



For the Best Global Pharmaceutical Company

KOREA UNITED PHARM. INC.**CERTIFICATE OF ANALYSIS**
(FINISHED PRODUCT)Product Name: **BLEOMYCIN 15 IU Lyophilized for Injectable Solution**

Active Ingredient: Bleomycin Sulfate

Analysis No.: I9-062401

Lot No.: E1174904

Analysis Date: July 09, 2019

Batch Size : 5,000 Vials

Mfg. Date: June 18, 2019

Reference: USP 42

Exp. Date: June 17, 2021

TESTS	SPECIFICATIONS	RESULTS
Description	White lyophilized powder	White lyophilized powder
Identification		
A. By IR	The IR absorption spectrums of the Test specimen and the Standard specimen exhibit maxima at the same wavelengths	Meets the requirements
B. Test for Sulfate	The turbidity of Test solution develops as like Standard solution	Meets the requirements
pH	Between 4.5 and 6.0	5.2
Water	Not more than 6.0 %	3.5 %
Copper	Not more than 0.1 %	0.0%
Dilution Time	Not more than 1 minute	Not more than 1 minute
Constituted Solution		
1) Completeness and Clarity of solution	Meets the requirement	Meets the requirement
2) Foreign matter	Not detected	Not detected
Content of Bleomycin	A ₂ : Between 55 % and 70 % B ₂ : Between 25 % and 32 % B ₄ : Not more than 1.0 % A ₂ &B ₂ : Not less than 90 %	66.2 % 30.9 % 0.4 % 97.1%
Bacterial Endotoxins	Not more than 10.0 EU per Unit	Complies
Sterility	Sterile	Sterile
Particulate Matter	Not more than 6000 per vial ($\geq 10\mu m$) Not more than 600 per vial ($\geq 25\mu m$)	10/vial 0/vial
Nominal weight	7.5 mg $\pm$ 10%	Average Weight : 8.1 mg
Weight Variation		(7.7 mg ~ 8.4 mg)
Acceptance value	Not more than 15.0 %	11.8 %
Assay	Between 90.0 % and 120.0 %	105.7 %

Remarks: Sample conforms to specifications.

**KOREA UNITED PHARM, INC.****조기영**
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QC/QA Director