

检验报告单

Certificate of Analysis



BLEOMYCIN SULFATE PhEur

BATCH NUMBER	1018011N210503	MANUFACTURE DATE	2021.05.31
BATCH SIZE	553.67g	TEST DATE	2021.06.10
QUANTITY	533g	RETEST DATE	2023.05.30

TEST	METHOD	ACCEPTANCE CRITERIA	RESULT
Appearance	Visual	White or yellowish-white powder	<u>Yellowish-white powder</u>
Identification A	EP Monograph	The retention times and sizes of the two principal peaks in the chromatogram obtained with the test solution are approximately the same as those of the two principal peaks in the chromatogram obtained with reference solution (a).	<u>Conforms</u>
Identification B	EP<2.3.1>	It gives the reactions of sulfates	<u>Conforms</u>
Appearance of Solution	EP<2.2.1> EP<2.2.25>	The solution is clear. The absorbance measured at 430 nm is not greater than 0.10.	<u>Conforms</u>
pH	EP<2.2.3>	4.5 to 6.0	<u>5.1</u>
Composition	EP Monograph		
Bleomycin A ₂		55% to 70%	<u>67%</u>
Bleomycin B ₂		25% to 32%	<u>29%</u>
Bleomycin A ₂ + B ₂		Not Less Than 90%	<u>96%</u>
Demethylbleomycin A ₂		Not More Than 2.0%	<u>0.4%</u>
Bleomycin B ₄		Not More Than 1.0%	<u><0.05%</u>
Any Other Impurity		Not More Than 2.5%	<u>1.0%</u>
Other Related Substances		Not More Than 8.5%	<u>3.9%</u>
Copper	In-house H0-AM-20064-01	Not More Than 200ppm	<u>67ppm</u>
Loss on Drying	EP<2.2.32>	Not More Than 3.0%	<u>1.7%</u>
Bacterial Endotoxins	EP<2.6.14>	Not More Than 5.0 IU/mg	<u><0.8IU/mg</u>
Assay	EP<2.7.2>	Not Less Than 1500 IU/mg (calculated on the dried basis)	<u>1579IU/mg</u>
Residual Solvents	USP<467>		
Acetone		Not More Than 20000ppm	<u>1860ppm</u>
Ethanol		Not More Than 5000ppm	<u>110ppm</u>
Bioburden	EP<2.6.12>		
Total Aerobic Count		Not More Than 100 cfu/g	<u><1cfu/g</u>
Total Mold and Yeast		Not More Than 50 cfu/g	<u><1cfu/g</u>

Analyst: 金阳凤

Checker: 李丽

Supervisor: 郭学东

FINAL BATCH DISPOSITION

Approved

Rejected

By: 7/10/21 2021.06.12

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