



丽珠医药 LIVZON 丽珠集团福州福兴医药有限公司

LIVZON GROUP FUZHOU FUXING PHARMACEUTICAL CO., LTD.

Nº lote ACOFARMA:

213158

Firma y fecha:

210612

检验报告单
CERTIFICATE OF ANALYSIS

No.: COA-TB-3505-006

品名 Product Name	硫酸妥布霉素 Tobramycin Sulfate	批号 Batch No.	TB2104001
包装规格 Packaging	7kg/Tin	生产日期 Mfg. Date	2021.04.28
批量 Batch Size	112.50kg	有效期 Exp. Date	2025.04.27
储存条件 Storage Conditions	密封, 15~30℃保存。 Preserve in tight containers, store at 15~30℃.		

项目 Tests		标准 Specifications	结果 Results
性状 Characters		白色或类白色粉末, 有引湿性。 White or almost white, hygroscopic powder.	符合规定 Conform
鉴别 Identification	TLC 鉴别 TLC Identification	供试品溶液所显示主斑点的位置和颜色应与标准品溶液的相同。 The colour and location of the principal spot obtained from test solution correspond to that obtained from standard solution.	符合规定 Conform
	HPLC 鉴别 HPLC Identification	供试品溶液主峰的保留时间应与标准品溶液一致。 The retention time of major peak of the sample solution corresponds to that of the standard solution obtained as directed in the assay.	符合规定 Conform
	硫酸盐鉴别 Sulfate test	显硫酸盐的鉴别反应 Present the identification reaction of sulfate.	符合规定 Conform
pH		6.0~8.0	7.47
水分 Water		≤2.0%	0.41%
重金属 Heavy metals		≤30ppm	<30ppm
炽灼残渣 Residue on ignition		≤1.0%	0.10%
色谱纯度(TLC) Chromatographic purity		任何单个杂质不大于 1.0% Any individual impurity ≤1.0%	<1.0%
含量 Assay		634~739µg/mg	706µg/mg
残留溶剂 Residual solvent	乙醇 Ethanol	≤5000ppm	未检出 Not detected
	乙醛 Acetaldehyde	≤450ppm	未检出 Not detected
细菌内毒素 Bacterial endotoxins		<2.0EU/mg	<2.0EU/mg
无菌检查 Sterility test		不得有菌生长 No growth of microorganisms occurs.	符合规定 Conform
结论 Conclusion		符合美国药典及企业内控标准 The product complies with USP and In-house Specifications.	

准备人 Prepared by:	日期 Date:	2021.05.17
复核人 Checked by:	日期 Date:	2021.05.17
批准人 Approved by:	日期 Date:	2021.05.17

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