Intervet International GmbH
Feldstraße 1a
85716 UNTERSCHLEISSHEIM
GERMANY

Certificate of Analysis

Product: ***Caninsulin cartridges 10x2,7ml 290***
Batch: ***A330A01***

MSD Animal Health

Results of Analysis

Test	Method	Specification	Result
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 - 7.8	7.2
Particle Size Amorphous: 100 % ≤ 2 µm	Light Microscopy	Complies	Complies
Particle Size rhombohedral: 10 - 40 µm	Light Microscopy	Complies	Complies
Resuspendability	Visual Examination	≤ 30 Seconds	Complies
Assay, Total Zinc	AAS	48 - 100 µg/mL	78 µg/mL
Assay, Zinc Supernatant	AAS	20 - 65 %	61 %
Extractable Volume	Ph. Eur. 2.9.17.	2.7 - 2.9 mL	2.8 mL
Fill Volume	Weight Measurement	2.7 - 2.9 mL	2.9 mL
Identification Insulin	HPLC	Rt of the Corresponding Peaks Comply	Complies
ID Methyl Parahydroxybenzoate	HPLC	Rt and Size of the Corresp. Peaks Comply	Complies
Assay Methyl Parahydroxybenzoate	HPLC	0.90 - 1.10 mg/mL	1.00 mg/mL
Assay Insulin + A21 Desamido Insulin	HPLC	36.0 - 44.0 IU/mL	40.6 IU/mL
Assay Insulin, non extractable	HPLC	63 - 77 %	65 %
Assay Insulin, in Solution	HPLC	≤ 1.0 IU/mL	0.1 IU/mL
Rel. Sub., A21 Desamido Porcine Insulin	HPLC	≤ 5.0 %	1.3 %
Related Proteins, (Sum Other)	HPLC	≤ 6.0 %	0.4 %
Impur. with Mol.Mass > Insulin	HPLC	≤ 2.0 %	0.2 %
Bacterial Endotoxins	Ph. Eur. 2.6.14.	≤ 31 IU/mL	31 IU/mL
Sterility	Ph. Eur. 2.6.1.	No Growth Detectable	Complies
Gliding Force		≤ 15 N	15 N

a) The only ingredients of animal origin used in manufacture of Caninsulin are:
insulin manufactuered by Diosynth and derived from porcine pancreatic materials of Dutch and/or French origin. The porcine pancreatic material was processed to inactivate pathogenic viral agents by treatment with 88% alcohol for several hours at 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 Certifica of Suitability No. CEP 2000-230. This Product is manufactured from bovine pancreas of Australian and New Zealand origin. The bovi pancreatic material was processed to inactivate pathogenic viral agents by treatment with low pH of approximately 3.0 and with alcoh at a concentration of a minimum of 60%.

b) The insulin is purified by chromatograph

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Country:	**Distribution via Hungary**
Sales Order Number:	**1103267461 / 10**
Delivery Number:	**1204228124 / 900001**

Material Number:
112723

Package Size:
2,70 ML

Manufacturing Date:
22-May-2014

Expiry Date:
Apr-2016

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:

This document has been created electronically and is valid without signature

Released by Qualified Person