

**CERTIFICATE OF ANALYSIS**

<b>Generic Name</b>	Gentamicin Sulphate Injection IP 80 mg / 2 ml		
<b>Brand Name</b>	GENTACAN	<b>Product Code</b>	GT
<b>Batch No.</b>	GTA25003	<b>Batch Size</b>	365 Liters
<b>Mfg. Date</b>	SEP.2025	<b>Exp. Date</b>	AUG.2028
<b>Date of Sampling</b>	03/09/2025	<b>Completed Date</b>	27/09/2025
<b>A. R. No.</b>	RLS/FP/250229	<b>Specification No.</b>	FPS008-02





Sr. No.	Tests	Method	Specification	Results
1	Description	IP/ IH	A clear, colourless to pale-yellow solution with a faint odour filled in USP type I glass container.	A clear colourless to pale yellow solution with a faint odour filled in USP type I, 2 ml clear ampoule with blue dot.
2	Identification			
	Identification A	IP	The three principal spot 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	3.31
4	Extractable volume	IP	NLT nominal volume in ml	2.0 ml
5	Particulate Matter			
	A Visual inspection	IP	Clear and practically free from particles when observed by visual inspection by unaided eyes.	Complies
	B	Particle size $\geq 10 \mu\text{m}$	IH	NMT 6000 particles per container.
Particle size $\geq 25 \mu\text{m}$		NMT 600 particles per container.		3.20

**CERTIFICATE OF ANALYSIS**

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6	Composition of gentamicin sulphate	IP	The proportions are within the following limits.	
			C <sub>1</sub> is between 25.0% and 50.0%	29.2 %
			C <sub>1a</sub> is between 10.0% and 35.0%	27.3 %
			The sum of the contents of gentamicin C <sub>2a</sub> and gentamicin C <sub>2</sub> is between 25.0 % to 55.0%	42.5 %
7	Assay (Each 1 ml of solution contains 40 mg Gentamicin )	IP	NLT 95.0% and NMT 110.0% of the gentamicin	102.74 % (41.096 mg/ml)
8	BET	IP	NMT 1.67 EU/ mg of gentamicin	Less than 0.82 EU/mg
9	Sterility	IH	Should be sterile	Sterile
Additional tests				
10	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	99.7 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	99.2 %

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

	Prepared by	Reviewed by	Approved by	Authorized by
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<b>Signature</b>				
<b>Date</b>	27/09/2025	27/09/2025	27/09/2025	27/09/2025