

检验报告单

Certificate of Analysis



MITOMYCIN PhEur

BATCH NUMBER	1127011N240301	MANUFACTURE DATE	2024.03.31
BATCH SIZE	1860.23g	TEST DATE	2024.04.07
RETEST DATE	2027.03.30		

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	6.5
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.	99.9%
Residual Solvents		
Acetone	Not More Than 1000ppm	<20ppm
Methanol	Not More Than 1000ppm	378ppm
Ethyl Ether	Not More Than 1000ppm	12ppm
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: 王世成

FINAL BATCH DISPOSITION

By: 王世成, 2024.4.7

Approved

Rejected

METAPHARMACEUTICAL

N DE LOTE:
024 10 24

25/10/2024

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Zhejiang Hisun Pharmaceutical Co., Ltd.