BACHEM

Certificate of Analysis

Lot number	**1036861**
Product	**Protirelin** (Pyr-His-Pro-NH_2)
Product number	4003036
Molecular formula (net)	$C_{16}H_{22}N_6O_4$
Relative molecular mass	362.4
Date of Manufacture	June 24, 2011
Date of Release	August 23, 2011
Date of Retest	June 2013
Specifications	QS-4003036A/04
Storage Conditions	< -15 °C

Tests	Specifications	Results
Appearance	white to yellowish-white powder	white powder
Appearance of solution	clear solution in water (10 mg/mL), not more intensely colored than reference solution Y_5	complies
Identification (IR)	spectrum to comply with reference spectrum	complies
Identification (HPLC)	main peak corresponds to the main peak of the reference chromatogram with regard to retention time and peak size	complies
Specific optical rotation	$[a]_D^{20}$ (1% in water) = -62° to -70° (calculated with reference to the anhydrous, acetic acid-free substance)	-68°
Related peptides (HPLC)	report each individual ≥ 0.10% ≤ 2.0% each individual	RRT area% 0.656 0.52 0.920 0.76
	≤ 3.0% total	1.3%
Assay (HPLC)	97.0 - 102.0% (calculated with reference to the anhydrous, acetic acid-free substance)	99.7%
Water content	≤ 7.0%	4.1%
Acetic acid content	≤ 2.0%	0.079%
Residual organic solvents (GC)	≤ 410 mg/kg acetonitrile	< 27 mg/kg (LOQ)
	≤ 880 mg/kg DMF	< 35 mg/kg (LOD)
	≤ 3000 mg/kg methanol	< 35 mg/kg (LOQ)
	≤ 5000 mg/kg ethyl acetate	< 11 mg/kg (LOD)
	≤ 5000 mg/kg diisopropyl ether	< 13 mg/kg (LOD)
	≤ 5000 mg/kg ethanol	< 14 mg/kg (LOD)
	≤ 5000 mg/kg n-butanol	< 15 mg/kg (LOD)
	≤ 5000 mg/kg t-butanol	< 9 mg/kg (LOD)
	≤ 5000 mg/kg isopropanol	136 mg/kg

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Lot number	**1036861**
Product	**Protirelin**

Tests	**Specifications**	**Results**
Bacterial endotoxins (Ph. Eur. 2.6.14)	≤ 0.7 IU/mg	< 0.01 IU/mg
Microbial limit test (Ph. Eur. 2.6.12)		
Total aerobic microbial count (TAMC)	≤ 10^3 CFU/g	< 1 CFU/g
Total yeasts and moulds count (TYMC)	≤ 10^2 CFU/g	< 1 CFU/g

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 for use in Clinical Trials". The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date: August 25, 2011
Bachem AG

D. Arn

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 130608

Signature: M. Kraemer

Name: M. Kraemer
Quality Assurance

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Retest Date Extension Certificate

Lot number	**1036861**
Product	**Protirelin** (Pyr-His-Pro-NH_2)
Product number	4003036
Molecular formula (net)	$C_{16}H_{22}N_6O_4$
Molecular mass (average)	362.4
Date of manufacture	June 24, 2011
Date of retest	July 04, 2013
New retest date	July 2014
Specification	QS-4003036A/04
Storage condition	< -15 °C

Tests	Specifications	Results
Appearance	white to yellowish-white powder	white powder
Appearance of solution	clear solution in water (10 mg/mL), not more intensely colored than reference solution Y_5	complies
Related peptides (HPLC)	report each individual ≥ 0.10% ≤ 2.0% each individual ≤ 3.0% total	RRT area% 0.65 0.51 0.92 0.75 1.03 0.14 ≤ 0.75% 1.4%
Assay (HPLC)	97.0 - 102.0% (calculated with reference to the anhydrous, acetic acid-free substance)	98.9%
Water content	≤ 7.0%	3.9%

A sample of the above mentioned lot was obtained from Bachem AG inventory and was retested by Bachem AG.
I hereby certify that the above information is authentic and accurate. This batch of product has been analyzed 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 for use in Clinical Trials". The analysis records were reviewed and found to be in compliance with GMP.

This Retest Date Extension Certificate should be used complementary to the Certificate of Analysis.

Date: July 26, 2013
Bachem AG

Dieter Arn, Ph.D.
QA Release Manager

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