

质检报告单——CERTIFICATE OF ANALYSIS

产品名称 Product Name	两性霉素 B 注射级 (分子式: C ₄₇ H ₇₃ NO ₁₇ 分子量: 924.08) Amphotericin B injection grade		
CAS NO.	1397-89-3	产品批号 Batch No.	HBW230701-2
包装规格 Packaging	0.5KG/听/Tin	生产日期 Man. Date	2023-07-06
有效日期 Expiry Date	2026-07-05	报告日期 Report Date	2023-07-23
检验项目 Test Items	检验指标 Standard	检验结果 Test Results	
性状 Characteristics	黄色至橙色粉末 Yellow to orange powder	符合规定 Complies	
溶解性 Solubility	符合规定 Complies	符合规定 Complies	
鉴别 Identification	IR、HPLC 符合规定 Complies	符合规定 Complies	
干燥失重 loss on drying	≤5.0%	2.2%	
炽灼残渣 Residue on ignition	≤0.5%	0.04%	
有关物质 Related substances	杂质 A (303nm) Impurity A at 303nm ≤2.0% 其他任何杂质 (303nm) Any other impurity at 303nm ≤1.0% 杂质 B (383nm) Impurity B at 383nm ≤4.0% 其他任何杂质 (383nm) Any other impurity at 383nm ≤2.0% 总杂质 (303nm&383nm) Total Impurities at 303nm and 383nm ≤15.0%	ND ND 0.2% 1.6% 4.6%	
微生物限度 Microbial Limits	菌落总数 Total Aerobic count ≤100CFU/g 沙门氏菌 Salmonella Species 不得检出 Negative 大肠埃希菌 Escherichia Coli 不得检出 Negative	0CFU/g ND ND	
细菌内毒素 Bacterial endotoxins	≤1.0IU/mg	符合规定 Complies	
残留溶剂 Residual solvents	乙醇 Ethanol ≤5000ppm DMF ≤4000ppm 丙酮 Acetone ≤5000ppm 三乙胺 Triethylamine ≤2000ppm	1651ppm 2340ppm 1722ppm 97ppm	
含量 (干品) Assay (On dried)	≥750IU/mg(干品计, on dried basis)	1069IU/mg	
结论 Conclusion	本品符合 EP11.0 质量标准 Complies with EP11.0 standard		

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