

CERTIFICATE OF ANALYSIS

Generic Name	Gentamicin Sulphate Injection IP 80 mg/2ml, 2ml		
Brand Name	GENTACAN	Product Code	GT
Batch No.	GTA26001	Batch Size	355 Liters
Mfg. Date	APR.2026	Exp. Date	MAR.2029
Date of Sampling	18/05/2026	Completed Date	16/06/2026
A. R. No.	RLS/FP/260227	Specification No.	FPS008-03

Sr. No.	Tests	Method	Specification	Results
1	Description	IP	A clear, colourless to pale-yellow solution filled in glass container (Ampoule/Vial).	A clear, colourless to pale-yellow solution filled in USP type I, 2ml clear ampoule with blue dot.
2	Identification			
	Identification A	IP	The three principal spots in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solution.	Complies
	Identification B	IP	In the test for Composition of Gentamicin sulphate, the four principal peaks in the chromatogram obtained with the test solution correspond to the four peaks in the chromatogram obtained with the reference solution.	Complies
3	pH	IP	NLT 3.0 and NMT 5.0	3.98
4	Extractable volume	IP	NLT nominal volume.	2.1 ml
5	Particulate matter			
	A Visual inspection	IP	Should be clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
	B Particle size $\geq 10\mu\text{m}$		NMT 6000 particles per container.	307.60
	Particle size $\geq 25\mu\text{m}$		NMT 600 particles per container.	14.27

Corporate Office: No.07, KHB, Industrial Estate, Yelahanka New Town, Bengaluru-560064, India
CIN : U24111KA19991PT012343

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6	Composition of Gentamicin sulphate	IP	The proportions are within the following limits.	
			C ₁ - 25.0% to 50.0%	25.9%
			C _{1a} - 10.0% to 35.0%	27.8%
			C ₂ +C _{2a} - 25.0% to 55.0%	43.5%
7	Assay (Content of Gentamicin)	IP	NLT 95.0% and NMT 110.0%	104.7% (41.876 mg/ml)
8	Preservative contents by HPLC			
	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	101.7%
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	100.9%
9	BET	IP	NMT 1.67 Endotoxin Units per mg of Gentamicin.	Less than 0.82 EU/mg
10	Sterility	IH	Should be sterile	Sterile

Remarks: The product complies as per IP and In-house specification

	Prepared by	Reviewed by	Approved by	Authorized by
Department	Quality Control	Quality Control	Quality Control	Quality Assurance
Name	Sudeep.s	Sumit kumar	Manoj K Raset	Dattajin & Dasi
Designation	QC-officer	Executive	Manager	Manager QA
Signature				
Date	16/06/2026	16/06/2026	16/06/2026	16/06/2026