

Kalchem International

Chemicals & Compounding Supplies

Product Name: Gentamycin Sulphate Sterile USP26.			
The Batch No.	13082609	Manufacturing Date	AUG.,2013
Reporting No.	133609	Expiry Date	JUL.,2017
Contents	5BOU/ Tin , 2Tin/ Carton	Quantity	10 BOU
Analytical results			
Items:	Specifications	Results	
Characters:	A almost white powder, freely soluble in water, Practically insoluble in alcohol and in ether .	Complies	
Identification:	Meets the requirements	Complies	
pH:	3.5 to 5.5	4.4	
Specific optical rotation:	+107° to +121°	+114°	
Methanol:	Not more than 1.0 percent	Complies	
Composition:	C ₁ 25 to 50 per cent	26	Per cent
	C _a 10 to 35 per cent	32	Per cent
	C _{1a} + C ₂ 25 to 55 per cent	42	Per cent
Loss on drying :	Not more than 18.0 per cent	9.2	Per cent
Residues on ignition:	Not more than 1.0 per cent	0.5	Per cent
Sterility:	Meets the requirements	Complies	
Bacterial endotoxins:	not more than 0.71 IU/mg	Complies	
Assay:	Potency equivalent to not less than 590 µg of		
Gentamycine per milligram, calculated on the dry basis			
(anhydrous substance)		676	µg / mg
(hydrated substance)		614	µg / mg
Conclusion :complies with the standard of USP26.			

Kalchem International, Inc
 224 South Main Street - Lindsay, OK 73052
 Toll Free 888-298-9905 | FAX: 405-756-2373