Meeting System Suitability for USP Octreotide Acetate Assay

Grace Guo and Bryan Tackett, PhD
Phenomenex Inc., 411 Madrid Ave., Torrance, CA 90501, USA

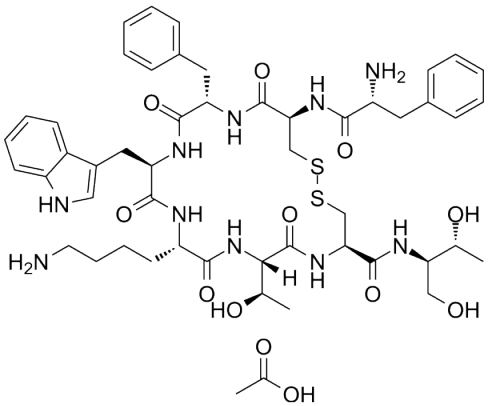
Overview

Octreotide Acetate is a cyclic octapeptide with pharmacologic actions mimicking those of the natural hormone somatostatin, which inhibits the secretion of growth hormone. It is used for the treatment of acromegaly and symptoms arising from various tumors. The development of a quick and efficient analysis of Octreotide Acetate is of interest for generic drug manufacturers. In this application note, we report meeting system suitability requirements of the USP Monograph for Octreotide Acetate using an L87 (dodecyl silane) column. The USP Chromatographic Columns database lists Synergi 4 µm Max-RP column, with dimensions of 250 x 4.6 mm, as the referenced column for this monograph.

System suitability per USP Monograph for Octreotide Acetate Assay is resolution no less than 2.0 between Octreotide Acetate and non-cyclic Octreotide Acetate, and a percent relative standard deviation (%RSD) no more than 2.0 %, using 5 replicates. All system suitability requirements for Octreotide Acetate Assay were met by the Synergi 4 µm Max-RP column.

All solutions were prepared as indicated in the USP Monograph for Octreotide Acetate. USP Octreotide Acetate RS (Catalog No. 1477604) and USP Octreotide Acetate Non-Cyclic System Suitability Marker RS (Catalog No. 1477615) were purchased from USP.

Figure 1. Octreotide Acetate Structure.



LC-UV Conditions

Columns: Synergi™ 4 µm Max-RP
Dimensions: 250 x 4.6 mm
Part No.: 00G-4337-E0
Mobile Phase: A: 0.02 % Trifluoroacetic Acid in Water
B: Acetonitrile

Gradient:

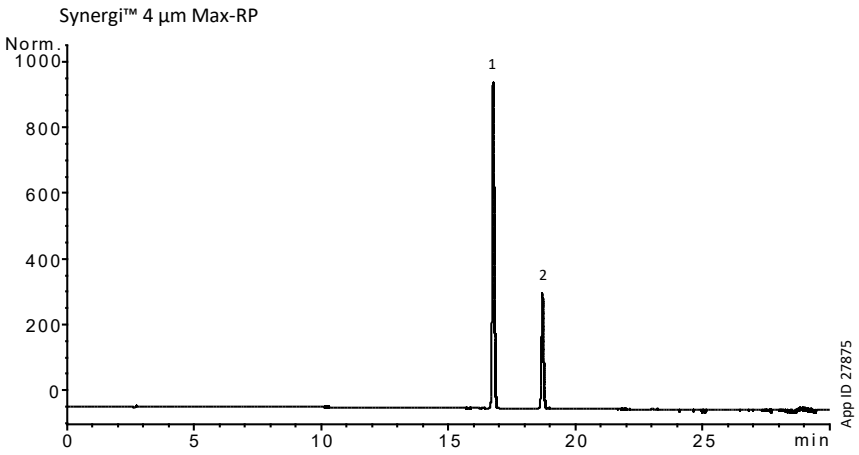
Time (min)	%B
0	10
25	35
30	90
35	90
40	10
45	10

Flow Rate: 1.0 µL/min
Injection Volume: 10 µL
Temperature: 40 °C
LC System: Agilent® 1260 Series
Detector: UV @ 220 nm

Table 1. Preparation of Solutions.

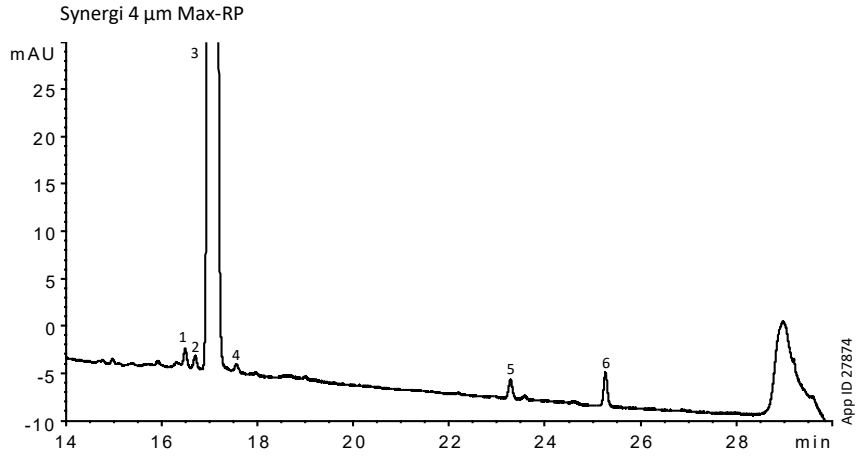
Solution	Composition
System Suitability Solution	0.5 mg/mL of *USP Octreotide Acetate RS* and 0.2 mg/mL of *USP Octreotide Acetate Non-Cyclic System Suitability Marker RS* in Mobile Phase A.
Standard Solution	0.5 mg/mL of *USP Octreotide Acetate RS* in Mobile Phase A.
Sample Solution	Same as Standard Solution.

Figure 2. System Suitability Solution for Assay.



Peak No.	Analyte	Retention Time (min)	Area	Height	Resolution
1	Octreotide Acetate	16.76	5012.1	884.2	13.4
2	Non-cyclic Octreotide Acetate	18.70	1741.1	314.6	
N = 3 Injections					

Figure 3. Standard Solution for Assay.



Peak No.	Analyte	Retention Time (min)	Relative Retention Time	Area	Height	Height %RSD
1	Unspecified Impurity A	16.50	0.97	8.2	1.80	-
2	Unspecified Impurity B	16.70	0.98	6.4	1.30	-
3	Octreotide Acetate	17.02	1.00	9856.4	1411.80	1.15
4	Unspecified Impurity C	17.56	1.03	4.7	0.85	-
5	Acetyl-Lys^{5}-Octreotide	23.29	1.37	11.2	2.00	-
6	Acetyl-Phe^{1}-Octreotide	25.27	1.48	20.1	3.60	-
N = 5 Injections						

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Australia
t: +61 (0)2-9428-6444
auinfo@phenomenex.com

Austria
t: +43 (0)1-319-1301
anfrage@phenomenex.com

Belgium
t: +32 (0)2 503 4015 (French)
t: +32 (0)2 511 8666 (Dutch)
beinfo@phenomenex.com

Canada
t: +1 (800) 543-3681
info@phenomenex.com

China
t: +86 400-606-8099
cninfo@phenomenex.com

Czech Republic
t: +420 272 017 077
cz-info@phenomenex.com

Denmark
t: +45 4824 8048
nordicinfo@phenomenex.com

Finland
t: +358 (0)9 4789 0063
nordicinfo@phenomenex.com

France
t: +33 (0)1 30 09 21 10
franceinfo@phenomenex.com

Germany
t: +49 (0)6021-58830-0
anfrage@phenomenex.com

Hong Kong
t: +852 6012 8162
hkinfo@phenomenex.com

India
t: +91 (0)40-3012 2400
indiainfo@phenomenex.com

Indonesia
t: +62 21 5019 9707
indoinfo@phenomenex.com

Ireland
t: +353 (0)1 247 5405
eireinfo@phenomenex.com

Italy
t: +39 051 6327511
italiainfo@phenomenex.com

Japan
t: +81 (0) 120-149-262
jpinfo@phenomenex.com

Luxembourg
t: +31 (0)30-2418700
nlinfo@phenomenex.com

Mexico
t: 01-800-844-5226
tecnicomx@phenomenex.com

The Netherlands
t: +31 (0)30-2418700
nlinfo@phenomenex.com

New Zealand
t: +64 (0)9-4780951
nzinfo@phenomenex.com

Norway
t: +47 810 02 005
nordicinfo@phenomenex.com

Poland
t: +48 22 104 21 72
pl-info@phenomenex.com

Portugal
t: +351 221 450 488
ptinfo@phenomenex.com

Singapore
t: +65 6559 4364
sginfo@phenomenex.com

Slovakia
t: +420 272 017 077
sk-info@phenomenex.com

Spain
t: +34 91-413-8613
espinfo@phenomenex.com

Sweden
t: +46 (0)8 611 6950
nordicinfo@phenomenex.com

Switzerland
t: +41 (0)61 692 20 20
swissinfo@phenomenex.com

Taiwan
t: +886 (0) 0801-49-1246
twinfo@phenomenex.com

Thailand
t: +66 (0) 2 566 0287
thaiinfo@phenomenex.com

United Kingdom
t: +44 (0)1625-501367
ukinfo@phenomenex.com

USA
t: +1 (310) 212-0555
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All other countries/regions
Corporate Office USA
t: +1 (310) 212-0555
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