

**烟台只楚药业有限公司**

YANTAI JUSTAWARE PHARMACEUTICAL CO., LTD

NO.1 YANFU ROAD,ZHIFU DISTRICT,YANTAI,CHINA

**CERTIFICATE OF ANALYSIS**

Product Name: GENTAMICIN SULPHATE IP.

Batch No.	151221391	Manufacturing Date	DEC.,2015
Reporting No.	1521391	Expiry Date	NOV.,2019
Package Size	5BOU/Tin , 2Tin/Carton	Quantity	170 BOU

Analytical results

Items	Specifications	Results
Characters	A white or almost white powder, freely soluble in water, Practically insoluble in alcohol and in ether .	Complies
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	4.8
Specific optical rotation:	+107° to +121°	+116°
Methanol	Not more than 1.0 percent	Complies
Composition	C ₁ : 25.0 to 50.0 per cent	26 %
	C _{1a} : 10.0 to 35.0 per cent	28 %
	C _{2a} + C ₂ : 25.0 to 55.0 per cent	46 %
Loss on drying	Not more than 18.0 per cent	6.4%
Sulphated ash	Not more than 1.0 per cent	0.3%
Sulphate	32.0 to 35.0 per cent	33.5%
Sterility	Complies with the test for sterility	Complies
Bacterial endotoxins	Not more than 1.67 EU/mg	<0.71 EU/mg
Assay	Not less than 590 µg/ mg(anhydrous substance)	662 µg/ mg
	(hydrous substance)	620 µg/ mg

Conclusion :complies with the standard of IP2015.

Approver:

Reviewer:

Reporter: