



Certificate of analysis

Productname: Polymyxin B sulfate

Cas number: 1405-20-5

Molecular Formula: $C_{56}H_{98}N_{16}O_{13} \cdot H_2SO_4$

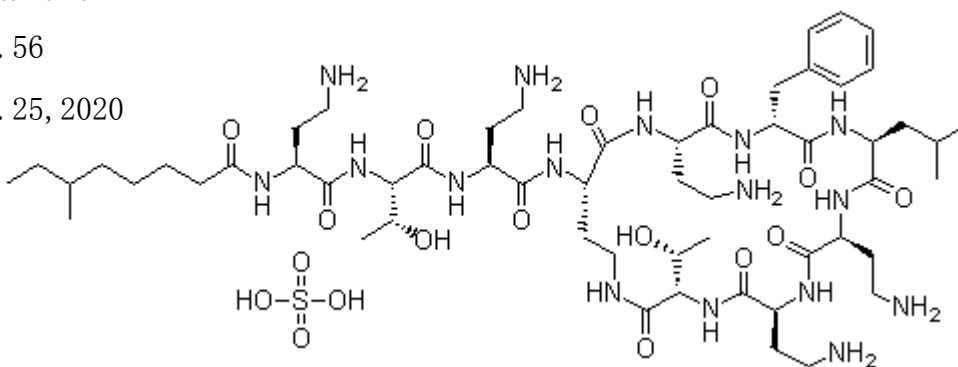
Molecular Weight: 1301.56

Date of production: Mar. 25, 2020

Batch No: 20200325

EXP DATE: Mar. 24, 2022

Chemical structure:



ITEMS	SPECIFICATIONS	RESULTS
Description	White to almost white powder, hygroscopic.	Complies
Solubility	Freely soluble in water; slightly soluble in alcohol	Complies
Identification	Liquid chromatographic identification test. A reddish violet color is produced. Test for sulfate	Complies
Ph (2%)	5.0~7.0%	5.6
Ph (0.5%)	5.0~7.5 %	5.6
Specific Rotation	-78° ~ -90°	-80.0°
Loss on drying	Not more than 7.0%	5.5%
Phenylalanine	9.0%~12.0%	10.45%
Sulphated ASH	Not more than 0.75%	0.23%
Sulphate	15.5%~17.5%	16.70%
Heavy metals	Not more than 20ppm	<20PPM
Sterility	Meets the requirements	Complies
Assay (Microbial) (on dried basis)	Not less than 6500IU/MG	8190IU/MG
Particle size	99.0%: Not more than 30 μ M by vol. 90.0%: Not more than 25 μ M by vol. 75.0%: Not more than 20 μ M by vol. Mean diameter: Not more than 8.0 μ M	Complies

Conclusion: It complies with the USP32 Standard.

Storage: Preserve in well-closed, light-resistant & tight containers; in cool & dry place.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F