



培养液瓶最终质量检查报告 Solution Bottles Quality Final Check List

目录号 Catalog Number	CTF010150	规格 Specifications	150mL
批号 Lot Number	220519-109-A	有效期 Expiration Date	2025-05-19
生产日期 Manufacture Date	2022-05-19	检验日期 Inspection Date	2022-05-22

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	产品无油污、破裂、缩水变形现象，无披锋，包装完整 No oil, crack, shrinkage deformation, burr. 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：允差：±5% Capacity: within ±5%	C=0	10	0:1	符合/Meet criteria	合格/OK
	耐温性能:-20℃,24h; Temperature resistance : -20℃ , 24 hour	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
	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
	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
	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			
张江伟			马菊菊			