



福安药业集团烟台只楚药业有限公司

Fuan Pharmaceutical Group Yantai Zhichu Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Product Name: Gentamicin Sulphate BP2002/EP4			
Batch No.	220211003	Manufacturing Date	Feb.,2022
Reporting No.	222005100	Expiry Date	Jan.,2026
Package Size	5 BOU/Tin, 2 Tin/Carton	Quantity	/
Analytical results			
Items	Specifications		Results
Characters	A white or almost white powder, freely soluble in water, Practically insoluble in alcohol and in ether .		Almost white powder
Identification	Tests according to monograph		Complies
Appearance of solution	Clear and not more intensely colored than degree 6 of the Range of reference solutions of the most appropriate color		Complies
pH	3.5 to 5.5		4.6
Specific optical rotation	+107° to +121°		+119°
Methanol	Not more than 1.0 percent		Complies
Composition	C ₁ :	25.0 to 50.0 per cent	27.0%
	C _{1a} :	10.0 to 35.0 per cent	19.8%
	C _{2a} + C ₂ :	25.0 to 55.0 per cent	53.2%
Water	Not more than 15.0 per cent		8.8%
Sulphated ash	Not more than 1.0 per cent		0.3%
Sulphate	32.0 to 35.0 per cent		33.4%
Bacterial endotoxins	Less than 1.67 IU/mg		Less than 0.71 IU/mg
Microbial limit	Total Aerobic Microbial Count	Not more than 1000 cfu/g	Less than 10 cfu/g
	Total yeast and mold Count	Not more than 100 cfu/g	Less than 10 cfu/g
Assay	Not less than 590 IU/ mg(anhydrous substance)		675 IU/mg
	(hydrous substance)		616 IU/mg
Conclusion :complies with the standard of BP2002/EP4			

Approver:

Reviewer :

Reporter :

地址: 中国山东省烟台市芝罘区烟福路 1 号 邮编: 264002
ADD: No.1 Yanfu Road, Zhifu District, Yantai, Shandong Province, China