

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 $-20 \pm 2^\circ\text{C}$

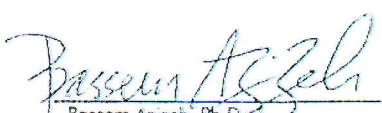
| Tests | Specifications | Results |
|--|---|---|
| Appearance | White to off-white powder | White powder |
| Appearance of solution | Clear, colorless solution (0.5% in 95% acetic acid) | Clear, colorless solution |
| Solubility | Clear solution (60 mg/mL in water) | Clear solution |
| pH in solution | 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 ± 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-al 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

| | |
|-----------------------|---------------------------|
| Lot number | 7001355 |
| Product | Octreotide Acetate |
| Product number | 4076320 |

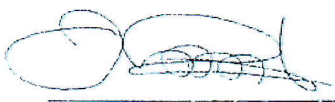
| Tests | Specifications | Results |
|--|------------------------|----------------|
| Peptide content (CHN analysis; N _{in} 13.74%) | ≥ 80.0% | 91.7% |
| Water content (Karl Fischer) | ≤ 8.0% | 2.7% |
| Acetic acid content (HPLC) | 4.0% to 12.0% | 9.5% |
| Trifluoroacetic acid content (HPLC) | ≤ 0.3% | < 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 Azizah, 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

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

BACHEM

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: 0009168699

Signature: Veronica Loya

12-13-13

Date

Name: Veronica Loya
Quality Assurance

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