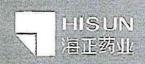
## 检验报告单

## Certificate of Analysis



## BLEOMYCIN SULFATE PhEur

**BATCH NUMBER** BATCH SIZE

1018011N250301

TEST DATE RETEST DATE 2025.03.19

MANUFACTURE DATE

2025.03.17

673.86g

2027.03.16

TEST Appearance

**METHOD** Visual

ACCEPTANCE CRITERIA

RESULT

White or yellowish-white powder

Yellowish-white powder

Conforms

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

Identification B Appearance of Solution

pН

EP<2.3.1> EP<2.2.1>

EP Monograph

reference solution (a). It gives the reactions of sulfates The solution is clear. The absorbance measured at 430

chromatogram obtained with

Conforms 0.02

EP<2.2.25>

nm is not greater than 0.10. EP<2.2.3> 4.5 to 6.0

5.1

Composition Bleomycin A<sub>2</sub> Bleomycin B2 Bleomycin A2 +B2

Demethylbleomycin A2 Bleomycin B4 Any Other Impurity

Other Related Substances Copper

In-house

EP<2.2.32> EP<2.6.14>

25% to 32% Not Less Than 90% Not More Than 2.0% Not More Than 1.0% Not More Than 2.5% Not More Than 8.5% Not More Than 200ppm

55% to 70%

29% 97% 0.2% <0.05% 0.4% 2.4% 7ppm

68%

H0-AM-20064-01

EP<2.7.2>

Not More Than 3.0% Not More Than 5.0 IU/mg Not Less Than 1500 IU/mg(calculated on the dried 1.0% <0.81U/mg 1672IU/mg

Residual Solvents

Bacterial Endotoxins

Loss on Drying

Acetone Ethanol Bioburden

Assay

EP<2.6.12>

USP<467>

Not More Than 20000ppm Not More Than 5000ppm

4699ppm 333ppm

Total Aerobic Count Total Mold and Yeast Not More Than 100 cfu/g Not More Than 50 cfu/g

basis)

2cfu/g <1cfu/a

Prepared by:

Reviewed by:

DISTRIBUIDO PORTA

FINAL BATCH DISPOSITION

Approved

METAPHERMAGEUT

Manufacturer Zhejiang Hisun Pharmaceutical Co., Ltd. 46 Waisha Road, Jiaojiang District Taizhou City, Zhejiang Province People's Republic of China

Manufacturing Sit Zhejiang Hisun Pha 56 Binhai Road Jiao Taizhou City, Zhejia People's Republic of China

COS Version 1.0 10/09/22

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