

Certificate of Analysis

Product Name	Insulin Human, recombinant
Glentham Code	GE1021
CAS Number	11061-68-0
EINECS	234-279-7
MDL Number	MFCD00131380
Batch Number	314TVY

Molecular Weight	5807.57
Molecular Formula	$C_{257}H_{383}N_{65}O_{77}S_6$
Storage Temp.	-20°C

Property	Specification	Batch 314TVY
Physical Description	White to off-white powder	White powder
Identification	A, B according to USP	Conforms
Individual Impurities	High molecular weight proteins: $\leq 0.4\%$	0.1
	A-21 desamido insulin: $\leq 1.0\%$	0.3
	Insulin related proteins: $\leq 1.0\%$	0.4
Zinc (Zn)	$\leq 0.6\%$ (dried basis)	0.4%
Loss on Drying	$\leq 10.0\%$	5.2%
Residue on Ignition	$\leq 2.0\%$	0.7%
Assay	$\geq 27.5IU/mg$ (dried basis)	28.5IU/mg
Assay	95.0 - 105.0 % (dried basis)	97.9%
Total Plate Count	$\leq 300CFU/g$	$< 10CFU/g$
Bacterial Endotoxins	$\leq 10IU/mg$	$< 0.3IU/mg$
Pharmacopoeia Specification(s)	USP, EP	Conforms

Specification Version	v1.0
Manufacture Date	2022-06-23
Re-Test Date	2028-11-10

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

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