

Certificate of Analysis

Product Name : Insulin human meets USP testing specifications
Product Number : I0908-50MG
Batch Number : 0000469283
 Source Batch : 0000444438
 CAS Number : 11061-68-0
 MDL Number : MFCD00131380
 Storage Temperature : -20°C
 Molecular Formula : $C_{257}H_{383}N_{65}O_{77}S_6$
 Formula Weight : 5807.57 g/mol
 Quality Release Date : 28 Jun 2025

Test	Specification	Result
Identity	Pass	Pass
Total Microbial Count	≤ 300	< 10
Microbial Enumeration tests and Absence of Specified Microorganism; Expressed in CFU/g		
Endotoxin Level	≤ 10 EU/mg	< 0 EU/mg
USP Endotoxins units/mg		
Loss on Drying	≤ 10.0 %	4.7 %
Zinc (Zn)	≤ 1.0 %	0.4 %
Dry basis		
Limit Test	≤ 1.0 %	0.2 %
High molecular weight proteins		
Residual Solvents USP <467>	Meets Requirements	Meets Requirements
Two class 2 solvents (meets option 1 limit) and Three class 3 solvents.		
Related Compound	≤ 2.0 %	0.5 %
Assay	≥ 27.5	28.2
dry basis USP Insulin Human Units/mg		
Host Cell Derived Protein	Pass	Pass
< or = 10ppm		

Sigma-Aldrich warrants, that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current Specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchase must determine the suitability of the product for its particular use. See reverse side of website or packing slip for additional terms and conditions of sale



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Batch 0000469283

J. Yasomanee

Jagodige Yasomanee, Supervisor
Quality Assurance
St. Louis, Dekalb
US

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Page 2 of 2

