

# Certificate of Analysis

**Lot number** 7001016  
**Product** Octreotide Acetate  
 H-D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Threoninol (Disulfide bond)  
**Product number** 4076320  
**Molecular formula (net)**  $C_{20}H_{26}N_{10}O_{10}S_2$   
**Molecular mass (average)** 1019.3  
**Date of manufacture** February 19, 2013  
**Date of release** April 17, 2013  
**Retest date** February 2015  
**Specification** Octreo/v09  
**Storage condition**  $-20 \pm 2^\circ\text{C}$

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 $[\alpha]_D^{25}$ (c = 0.2, 95% HOAc)	$-45^\circ$ to $-70^\circ$ (corrected for peptide content)	$-60.7^\circ$
Identity (mass spectrometry)	$1018.4 \pm 1.0$ Da (monoisotopic mass)	1018.4 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 0.90 1.89 2.02 1.03 1.01
Identity (HPLC)	Coelutes with reference standard	TM010.OctreoTFA: Coelutes TM010.OctreoTEAP: Coelutes
Purity (HPLC)	$\geq 98.5\%$	TM010.OctreoTFA: 99.5% TM010.OctreoTEAP: 99.5%
Related substances (HPLC)	$\leq 0.5\%$ individual $\leq 1.5\%$ total Report individual related substances $> 0.1\%$	TM010.OctreoTFA: $< 0.5\%$ individual $0.5\%$ total No individual related substance $> 0.1\%$  TM010.OctreoTEAP: $< 0.5\%$ individual $0.5\%$ total No individual related substance $> 0.1\%$

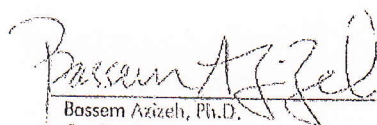
Bachem Americas, Inc.  
 3132 Kashiwa Street  
 Torrance, CA 90505  
 USA  
 Tel 1-310-539-4171  
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**BACHEM**

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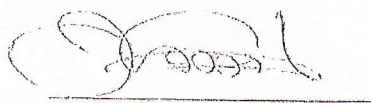
Tests	Specifications	Results
Peptide content (CHN analysis; N <sub>x</sub> 13.74%)	≥ 80.0%	90.5%
Water content (Karl Fischer)	≤ 8.0%	1.4%
Acetic acid content (HPLC)	4.0% to 12.0%	9.5%
Trifluoroacetic acid content (HPLC)	≤ 0.3%	< 0.05%
Residual solvents (GC)	Acetonitrile ≤ 410 ppm	< 127 ppm
Mass balance	95.0% to 105.0%	101.4%
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)	< 0.02%

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

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

April 16, 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.

April 17, 2013  
Date

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## TSE-Safety Certificate

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*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: April 17, 2013  
Bachem Americas, Inc.



Jackie Little  
Quality Assurance

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