

检验报告单

Certificate of Analysis



MITOMYCIN PhEur

BATCH NUMBER	1127011N250101	MANUFACTURE DATE	2025.01.25
BATCH SIZE	1550.32g	TEST DATE	2025.02.10
RETEST DATE	2028.01.24		

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	Blue-violet crystals or crystalline powder.	Blue-violet crystalline powder
Identification A	IR spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of the reference standard.	Conforms
Identification B	The principal peak in the chromatogram obtained with the Assay Preparation is similar in retention time and size to the principal peak in the chromatogram obtained with Standard Preparation.	Conforms
pH	5.5 to 7.5	6.3
Water Content	Not More Than 2.5%	0.1%
Related Substances		
Impurity A	Not More Than 0.5%	<0.02%
Impurity B	Not More Than 0.5%	<0.02%
Impurity C	Not More Than 0.5%	<0.02%
Impurity D	Not More Than 0.5%	<0.02%
Any Other Impurity	Not More Than 0.5%	<0.02%
Total Impurities	Not More Than 2.0%	<0.02%
Assay	97.0% to 102.0%, calculated on the anhydrous and solvent-free basis.	100.4%
Residual Solvents		
Acetone	Not More Than 1000ppm	<20ppm
Methanol	Not More Than 1000ppm	195ppm
Ethyl Ether	Not More Than 1000ppm	19ppm
Ethyl Acetate	Not More Than 5000ppm	<99ppm
Bacterial Endotoxins	Less Than 10.0 IU/mg	<0.5IU/mg

Conclusion: The results conform to EP specification.

Prepared by: 金锡银

Reviewed by: 王林

FINAL BATCH DISPOSITION

By: 王林 2025.2.10

Approved

Rejected

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GN2 Version 1.0
02/04/24
Zhejiang Hisun Pharmaceutical Co., Ltd.

METAPHARMACEUTICAL

N DE LOTE: 040725

25/07/2025