

# Certificate of Analysis

<b>Lot number</b>	<b>7001355</b>
<b>Product</b>	<b>Octreotide Acetate</b> H-D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Threoninol (Disulfide bond)
<b>Product number</b>	4076320
<b>Molecular formula (net)</b>	C <sub>49</sub> H <sub>66</sub> N <sub>10</sub> O <sub>10</sub> S <sub>2</sub>
<b>Molecular mass (average)</b>	1019.3
<b>Date of manufacture</b>	September 30, 2013
<b>Date of release</b>	October 21, 2013
<b>Retest date</b>	September 2015
<b>Specification</b>	Octreo/v09
<b>Storage condition</b>	-20 ± 2°C

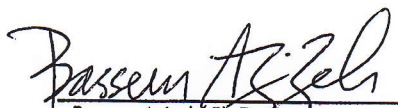
Tests	Specifications	Results
Appearance	White to off-white powder	White powder
Appearance of solution	Clear, colorless solution (0.5% in 95% acetic acid)	Clear, colorless solution
Solubility	Clear solution (60 mg/mL in water)	Clear solution
pH in solution	pH 5 to 7 (10 mg/mL in water)	6.4
Specific optical rotation [α] <sub>D</sub> <sup>25</sup> (c = 0.2, 95% HOAc)	-45° to -70° (corrected for peptide content)	-58.3°
Identity (mass spectrometry)	1018.4 ± 1.0 Da (monoisotopic mass)	1018.7 Da (monoisotopic mass)
Identity (amino acid analysis)	Lys 0.90 to 1.10 Thr 0.80 to 1.00 Cys 1.60 to 2.40 Phe 1.80 to 2.20 Trp 0.80 to 1.10 Thr-ol 0.90 to 1.10	0.99 0.88 1.85 2.02 0.98 0.99
Identity (HPLC)	Coelutes with reference standard	TM010.OctreoTFA: Coelutes TM010.OctreoTEAP: Coelutes
Purity (HPLC)	≥ 98.5%	TM010.OctreoTFA: 99.7% TM010.OctreoTEAP: 99.6%
Related substances (HPLC)	≤ 0.5% individual ≤ 1.5% total Report individual related substances >0.1%	TM010.OctreoTFA: < 0.5% individual 0.3 % total No individual related substance >0.1%  TM010.OctreoTEAP: < 0.5% individual 0.4 % total No individual related substance >0.1%

Bachem Americas, Inc.  
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USA  
Tel 1-310-539-4171  
Fax 1-310-539-9428

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**Product** Octreotide Acetate  
**Product number** 4076320

Tests	Specifications	Results
Peptide content (CHN analysis; N <sub>th</sub> 13.74%)	≥ 80.0%	91.7%
Water content (Karl Fischer)	≤ 8.0%	2.7%
Acetic acid content (HPLC)	4.0% to 12.0%	9.5%
Trifluoroacetic acid content (HPLC)	≤ 0.3%	< 0.05%
Residual solvents (GC)	Acetonitrile ≤ 410 ppm	< 127 ppm
Mass balance	95.0% to 105.0%	103.9%
Microbial enumeration	TAMC ≤ 100 CFU/g	< 10 CFU/g
	TYMC ≤ 20 CFU/g	< 10 CFU/g
Endotoxins (LAL)	≤ 1 EU/mg	< 0.1 EU/mg
Residue on ignition	≤ 0.3% (w/w)	< 0.1%

I hereby certify that the above information is authentic and accurate.

  
Bassem Azizeh, Ph.D.  
Quality Control  
Bachem Americas, Inc.

October 21, 2013  
Date

I hereby certify that this lot has been manufactured and analyzed in compliance with Good Manufacturing Practice and is appropriate for use in clinical trials as specified in the International Conference on Harmonisation (ICH) Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

  
Jackie Little  
Quality Assurance  
Bachem Americas, Inc.

October 21, 2013  
Date

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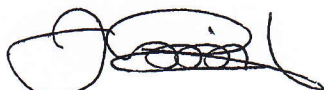
## TSE-Safety Certificate

Lot number 7001355  
Product Octreotide Acetate  
Product number 4076320

I hereby certify that the above mentioned lot is

a synthetic peptide manufactured using synthetic amino acid derivatives as well as solvents and reagents of non-human and non-animal sources. Supplies of synthetic amino acid derivatives are manufactured using amino acids of non-human and non-animal sources. Therefore, monograph 5.2.8 of the European Pharmacopoeia on **Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products** and the **Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products** (EMA/410/01) do not apply.

Date: October 21, 2013  
Bachem Americas, Inc.



Jackie Little  
Quality Assurance

## Packaging and Labeling Certificate

**Lot number** 7001355  
**Product** Octreotide Acetate  
**Product number** 4076320

This shipment has been packaged and labelled in accordance with Good Manufacturing Practice as specified in the International Conference on Harmonisation (ICH) Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

Sales Order Number: 0009165391

Signature: Veronica Loya 10-21-13  
Date

Name: Veronica Loya  
Quality Assurance

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