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Certificate of analysis

品名	重组人胰岛素 Human Insulin, Solution	CAS	11061-68-0
货号	D11080	批次	OK20260609E
生产日期	2026-06-09	复测日期	2028-06-08
执行标准:企业标准			
分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS	
性状 Description	本品为白色或类白色粉末 This product is white or off-white powder	白色粉末 White powder	
鉴别 I Identification I	在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，保留时间之差绝对值 $\leq 0.5\text{min}$ In the chromatogram recorded under the Assay item, the retention time of the main peak of the test solution shall be consistent with that of the reference solution, and the absolute difference in retention time shall not exceed 0.5 min	符合规定 Complies with specification	
鉴别 II Identification II	供试品溶液的肽图谱应与对照品溶液的肽图谱一致，保留时间之差绝对值 $\leq 0.5\text{min}$ The peptide map of the test solution shall be consistent with that of the reference solution, and the absolute difference in retention time shall not exceed 0.5 min	符合规定 Complies with specification	
有关物质 Related Substances	含 A ₂ 1 脱氨人胰岛素应 $\leq 1.0\%$ Content of A ₂ 1 -deamidated	0.04%	

	human insulin shall not exceed 1.0%	
	其他杂质（除 A ₂₁ 脱氨人胰岛素以外杂质）峰面积之和应≤1.0% Total peak area of other impurities (excluding A ₂₁ -deamidated human insulin) shall not exceed 1.0%	0.22%
高分子蛋白质 High Molecular Weight Proteins	保留时间小于人胰岛素主峰的所有峰面积之和应≤1.0% Total area of all peaks with retention time shorter than the main peak of human insulin shall not exceed 1.0%	0.04%
干燥失重 Loss on Drying	应≤10.0% Shall not exceed 10.0%	2.0%
炽灼残渣 Residue on Ignition	应≤2.0% Shall not exceed 2.0%	1.3%
锌 Zinc	应≤1.0% Shall not exceed 1.0%	0.38%
微生物限度 Microbial Limit	需氧菌总数应≤300cfu/g Total aerobic microbial count shall not exceed 300 cfu/g	<10cfu/g
细菌内毒素 Bacterial Endotoxins	应 < 10EU/mg Shall be less than 10 EU/mg	<10EU/mg
宿主蛋白残留量 Host Cell Protein Residue	应≤10ng/mg Shall not exceed 10 ng/mg	0.09ng/mg
宿主 DNA 残留量 Host DNA Residue	应≤10ng/1.5mg Shall not exceed 10 ng/1.5 mg	7×10^{-4} ng/1.5mg
单链前体 Single-chain Precursor	应≤10ng/mg Shall not exceed 10 ng/mg	0.5ng/mg
生物学活性 Biological Activity	应≥15 单位 /mg Shall be no less than 15 Units/mg	27.7 Units/mg
N 末端氨基酸序列 N-terminal Amino Acid Sequence	A 链 N - 末端 15 个氨基酸序列: Gly-Ile-Val-Glu-Gln-Cys-Cys-Thr-Ser-Ile-Cys-Ser-Leu-Tyr-Gln; N-terminal 15 amino acid sequence of A chain: Gly-Ile-Val-Glu-Gln-Cys-Cys-Thr-Ser-Ile-Cys-Ser-Leu-Tyr-Gln; B 链 N 末端 15 个氨基酸序列: Phe-Val-Asn-Gln-His-Leu-Cys-Gly-Ser-His-Leu-Val-Glu-Ala-Leu N-terminal 15 amino acid	A 链 N - 末端 15 个氨基酸序列: Gly-Ile-Val-Glu-Gln-Cys-Cys-Thr-Ser-Ile-Cys-Ser-Leu-Tyr-Gln; N-terminal 15 amino acid sequence of A chain: Gly-Ile-Val-Glu-Gln-Cys-Cys-Thr-Ser-Ile-Cys-Ser-Leu-Tyr-Gln; B 链 N 末端 15 个氨基酸

	sequence of B chain: Phe-Val-Asn-Gln-His-Leu-Cys-Gly-Ser-His-Leu-Val-Glu-Ala-Leu	序列: Phe-Val-Asn-Gln-His-Leu-Cys-Gly-Ser-His-Leu-Val-Glu-Ala-Leu N-terminal 15 amino acid sequence of B chain: Phe-Val-Asn-Gln-His-Leu-Cys-Gly-Ser-His-Leu-Val-Glu-Ala-Leu
乙腈残留 Acetonitrile Residual	应 $\leq$ 410ppm Not more than 410 ppm	46ppm
醋酸、三氟乙酸残留 Acetic Acid & Trifluoroacetic Acid Residual	醋酸应 $\leq$ 5000ppm Acetic acid: not more than 5000 ppm	醋酸 2317ppm Acetic acid: 2317 ppm
	三氟乙酸 $\leq$ 5000ppm Trifluoroacetic acid: not more than 5000 ppm	三氟乙酸未检出 Trifluoroacetic acid: Not Detected
含量 Assay	按干燥品计算, 含人胰岛素 (包括 A ₂₁ , 脱氨人胰岛素) 应为 95.0%~105.0% Calculated on dried basis, the content of human insulin (including A ₂₁ -deamidated human insulin) shall be between 95.0% and 105.0%	99.2%

注: 此产品仅限用于科研, 禁止直接用于临床, 如有失误, 后果自负。

QA: 杜冰冰

QC: 谢辉

