

# Certificate of Analysis

<b>Lot number</b>	<b>1072380</b>
<b>Product</b>	<b>Gonadorelin Acetate Ph. Eur.</b> (LHRH acetate, GnRH acetate)
<b>Product number</b>	4008614
<b>Molecular formula (net)</b>	C <sub>55</sub> H <sub>75</sub> N <sub>17</sub> O <sub>13</sub>
<b>Molecular mass (average)</b>	1182.3
<b>Date of manufacture</b>	July 27, 2018
<b>Date of release</b>	October 04, 2018
<b>Retest date</b>	July 2021
<b>Specification</b>	QS-4008614A/11
<b>Test procedure</b>	SAV-4008614/08
<b>Storage condition</b>	< -15 °C

Tests	Specifications	Results
Appearance	white to slightly yellowish powder	white powder
Appearance of solution	not more opalescent than reference suspension I, not more colored than reference solution Y <sub>5</sub> (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    His 0.95 - 1.05 Glx 0.95 - 1.05    Arg 0.95 - 1.05 Pro 0.95 - 1.05    Trp detected Gly 1.9 - 2.1    Ile absent Leu 0.9 - 1.1    Lys absent Tyr 0.7 - 1.05 other amino acids: not more than traces present	Ser 0.8    His 1.05 Glx 0.97    Arg 0.99 Pro 1.00    Trp detected Gly 2.0    Ile absent Leu 1.0    Lys absent Tyr 1.0 complies
Specific optical rotation (Ph. Eur.)	[α] <sub>D</sub> <sup>20</sup> (1% in 1% acetic acid) = -58° to -65° (corrected for water and acetic acid content)	-62°
Absorbance	0.55 - 0.61 (0.01% in water at 278 nm) (corrected for water and acetic acid content)	0.56
Water content (Karl Fischer)	≤ 7.0%	2.8%
Acetic acid content (HPLC)	4.0 - 7.5%	6.4%
Assay (HPLC)	report net value 95.0 - 102.0% (corrected for water and acetic acid content)	90.4% 99.6%

Bachem AG  
Hauptstrasse 144  
4416 Bubendorf  
Switzerland  
Tel +41 58 595 2021

*De*

**Lot number** 1072380  
**Product** Gonadorelin Acetate Ph. Eur.

Tests	Specifications	Results
Related substances (HPLC)	$\leq 0.5\%$ (Desamido-Gly <sup>10</sup> )-Gonadorelin (Gonadorelin free acid) $\leq 0.5\%$ (D-Tyr <sup>5</sup> )-Gonadorelin $\leq 0.5\%$ (D-His <sup>2</sup> )-Gonadorelin $\leq 0.5\%$ Pyr-His-Trp-Ser-Tyr-OH $\leq 0.5\%$ each other impurity report each other individual $\geq 0.10\%$ $\leq 1.0\%$ total	$< 0.05\%$ (LOQ) 0.12% 0.09% $< 0.05\%$ (LOQ) 0.08% no other individual $\geq 0.10\%$ 0.29%
Residual organic solvents (GC) <sup>1)</sup>	$\leq 5000$ mg/kg isopropanol $\leq 5000$ mg/kg n-butanol	$< 4$ mg/kg (LOD) $< 7$ mg/kg (LOQ)
Heavy metals (ICP-MS) <sup>2)</sup>	$\leq 10$ mg/kg palladium	0.1 mg/kg
Bacterial endotoxins (Ph. Eur.) <sup>3)</sup>	$< 70$ IU/mg	$< 0.10$ IU/mg
Microbial limit test (Ph. Eur.)		
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

<sup>1)</sup> Analysis performed by C.A.T. GmbH & Co. Chromatographie und Analystechnik KG, Heerweg 10, 72070 Tübingen, Germany

<sup>2)</sup> Analysis performed by Solvias AG, Römerpark 2, 4303 Kaiseraugst, Switzerland

<sup>3)</sup> Analysis performed by Labor LS SE & Co. KG, Mangelsfeld 4-6, 97708 Bad Bocklet-Grossenbrach, Germany

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 and the above mentioned sites 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: October 08, 2018  
Bachem AG

*S. Dunkel*

Silke Dunkel, Ph.D.  
QA Release Manager

Bachem AG  
Hauptstrasse 144  
4416 Bubendorf  
Switzerland  
Tel +41 58 595 2021

**BACHEM**

**Lot number**

**1072380**

**Product**

**Gonadorelin Acetate Ph. Eur.**

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:

Bachem AG

Jan. 02, 2019  
month day, year

Weighing Record Number: GM

181013

Signature:

Name:

Steve. Bammr  
Quality Assurance

Bachem AG  
Hauptstrasse 144  
4416 Bubendorf  
Switzerland  
Tel +41 58 595 2021

Certificate of Analysis  
page 3 of 3

*Jul*