

冻存管最终质量检查表 Freezing Tubes Quality Final Check list

目录号 Catalog Number	FCT512020	规格 Specifications	2mL			
批号 Lot Number	210702-539	有效期 Expiration Date	2024-07-02			
生产日期 Manufacture Date	2021-07-02	检验日期 Inspection Date	2021-07-05			
检验项目及结果 Inspection Item and Result						
检验项目及标准 Inspection Item and Standard		接收水平 Acceptance Level		检验结果 Inspection Result		
		检验水平 Quality Level	样品数 Sample Size	收:退 Ac:Re	结果 Result	判断 Judgement
外观 Appearance	产品无异色杂质、无油污、破裂、缩水变形现象,无披锋,包装完整 No heterochromatic impurities. No oil, crack, shrinkage deformation, burrs. With complete packaging.	依据标准:GB/T 2828.1-2012 Standard:GB/T2828.1-2012 抽样水平:Level II, AQL 1.5 Sample Level: Level II, AQL 1.5			符合/Meet criteria	合格/OK
性能 Function	容量:±2% Capacity: within ±2%	N/A				
	密封性: -90kPa, 60 秒 Leakage: -90kPa, 60S	C=0	10	0:1	符合/Meet criteria	合格/OK
	耐高温: 121°C, 20 分钟 High temperature performance: 121°C, 20min	C=0	10	0:1	符合/Meet criteria	合格/OK
	冻存测试: -196°C, 24 小时 Freezable: -196°C, 24hour	C=0	10	0:1	符合/Meet criteria	合格/OK
生物性能 Biological Performance	无菌 Sterilized(SAL=10 ⁻⁶)	C=0	3	0:1	样品 Samples: --- 阳性对照 Positive: +++ 阴性对照 Negative: ---	合格/OK
	细胞毒性 Cytotoxicity	C=0	3	0:1	样品 Samples: --- 阳性对照 Positive: +++ 阴性对照 Negative: ---	合格/OK
	热原≤0.5EU/mL Non-Pyrogenic (≤0.5EU/mL)	C=0	3	0:1	样品 Samples: --- 阳性对照 Positive: +++ 阴性对照 Negative: ---	合格/OK
	无酶 DNase & RNase Free	C=0	3	0:1	样品 Samples: --- 阳性对照 Positive: +++ 阴性对照 Negative: ---	合格/OK
最终判断 Final Judgement	接收 Accept	✓			拒收 Reject	
签名 Signature						
检验 Inspected by			审核 Approved by			
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