



南京都莱生物技术有限公司 Nanjing Duly Biotech Co.,Ltd  
025-84699383/84699415  
网址: [www.njduly.com](http://www.njduly.com) 邮箱: njduly@126.com

质量报告单  
**CERTIFICATE OF ANALYSIS**

产品名称 Product name	牛胰岛素 Insulin		
CAS号 CAS No.	11070-73-8		
批号 Batch number	Lot:N2410270028		
生产日期 Production date	2024年10月27日	有效期 Expiring date	2025年10月26日
执行标准 Standard adopted	企业标准 Enterprise standard		
分析项目 Items of analysis	质量标准 Specification	实测结果 Results	
外观 appearance	应为白色或类白色的结晶 Shall be white or off white crystals	白色结晶性粉末 White crystalline powder	
溶解度 solubility	在水、乙醇中几乎不溶; 在无机酸或氢氧化钠溶液中易溶 Almost insoluble in water and ethanol; Soluble in inorganic acid or sodium hydroxide solution	符合规定 Compliance with regulations	
保留时间 retention time	含量测定项下记录的色谱图中, 供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 In the chromatogram recorded under the content determination item, the retention time of the main peak of the test solution should be consistent with the retention time of the main peak of the reference solution	保留时间一致 Consistent retention time	

肽图谱 Peptide map	供试品的肽图谱应与对照溶液的肽图谱一致 The peptide map of the test sample should be consistent with that of the control sample	肽图谱一致 The peptide map is consistent
相关蛋白质 Related proteins	A21脱氨胰岛素不得大于5.0%；其他相关蛋白质不得大于5.0% A21 deamination insulin shall not be greater than 5.0%； Other related proteins shall not be greater than 5.0%	A21脱氨胰岛素0.2%； 其他相关蛋白质3.3% A21 deamination insulin 0.2%； Other related proteins 3.3%
高分子蛋白质 Macromolecular protein	总量不得大于1.0% The total amount shall not be greater than 1.0%	0.5%
干燥失重 Loss on drying	105℃干燥至恒重，减失重量≤10.0% Dry at 105 °C to constant weight, reduce weight loss by ≤10.0%	6.2%
锌 zinc	按干燥品计，含锌量不得过1.0% The zinc content shall not exceed 1.0% based on the dry product	0.4%
残留有机溶剂 Residual organic solvent	乙醚不得过0.5% Ether must not exceed 0.5% 乙醇不得过0.5% Ethanol shall not exceed 0.5% 丙酮不得过0.5% Acetone shall not exceed 0.5%	乙醚0.00004% Ether 0.00004% 乙醇0.009% Ethanol 0.009% 丙酮0.009% Acetone 0.009%
生物活性 biological activity	每1mg的效价不得少于15单位 The potency per 1mg shall not be less than 15 units	26u/mg
含量测定 Content determination	按干燥品计，含胰岛素（包括脱氨胰岛素）应为95.5%~105.0% According to the dry product, the content of insulin (including deamination insulin) should be 95.5% ~ 105.0%	折干效价28.4u/mg；折干含量97.9% The dry titer was 28.4u/mg; Dry content 97.9%
结论 Conclusion	合格 Qualified	

质检员：石雨  
Quality inspector: Yu Shi

审核员：宋红梅  
Auditor: Hongmei Song

