



BDG SYNTHESIS

Certificate of Analysis

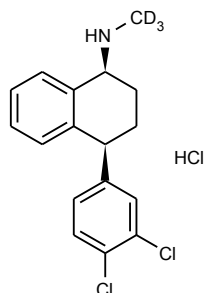
BDG Synthesis certifies that this reference material meets or exceeds the specifications stated herein.

Barry Dent

Barry R. Dent, PhD, Director
17 August 2008

Name: Sertraline-d₃ HCl
CAS Number: 79559-97-0 (unlabelled)

Structure:



Molecular Weight: C₁₇H₁₄D₃Cl₂N.HCl = 345.71
Lot Number: BDG 2412.1
Appearance: White, crystalline powder
Purity By HPLC: 99.9 %
Isotopic Purity: Under 0.5 % d₀
Re-test Date: 17 August 2013
Storage and Handling: Temperature: ambient laboratory temperature; may be refrigerated.
Humidity: not believed to be hygroscopic; may be handled in normal laboratory atmosphere.
Light: protect from strong sunlight.
Caution: only experienced laboratory personnel should handle the material.

Identity and Purity

Proton NMR Spectrum

Identity: the signals are consistent with the proposed structure and in accord with literature where available.

Isotopic Labelling: signals at the sites of deuteration are absent, compared with the spectrum of unlabelled material, indicating clean deuteration.

Residual Solvents: no residual solvents are observed.

Impurities: no significant impurities are evident in the spectrum.

Carbon-13 NMR Spectrum

Identity: the signals are consistent with the proposed structure and in accord with literature where available.

Isotopic Labelling: signals at the sites of deuteration have collapsed to small multiplets compared with the spectrum of unlabelled material, indicating clean deuteration.

High-resolution Mass Spectrum (ESI+)

Found m/z 309.1004. $C_{17}H_{15}D_3^{35}Cl_2N$ $[M+H]^+$ (free base) requires m/z 309.1005. The deviation of 0.3 ppm is within normally accepted limits for the establishment of identity by HRMS. No signal for d_0 material was seen (detection limit about 0.5 %).

HPLC

A somewhat broadened, slightly tailing peak is observed (99.9 %). Note: in the absence of reference materials for preparing calibration curves, it is assumed that all peaks have the same detector response. Where possible, the conditions of analysis follow a pharmacopeial or literature method, or have been adapted from same.

Elemental Analysis

| | | |
|----------------------------|-----------|---|
| | Found: | C 59.30, H 4.38, D 1.75, Cl 30.76, N 4.05 % |
| $C_{17}H_{14}D_3Cl_2N.HCl$ | Requires: | C 59.06, H 4.37, D 1.75, Cl 30.77, N 4.05 % |

The elemental analyses fall within generally accepted limits for establishing the molecular formula given. The results may also be taken to imply the absence of significant quantities of water or inorganic salts (which have not been elsewhere tested for because of sample size limitations).

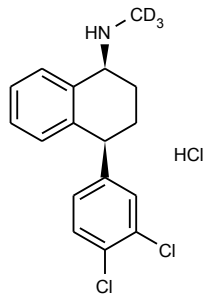
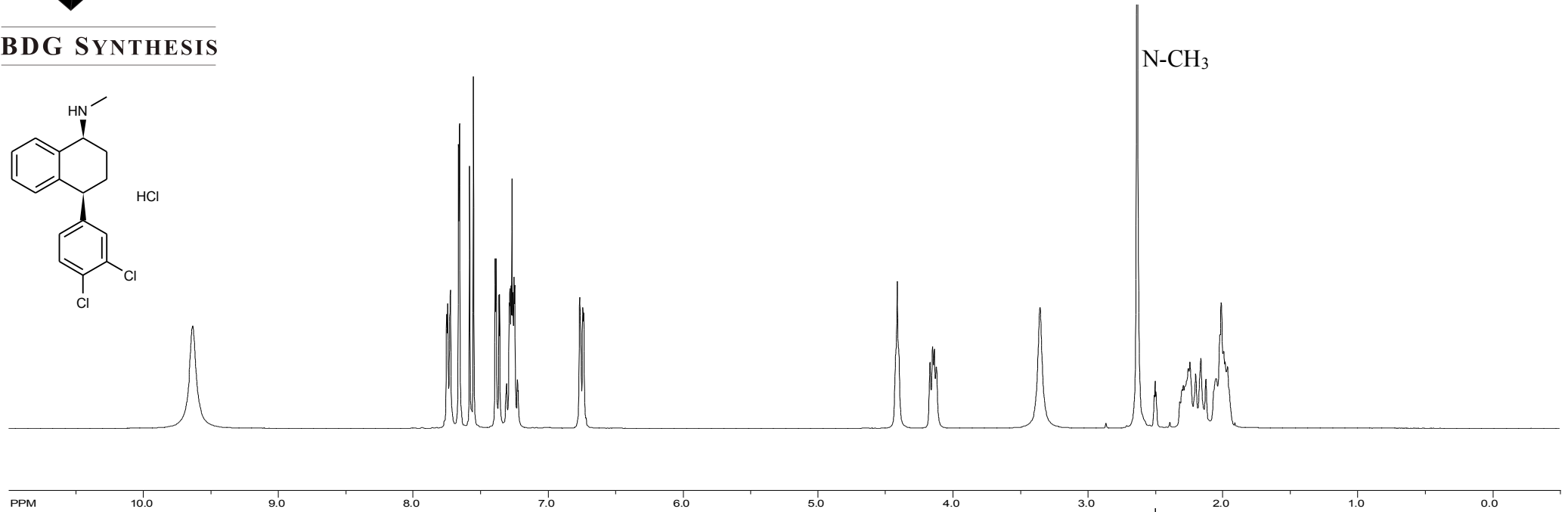
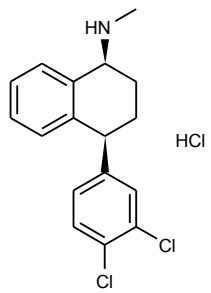
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials often contain higher levels of residual solvents and/or water, and we urge you to use the corrected purity where needed rather than the raw HPLC purity. This compound is intended for use as an analytical reference material and it is not for human administration.

The re-test date is assigned from experience gained with the material in the laboratory and/or on storage. It is not possible to perform formal storage studies because of the small amount of material available.

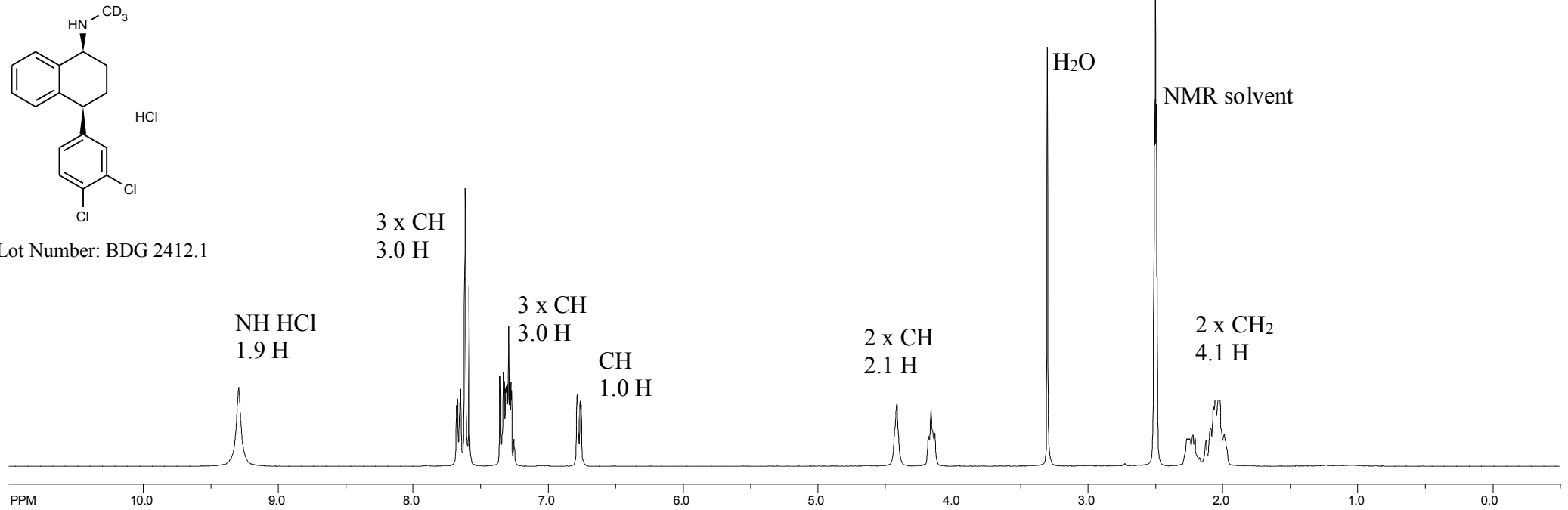


Proton NMR Spectrum of Sertraline HCl (top) and Sertraline-d₃ HCl (bottom) in DMSO-d₆

BDG SYNTHESIS



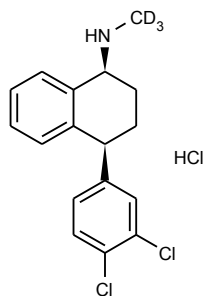
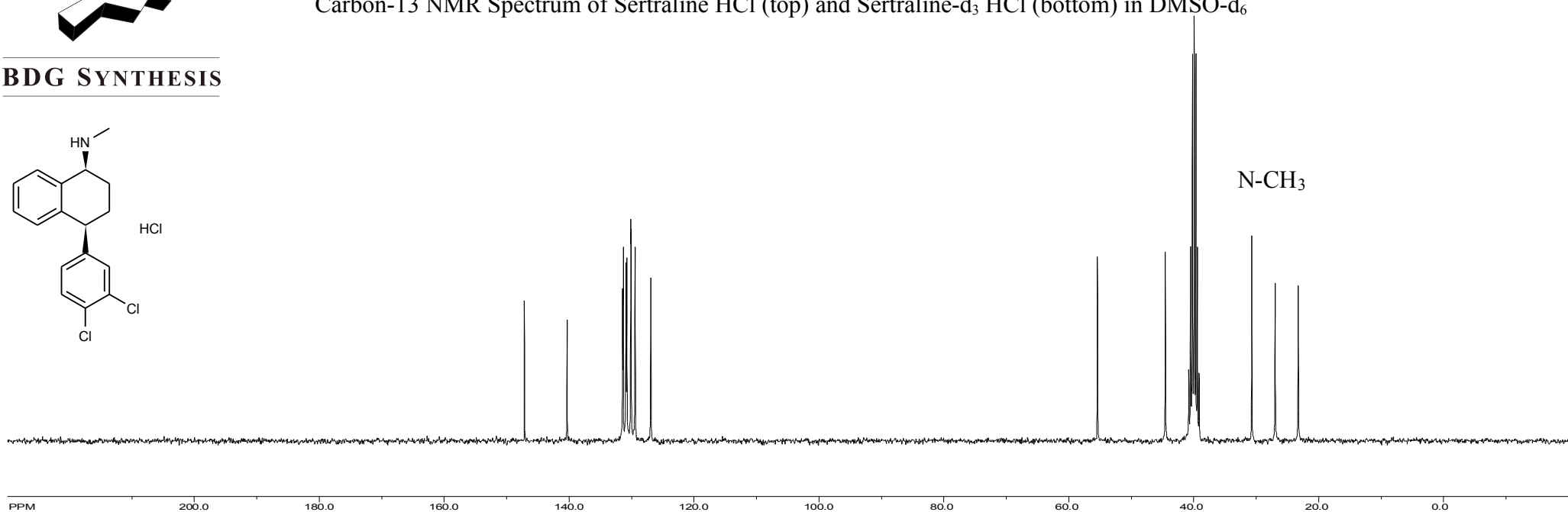
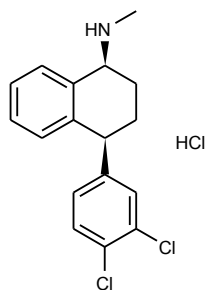
Lot Number: BDG 2412.1



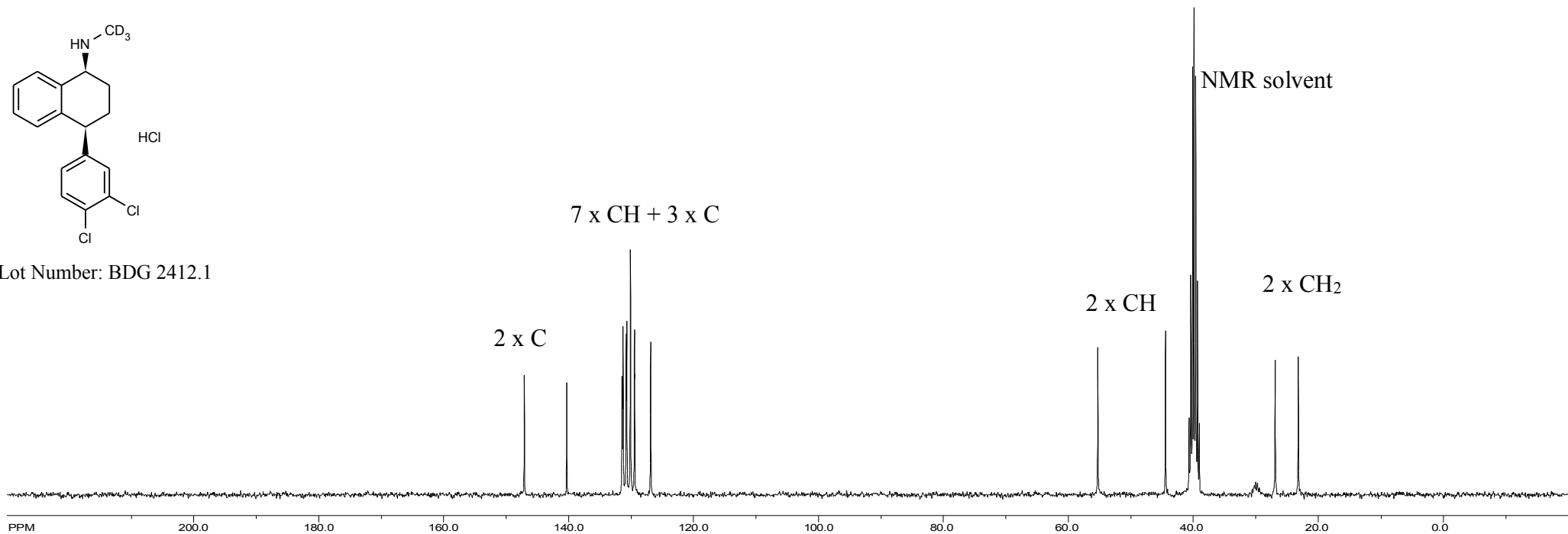


Carbon-13 NMR Spectrum of Sertraline HCl (top) and Sertraline-d₃ HCl (bottom) in DMSO-d₆

BDG SYNTHESIS



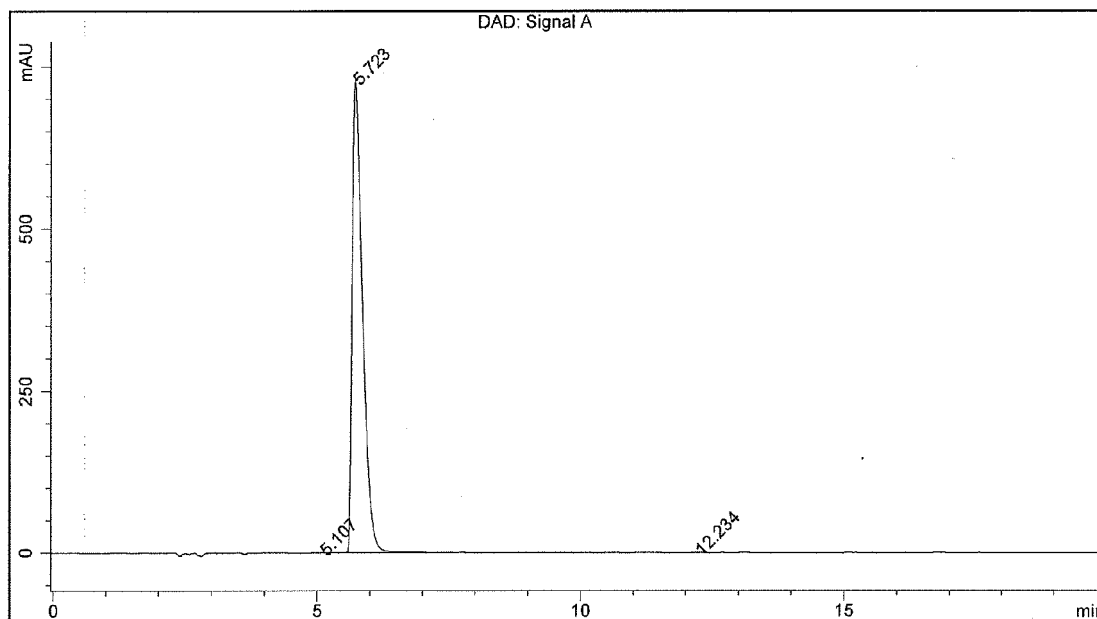
Lot Number: BDG 2412.1



BDG - Analysis of Sertraline-d3 Hydrochloride

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm
 Guard : Phenomenex Security Guard C18 4 x 3 mm
 Mobile Phase 40:45:15 EP Buffer pH=4.5 : Acetonitrile : Methanol
 Flow Rate : 1.0 mL/min
 Sample Solvent : Mobile Phase
 Column Temperature : 20C
 Injection Volume : 10 uL
 Detection : UV at 230 nm

| | | | |
|--------------------|--------------------------|----------------------|----------------|
| Sample Name | BDG 2412.1 | Instrument | AnalyticalLC01 |
| Acquisition | 17/08/2008, 17:34:20 | Method (rev.) | LC10282a (5) |
| Sequence | BDG_17Aug2008f | Vial Position | 71 |
| Operator | solvation010\cerityadmin | Injection | 1 of 1 |



Area Percent Report

| Peak# | RT | Peak Height | Peak Area | Width | Area % |
|-------|-----------|-------------|-----------|------------|----------|
| 1 | 5.11 min | 0.2875 | 3.5263 | 0.1831 min | 0.035 % |
| 2 | 5.72 min | 729.3977 | 9947.1915 | 0.2031 min | 99.908 % |
| 3 | 12.23 min | 0.4019 | 5.5927 | 0.1864 min | 0.056 % |