

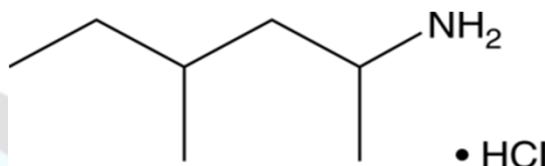
Certificate of Analysis

Methylhexanamine HCl

DMMA HCl

Cerilliant Quality
ISO GUIDE 34
ISO/IEC 17025
ISO 13485
ISO 9001
GMP/GLP

Catalog Number: M-157
Solution Lot: FN081012-01
Retest Date: November 2015
Solvent: Methanol
Volume per Ampule: Not less than 1 mL
Storage: Store unopened in freezer.
Shipping: Ambient. See Stability Section.
Intended Use: For R&D/ analytical purposes only. Not suitable for human or animal consumption.
Safety: Flammable, Poison



- Retest Date - stability studies ongoing. Certificate of Analysis will be updated upon completion of retest.
- Ampules are overfilled to ensure a minimum 1 mL volume fill. We advise laboratories to use measured volumes of this standard solution before diluting to the desired concentration.
- For quantitative applications, the minimum sample size for intended use is 1 μ L.

Component	Solution Purity	Certified Concentration
Methylhexanamine HCl	95.9%	1.000 \pm 0.006 mg/mL (as free base)
<ul style="list-style-type: none"> Uncertainty of the concentration is expressed as an expanded uncertainty in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of $k = 2$ and has been calculated by statistical analysis of our production system and incorporates uncertainty of the purity factor, material density, and balance and weighing technique. This standard is prepared gravimetrically and mass results are reported on the conventional basis for weighing in air. Concentration is calculated based on: the actual measured mass; Purity Factor of the analyte(s); measured mass of the solution; and the density of the pure diluent at 20°C. Concentration is corrected for chromatographic purity, residual water, residual solvents and residual inorganics. 		

Solution Standard Verification and Homogeneity

Standard Solution	Lot Number	Verified Concentration (mg/mL)		%RSD - Homogeneity	
		Actual Results	Acceptance Criteria	Actual Results	Acceptance Criteria
New Lot	FN081012-01	1.005	$\pm 3\%$	0.6	$\leq 3\%$
<ul style="list-style-type: none"> Concentration is verified through multiple analyses and is calculated as the average of multiple analyses compared to an independently prepared calibration solution. Homogeneity of the New Lot is ensured through rigorous production process controls statistically analyzed to evaluate risk and verified by analysis. The % RSD of samples pulled from across the lot demonstrate homogeneity of the New Lot. 					

Traceability

<ul style="list-style-type: none"> Gravimetrically prepared using qualified balances calibrated semi-annually by Mettler Toledo using NIST traceable weights. Calibration verification performed weekly and prior to each use utilizing NIST traceable weights. Each balance has been assigned a minimum weighing by Mettler Toledo taking into consideration the balance and installed environmental conditions to ensure weighing complies with USP tolerances of no more than 0.1% relative error. Concentration is verified against an independently prepared calibration solution gravimetrically prepared using balances calibrated to NIST. In addition, each neat material utilized has been identified and thoroughly characterized through the use of multiple analytical techniques. Spectral data is provided on subsequent pages of the COA.
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Cerilliant certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration/retest date when stored unopened as recommended. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.




Darron Ellsworth, Quality Assurance Manager

November 26, 2014

Date

Standard Solution Assay Parameters

Analysis Method: GC/FID
Column: DB-5ms 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 60 °C to 200 °C at 40 °C/min
 200 °C to 260 °C at 15 °C/min; hold 1.5 min
Injector Temp: Cool-on-Column
Detector Temp: 325°C

Calibration Curve

Calibration Curve: Linear Regression
Number of Points: 4
Linearity (r): 1.000

Neat Material Data

Compound Name: Methylhexanamine HCl
Compound Lot: PN051812-01
Chemical Formula: C₇H₁₇N • HCl
CAS Number: 13803-74-2
Molecular Weight: 151.68

Neat Material Characterization Summary

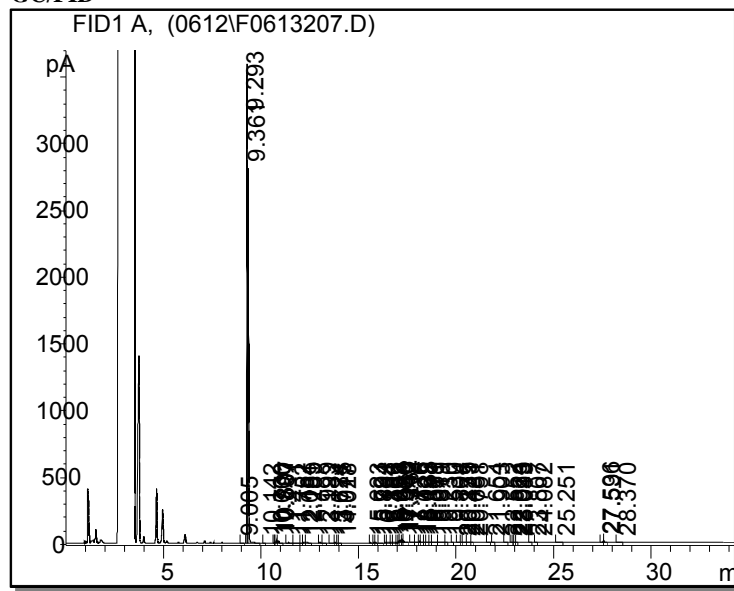
Analytical Test	Method	Results
Chromatographic Purity by GC/FID Analysis	SP10-0101	96.5%
Identity by LC/MS Analysis	SP10-0107	Consistent with Structure
Identity by ¹ H-NMR Analysis	USP <761>, SP10-0116	Consistent with Structure
Residual Solvent Analysis by GC/FID Headspace	AM1087 ¹	Below Quantitation Limit
Residual Water Analysis by Karl Fischer Coulometry	USP <921>, SP10-0103	0.94%
Inorganic Content by Microash Analysis	SP10-0135	< 0.2%
Purity Factor		95.61%

- ♦ 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 chromatographic purity value is used to calculate the Purity Factor.
- ♦ Purity Factor = [(100 - wt% residual solvent - wt% residual water - wt% residual inorganics) x Chromatographic Purity/100].
- ♦ Purity factor does not include adjustment for chiral and/or isotopic purity.

¹ Validated analytical method.

Spectral and Physical Data

GC/FID



Column: DB-5ms, 30 m x 0.53 mm ID, 1.5 µm film thickness
Temp Program: 35°C (hold 5 mins) to 280°C at 10°C/min (hold 9 mins)
Injector Temp: Cool-on-Column
Detector Temp: 325°C

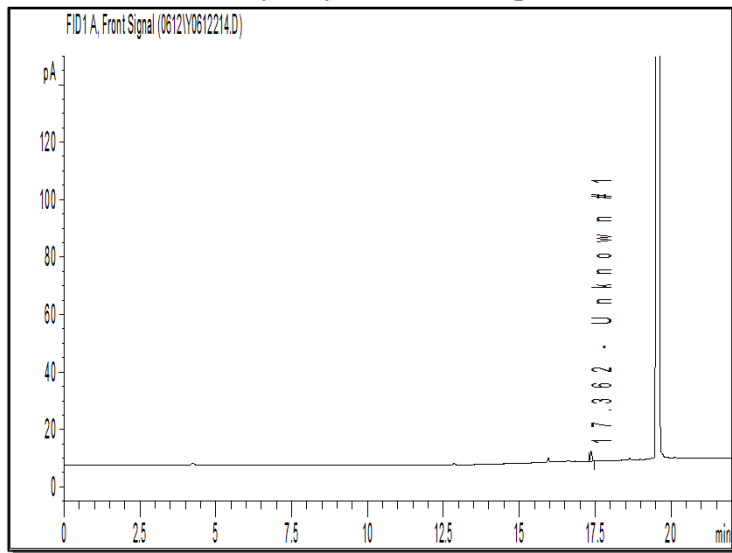
Data File Name: S:\GC\GC6\2012\0612\F0613207.D
Instrument: GC#6
Sample Name: PN051812-01
Acquired: June 14, 2012

Note: Purity value is the sum of peaks 2 and 3.

Peak #	Ret Time	Area	Height	Area %	Peak #	Ret Time	Area	Height	Area %
1	9.01	1.35	0.27	0.01	32	17.31	41.41	10.08	0.23
2	9.29	9577.83	3581.01	54.21	33	17.74	1.36	0.18	0.01
3	9.36	7400.11	2801.33	41.89	34	18.03	16.72	5.94	0.09
4	10.14	0.52	0.19	0.00	35	18.14	47.38	12.39	0.27
5	10.66	0.17	0.14	0.00	36	18.20	16.27	4.56	0.09
6	10.70	4.76	1.53	0.03	37	18.38	1.02	0.29	0.01
7	10.80	60.85	19.31	0.34	38	18.54	2.04	0.36	0.01
8	10.89	49.24	14.35	0.28	39	18.67	3.92	1.01	0.02
9	11.43	8.30	0.95	0.05	40	18.82	3.27	0.33	0.02
10	11.75	4.45	0.58	0.03	41	19.23	1.96	0.20	0.01
11	12.08	1.28	0.30	0.01	42	19.53	0.62	0.14	0.00
12	12.20	23.89	8.48	0.14	43	19.80	0.51	0.18	0.00
13	12.29	18.75	3.41	0.11	44	20.18	1.18	0.18	0.01
14	13.00	9.53	2.37	0.05	45	20.24	0.55	0.16	0.00
15	13.18	1.80	0.31	0.01	46	20.42	5.65	1.10	0.03
16	13.62	1.25	0.23	0.01	47	20.63	6.77	1.20	0.04
17	13.78	4.07	0.90	0.02	48	20.80	0.30	0.09	0.00
18	13.92	1.36	0.33	0.01	49	21.65	12.91	2.90	0.07
19	14.03	1.53	0.29	0.01	50	21.90	8.09	2.56	0.05
20	15.62	1.35	0.40	0.01	51	22.55	0.78	0.15	0.00
21	15.79	2.56	0.95	0.01	52	22.82	0.36	0.14	0.00
22	15.88	2.07	0.72	0.01	53	22.92	1.08	0.36	0.01
23	16.13	0.68	0.13	0.00	54	23.01	0.99	0.33	0.01
24	16.39	10.45	3.34	0.06	55	23.10	0.35	0.12	0.00
25	16.46	19.75	3.14	0.11	56	23.81	0.23	0.07	0.00
26	16.68	4.80	0.96	0.03	57	24.08	2.02	0.73	0.01
27	16.82	8.45	1.36	0.05	58	25.25	4.08	0.40	0.02
28	16.99	16.61	6.56	0.09	59	27.54	31.69	6.56	0.18
29	17.06	38.79	12.53	0.22	60	27.59	32.14	7.04	0.18
30	17.14	63.84	18.78	0.36	61	28.37	2.59	0.31	0.01
31	17.23	78.35	25.80	0.44					

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 (12 min) to 220°C at 40°C/min (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

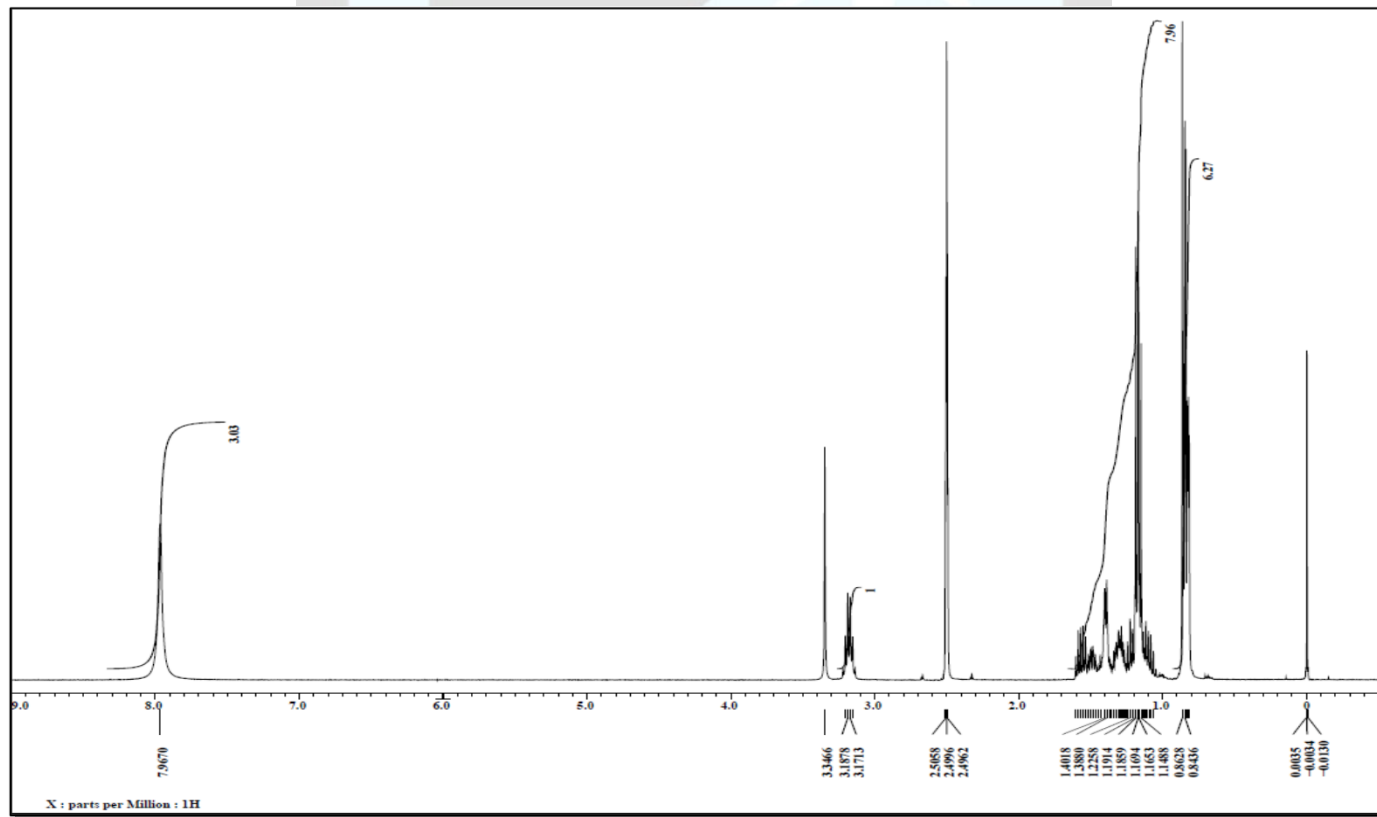
Data File Name: S:\GC\GC-HS11\2012\0612\Y0612214.D
Instrument: GC#11
Sample Name: PN051812-01
Acquired: June 12, 2012

Peak	Compound	Area	Weight %
1	Unknown # 1	14.11	BQL
2	NMP	NA	NA
Total			BQL

BQL - Below Quantitation Limit

¹H NMR

Instrument: JEOL ECS 400
Solvent: DMSO-D₆



Spectral and Physical Data (cont.)

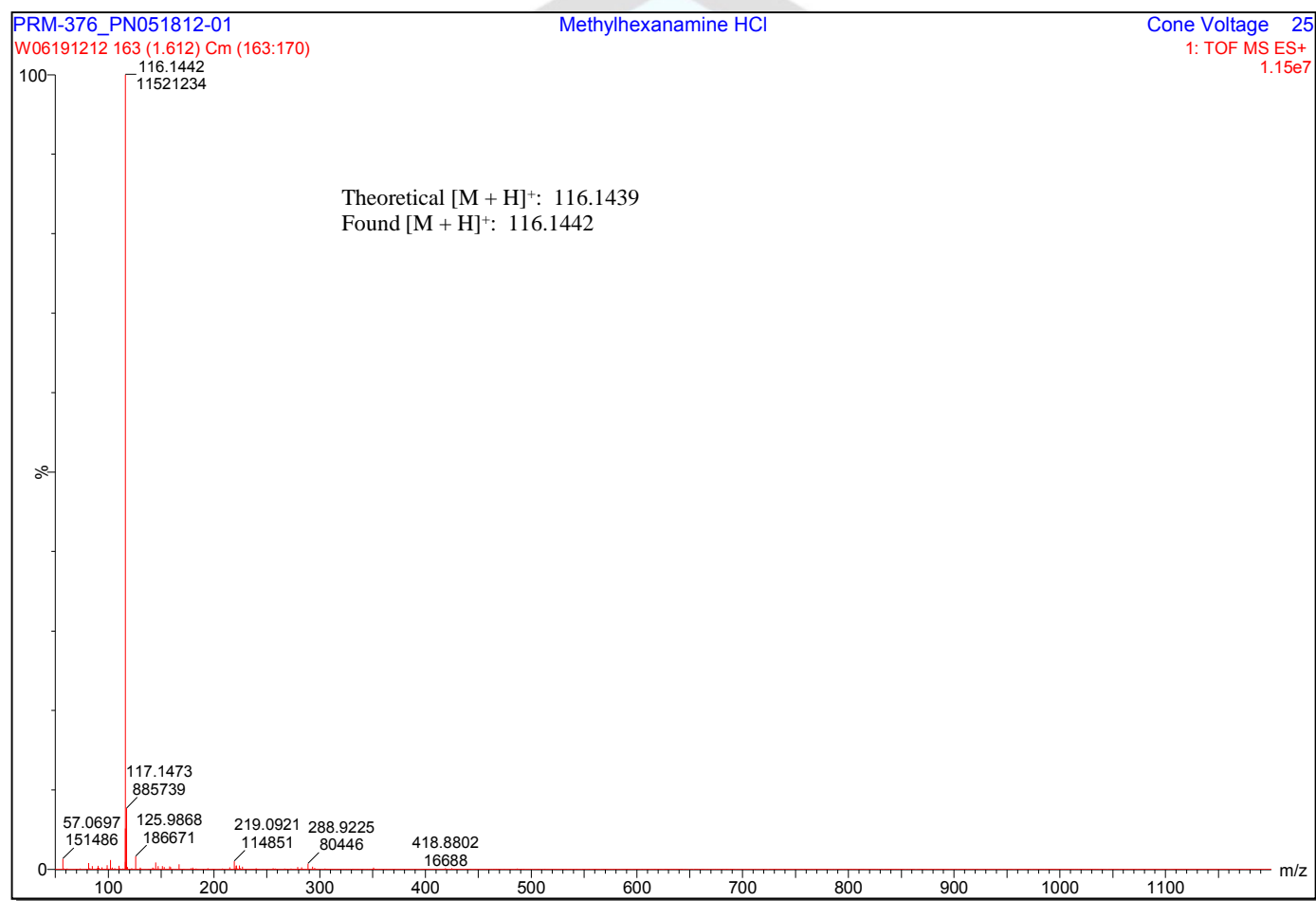
LC/MS

Column: Zorbax Eclipse Plus RRHD 1.8 μ , 2.1 x 50 mm
Mobile Phase: A::0.1% Formic acid in Water B::Acetonitrile
Gradient

Time (min)	%A	%B
0.0	95	5
2.5	80	20
4.0	80	20
5.0	95	5
8.0	95	5

Program:

Flow Rate: 0.4 mL/min
Scan Range: 50-1200 amu
Ionization: Electrospray, Positive Ion
Data File Name: W06191212
Instrument: Waters XEVO G2 QTOF
Sample Name: PN051812-01
Acquired: June 19, 2012



Stability

Short Term Stability : A summary of accelerated stability findings for this product is listed below.		
Storage Condition	Mean Kinetic Temperature (MKT)	Time Period
Freezer	-15°C	No decrease in purity was noted after four weeks.
Refrigerator	4°C	
Room Temperature	21°C	
40°C	40°C	
Transport/Shipping : Stability data supports transport of this product at ambient conditions.		
Short Term Storage : Stability data supports short term storage for no more than 3 months at Refrigerate conditions.		
Long Term Stability : Long term stability has been assessed for Freezer storage (-10 °C to -25 °C) conditions. Stability of a minimum of 27 months has been established through real-time stability studies.		

COA Revision History

Revision No.	Date	Reason for Revision
00	August 28, 2012	Initial version
01	September 24, 2012	Updated Stability Section.
02	November 05, 2013	Revised Retest Date from October 2013 to November 2014.
03	November 26, 2014	Revised Retest Date from November 2014 to November 2015.
		Added minimum sample size statement to first page.