



BDG SYNTHESIS

Certificate of Analysis

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

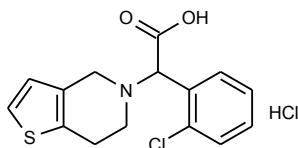
Neil Beare

Neil Beare, PhD, Director
28 October 2016

Name: Clopidogrel Acid HCl

CAS Number: 144750-42-5

Structure:



Molecular Weight: $C_{15}H_{14}ClNO_2S \cdot HCl = 344.26$

Lot Number: BDG 6150.1

Appearance: White powder

Corrected Purity: 99.1 % (HPLC) - 0.6 % (acetone) - 0.3 % (diethyl ether) = 98.2 %

Re-test Date: 28 October 2021

Storage and Handling: Temperature: refrigerate for prolonged storage; may be handled and shipped at ambient temperature.

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.
Residual Solvents: small amounts of diethyl ether (0.3 % w/w) and acetone (0.6 % w/w) 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.

High-resolution Mass Spectrum (ESI+)

Found m/z 308.0502. $C_{15}H_{15}ClNO_2S$ $[M+H]^+$ requires m/z 308.0512. The deviation of 0.4 ppm is within normally accepted limits for the establishment of identity by HRMS.

HPLC

A sharp, symmetrical peak is observed (99.1 %). 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

| | | |
|---------------------------------|-----------|---------------------------|
| $C_{15}H_{14}ClNO_2S \cdot HCl$ | Found: | C 52.20, H 4.45, N 3.91 % |
| | Requires: | C 52.33, H 4.39, N 4.07 % |

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).

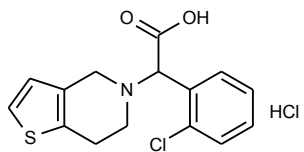
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials 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. Structures are shown with relative stereochemistry unless otherwise specified.

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.

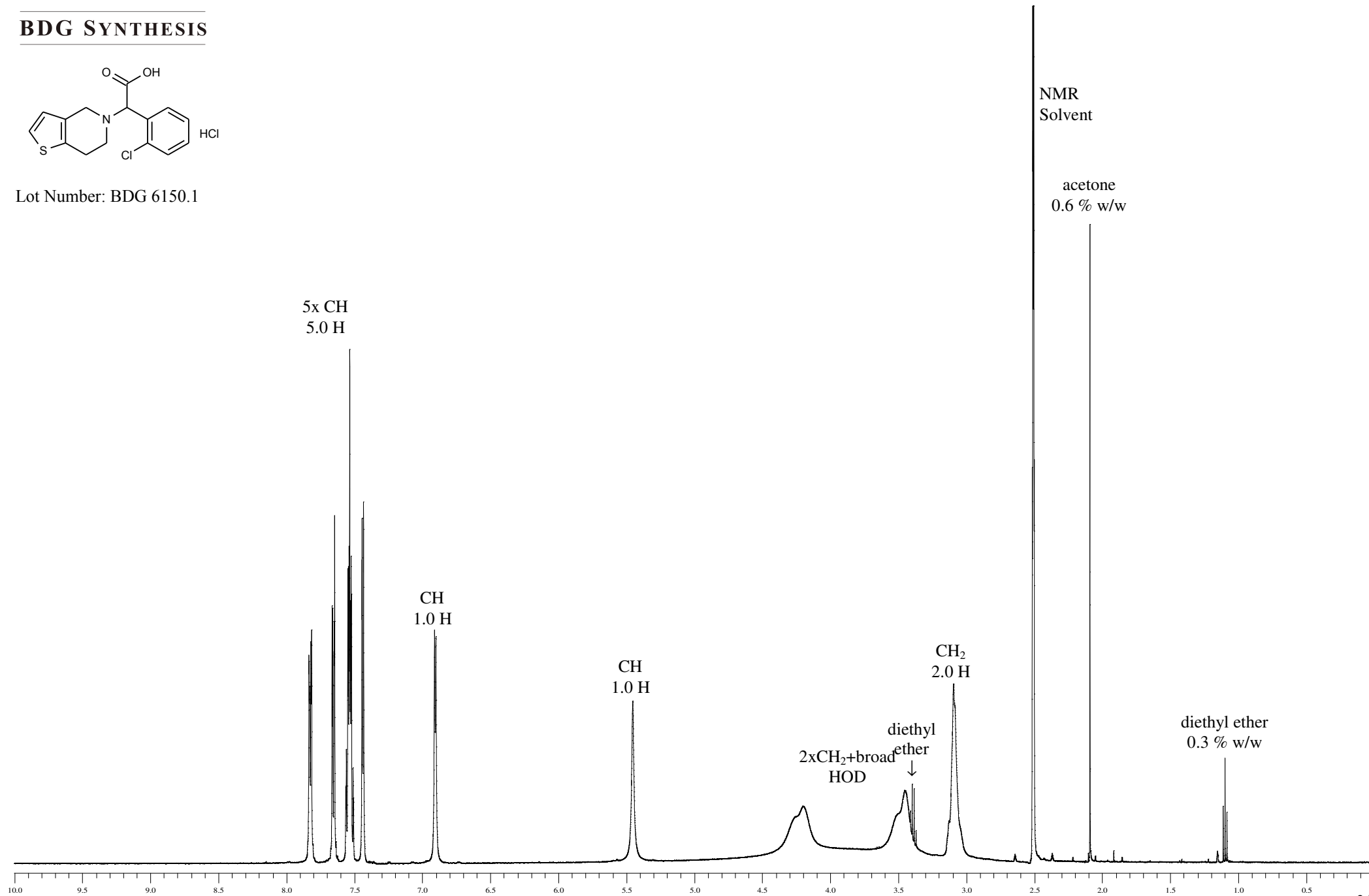


Proton NMR Spectrum of Clopidogrel Acid HCl in DMSO-d₆

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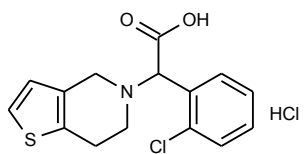
Lot Number: BDG 6150.1



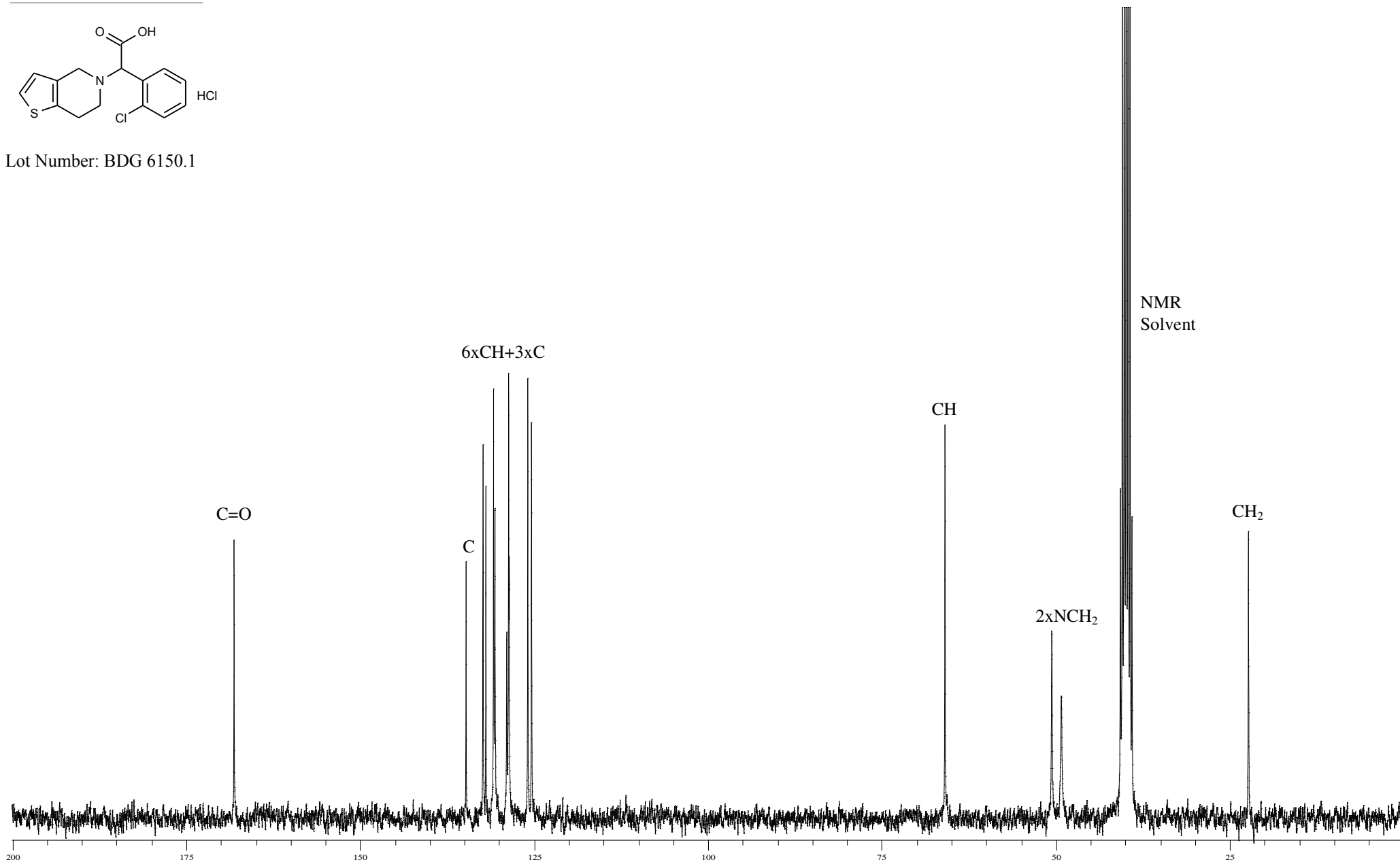


Carbon-13 NMR Spectrum of Clopidogrel Acid HCl in DMSO-d₆

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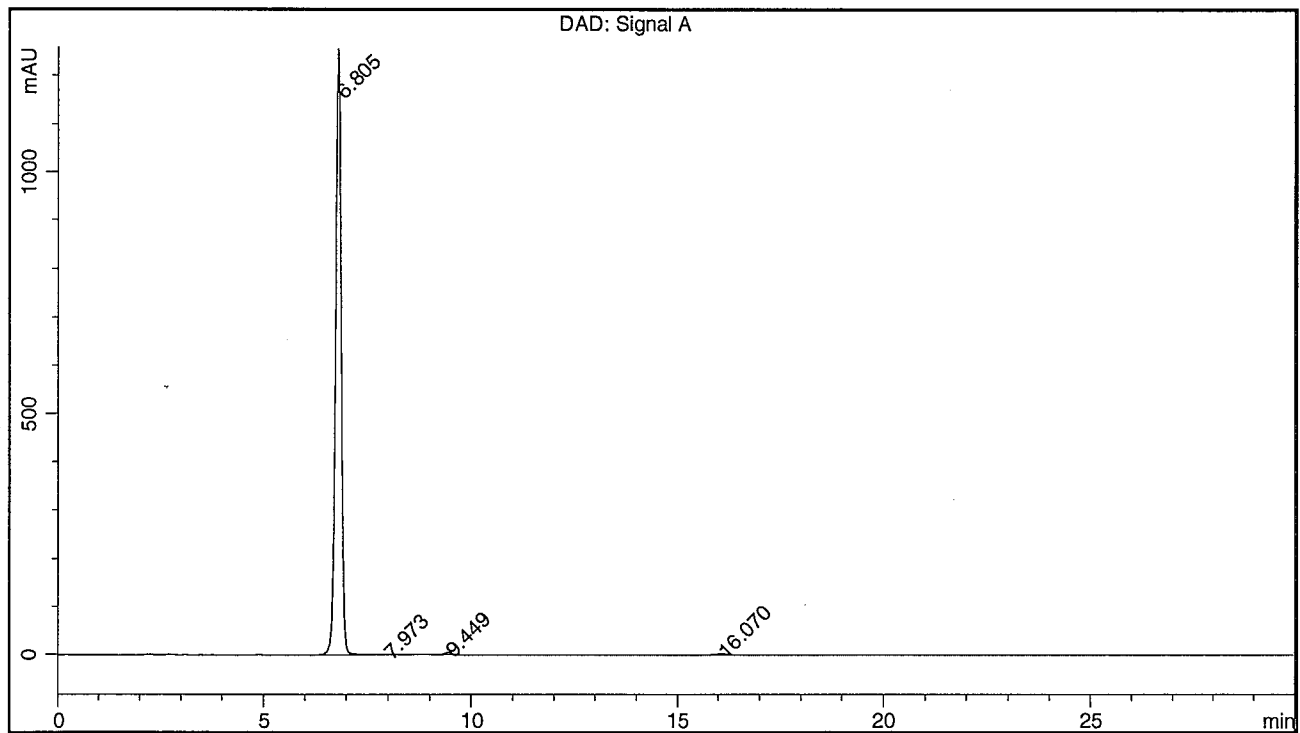
Lot Number: BDG 6150.1



BDG - Analysis of Clopidogrel Acid HCl

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm
 Guard : Phenomenex Security Guard C18 RP 4 x 3 mm
 Mobile Phase : 75:25 50 mM Potassium diHydrogen Phosphate pH=3.0 : Acetonitrile
 Flow Rate : 1.0 mL/min
 Sample Solvent : Mobile Phase
 Column Temperature : 20 C
 Injection Volume : 10 uL
 Detection : UV at 240 nm

| | | | |
|--------------------|--------------------------|----------------------|----------------|
| Sample Name | BDG 6150.1 | Instrument | AnalyticalLC01 |
| Acquisition | 28/10/2016, 17:12:30 | Method (rev.) | LC10185c (3) |
| Sequence | BDG_28Oct2016c | Vial Position | 11 |
| Operator | solvation010\cerityadmin | Injection | 1 of 1 |



Area Percent Report

| Peak# | RT | Peak Height | Peak Area | Width | Area % |
|-------|-----------|-------------|------------|------------|----------|
| 1 | 6.81 min | 1258.9796 | 11939.0187 | 0.1466 min | 99.134 % |
| 2 | 7.97 min | 0.3344 | 6.9390 | 0.2541 min | 0.058 % |
| 3 | 9.45 min | 4.3856 | 55.4220 | 0.1934 min | 0.460 % |
| 4 | 16.07 min | 2.0870 | 41.8772 | 0.3041 min | 0.348 % |