

Certificate of Analysis

Product: **Caninsulin 10x2,5ml 296**
Batch: **A587V01**



Country: Russian Fed.
Sales Order Number: 1107943774 / 10
Delivery Number: 1210216185 / 900001
Strength: Insulin 40 IU/ML, Susp., 2,5 ml
(30% amorph and 70% crystalline Insulin of porcine origin)/ml

Material Number:
024455

Type of Container: Package Size:
glass vial, type I, colorless 2,50 ML

Manufacturing Date: Expiry Date:
19-May-2020 Apr-2022

Storage Conditions:
2-8°C

CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name:
Function:
Date:
Signature:

A blue ink stamp with a rectangular border. Inside the stamp, the text "Dr. S. Jost" and "Qualified Person" is printed. Below this, the date "26. Aug. 2020" is handwritten in blue ink. A large, stylized blue ink signature is written across the bottom of the stamp.

Dr. Susanne Jost, Qualified Person

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Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Characters - Color	Visual Examination	White or Almost White	Complies
Characters - Physical State	Visual Examination	Suspension	Complies
Color (supernatant)	Ph. Eur. 2.2.2.	≤ B9	Complies
Clarity (supernatant)	Ph. Eur. 2.2.1.	Opalescence ≤ Reference I	Complies
pH	Ph. Eur. 2.2.3	6.9 ≤ X ≤ 7.8	7.2
Particle Size Amorphous: 100 % ≤ 2 µm	Light Microscopy	Rarely Exceeding 2 µm	Complies
Particle Size rhombohedral: 10 - 40 µm	Light Microscopy	> 10 µm, but Rarely Exceeding 40 µm	Complies
Resuspendability	Visual Examination	≤ 30 Seconds	Complies
Assay, Total Zinc	AAS	48 ≤ X ≤ 100 µg/mL	78 µg/mL
Assay, Zinc Supernatant	AAS	20 ≤ X ≤ 65 %	59 %
Extractable Volume	Ph. Eur. 2.9.17.	2.5 ≤ X ≤ 3.0 mL	2.7 mL
Fill Volume	Weight Measurement	2.5 ≤ X ≤ 3.0 mL	2.8 mL
Identification Insulin	HPLC	Rt of the Corresponding Peaks Comply	Complies
ID Methyl Parahydroxybenzoate	HPLC	Rt of the Corresponding Peaks Comply	Complies
Assay Methyl Parahydroxybenzoate	HPLC	0.90 ≤ X ≤ 1.10 mg/mL	0.98 mg/mL
Assay Insulin + A21 Desamido Insulin	HPLC	36.0 ≤ X ≤ 44.0 IU/mL	39.9 IU/mL
Assay Insulin, in Solution	HPLC	≤ 1.0 IU/mL	0.0 IU/mL
Rel. Sub., A21 Desamido Porcine Insulin	HPLC	≤ 5.0 %	1.2 %
Related Proteins, (Sum Other)	HPLC	≤ 6.0 %	1.1 %
Impur. with Mol.Mass > Insulin	HPLC	≤ 2.0 %	0.1 %
Bacterial Endotoxins	Ph. Eur. 2.6.14.	≤ 31 IU/mL	31 IU/mL
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies
Assay Insulin, non extractable		63 ≤ X ≤ 77 %	65 %

a) The only ingredients of animal origin used in manufacture of Caninsulin are:
 insulin manufactured by Amphastar and derived from porcine pancreatic materials of European origin.
 The porcine pancreatic material was processed to inactivate pathogenic viral agents by treatment with 88% alcohol for several hours
 a pH no greater than 2;

and

bovine insulin crystals manufactured by Novo Nordisk as described in the European Directorate for the Quality of Medicines.
 Certificate of Suitability No. CEP 2000-230. This Product is manufactured from bovine pancreas of Australian and New Zealand
 origin.

The bovine pancreatic material was processed to inactivate pathogenic viral agents by treatment with low pH of approximately 3.0 an
 with
 alcohol at a concentration of a minimum of 60%.

b) The insulin is purified by chromatograph.