BACHEM

Certificate of Analysis

Lot number	**1053371**
Product	**Glucagon**
Product number	4074733
Molecular formula (net)	$C_{153}H_{225}N_{43}O_{49}S$
Molecular mass (average)	3482.8
Date of manufacture	October 30, 2014
Date of release	December 17, 2014
Retest date	October 2016
Specification	QS-4074733A/01
Test procedure	SAV 4074733/02
Storage condition	< -15 °C

Tests	Specifications	Results
Appearance	white powder	white powder
Appearance of solution	clear and colorless solution in 0.1 N HCl (8 mg/mL) and 0.01 N HCl (10 mg/mL)	complies
Identification (HPLC)	retention time corresponds to reference standard	complies
Identification (amino acid analysis) (molar ratio: Ala = 1.00)	Arg 1.6 - 2.2 Asx 3.6 - 4.2 Glx 2.7 - 3.3 Gly 0.8 - 1.3 His 0.8 - 1.3 Leu 1.7 - 2.3 Lys 0.7 - 1.2 Met 0.7 - 1.2 Phe 1.6 - 2.2 Ser 3.1 - 4.1 Thr 2.4 - 3.1 Trp detected Tyr 1.6 - 2.2 Val 0.8 - 1.3	Arg 1.9 Asx 3.9 Glx 2.7 Gly 1.0 His 1.0 Leu 1.9 Lys 1.0 Met 0.9 Phe 1.9 Ser 3.1 Thr 2.6 Trp detected Tyr 1.9 Val 0.9
Specific optical rotation	$[\alpha]_D^{20}$ (4 mg/mL in 0.1 N HCl) = -29.0° to -41.0° (corrected for peptide content)	-31.3°
Related impurities (HPLC)	≤ 1.0% (Des-Thr^5)-Glucagon ≤ 0.5% each other individual ≤ 2.0% total	< 0.05% (LOQ) ≤ 0.11% 0.19%
Water content (Karl Fischer)	≤ 10.0%	2.7%
Residue on ignition	≤ 2.5%	0.1%
Acetate content (HPLC)	≤ 1.2%	< 0.24%
Ammonium content (IC)	≤ 1.2%	0.90%
Chloride content (Titration)	≤ 4.0%	3.0%
Peptide content (elemental analysis)	≥ 80%	92.6%
Residual organic solvents (GC)	≤ 410 mg/kg acetonitrile ≤ 5000 mg/kg diethyl ether ≤ 5000 mg/kg isopropanol	64 mg/kg 264 mg/kg < 16 mg/kg (LOQ)
Mass balance	95 - 105%	99.2%

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Product **Glucagon**

Tests	Specifications	Results
Nitrogen content (elemental analysis)	16.0 - 18.5% (calculated for water-free substance)	17.2%
Zinc (ICP-OES)	≤ 500 mg/kg	8 mg/kg
Bioassay	1 USP Unit/mg (as is) (80 - 125%)	1.07 USP Units/mg
Bacterial endotoxins (LAL test) (USP)	< 1 IU/mg	< 0.50 IU/mg
Microbial limit test (USP <61>, harmonized method)		
Total aerobic microbial count (TAMC)	≤ 10^2 CFU/g (0.2 g tested)	< 5 CFU/g
Total yeasts and moulds count (TYMC)	≤ 10^2 CFU/g (0.2 g tested)	< 5 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: December 18, 2014
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: Jan. 16, 2015 (month day, year)
Bachem AG

Weighing Record Number: GM 150021

Signature: M. Kreimer

Name: M. Kreimer
Quality Assurance

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