

Certificate of Analysis

Lot number 7001355

Product **Octreotide Acetate**
H-D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Threoninol (Disulfide bond)

Product number 4076320

Molecular formula (net) $C_{49}H_{66}N_{10}O_{10}S_2$

Molecular mass (average) 1019.3

Date of manufacture September 30, 2013

Date of release October 21, 2013

Retest date September 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° to -70° (corrected for peptide content)	-58.3°
Identity (mass spectrometry)	1018.4 \pm 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)	$\geq 98.5\%$	TM010.OctreoTFA: 99.7% TM010.OctreoTEAP: 99.6%
Related substances (HPLC)	$\leq 0.5\%$ individual $\leq 1.5\%$ 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%

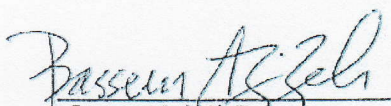
Bachem Americas, Inc.
3132 Kashiwa Street
Torrance, CA 90505
USA
Tel 1-310-539-4171
Fax 1-310-539-9428

BACHEM

Lot number 7001355
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Tests	Specifications	Results
Peptide content (CHN analysis; N _{in} 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 Azizeli, 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

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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: 0009176981

Signature: Todd Rose

06/02/14
Date

Name: Todd Rose

Quality Assurance

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