

YANTAI JUSTAWARE PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name: Gentamycin Sulphate BP2002. Sterile			
The Batch No.	0805260	Manufacturing Date	MAY.,2008
Reporting No.	085209	Expiry Date	APR,2012
Contents	5BOU/Tin ,2Tin/Cartron	Quantity	230 B.O.U
Analytical results			
Items:	Requirements	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	4.9	
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	27.3	Per cent
	C _{1a} 10.0 to 35.0 per cent	28.6	Per cent
	C _{2a} + C ₂ 25.0 to 55.0 per cent	44.1	Per cent
Water:	Not more than 15.0 per cent	9.0	Per cent
Sulphated ash :	Not more than 1.0 per cent	0.1	Per cent
Sulphate:	32.0 to 35.0 per cent	34.8	Per cent
Sterility:	Complies with the test for sterility	Complies	
Bacterial endotoxin:	not more than 1.67IU/mg	Complies	
Assay:	not less than 590 IU/ mg		
	(anhydrous substance)	659	IU/ mg
	(hydrous substance)	600	IU/mg
Conclusion :complies with the standard of BP2002.			

Analysis: 李雪霞

Checker : 王焕意

Supervisor :

