

Certificate of analysis

品名	C7695 门冬胰岛素	CAS	116094-23-6
生产日期	2025-03-06	复测日期	2027-03-05
执行标准: 企业标准			
分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS	
Description 描述	White or almost white powder 白色或近乎白色的粉末	White powder 白色粉末	
Identification 1 by Assay 通过测定确定 1	The retention time of major peak of sample solution should correspond to that of standard solution, as obtained in Assay 样品溶液主峰的保留时间应与标 准溶液的保留时间相对应, 如含 量测定中获得的	Conform 符合	
Identification 2 by Peptide Mapping 肽图谱鉴定 2	The chromatographic profile of sample solution should correspond to that of standard solution 样品溶液的色谱图应与标准溶液 的色谱图谱相对应	Conform 符合	
High Molecular Weight Protein 高分子量蛋白质	NMT 0.5%	0.02%	
Loss on Drying 干燥失重	NMT 10.0%	2.0%	
Residue on Ignition 灼烧残渣	NMT 6.0%	0.60%	
Zinc 锌	NMT 1.0%	0.30%	
Related Substances 有关物质	B _{28iso} Asp insulin aspart : NMT 0.3%	0.09%	

	B28isoAsp 门冬胰岛素：不超过 0.3%	
	Total of A ₂₁ Asp insulin aspart, B ₃ Asp insulin aspart, B _{3iso} Asp insulin aspart: NMT 1.0% A21Asp 门冬胰岛素、B3Asp 门冬胰岛素和 B3 异门冬胰岛素的总量：不超过 1.0%	0.12%
	Total of other Impurities: NMT 1.0% 其他杂质总量：不超过 1.0%	0.16%
Residual Solvents 残留溶剂	Acetic acid: NMT 5000 ppm 醋酸：不超过 5000 ppm	Not detected 未检测到
	TFA: NMT 5000 ppm TFA:不超过 5000 ppm	Not detected 未检测到
	Citric acid: NMT 5000 ppm 柠檬酸：不超过 5000 ppm	149ppm
	Acetonitrile NMT 410 ppm 乙腈不超过 410 ppm	5 ppm
Bacterial Endotoxins 内毒素	NMT 10 EU/mg	Conform 符合
Microbial Limit 微生物限度	Total aerobic count does not exceed 300 CFU/g 总需氧菌计数不超过 300 CFU/g	Conform 符合
Biological Activity 生物活性	NLT 15U/mg	Conform 符合
Residual Host Cell Protein 残留宿主细胞蛋白	NMT 10 ng/mg	Conform 符合
Residual Host Cell DNA 残留宿主细胞 DNA	NMT 10 ng/1.5mg	Conform 符合
Assay by HPLC HPLC 测定	90.0%~104.0%(calculated on dried basis) 90.0%~104.0%（按干基计算）	99.3%

QA: 杜冰冰

QC: 谢辉