

# 检验报告单

## Certificate of Analysis



### MITOMYCIN PhEur

BATCH NUMBER	1127011N230201	MANUFACTURE DATE	2023.02.27
BATCH SIZE	1709.42g	TEST DATE	2023.03.09
RETEST DATE	2026.02.26		

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	6.4
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.	99.5%
Residual Solvents		
Acetone	Not More Than 1000ppm	<20ppm
Methanol	Not More Than 1000ppm	337ppm
Ethyl Ether	Not More Than 1000ppm	40ppm
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: 金钊银

Reviewed by: 王敏

FINAL BATCH DISPOSITION

Approved

Rejected

By: 姜士林 2024.02.06

METAPHARMACEUTICAL

N DE LOTE:

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Zhejiang Hisun Pharmaceutical Co., Ltd.