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I28-1

CERTIFICATE OF ANALYSIS

Document effective from:
25-Sep-2015
Edition 3.0

Insulin Aspart Secondary Reference Material

Batch No.	**155.X14.07.2**
Commodity No.	499-0031
Substance	Insulin Aspart
Batch implementation date	04. August 2008
Content	Each vial contains 10 ml insulin aspart, 602 nmol/ml 95% confidence interval: [99.6%;100.4%] in percent of content

Method of Analysis	To be used as secondary reference material for insulin aspart drug substance and drug product. RP-HPLC assay, identification, and homogeneity.
Use	Thaw the reference solution at no more than room temperature and protected against light. Gently mix to obtain a clear solution before use. The thawed solution should be used as specified in the Method of analysis according to validation. If the reference solution is used for other purpose it is the responsibility of the user to validate the use. Be aware of low pressure inside the vial may occur.

Classification	Secondary Reference Material
Traceability	Insulin aspart secondary reference material is traceable to the insulin aspart primary reference material batch 132.X14.03.1
Matrix	Insulin aspart inj. 100 U/ml. Aqueous solution containing: Sodium phosphate, Sodium chloride, Glycerol, Zinc chloride, Phenol and m-Cresol.
Storage and Expiry date	–40°C (between –48°C to –34°C) Expiry date: 24. September 2021
	Storage at –25°C (between –30°C to –18°C) Expiry date: 12 month from date of issue from Metrology. If date of issue from Metrology + 12 month exceed 24. September 2021, the expiry date is 24. September 2021. 10 okt 2017 [signature] [signature] Date of issue Sign Metrology Control sign Metrology
Manufacturer	Novo Nordisk A/S

Change log	CR0620446: New expiry date. Ed. 3.0

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I28-1

Novo Nordisk A/S **Electronic Signature Page** **16 Apr 2015 06:37:41**

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