

NANJING SUNNY PHARMATECH CO., LTD.

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Certificate of Analysis

Product Name	POLYMYXIN B SULFATE (NON-STERILE) CAS: 1405-20-5		
Manufacture Date	2024/03/21	Quantity	35Kg
Batch Number	202403021	Expiry Date	2027/03/20

ITEMS	STANDARD	TEST RESULT
Appearance	White to almost white powder, Hygroscopic.	Conforms
Solubility	Clear colorless	Conforms
Identification	A. HPLC(USP/BP) B. Meets the requirements of the test for sulfate C. TLC(BP)	Conforms
PH (0.5%)	5.0 ~ 7.5	5.92
Specific Rotation	-78° ~ -90°	-83°
Loss on drying	Not more than 6.0%	1.35%
Sulphate ash	Not more than 0.75%	0.08%
Sulphate (On Dried Basis)	15.5% ~ 17.5%	16.20%
Heavy metals	Not more than 20ppm	<20ppm
Assay (microbial) (on dried basis)	Not less than 6000 IU/mg	8195 IU/mg
Composition of Polymyxins	Sum of polymyxin B1,B2,B3 and B1-I: Not less than 80.0% B3: Not more than 6.0% B1-I: Not more than 15.0%	83.28% 1.32% 5.28%
Related Substances (HPLC)	Any individual impurity: Not more than 3% Total impurities: Not more than 17%	2.39% 8.79%

Conclusion Conform to the **EP9/USP43** Standard**Storage** Preserve in well-closed, light-resistant & tight containers; in cool & dry place.**SURVEYOR: LIYONG**