

CERTIFICATE OF ANALYSIS

Product Name	Gentamycin sulfate	Batch NO.	RY190521
Production date	2019.05.21	Expired Date	2021.05.20
Package size	5BOU/Tin,2Tin/carton	Standard	BP2002/EP4.0
Tests	Limits	Test results	
Appearance	White or almost white powder, freely soluble in water, practically insoluble in alcohol and in ether	Conforms	
Identification	Tests according to monograph	Conforms	
Appearance of solution	Clear and not more intensely colored than degree 6 of the range of reference solutions of the most appropriate color	Conforms	
PH	3.5~5.5	4.8	
Specific optical rotation	+107° ~+121°	+119°	
Methanol	≤1.0%	Conforms	
Composition	C1: 25.0%~50.0%	27.4%	
	C1a: 10.0%~35.0%	25.2%	
	C2a+C2: 25.0%~55.0%	47.4%	
Water	≤15.0%	8.3%	
Sulphated ash	≤1.0%	0.3%	
Sulphated	32.0%~35.0%	33.3%	
Bacterial endotoxins	≤1.67IU/mg	conforms	
Microbial limit	Total aerobic microbial≤1000cfu/g	≤10cfu/g	
	Total yeast and mold count≤100cfu/g	≤10cfu/g	
Purity	≥590IU/mg(anhydrous substance)	658IU/mg	
	(hydrous substance)	603IU/mg	
Conclusion: it conforms BP2002/EP4.0			

Tested by: Esther

Checked by: Alice

Approved by: Mich

