检验报告单 Certificate of Analysis

HISUN 海正药业

BLEOMYCIN SULFATE PhEur

BATCH NUMBER	1018011N231001	TEST DATE	2023.10.26
BATCH SIZE	673.24g	RETEST DATE	2025.10.10
MANUFACTURE DATE	2023.10.11		

TEST	METHOD	ACCEPTANCE CRITERIA	RESULT
Appearance	Visual	White or yellowish-white powder	Yellowish-white powder
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).	Conforms
Identification B	EP<2.3.1>	It gives the reactions of sulfates	Conforms
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.	0.04
pH	EP<2.2.3>	4.5 to 6.0	5.1
Composition	EP Monograph		
Bleomycin A_2		55% to 70%	67%
Bleomycin B_2		25% to 32%	30%
Bleomycin A_2 +B_2		Not Less Than 90%	96%
Demethylbleomycin A_2		Not More Than 2.0%	0.2%
Bleomycin B_4		Not More Than 1.0%	<0.05%
Any Other Impurity		Not More Than 2.5%	0.8%
Other Related Substances		Not More Than 8.5%	3.6%
Copper	In-house H0-AM-20064-01	Not More Than 200ppm	27ppm
Loss on Drying	EP<2.2.32>	Not More Than 3.0%	1.9%
Bacterial Endotoxins	EP<2.6.14>	Not More Than 5.0 IU/mg	<0.8IU/mg
Assay	EP<2.7.2>	Not Less Than 1500 IU/mg(calculated on the dried basis)	1614IU/mg
Residual Solvents	USP<467>		
Acetone		Not More Than 20000ppm	1830ppm
Ethanol		Not More Than 5000ppm	<102ppm
Bioburden	EP<2.6.12>		
Total Aerobic Count		Not More Than 100 cfu/g	<1cfu/g
Total Mold and Yeast		Not More Than 50 cfu/g	<1cfu/g

Prepared by:

Reviewed by:

FINAL BATCH DISPOSITION

✓ Approved ____ Rejected

By: 2023.11.22

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