

分析证明书

CERTIFICATE OF ANALYSIS

Product name: Bleomycin sulphate 硫酸博莱霉素	
Batch no. 批号: 20220215	Quantity 数量: 200grs
Manuf. date 生产日期: 2022/02/10	Expiry date 有效期: 2022/02/09

ITEMS	STANDARD	RESULTS
Appearance	White to off-white amorphous powder	Off-white amorphous powder
Identification	(1) IR (2) Reaction of Sulfate	Conforms Conforms
Copper	≤0.1%	0.0%
PH	4.5 ~ 6.0	5.1
Loss on Dryings	≤6.0%	1.1%
Bacterial endotoxins	≤10.0 EU/U	<0.5 EU/U
Potency	1.5~2.0U/mg	1.6U/mg
Content of Bleomycins		
Bleomycin A2	55%~70%	67%
Bleomycin B2	25%~32%	29%
Bleomycin A2+ B2	≥90%	96%
Bleomycin B4	≤1.0%	<0.05%
Residual Solvents		
Acetone	≤20000ppm	12450ppm
Ethanol	≤5000ppm	954ppm
Bioburden		
Total Aerobic Count	Not more than 100cfu/gm	<1cfu/gm
Total Mold and Yeast	Not more than 50cfu/gm	<1cfu/gm
CONCLUSION: The results conform to USP specification.		

复核人 Checker:

化验人 Analyst:

