, and residual inorganics. No adjustment required before use.
Users should quantitatively transfer desired volume using established good laboratory practices to spike into matrix or to dilute to the desired concentration.
Each ampoule is intended for one-time use.
Nominal concentration is adjusted for HCl content. No adjustment required before use.
For MS Applications, we advise laboratories not to mix lots during a single sequence.

Health and safety information: Danger. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Accreditation: Cerilliant Corp. is accredited by the US accreditation authority ANAB as registered reference material producer AR-1353 in accordance with ISO 17034 and registered testing laboratory AT-1352 according to ISO/IEC 17025.

Darron Ellsworth, Quality Assurance Manager

June 16, 2021
Issue Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock, TX 78665, USA, Tel: 800-848-7837 / 512-238-9974

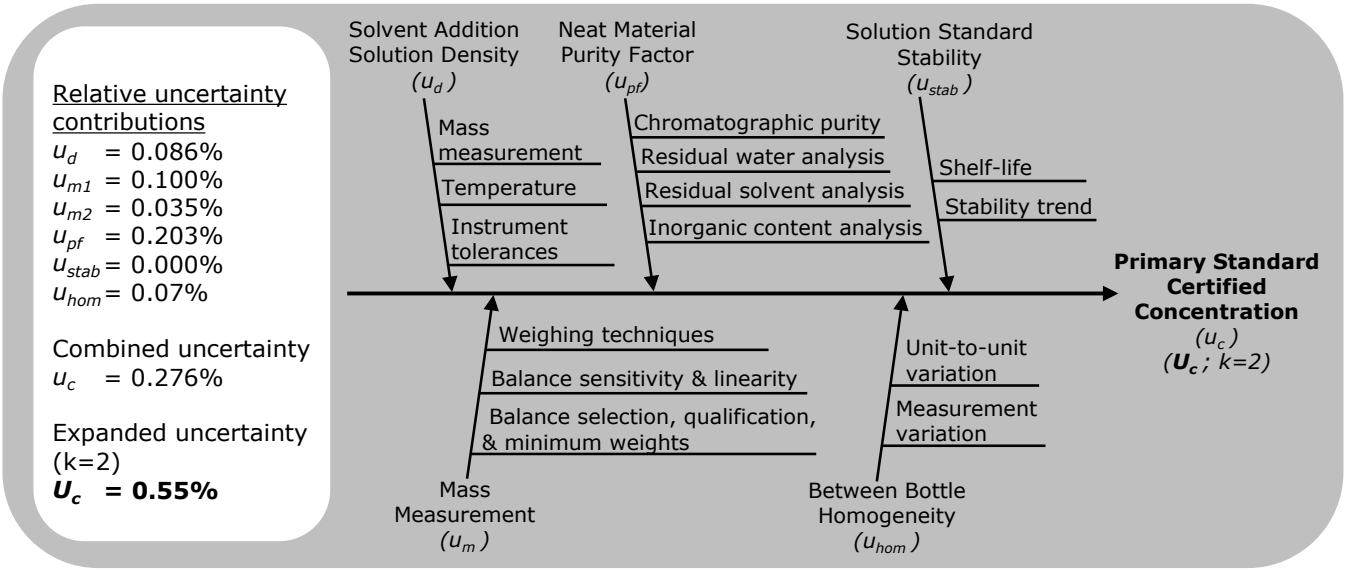
Packaging: 2 mL amber USP Type 1 glass ampoule containing not less than 1 mL of certified solution. Ampoules are overfilled to ensure a minimum of 1 mL volume can be transferred when using a 1mL Class A volumetric pipette.

Details on starting materials: Each raw material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques and is assigned a Mass Balance Purity Factor. Spectral data is provided on subsequent pages of this CoA.

Certificate of Origin: Cerilliant Corporation certifies no material of animal origin (BSE/TSE) was used in the preparation of this product. This material is a product of the USA.

Associated uncertainty:

The uncertainty has been calculated by statistical analysis of all aspects of our production system and incorporated uncertainty of the mass balance purity factor, material density, balance, weighing technique, and homogeneity. Uncertainty components of the gravimetrically prepared Primary Standard concentration are shown in the figure below. Uncertainty is expressed as an expanded uncertainty in accordance with ISO 17034 at the approximate 95% confidence interval using a coverage factor of k=2. Uncertainty contribution from neat material homogeneity was established to be negligible through establishment of process controls and verification of the control process. Stability uncertainty was determined to be negligible by regression analysis.



Details on metrological traceability:

- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- Fill volume to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.
- The density and material Mass Balance Purity Factor of each raw material is traceable to the SI and higher order reference materials through mass measurement and instrument qualification and calibrations.

Details about certification process:

This standard has been prepared and certified under the ISO 17034, ISO/IEC 17025, and ISO 9001 standards. This standard meets the requirements of a Certified Reference Material and a Primary Standard as defined by ISO and is traceable to the SI and higher order standards through an unbroken chain of comparisons.

- Nominal concentration is calculated based on: the actual mass; Mass balance purity factor of the analyte(s); measured mass of the solution; and the density of the pure diluent at 20°C.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.
- Concentration is verified against an independently prepared calibration solution gravimetrically prepared.
- Additional certification information available upon request.

Solution Standard Verification

Concentration accuracy and within- and between-bottle homogeneity are analytically verified against an independently prepared calibration solution.

Standard Solution Assay Parameters		**Calibration Curve**	
Analysis Method:	HPLC/UV	**Calibration Curve:**	Linear Regression
Column:	Ascentis Express C18, 2.7 µm, 3.0 x 100 mm	**Number of Points:**	4
Mobile Phase:	Acetonitrile:0.1% Phosphoric acid in Water (35:65)	**Linearity (r) :**	1.000
Flow Rate:	1.2 mL/min		
Wavelength:	240 nm		

		Verified Concentration (mg/mL)	**%RSD - Homogeneity**
Standard Solution	**Lot Number**	**Actual Results**	**Actual Results**
New Lot	FE04142125	1.016	1.9

- Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.
- Within-sample and between-sample homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. Multiple samples pulled from across the lot using a random stratified sampling plan were analyzed to verify homogeneity. % RSD results shown above for the New Lot demonstrate ampoule-to-ampoule homogeneity.

Analyte Certification - Mass Balance Purity Factor

Each analyte is thoroughly identified and characterized using an orthogonal approach. A mass balance purity factor is assigned incorporating chromatographic purity and residual impurities. The mass balance purity factor and salt adjustment are utilized to calculate the weighing adjustment necessary to ensure accuracy of the solution standard concentration.

Material Name:	Isotonitazene-$^{13}C_6$ HCl	**Molecular Weight (base):**	416.47
Material Lot:	FC10062003	**Molecular Weight (salt):**	452.93
Chemical Formula:	$C_{17}{}^{13}C_6H_{30}N_4O_3$ • HCl	**Salt Adjustment:**	1.088
CAS Number:	NA		

Material Characterization Summary

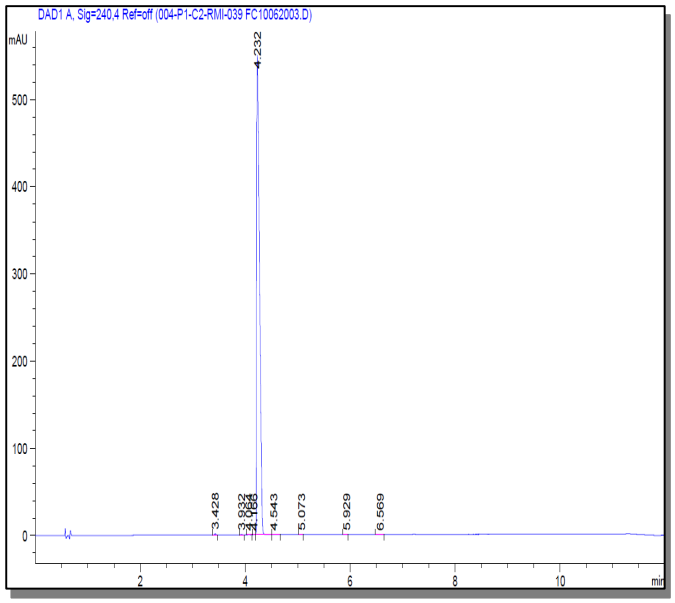
Analytical Test	**Method**	**Results**	
Primary Chromatographic Purity by HPLC/UV Analysis	20384348	99.8%	
Secondary Chromatographic Purity by GC/FID Analysis	20384346	99.3%	
Identity by LC/MS Analysis	20384217	Consistent with Structure	
Isotopic Purity and Distribution by LC/MS SIM Analysis	20384217	0.00% $^{13}C_0$ vs $^{13}C_6$	
		0.00% $^{13}C_0$ vs $^{13}C_3$	4.50% $^{13}C_5$
		0.10% $^{13}C_4$	95.40% $^{13}C_6$
Identity by ^{1}H-NMR Analysis	20384224	Consistent with Structure	
Residual Solvent Analysis by GC/FID Headspace	20397799 [1]	0.49%	
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	0.82%	
Inorganic Content by Microash Analysis	20384350	Below Quantitation Limit	
Mass Balance Purity Factor		98.46%	

[1] Validated analytical method

- The primary chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- The primary purity method was selected to optimize resolution of impurities while minimizing degradation of the analyte. Secondary purity methods with orthogonal detector capabilities from the primary purity method are used as controls to confirm an accurate purity value.
- The primary chromatographic purity value is used to calculate the Mass Balance Purity Factor.
- A secondary chromatographic purity method is utilized as a control.
- Mass Balance Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- Mass Balance Purity Factor does not include adjustment for chiral and/or isotopic purity.

Spectral and Physical Data

HPLC/UV



Column: Ascentis Express C18, 2.7 µm, 3.0 x 100 mm
Mobile Phase: A: Acetonitrile
B: 0.1% Phosphoric acid in Water
Gradient:

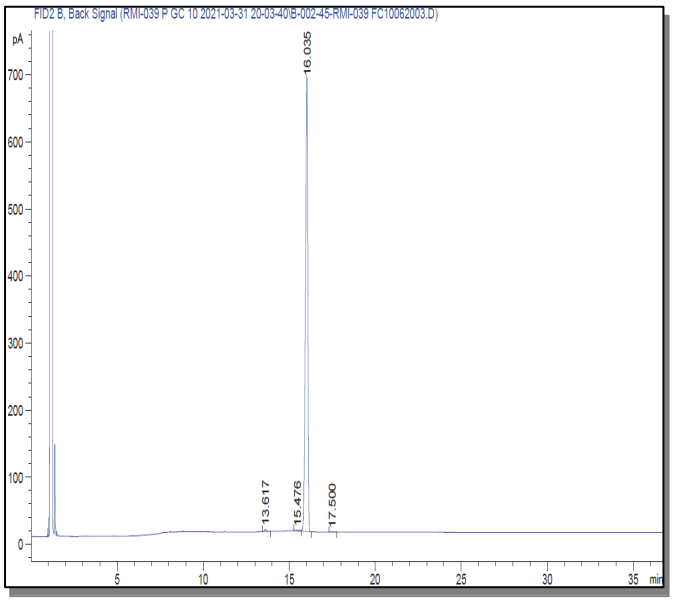
Time (min)	% A	% B
0.0	15	85
8.0	80	20
10.0	80	20
10.1	15	85

Flow Rate: 0.7 mL/min
Wavelength: 240 nm

Sample Name: FC10062003
Acquired: March 26, 2021

Peak #	Ret Time	Area %
1	3.43	0.09
2	3.93	0.01
3	4.06	0.01
4	4.17	0.03
5	4.23	99.77
6	4.54	0.04
7	5.07	0.02
8	5.93	0.01
9	6.57	0.01

GC/FID



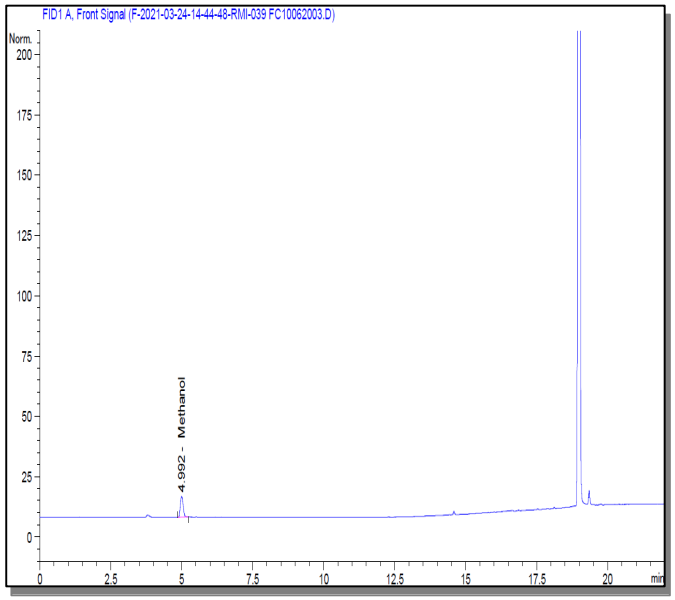
Column: DB-35ms, 30 m x 0.53 mm ID, 1.0 µm film thickness
Temp Program: 40°C to 310°C at 40°C/min hold 30 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C

Sample Name: FC10062003
Acquired: March 31, 2021

Peak #	Ret Time	Area %
1	13.62	0.35
2	15.48	0.26
3	16.04	99.34
4	17.50	0.05

Spectral and Physical Data (cont.)

Residual Solvent Analysis by GC/FID Headspace

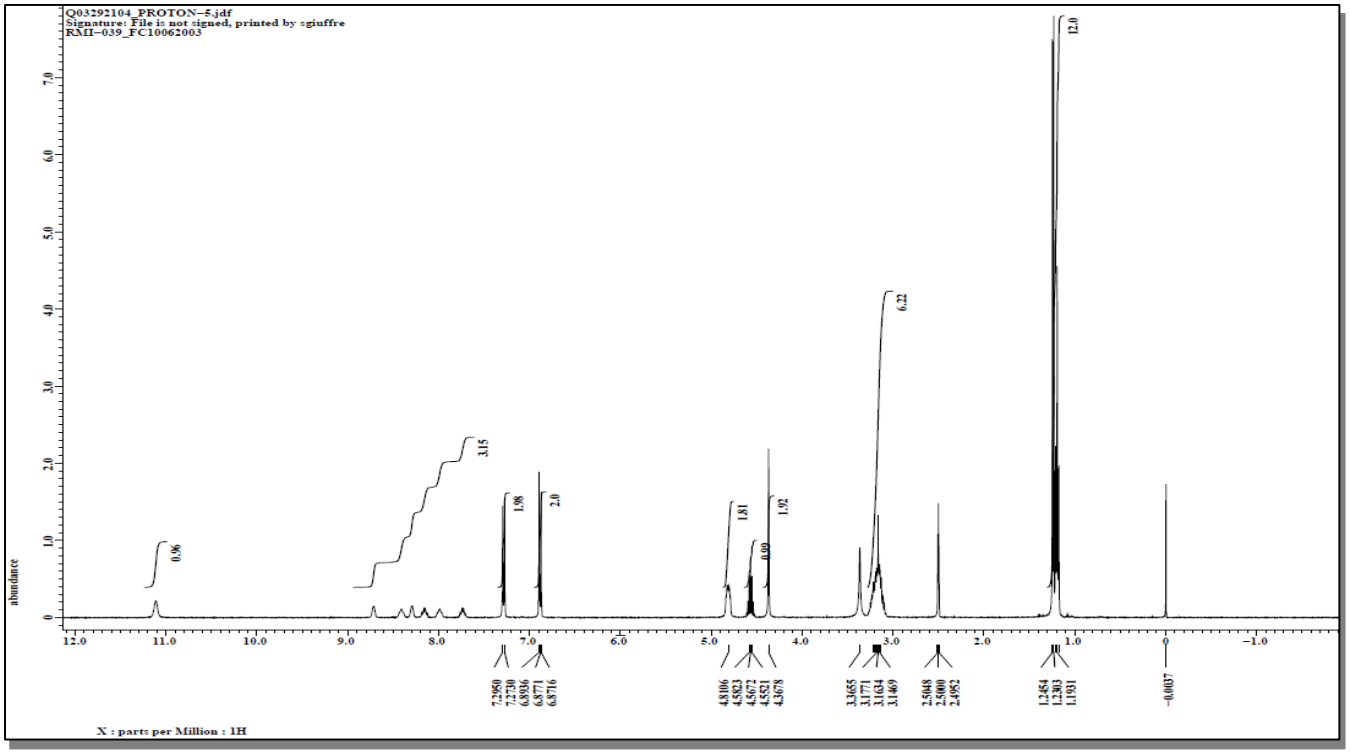


Column:	DB-ALC1 30 m x 0.53 mm, 3 µm film thickness
Temp Program:	40°C hold 12 min to 220°C at 40°C/min hold 5.5 min
Carrier Gas:	Helium
Flow Rate:	2.0 mL/min
Detector Heater Temp:	250°C
Injector:	Headspace Sampler
HS Oven Temp:	60°C
Vial Equilibration:	10 minutes
Sample Name:	FC10062003
Acquired:	March 24, 2021

Peak	Compound	Area	Weight %
1	Methanol	59.55	0.49
2	NMP	NA	NA
Total			**0.49**

^{1}H NMR

Instrument: JEOL ECS 400
Solvent: DMSO-D_6



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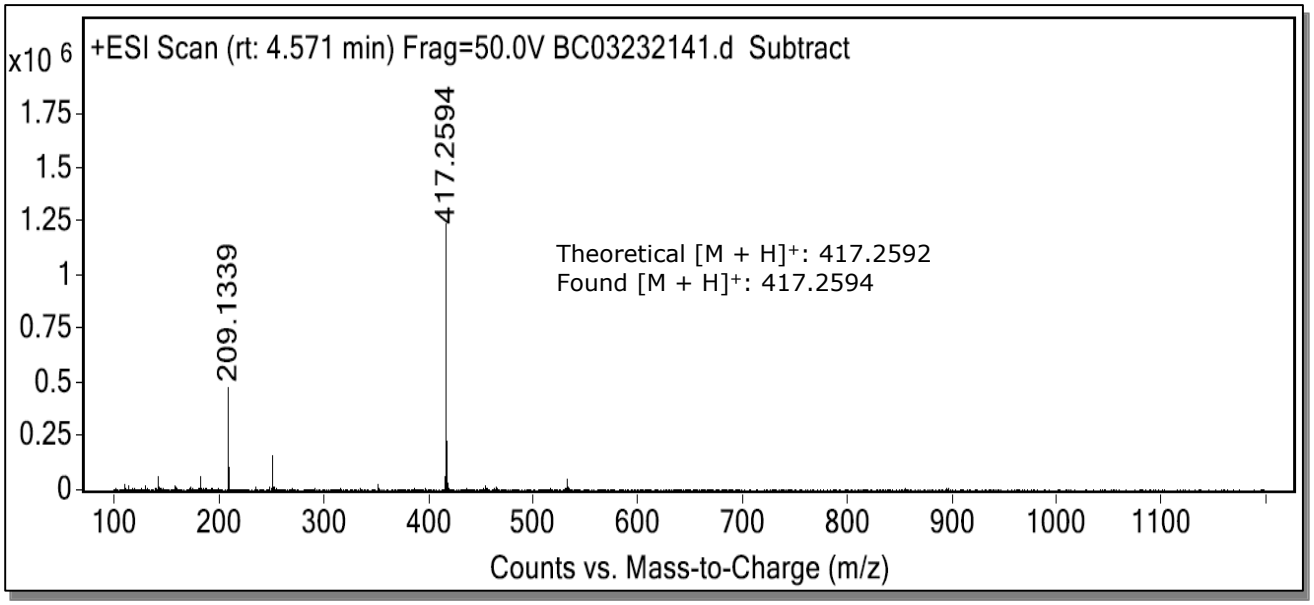
Spectral and Physical Data (cont.)

LC/MS

Column: Ascentis Express C18, 2.7 µm, 3.0 x 50 mm
Mobile Phase: A: 0.1% Formic acid
B: Acetonitrile
Gradient:

Time (min)	% A	% B
0.0	90	10
0.5	90	10
4.0	50	50
5.8	50	50
6.0	90	10
8.0	90	10

Flow Rate: 0.4 mL/min
Scan Range: 100-1200 amu
Ionization: Electrospray, Positive Ion
Instrument: Agilent 6545XT QTOF
Acquired: March 23, 2021



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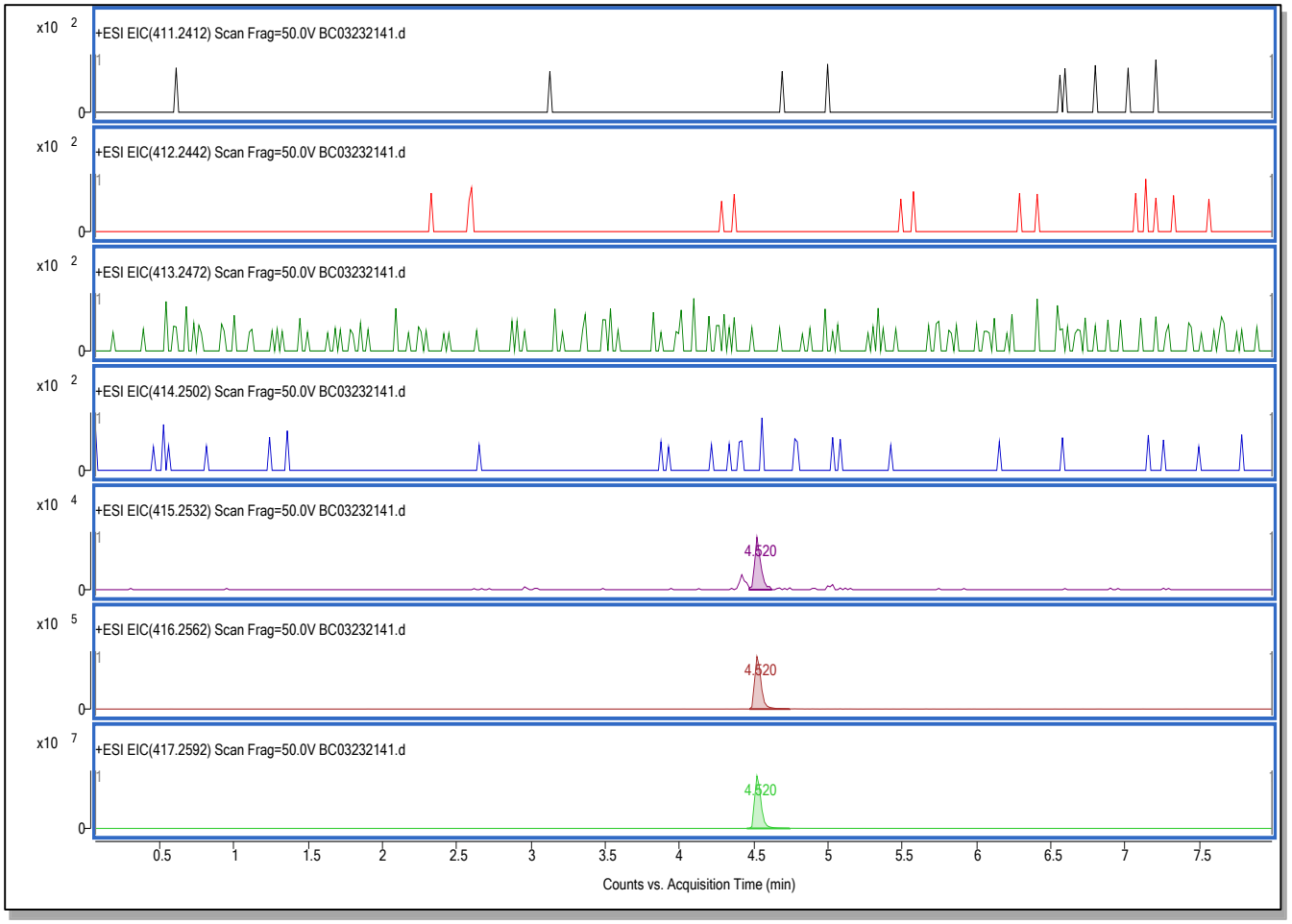
Spectral and Physical Data (cont.)

Isotopic Purity by LC/MS SIM

Column: Ascentis Express C18, 2.7 µm, 3.0 x 50 mm
Mobile Phase: A: 0.1% Formic acid
B: Acetonitrile
Gradient:

Time (min)	% A	% B
0.0	90	10
0.5	90	10
4.0	50	50
5.8	50	50
6.0	90	10
8.0	90	10

Flow Rate: 0.4 mL/min
Scan Range: 411-417 amu
Ionization: Electrospray, Positive Ion
Instrument: Agilent 6545XT QTOF
Acquired: March 23, 2021



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Stability

Short term stability studies have been performed in multiple storage conditions for a period of up to four weeks. Short term data is utilized to support transport conditions and normal laboratory use. Real-time stability studies are performed at the recommended storage conditions over the life of the product.

Short Term Stability: *A summary of stability findings for a related product (I-055-1ML, Isotonitazene HCl) is listed below.*

Storage Condition	Targeted Mean Kinetic Temperature (MKT)	Time Period/Result
Freezer	-20°C	No decrease in purity was noted after four weeks.
Refrigerator	5°C	
Room Temperature	20°C	
40°C	40°C	

Transport/Shipping: *Stability studies support the transport of this product at ambient conditions.*

Commutability

This standard is a solution of a pure substance in an organic solvent and is a Primary Standard. This Primary Standard is suitable for use in the preparation of calibrators and/or controls in any biological matrix. This standard is not in a biological matrix and therefore commutability to methods or standards in biological matrices does not apply.

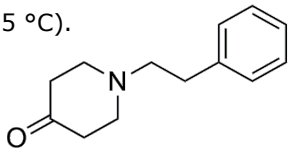
COA Revision History

Revision No.	Date	Reason for Revision
00	June 16, 2021	Initial version.

Certified Reference Material - Certificate of Analysis

N-Phenethyl-4-piperidone (NPP), Primary Measurement Standard

Product No.: P-165-1ML
Lot No.: FN06302103
Description of CRM: N-Phenethyl-4-piperidone (NPP) in Acetonitrile (Solution)
Retest Date: September 2022 See Stability Section
Storage: Store unopened in freezer (-10 °C to -25 °C).
Shipping: Ambient. See Stability Section
Chemical formula: $C_{13}H_{17}NO$
CAS No.: 39742-60-4



Cerilliant Quality
ISO 17034
ISO/IEC 17025
ISO 14001
ISO 9001

Analyte	Certified Concentration ± associated uncertainty U, $u = k * u$ ($k = 2$)
N-Phenethyl-4-piperidone (NPP)	**1.000 ± 0.006 mg/mL**

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. See "Details on metrological traceability" on page 3.

Measurement method: The certified value is calculated from high precision weighing of thoroughly characterized starting material. See "Details about certification process" on page 3.

Intended use: This Certified Reference Material is suitable for the in vitro identification, calibration, and quantification of the analyte(s) in analytical and R&D applications. Not suitable for human or animal consumption.

Minimum sample size: 1 µL for quantitative applications

Instructions for handling and correct use: Concentration is corrected for chromatographic purity, residual water, residual solvents, and residual inorganics. No adjustment required before use.
Users should quantitatively transfer desired volume using established good laboratory practices to spike into matrix or to dilute to the desired concentration. Each ampoule is intended for one-time use.

Health and safety information: Danger. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Accreditation: Cerilliant Corp. is accredited by the US accreditation authority ANAB as registered reference material producer AR-1353 in accordance with ISO 17034 and registered testing laboratory AT-1352 according to ISO/IEC 17025.

Darron Ellsworth, Quality Assurance Manager

August 06, 2021
Issue Date

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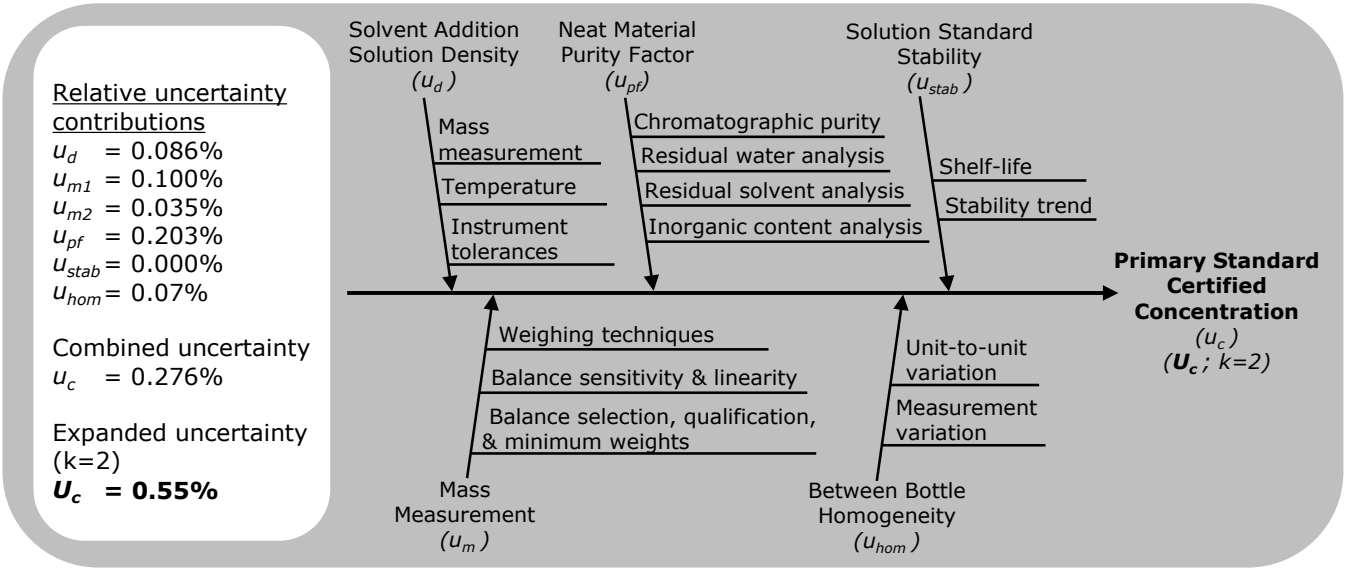
Packaging:	2 mL amber USP Type 1 glass ampoule containing not less than 1 mL of certified solution. Ampoules are overfilled to ensure a minimum of 1 mL volume can be transferred when using a 1mL Class A volumetric pipette.
Details on starting materials:	Each raw material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques and is assigned a Mass Balance Purity Factor. Spectral data is provided on subsequent pages of this CoA.
Certificate of Origin:	Cerilliant Corporation certifies no material of animal origin (BSE/TSE) was used in the preparation of this product. This material is a product of the USA.

Associated uncertainty:

The uncertainty has been calculated by statistical analysis of all aspects of our production system and incorporated uncertainty of the mass balance purity factor, material density, balance, weighing technique, and homogeneity. Uncertainty components of the gravimetrically prepared Primary Standard concentration are shown in the figure below. Uncertainty is expressed as an expanded uncertainty in accordance with ISO 17034 at the approximate 95% confidence interval using a coverage factor of k=2. Uncertainty contribution from neat material homogeneity was established to be negligible through establishment of process controls and verification of the control process. Stability uncertainty was determined to be negligible by regression analysis.



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Details on metrological traceability:

- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- Fill volume to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.
- The density and material Mass Balance Purity Factor of each raw material is traceable to the SI and higher order reference materials through mass measurement and instrument qualification and calibrations.

Details about certification process:

This standard has been prepared and certified under the ISO 17034, ISO/IEC 17025, and ISO 9001 standards. This standard meets the requirements of a Certified Reference Material and a Primary Standard as defined by ISO and is traceable to the SI and higher order standards through an unbroken chain of comparisons.

- Nominal concentration is calculated based on: the actual mass; Mass balance purity factor of the analyte(s); measured mass of the solution; and the density of the pure diluent at 20°C.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.
- Concentration is verified against an independently prepared calibration solution gravimetrically prepared.
- Additional certification information available upon request.

Solution Standard Verification

Concentration accuracy and within- and between-bottle homogeneity are analytically verified against an independently prepared calibration solution.

Standard Solution Assay Parameters		**Calibration Curve**	
Analysis Method:	HPLC/UV	**Calibration Curve:**	Linear Regression
Column:	Ascentis Express C18, 2.7 µm, 3.0 x 100 mm	**Number of Points:**	4
Mobile Phase:	Acetonitrile:0.1% Phosphoric acid in Water (12:88)	**Linearity (r) :**	1.000
Flow Rate:	1.25 mL/min		
Wavelength:	210 nm		

		Verified Concentration (mg/mL)	**%RSD - Homogeneity**
Standard Solution	**Lot Number**	**Actual Results**	**Actual Results**
New Lot	FN06302103	1.002	0.2

- Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.
- Within-sample and between-sample homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. Multiple samples pulled from across the lot using a random stratified sampling plan were analyzed to verify homogeneity. % RSD results shown above for the New Lot demonstrate ampoule-to-ampoule homogeneity.

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Analyte Certification - Mass Balance Purity Factor

Each analyte is thoroughly identified and characterized using an orthogonal approach. A mass balance purity factor is assigned incorporating chromatographic purity and residual impurities. The mass balance purity factor is utilized to calculate the weighing adjustment necessary to ensure accuracy of the solution standard concentration.

Material Name:	N-Phenethyl-4-piperidone (NPP)	**Chemical Formula:**	$C_{13}H_{17}NO$
Material Lot:	FN11112006	**CAS Number:**	39742-60-4
		Molecular Weight:	203.28

Material Characterization Summary

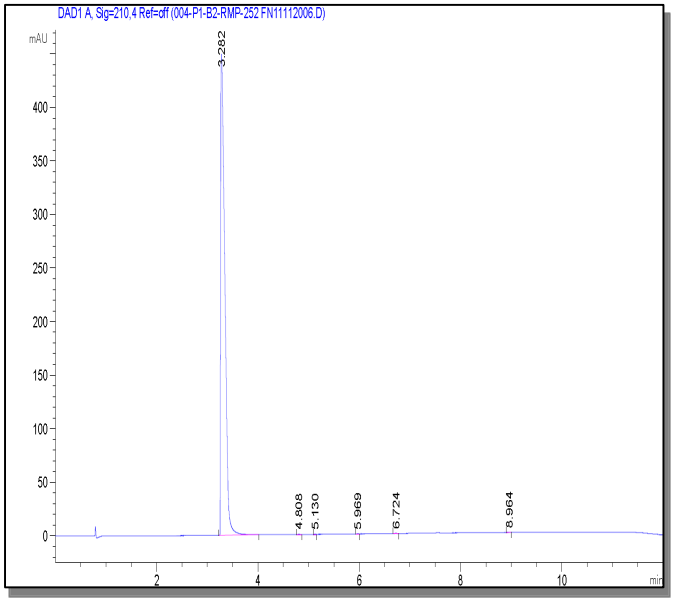
Analytical Test	Method	Results
Primary Chromatographic Purity by HPLC/UV Analysis	20384348	99.9%
Secondary Chromatographic Purity by GC/FID Analysis	20384346	> 99.9%
Identity by LC/MS Analysis	20384217	Consistent with Structure
Identity by ^{1}H-NMR Analysis	20384224	Consistent with Structure
Residual Solvent Analysis by GC/FID Headspace	20397799 [1]	0.17%
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	Below Quantitation Limit
Inorganic Content by Microash Analysis	20384350	Below Quantitation Limit
Mass Balance Purity Factor		99.73%

[1] Validated analytical method

- The primary chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- The primary purity method was selected to optimize resolution of impurities while minimizing degradation of the analyte. Secondary purity methods with orthogonal detector capabilities from the primary purity method are used as controls to confirm an accurate purity value.
- The primary chromatographic purity value is used to calculate the Mass Balance Purity Factor.
- A secondary chromatographic purity method is utilized as a control.
- Mass Balance Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- Mass Balance Purity Factor does not include adjustment for chiral and/or isotopic purity.

Spectral and Physical Data

HPLC/UV



Column: Ascentis Express C18, 2.7 µm, 3.0 x 100 mm
Mobile Phase: A: Acetonitrile
B: 0.1% Phosphoric acid in Water
Gradient:

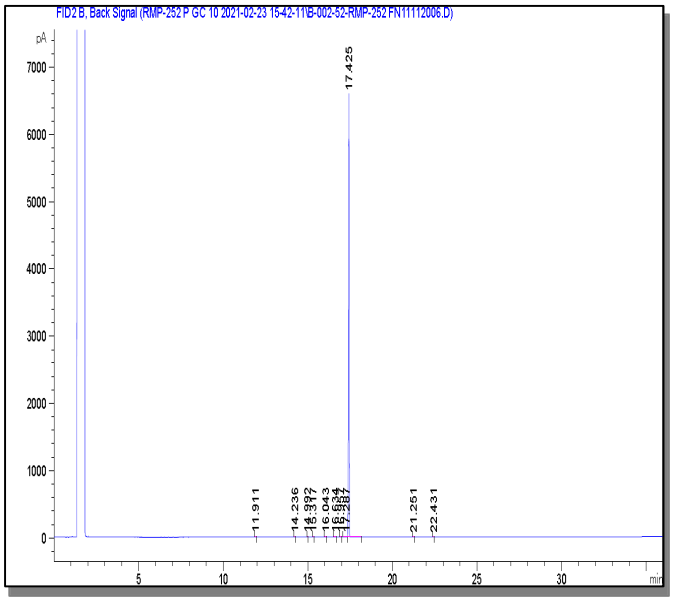
Time (min)	% A	% B
0.0	2	98
8.0	50	50
10.0	50	50
10.1	2	98

Flow Rate: 0.6 mL/min
Wavelength: 210 nm

Sample Name: FN11112006
Acquired: February 23, 2021

Peak #	Ret Time	Area %
1	3.28	99.91
2	4.81	0.03
3	5.13	0.01
4	5.97	0.01
5	6.72	0.03
6	8.96	0.01

GC/FID



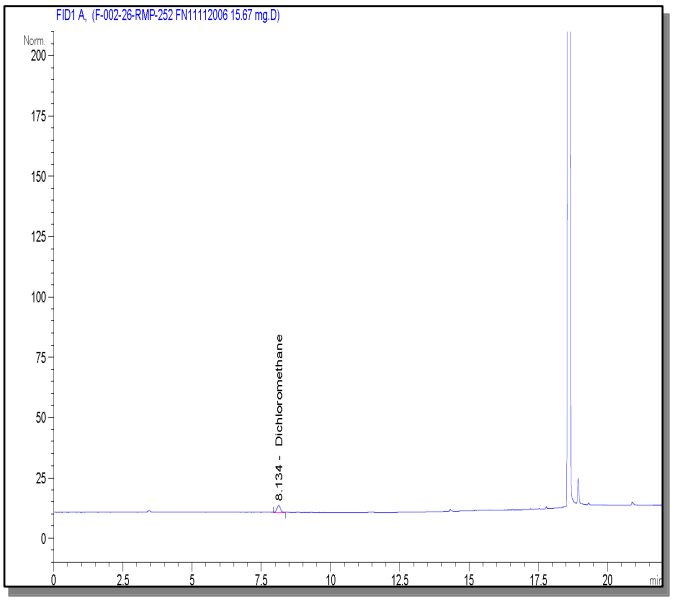
Column: DB-35ms, 30 m x 0.53 mm ID, 1.0 µm film thickness
Temp Program: 40°C to 280°C at 10°C/min hold 12 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C

Sample Name: FN11112006
Acquired: February 23, 2021

Peak #	Ret Time	Area %
1	11.91	0.00
2	14.24	0.00
3	14.99	0.00
4	15.32	0.00
5	16.04	0.01
6	16.63	0.00
7	16.96	0.00
8	17.29	0.01
9	17.43	99.96
10	21.25	0.01
11	22.43	0.00

Spectral and Physical Data (cont.)

Residual Solvent Analysis by GC/FID Headspace

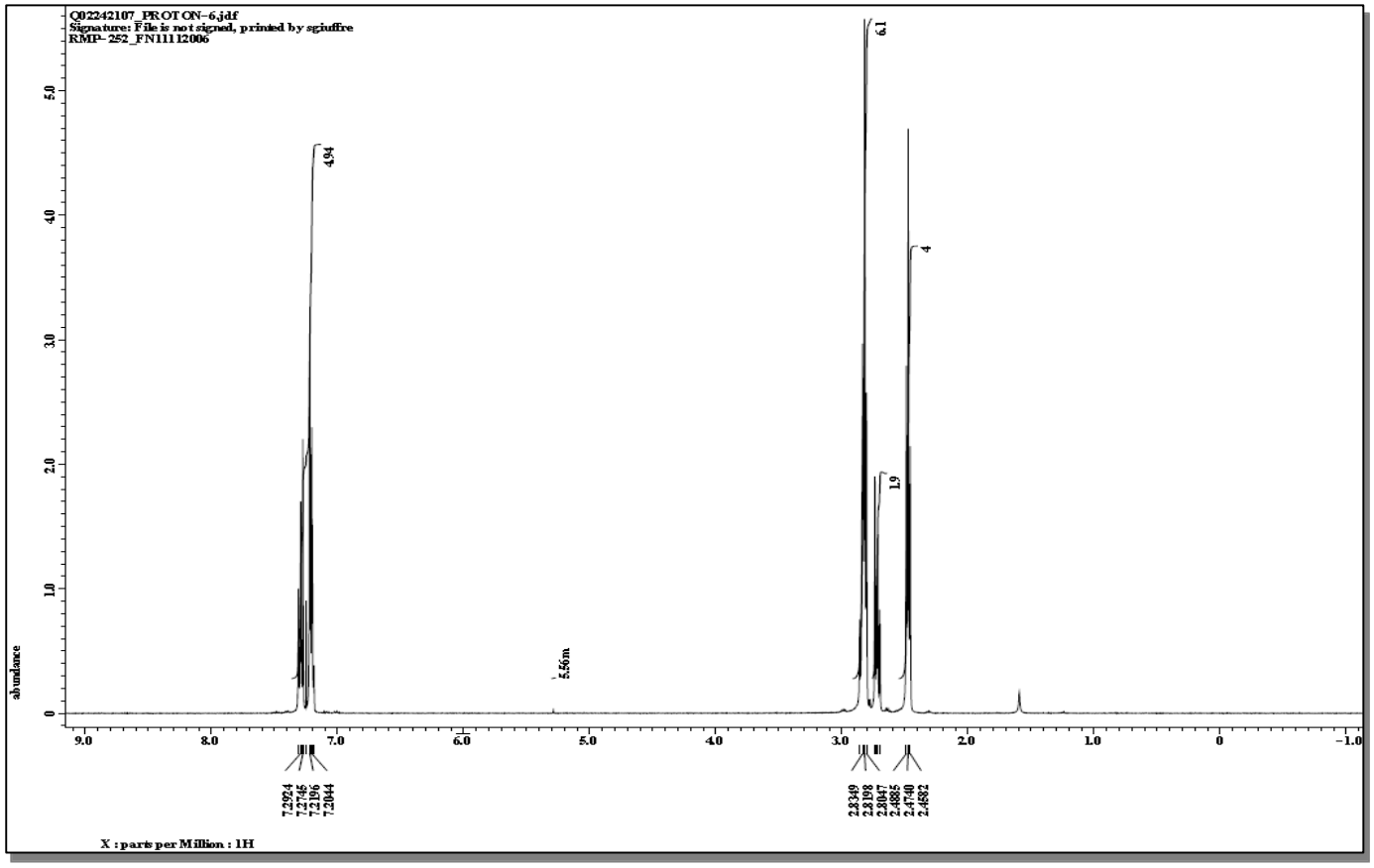


Column:	DB-ALC1 30 m x 0.53 mm, 3 µm film thickness
Temp Program:	40°C hold 12 min to 220°C at 40°C/min hold 5.5 min
Carrier Gas:	Helium
Flow Rate:	2.0 mL/min
Detector Heater Temp:	250°C
Injector:	Headspace Sampler
HS Oven Temp:	60°C
Vial Equilibration:	10 minutes
Sample Name:	FN11112006
Acquired:	March 02, 2021

Peak	Compound	Area	Weight %
1	Dichloromethane	25.10	0.17
2	NMP	NA	NA
Total			**0.17**

^{1}H NMR

Instrument:	JEOL ECS-400
Solvent:	Chloroform-D



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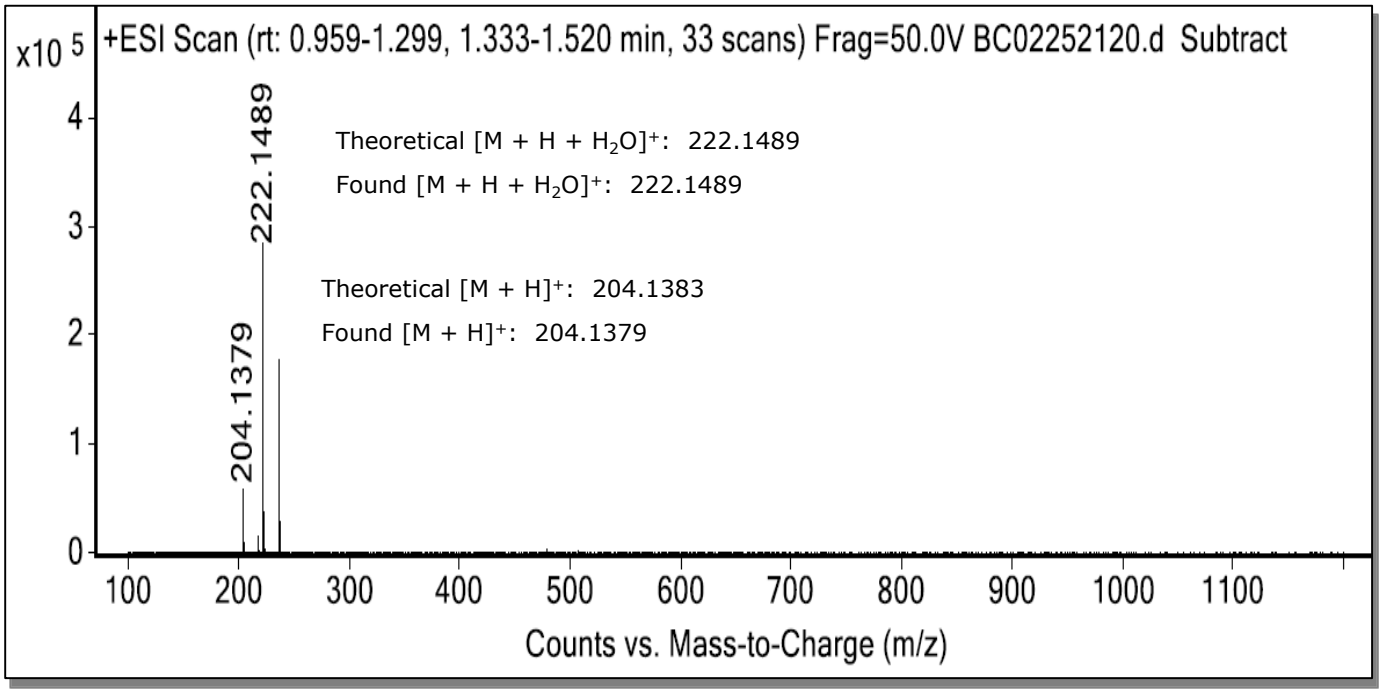
Spectral and Physical Data (cont.)

LC/MS

Column:	Ascentis Express C18, 2.7 µm, 3.0 x 50 mm	**Flow Rate:**	0.4 mL/min
Mobile Phase:	A: 0.1% Formic acid in Water B: Acetonitrile	**Scan Range:**	100-1200 amu
		Ionization:	Electrospray, Positive Ion
		Instrument:	Agilent 6545XT QTOF
Gradient:		**Acquired:**	February 26, 2021

Time (min)	% A	% B
0.0	90	10
0.5	90	10
4.0	50	50
5.8	50	50
6.0	90	10
8.0	90	10



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Stability

Short term stability studies have been performed in multiple storage conditions for a period of up to one week. Short term data is utilized to support transport conditions and normal laboratory use. Real-time stability studies are performed at the recommended storage conditions over the life of the product.

Short Term Stability: *A summary of stability findings for this product is listed below.*

Storage Condition	Targeted Mean Kinetic Temperature (MKT)	Time Period/Result
Freezer	-20°C	No decrease in purity was noted after one week.
Refrigerator	5°C	
Room Temperature	20°C	
40°C	40°C	

Transport/Shipping: *Stability studies support the transport of this product at ambient conditions.*

Commutability

This standard is a solution of a pure substance in an organic solvent and is a Primary Standard. This Primary Standard is suitable for use in the preparation of calibrators and/or controls in any biological matrix. This standard is not in a biological matrix and therefore commutability to methods or standards in biological matrices does not apply.

COA Revision History

Revision No.	Date	Reason for Revision
00	August 06, 2021	Initial version.

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock, TX 78665, USA, Tel: 800-848-7837 / 512-238-9974

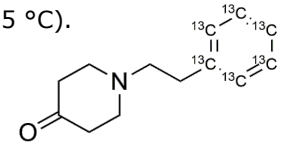
Certified Reference Material - Certificate of Analysis

N-Phenethyl-4-piperidone-$^{13}C_6$ (NPP-$^{13}C_6$), Primary Measurement Standard

1-Phenethyl-4-piperidone-$^{13}C_6$

Cerilliant Quality
ISO 17034
ISO/IEC 17025
ISO 14001
ISO 9001

Product No.: P-167-1ML
Lot No.: FN06142104
Description of CRM: N-Phenethyl-4-piperidone-$^{13}C_6$ (NPP-$^{13}C_6$) in Acetonitrile (Solution)
Retest Date: September 2022 See Stability Section
Storage: Store unopened in freezer (-10 °C to -25 °C).
Shipping: Ambient. See Stability Section
Chemical formula: $C_7{}^{13}C_6H_{17}NO$
CAS No.: NA



Analyte	Certified Concentration ± associated uncertainty U, $u = k * u$ ($k = 2$)
N-Phenethyl-4-piperidone-$^{13}C_6$ (NPP-$^{13}C_6$)	**1.000 ± 0.006 mg/mL**

Metrological traceability: Traceable to the SI and higher order standards from NIST through an unbroken chain of comparisons. See "Details on metrological traceability" on page 3.

Measurement method: The certified value is calculated from high precision weighing of thoroughly characterized starting material. See "Details about certification process" on page 3.

Intended use: This Certified Reference Material is suitable for the in vitro identification, calibration, and quantification of the analyte(s) in analytical and R&D applications. Not suitable for human or animal consumption.

Minimum sample size: 1 µL for quantitative applications

Instructions for handling and correct use: Concentration is corrected for chromatographic purity, residual water, residual solvents, and residual inorganics. No adjustment required before use.
Users should quantitatively transfer desired volume using established good laboratory practices to spike into matrix or to dilute to the desired concentration.
Each ampoule is intended for one-time use.
For MS Applications, we advise laboratories not to mix lots during a single sequence.

Health and safety information: Danger. Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Accreditation: Cerilliant Corp. is accredited by the US accreditation authority ANAB as registered reference material producer AR-1353 in accordance with ISO 17034 and registered testing laboratory AT-1352 according to ISO/IEC 17025.

Darron Ellsworth, Quality Assurance Manager

August 09, 2021
Issue Date

Cerilliant Corporation, 811 Paloma Drive, Suite A Round Rock, TX 78665, USA, Tel: 800-848-7837 / 512-238-9974

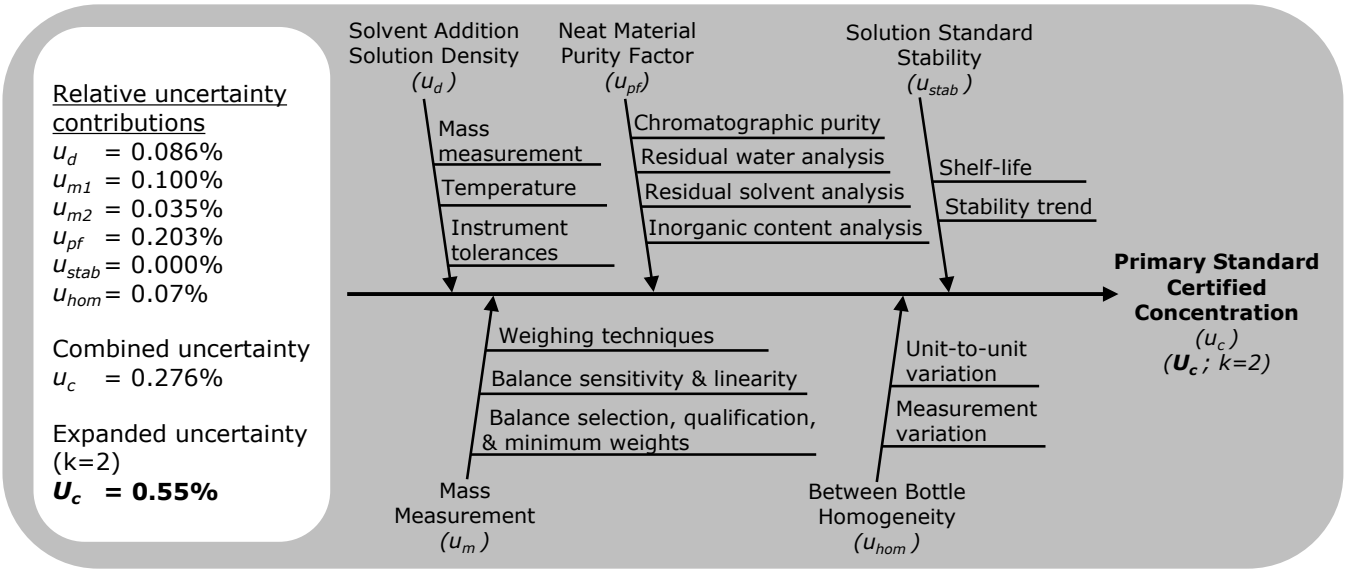
Packaging: 2 mL amber USP Type 1 glass ampoule containing not less than 1 mL of certified solution. Ampoules are overfilled to ensure a minimum of 1 mL volume can be transferred when using a 1mL Class A volumetric pipette.

Details on starting materials: Each raw material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques and is assigned a Mass Balance Purity Factor. Spectral data is provided on subsequent pages of this CoA.

Certificate of Origin: Cerilliant Corporation certifies no material of animal origin (BSE/TSE) was used in the preparation of this product. This material is a product of the USA.

Associated uncertainty:

The uncertainty has been calculated by statistical analysis of all aspects of our production system and incorporated uncertainty of the mass balance purity factor, material density, balance, weighing technique, and homogeneity. Uncertainty components of the gravimetrically prepared Primary Standard concentration are shown in the figure below. Uncertainty is expressed as an expanded uncertainty in accordance with ISO 17034 at the approximate 95% confidence interval using a coverage factor of k=2. Uncertainty contribution from neat material homogeneity was established to be negligible through establishment of process controls and verification of the control process. Stability uncertainty was determined to be negligible by regression analysis.



Details on metrological traceability:

- This standard has been gravimetrically prepared using balances that have been fully qualified and calibrated to ISO 17025 requirements. All calibrations utilize NIST traceable weights which are calibrated externally by a qualified ISO 17025 accredited calibration laboratory to NIST standards. Qualification of each balance includes the assignment of a minimum weighing by a qualified and ISO 17025 accredited calibration vendor taking into consideration the balance and installed environmental conditions to ensure compliance with USP tolerances of NMT 0.10% relative error.
- Fill volume to predetermined specifications is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.
- The density and material Mass Balance Purity Factor of each raw material is traceable to the SI and higher order reference materials through mass measurement and instrument qualification and calibrations.

Details about certification process:

This standard has been prepared and certified under the ISO 17034, ISO/IEC 17025, and ISO 9001 standards. This standard meets the requirements of a Certified Reference Material and a Primary Standard as defined by ISO and is traceable to the SI and higher order standards through an unbroken chain of comparisons.

- Nominal concentration is calculated based on: the actual mass; Mass balance purity factor of the analyte(s); measured mass of the solution; and the density of the pure diluent at 20°C.
- Fill volume is gravimetrically verified throughout the dispensing process using qualified and calibrated balances.
- Concentration is verified against an independently prepared calibration solution gravimetrically prepared.
- Additional certification information available upon request.

Solution Standard Verification

Concentration accuracy and within- and between-bottle homogeneity are analytically verified against an independently prepared calibration solution.

Standard Solution Assay Parameters		**Calibration Curve**	
Analysis Method:	HPLC/UV	**Calibration Curve:**	Linear Regression
Column:	Ascentis Express C18, 2.7 µm, 3.0 x 100 mm	**Number of Points:**	4
Mobile Phase:	Acetonitrile:0.1% Phosphoric acid in Water (12:88)	**Linearity (r) :**	1.000
Flow Rate:	1.25 mL/min		
Wavelength:	210 nm		

		Verified Concentration (mg/mL)	**%RSD - Homogeneity**
Standard Solution	**Lot Number**	**Actual Results**	**Actual Results**
New Lot	FN06142104	0.992	0.6

- Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution.
- Within-sample and between-sample homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. Multiple samples pulled from across the lot using a random stratified sampling plan were analyzed to verify homogeneity. % RSD results shown above for the New Lot demonstrate ampoule-to-ampoule homogeneity.

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Analyte Certification - Mass Balance Purity Factor

Each analyte is thoroughly identified and characterized using an orthogonal approach. A mass balance purity factor is assigned incorporating chromatographic purity and residual impurities. The mass balance purity factor is utilized to calculate the weighing adjustment necessary to ensure accuracy of the solution standard concentration.

Material Name:	N-Phenethyl-4-piperidone-$^{13}C_6$ (NPP-$^{13}C_6$)	**Chemical Formula:**	$C_7{}^{13}C_6H_{17}NO$
		CAS Number:	NA
Material Lot:	FN06032001	**Molecular Weight:**	209.24

Material Characterization Summary

Analytical Test	**Method**	**Results**	
Primary Chromatographic Purity by HPLC/UV Analysis	20384348	99.7%	
Secondary Chromatographic Purity by GC/FID Analysis	20384346	99.5%	
Identity by GC/MS Analysis	20384214	Consistent with Structure	
Isotopic Purity and Distribution by GC/MS SIM Analysis	20384214	0.48% $^{13}C_0$ vs $^{13}C_6$	
		0.35% $^{13}C_0$	11.97% $^{13}C_4$
		0.80% $^{13}C_1$	9.46% $^{13}C_5$
		0.90% $^{13}C_2$	74.34% $^{13}C_6$
		2.17% $^{13}C_3$	
Identity by ^{1}H-NMR Analysis	20384224	Consistent with Structure	
Residual Solvent Analysis by GC/FID Headspace	20397799 [1]	0.10%	
Residual Water Analysis by Karl Fischer Coulometry	20398075 [1]	1.25%	
Inorganic Content by Microash Analysis	20384350	< 0.2%	
Mass Balance Purity Factor		98.39%	

[1] Validated analytical method

- The primary chromatographic purity is calculated as the average of two independently performed analyses utilizing two different methods. Acceptance criteria requires the purity values to be within 0.5% of each other.
- The primary purity method was selected to optimize resolution of impurities while minimizing degradation of the analyte. Secondary purity methods with orthogonal detector capabilities from the primary purity method are used as controls to confirm an accurate purity value.
- The primary chromatographic purity value is used to calculate the Mass Balance Purity Factor.
- A secondary chromatographic purity method is utilized as a control.
- Mass Balance Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- Mass Balance Purity Factor does not include adjustment for chiral and/or isotopic purity.

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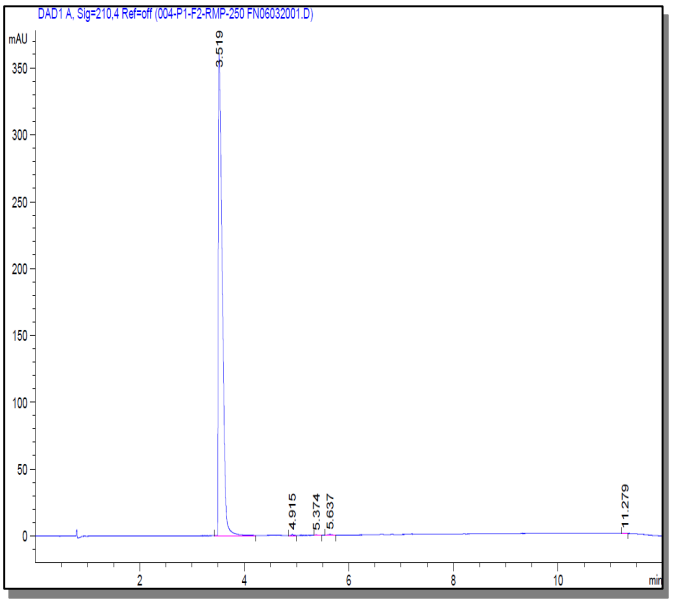
Spectral and Physical Data

HPLC/UV



Column: Ascentis Express C18, 2.7 µm, 3.0 x 100 mm

Mobile Phase: A: Acetonitrile
B: 0.1% Phosphoric acid in Water

Gradient:

Time (min)	% A	% B
0.0	2	98
8.0	50	50
10.0	50	50
10.1	2	98

Flow Rate: 0.6 mL/min

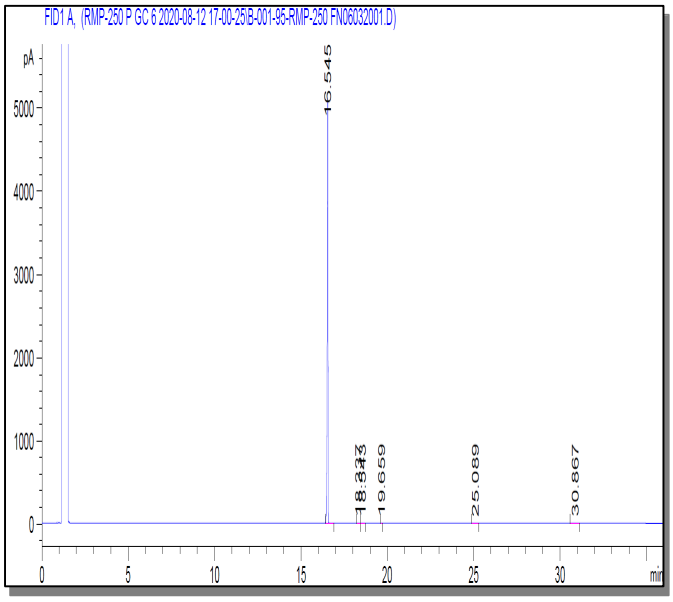
Wavelength: 210 nm

Sample Name: FN06032001

Acquired: August 29, 2020

Peak #	Ret Time	Area %
1	3.52	99.62
2	4.92	0.09
3	5.37	0.08
4	5.64	0.19
5	11.28	0.03

GC/FID



Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness

Temp Program: 40°C to 280°C at 10°C/min hold 12 min

Injector Temp: Cool-on-Column

Detector Temp: 325°C

Sample Name: FN06032001

Acquired: August 12, 2020

Peak #	Ret Time	Area %
1	16.55	99.53
2	18.34	0.10
3	18.54	0.11
4	19.66	0.00
5	25.09	0.14
6	30.87	0.11

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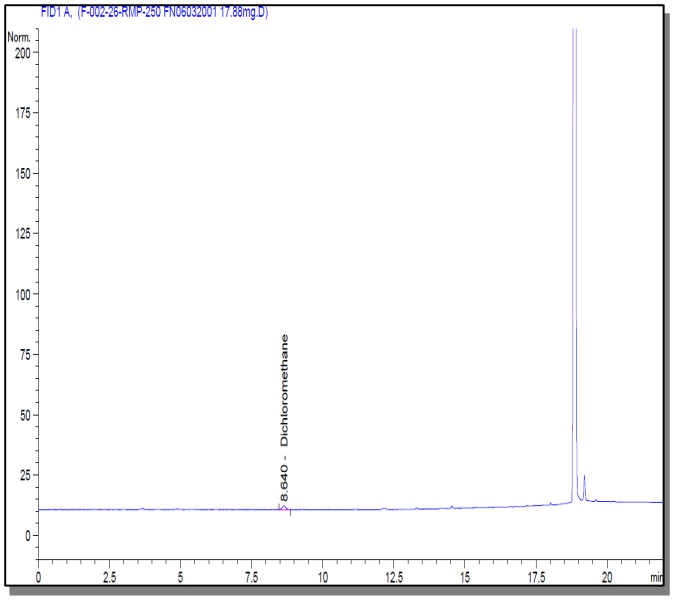
Spectral and Physical Data (cont.)

Residual Solvent Analysis by GC/FID Headspace

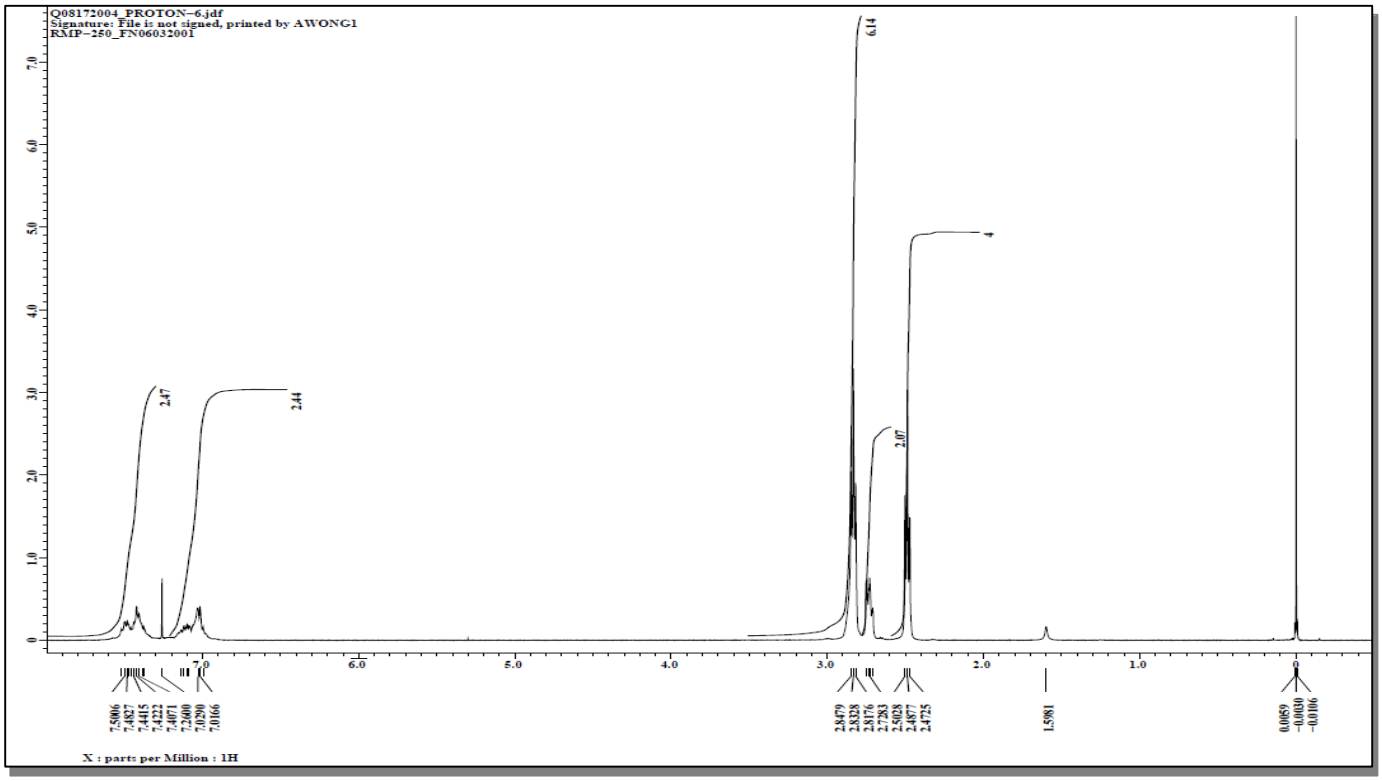


Column:	DB-ALC1 30 m x 0.53 mm, 3 µm film thickness
Temp Program:	40°C hold 12 min to 220°C at 40°C/min hold 5.5 min
Carrier Gas:	Helium
Flow Rate:	2.0 mL/min
Detector Heater Temp:	250°C
Injector:	Headspace Sampler
HS Oven Temp:	60°C
Vial Equilibration:	10 minutes
Sample Name:	FN06032001
Acquired:	August 04, 2020

Peak	Compound	Area	Weight %
1	Dichloromethane	14.67	0.10
2	NMP	NA	NA
Total			**0.10**

^{1}H NMR

Instrument:	JEOL ECS 400
Solvent:	Chloroform-D



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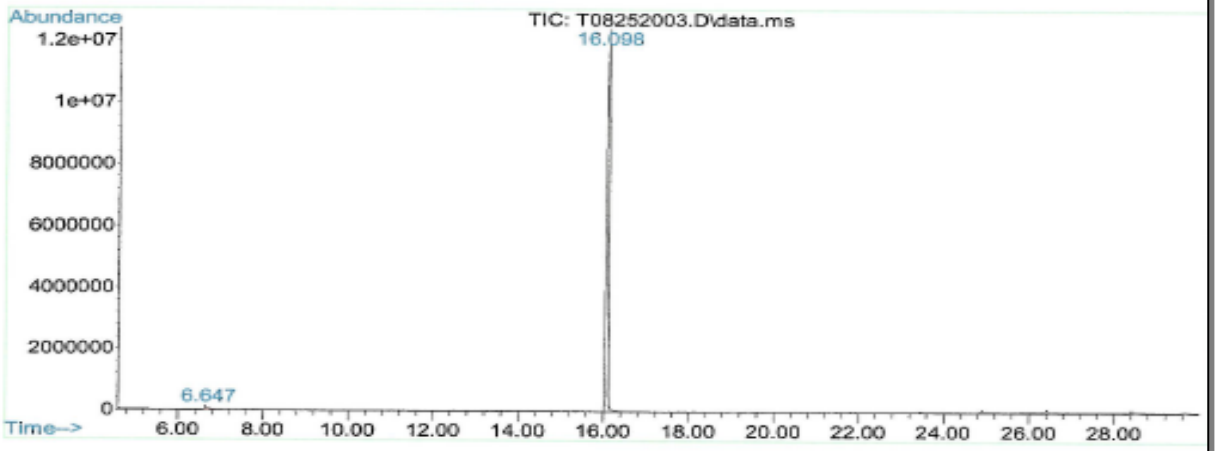
Spectral and Physical Data (cont.)

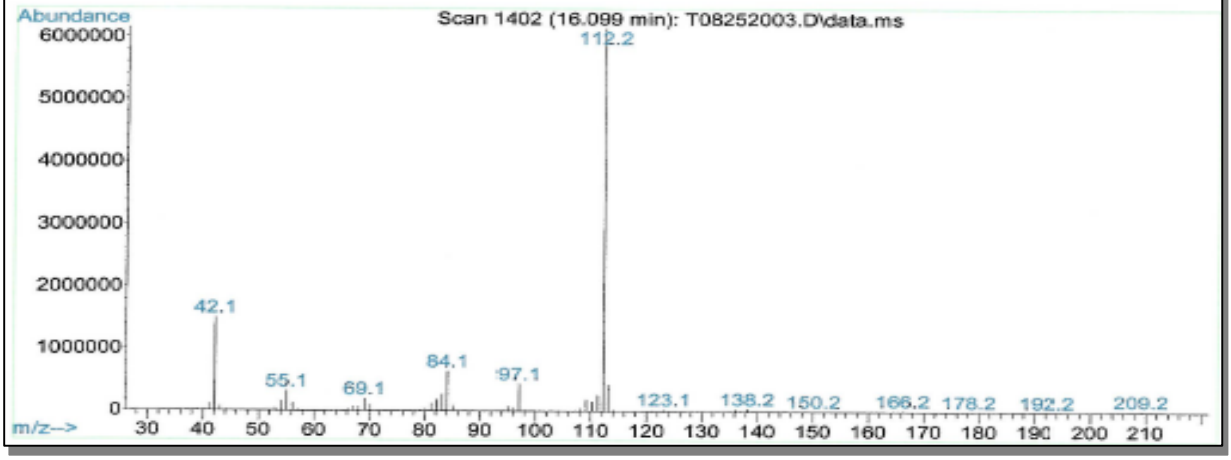
GC/MS

Compound Name	:	NNP-13C6
Lot Number	:	FN06032001
Instrument	:	Agilent GCMS
Operator	:	ECM(SGIUFFRE)
Date Reported	:	Wed Aug 26 06:08:41 2020
Column Type	:	DB-5ms, 30m x 0.25mm ID, 0.25um film thickness
Temp. Program	:	50°C to 300°C @ 10°C/min (hold for 5 min)
Injector Temp.	:	Cool on-column
Carrier Gas	:	Helium
Flow Rate (mL\min)	:	0.80 mL/min
Transfer Line Temp.	:	280°C
Scan Range	:	35-400

Total Ion Chromatogram



Mass Spectrum



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Stability

Short term stability studies have been performed in multiple storage conditions for a period of up to one week. Short term data is utilized to support transport conditions and normal laboratory use. Real-time stability studies are performed at the recommended storage conditions over the life of the product.

Short Term Stability: *A summary of stability findings for a related product (P-165-1ML, N-Phenethyl-4-piperidone (NPP)) is listed below.*

Storage Condition	Targeted Mean Kinetic Temperature (MKT)	Time Period/Result
Freezer	-20°C	No decrease in purity was noted after one week.
Refrigerator	5°C	
Room Temperature	20°C	
40°C	40°C	

Transport/Shipping: *Stability studies support the transport of this product at ambient conditions.*

Commutability

This standard is a solution of a pure substance in an organic solvent and is a Primary Standard. This Primary Standard is suitable for use in the preparation of calibrators and/or controls in any biological matrix. This standard is not in a biological matrix and therefore commutability to methods or standards in biological matrices does not apply.

COA Revision History

Revision No.	Date	Reason for Revision
00	August 09, 2021	Initial version.

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