

CERTIFICATE OF ANALYSIS

Insulin	Cat.No. : 26360
recombinant human	Contr.No.: 130610

Parameter	Method	Specification	Result
Molecular weight		ca. 5800	
Assay (%)	calculated on dry basis	95.0 – 105.0	99.3
Assay (U/mg)	USP calculated on dry basis	min. 27.5	28.8
Assay (U/mg)	as is	N/A	26.3
Loss on drying (%)		max. 10.0	8.7
Bacterial endotoxins (IU/mg)		max. 10	< 0.4
Zinc (%)	calculated on dry basis	0.3 – 0.6	0.5
Minimum shelf life			10/ 2015
Storage (°C)			-15 to -25

The physical/ chemical data corresponds to the requirements of Ph. Eur. and USP.

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Qualitätskontrolle/ Quality Control

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Dipl.-Ing. (FH) Bernhard Göckel

Patricia Steinmann

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