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Certificate of analysis

中文名	重组人胰岛素	CAS	11061-68-0
货号	D11080	批次	OK20221223E
生产日期	2022-12-23	复测日期	2024-12-23

执行标准:企业标准

检测报告 (CERTIFICATE OF ANALYSIS)

检测项目 Items	检测标准 Specifications	检测结果 Results
性状 character	应为白色或类白色粉末 It shall be white or off white powder	白色粉末 White powder
鉴别 (1) Identification (1)	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。 In the chromatogram recorded under the content determination item, the retention time of the main peak of the test solution should be consistent with that of the control solution.	符合规定 Compliance
鉴别 (2) Identification (2)	供试品溶液的肽图谱应与对照品溶液的肽图谱一致 The peptide map of the test solution should be consistent with that of the reference solution	符合规定 Compliance
有关物质 Related substances	A21 脱氨人胰岛素不得过 2.0% A21 deaminated human insulin should not exceed 2.0%	0.2%
	其他杂质峰面积之和不得过 2.0% The sum of peak areas of other impurities shall not exceed	0.8%
	单链前体不得过 0.1% Single chain precursors should not exceed 0.1%	0.01%
高分子蛋白质 High molecular protein	不得过 1.0% Not more than 1.0%	0.2%

干燥失重 Loss on drying	不得过 10.0% No more than 10.0%	2.2%
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	29 单位/mg 29 units / mg
硫酸灰分 Sulphate ash	不得过 2.5% No more than 2.5%	0.6%
锌 zinc	按干燥品计, 含锌 (Zn) 量不得过 1.0% The content of zinc (Zn) should not exceed 1.0% according to the dry product	0.5%
微生物限度 microbial limit	不得过 300cfu/g No more than 300cfu/g	<100cfu/g
细菌内毒素 Bacterial endotoxin	应小于 10EU/m It should be less than 10eu / m	符合规定 Compliance
菌体蛋白残留量 Bacterial protein residue	不得过 10ng/m No more than 10NG / M	符合规定 Compliance
残留溶剂 Residual solvents	甲醇不得过 3000ppm Methanol shall not exceed 3000ppm	未检出 Not detected
	乙醇不得过 5000pp Ethanol should not exceed 5000pp	未检出 Not detected
	乙腈不得过 410ppm Acetonitrile shall not exceed 410 ppm	10ppm
含量 content	按干燥品计, 含重组人胰岛素 (包括 A21 脱氨人胰岛素) 应为 95.0%~105.0% The content of recombinant human insulin (including A21 deaminated human insulin) should be 95.0% ~ 105.0% based on dry product	100.6%
结论 conclusion	本品检测结果符合 Ph. Eur “InsulinHuman” 规定 The test results of this product meet the requirements of Ph. Eur “insulin human”	

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

