BACHEM

Certificate of Analysis

Lot number	**1029670**
Product	**Gonadorelin Acetate Ph.Eur.** (LHRH acetate, GnRH acetate)
Product number	4008614
Molecular formula (net)	$C_{55}H_{75}N_{17}O_{13}$
Relative molecular mass	1182.3
Date of Manufacture	February 10, 2011
Date of Release	May 12, 2011
Date of Retest	February 2013
Specifications	QS-4008614A/09
Test Procedure	SAV 4008614/05
Storage Conditions	< -15 °C

Tests	Specifications	Results
Appearance	white to slightly yellowish powder	white powder
Appearance of solution (Ph. Eur.)	not more opalescent than reference suspension I, not more colored than reference solution Y_5 (10 mg/mL in water)	complies
Identification (ESI-MS)	m = 1181.6 ± 1.0 u (monoisotopic mass)	m = 1181.6 u
Identification (HPLC)	main peak corresponds to the main peak of the reference chromatogram with regard to retention time and peak size	complies
Identification (amino acid analysis) (Ph. Eur.)	Ser 0.7 - 1.05 Tyr 0.7 - 1.05 Glx 0.95 - 1.05 His 0.95 - 1.05 Pro 0.95 - 1.05 Arg 0.95 - 1.05 Gly 1.9 - 2.1 Trp detected Leu 0.9 - 1.1	Ser 0.9 Tyr 1.0 Glx 0.98 His 1.01 Pro 0.99 Arg 1.03 Gly 2.0 Trp detected Leu 1.0
Specific optical rotation (Ph. Eur.)	$[\alpha]_D^{20}$ (1% in 1% acetic acid) = -54° to -66° (corrected for water and acetic acid content)	-63°
Absorbance (Ph. Eur.)	0.55 - 0.61 (0.01% in water at 278 nm) (corrected for water and acetic acid content)	0.55
Water content (Karl Fischer)	≤ 7.0%	3.4%
Acetic acid content (HPLC)	4.0 - 7.5%	6.0%
Assay (HPLC)	report net value 95.0 - 102.0% (corrected for water and acetic acid content)	90.2% 99.5%

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Lot number **1029670**

Product **Gonadorelin Acetate Ph.Eur.**

Tests	Specifications	Results
Related substances (HPLC)	≤ 0.5% (Desamido-Gly[10])-Gonadorelin (Gonadorelin free acid)	< 0.05% (LOQ)
	≤ 0.5% (D-Tyr[5])-Gonadorelin	0.06%
	≤ 0.5% (D-His[2])-Gonadorelin	0.17%
	≤ 0.5% Pyr-His-Trp-Ser-Tyr-OH	< 0.05% (LOQ)
	≤ 0.5% each other impurity	≤ 0.05%
	≤ 1.0% total	0.28%
Residual organic solvents (GC)	≤ 5000 mg/kg isopropanol	< 3 mg/kg (LOD)
	≤ 5000 mg/kg n-butanol	< 1 mg/kg (LOD)
Heavy metals (ICP-MS)	≤ 10 mg/kg palladium	< 0.1 mg/kg
Bacterial endotoxins (Ph. Eur.)	< 70 IU/mg	< 0.10 IU/mg
Microbial limit test (Ph. Eur. 2.6.12 (harmonized method))		
Total aerobic microbial count (TAMC)	≤ 10^2 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. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Date: January 04, 2012
Bachem AG

S. Dunkel

Silke Dunkel, 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 130607

Signature: M. Kraemer

Name: M. Kraemer
Quality Assurance

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BACHEM

Retest Date Extension Certificate

Lot number	**1029670**
Product	**Gonadorelin Acetate Ph.Eur.** (LHRH acetate, GnRH acetate)
Product number	4008614
Molecular formula (net)	$C_{55}H_{75}N_{17}O_{13}$
Molecular mass (average)	1182.3
Date of manufacture	February 10, 2011
Date of retest	January 25, 2013
New retest date	January 2014
Specification	QS-4008614A/09
Test procedure	SAV 4008614/06
Storage condition	< -15 °C

Tests	Specifications	Results
Appearance	white to slightly yellowish powder	white powder
Water content (Karl Fischer)	≤ 7.0%	3.2%
Assay (HPLC)	report net value 95.0 - 102.0% (corrected for water and acetic acid content)	90.5% 99.6%
Related substances (HPLC)	≤ 0.5% (Desamido-Gly^{10})-Gonadorelin (Gonadorelin free acid) ≤ 0.5% (D-Tyr^{5})-Gonadorelin ≤ 0.5% (D-His^{2})-Gonadorelin ≤ 0.5% Pyr-His-Trp-Ser-Tyr-OH ≤ 0.5% each other impurity ≤ 1.0% total	< 0.05% (LOQ) 0.07% 0.17% < 0.05% (LOQ) < 0.05% (LOQ) 0.24%

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. 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: February 22, 2013
Bachem AG

Dieter Arn, Ph.D.
QA Release Manager

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