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分析证明书

CERTIFICATE OF ANALYSIS

Product name 品名: Idarubicin Hydrochloride 盐酸依达比星(CAS# 57852-57-0)	
Batch no. 批号: 20220501	Quantity 数量: 25g
Manuf. date 生产日期: 2022/05/02	Expiry date 有效期: 2024/05/01

项目 Item	标准 Specifications	结果 Results
Appearance	Yellow red powder	Yellow red powder
IDENTIFICATION	IR should comply with spectrums	Positive
pH (5.0mg/ml)	5.0~6.5	5.7
Crystallinity	Should meet the requirements	Complies
Water content (K.F.)	≤5.0%	1.7%
Residue on Ignition	≤0.5%	0.18%
Heavy metals	≤20ppm	<20ppm
Palladium content	≤10ppm	n.d.
Single impurities	≤0.1%	0.03%
Total impurities	≤2.0%	0.03%
Residual solvents	Acetone≤0.5%	n.d
	Methanol≤0.3%	0.005%
	Dichloromethane ≤0.06%	0.021%
ASSAY	97.0%~103.0%(on the dried substance)	100.0% (on the dried substance)
Bacterial microbial limit	≤ 5EU/mg	Complies
Microbial limit	Bacteria and Fungi count ≤ 100cfu/g	Complies
Conclusion	The product conforms to the USP35 Standard	

复核人 Checker:

化验人 Analyst:

