

METAPHARMACEUTICAL

N DE LOTE:

0111222

Wuxi Fortune Pharmaceutical Co., Ltd

无锡福祈制药有限公司

No. 2 Rongyang 1st Road, Xishan Economic Zone, Wuxi City, Jiangsu Province, P. R. China
中国江苏省无锡市锡山经济开发区蓉洋一路2号 Tel: +86 510-83104425 Fax: +86 510-83101257

Handed over by:

VIVATIS FARM

Calle Téllez 52, Loc. 28007 Madrid (Spain)

Tel: +34 91 433 85 81 - CIF 28007

Certificate of Analysis

检验报告书

CEP No.: RO-CEP 2016-034-Rev 02

Analysis No. (检验编号): Pr20221222

Product Name: 产品名称	Mitomycin 丝裂霉素	Specification: 规格	API 原料药
Batch No.: 批号	AD220802A-1	Quantity: 数量	875.00 g
MFG. Date: 生产日期	2022/08/12	RET. Date: 复验期	2027/08/11
Test Standard 检验依据	EP10th	Report Date: 报告日期	2022/11/28

Test Items 检验项目	Acceptable Criteria 标准规定	Results 结果
Appearance 性状	Blue-violet crystals or crystalline powder. 应为蓝紫色结晶或结晶性粉末	Blue-violet crystalline powder 蓝紫色结晶性粉末
Identification 鉴别		
A: Infrared absorption spectrum 红外吸收光谱	A: The infrared absorption spectrum is concordant with that of the reference standard 应与对照品的红外光吸收图谱一致	The infrared absorption spectrum is concordant with that of the reference standard 与对照品的红外光吸收图谱一致
B: HPLC 液相色谱	B: In the assay, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a). 含量测定项下, 供试品溶液与对照品溶液主峰的保留时间和大小与对照溶液 (a) 所获得的图谱类似。	In the assay, the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a). 含量测定项下, 供试品溶液与对照品溶液主峰的保留时间和大小与对照溶液 (a) 所获得的图谱类似。
Tests 检查		
pH	5.5 ~ 7.5	6.4
Water 水分	≤ 2.5%	0.1 %
Related substances 有关物质	Impurity 杂质A ≤ 0.5% Impurity 杂质B ≤ 0.5% Impurity 杂质C ≤ 0.5% Impurity 杂质D ≤ 0.5% Any other impurity 其他 单个杂质 ≤ 0.15 % Total impurities 总杂 ≤ 2.0%	< Disregard limit (0.05%) < Disregard limit (0.05%) < Disregard limit (0.05%) < Disregard limit (0.05%) 0.05 % 0.1 %
Bacterial endotoxins 细菌内毒素	Less than 10 IU/mg 应 < 10 IU/mg	< 10 IU/mg
Microbial contamination 微生物限度	TAMC需氧菌总数 ≤ 10 ³ cfu/g TYMC霉菌和酵母菌总数 ≤ 10 ² cfu/g	< 10cfu/g < 10cfu/g
Assay 含量测定	97.0% ~ 102.0% (anhydrous substance) 应为97.0% ~ 102.0% (按无水物计算)	99.5 %
Residual solvents 残留溶剂	Methanol 甲醇 ≤ 3000ppm Ethyl ether 乙醚 ≤ 5000ppm Ethyl acetate 乙酸乙酯 ≤ 500ppm	316 ppm 8 ppm ND

Conclusion: Conform to the specification of EP10th
结论: 本品按EP10版标准检验, 结果符合规定

Prepared by: [Signature]
制单:

Approved by: [Signature]
批准: [Signature]

