

# Certificate of Analysis

<b>Lot number</b>	<b>FOCTREO1102</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>	FBC0051
<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>	October 04, 2011
<b>Date of release</b>	November 18, 2011
<b>Retest date</b>	October 2013
<b>Specification</b>	Octreo/v08
<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)	6.2
Specific optical rotation [α] <sub>D</sub> <sup>25</sup> (c = 0.2, 95% HOAc)	-45° to -70° (corrected for peptide content)	-55.7°
Identity (Mass Spectrometry)	1018.4 ± 1.0 Da (monoisotopic mass)	1018.6 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	1.03 0.85 2.00 1.97 0.88 1.01
Identity (HPLC)	Coelutes with reference standard	TM010.OctreoTFA: Coelutes TM010.OctreoTEAP: Coelutes
Purity (HPLC)	≥ 98.5%	TM010.OctreoTFA: 99.7% TM010.OctreoTEAP: 99.7%
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 0.3 % total No individual related substance >0.1%

Bachem Inc.  
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<b>Product</b>	<b>Octreotide Acetate</b>
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<b>Tests</b>	<b>Specifications</b>	<b>Results</b>
Peptide content (CHN analysis; N <sub>th</sub> 13.74%)	≥ 80.0%	86.8%
Water content (Karl Fischer)	≤ 8.0%	1.7%
Acetic acid content (HPLC)	4.0% to 12.0%	9.7%
Trifluoroacetic acid content (HPLC)	≤ 0.3%	< 0.05%
Residual solvents (GC)	Acetonitrile ≤ 410 ppm	< 127 ppm
Mass balance	95.0% to 105.0%	98.3%
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.

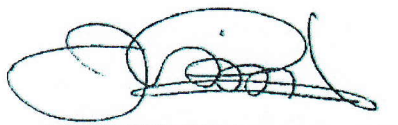


Bassem Azizeh, Ph.D.  
Quality Control  
Bachem Inc.

11/18/11

Date

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



Jackie Little  
Quality Assurance  
Bachem Inc.

November 18, 2011

Date

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