



SANOFI

Certificate of Analysis

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INSULIN GLARGINE

Material: 156418

Batch: U302

GMID: 172110

Date of manufacturing: 11.Dec.2018 Expiry date.: 09.Dec.2020

Test item	Result	Specification
Appearance	corresponds	powder, white to almost white
Insulin glargine (LC)	corresponds to reference standard	Rt (sample) = Rt (standard)
Fingerprint	corresponds to reference standard	rel. Rt fragments (sample) = rel. Rt fragments (standard)
Largest single related protein (LC)	0,2 per cent	<= 0,4 per cent
Sum of related proteins (LC)	0,5 per cent	<= 1,0 per cent
High molecular weight protein (LC), (Ph.Eur.)	< 0,1 per cent	<= 0,3 per cent
E.coli proteins	Compliance guaranteed (randomly tested)	<=10 µg/g
Content of water	2,2 per cent	<= 8,0 per cent

This certificate of analysis was issued electronically



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Test item Result	Specification
Total aerobic microbial count < 10 CFU/g	<= 300 CFU/g
Total yeasts and moulds count < 10 ² CFU/g	<= 10 ² CFU/g
Bacterial endotoxins corresponds	< 10 EU/mg
Zinc (AAS) as is 0,36 per cent	<= 0,80 per cent
Insulin glargine (LC) calculated with reference to anhydrous substance 96,9 per cent	94,0 - 105,0 per cent

COMPLIES to the requirements.

Data on stability and shelf-life only apply under appropriate conditions of storage.

batch technically released and electronically signed by

Andreas Veith

22.Feb.2019 10:04

Release authorized by Product Responsible Manager respectively Qualified Person

Dr. A.Veith

A. Tziridis (QP) 20-Aug-2019

Dr. A. Tziridis

This certificate of analysis was issued electronically