

Certificate of Analysis

Lot number	1046778
Product	Tetracosactide (H-Ser-Tyr-Ser-Met-Glu-His-Phe-Arg-Trp-Gly-Lys-Pro-Val-Gly-Lys-Lys-Arg-Arg-Pro-Val-Lys-Val-Tyr-Pro-OH acetate salt)
Product number	4042686
Molecular formula (net)	C ₁₃₆ H ₂₁₀ N ₄₀ O ₃₁ S
Molecular mass (average)	2933.5
Date of manufacture	July 09, 2013
Date of release	August 06, 2013
Retest date	July 2015
Specification	QS-4042686B/02
Test procedure	SAV 4042686/07
Storage condition	2 - 8 °C

Tests	Specifications	Results																																																				
Appearance	white to yellow powder	white powder																																																				
Appearance of solution	clear, colorless solution in water (1 mg/mL)	complies																																																				
Identification (ESI-MS)	m = 2931.6 ± 2.0 u (monoisotopic mass)	m = 2931.6 u																																																				
Identification (HPLC)	main peak corresponds to the main peak of the reference chromatogram with regard to retention time, peak shape, and peak size	complies																																																				
Identification (amino acid analysis)	<table><tr><td>Glx</td><td>0.9 - 1.1</td></tr><tr><td>Gly</td><td>1.8 - 2.2</td></tr><tr><td>His</td><td>0.9 - 1.1</td></tr><tr><td>Arg</td><td>2.8 - 3.4</td></tr><tr><td>Tyr</td><td>1.7 - 2.2</td></tr><tr><td>Ser</td><td>1.1 - 2.2</td></tr><tr><td>Met</td><td>0.9 - 1.1</td></tr><tr><td>Lys</td><td>3.5 - 4.7</td></tr><tr><td>Pro</td><td>2.5 - 3.5</td></tr><tr><td>Phe</td><td>0.9 - 1.1</td></tr><tr><td colspan="2">(calculation based on Val (3))</td></tr><tr><td>Trp</td><td>detected</td></tr><tr><td colspan="2">other amino acids: not more than traces present</td></tr></table>	Glx	0.9 - 1.1	Gly	1.8 - 2.2	His	0.9 - 1.1	Arg	2.8 - 3.4	Tyr	1.7 - 2.2	Ser	1.1 - 2.2	Met	0.9 - 1.1	Lys	3.5 - 4.7	Pro	2.5 - 3.5	Phe	0.9 - 1.1	(calculation based on Val (3))		Trp	detected	other amino acids: not more than traces present		<table><tr><td>Glx</td><td>1.0</td></tr><tr><td>Gly</td><td>1.9</td></tr><tr><td>His</td><td>1.0</td></tr><tr><td>Arg</td><td>3.0</td></tr><tr><td>Tyr</td><td>1.9</td></tr><tr><td>Ser</td><td>1.6</td></tr><tr><td>Met</td><td>1.0</td></tr><tr><td>Lys</td><td>3.8</td></tr><tr><td>Pro</td><td>2.9</td></tr><tr><td>Phe</td><td>1.0</td></tr><tr><td colspan="2">(calculation based on Val (3))</td></tr><tr><td>Trp</td><td>detected</td></tr><tr><td colspan="2">other amino acids: not more than traces present</td></tr></table>	Glx	1.0	Gly	1.9	His	1.0	Arg	3.0	Tyr	1.9	Ser	1.6	Met	1.0	Lys	3.8	Pro	2.9	Phe	1.0	(calculation based on Val (3))		Trp	detected	other amino acids: not more than traces present	
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Specific optical rotation	[α] _D ²⁰ (10 mg/mL in 1% acetic acid) = -104 ± 5° (calculated for water- and acetic acid-free substance)	-106°																																																				
Purity (HPLC)	≥ 95.0%	97.8%																																																				

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Product Tetracosactide

Tests	Specifications	Results
Related substances (HPLC)	$\leq 2.0\%$ Met(O) ⁴ -Tetracosactide $\leq 0.5\%$ Endo-Arg ^{16a} -Tetracosactide $\leq 0.5\%$ D-His ⁶ -Tetracosactide $\leq 1.0\%$ Des-Ser ¹ -Tetracosactide, Des-Ser ³ -Tetracosactide, D-Met ⁴ -Tetracosactide (combined peak) $\leq 1.0\%$ Endo-Glu ^{4a} -Tetracosactide and unknown (combined peak) RRT approx 1.04 - 1.08 $\leq 1.0\%$ Endo-Gly ^{13a} -Tetracosactide $\leq 1.0\%$ Des-Glu ⁵ -Tetracosactide, Ac-[3-24]-Tetracosactide (combined peak) $\leq 0.5\%$ Ac-[7-24]-Tetracosactide $\leq 0.5\%$ each individual unknown report each individual unknown $\geq 0.10\%$ $\leq 5.0\%$ total	0.32% < 0.05% (LOQ) 0.12% 0.24% 0.47% 0.44% 0.29% 0.12% $\leq 0.08\%$ no individual unknown $\geq 0.10\%$ 2.2%
Assay (HPLC)	90 - 102% (corrected for water content and acetic acid content)	97.6%
Water content (Karl Fischer)	6.0 - 11.0%	7.6%
Acetic acid content (HPLC)	8.0 - 13.0%	10.7%
Trifluoroacetic acid content (IC)	$\leq 0.1\%$	0.051%
Residual organic solvents (GC)	≤ 410 mg/kg acetonitrile ≤ 5000 mg/kg isopropanol ≤ 1000 mg/kg triethylamine	< 175 mg/kg < 116 mg/kg < 150 mg/kg
Heavy metals (ICP-OES)	≤ 2.5 ppm Ni ≤ 130 ppm Fe ≤ 130 ppm Zn ≤ 25 ppm Cu ≤ 25 ppm Mn	< 1 ppm < 1 ppm < 1 ppm < 1 ppm < 1 ppm
Bacterial endotoxins	< 10 IU/mg	< 0.10 IU/mg
Microbial limit test		
Total aerobic microbial count (TAMC)	$\leq 10^2$ CFU/g	1 CFU/g
Total yeasts and moulds count (TYMC)	$\leq 10^2$ CFU/g	< 1 CFU/g

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I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at Bachem AG in Bubendorf / Switzerland in full compliance with the GMP requirements of the local Regulatory Authority and according to the ICH Q7 Guideline for APIs. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date: August 13, 2013
Bachem AG



Dieter Arn, Ph.D.
QA Release Manager

This shipment has been dispensed and labeled according to the above mentioned GMP requirements. The dispensing record was reviewed and found to be in compliance with GMP.

Date: Oct. 07, 2013
Bachem AG month day, year

Weighing Record Number: GM 130606

Signature: M. Kreimel

Name: M. Kreimel
Quality Assurance

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