

CERTIFICATE OF ANALYSIS


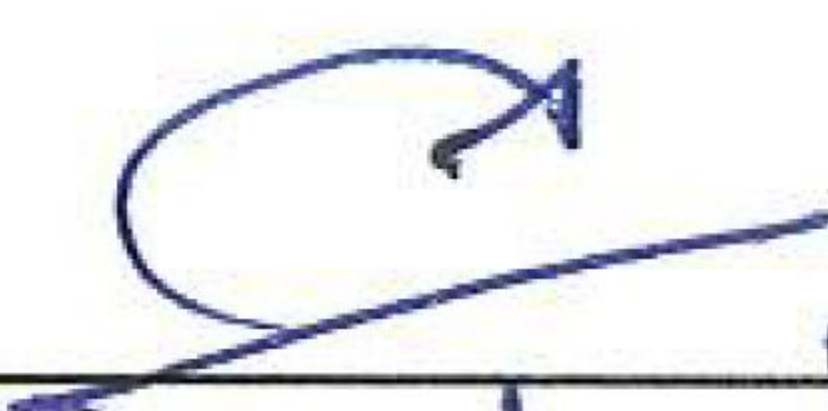

Product Name	GENTACAN		
Generic Name	Gentamicin Sulphate Injection IP 40mg/ml, 2ml	Product Code	GT
Batch No.	GTA24003	Batch size	370 Liters
Mfg. Date	OCT.2024	Exp. Date	SEP. 2027
Date of sampling	11/10/2024	Completed Date	26/10/2024
A.R. No.	RLS/FP/240245	Specification No.:	FPS008

Sr. No.	Tests	Method	Specification	Result
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, 2ml clear ampoule with yellow ring.
2	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	3.53
4	Extractable volume	IP	NLT nominal volume in ml	2.0ml
5	Particulate Matter		IP	Complies
	A	Visual inspection		
	B	Particle size \geq 10 μ m		
Particle size \geq 25 μ m		NMT 600 per container.	3.20 per container	

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6	Composition of gentamicin sulphate	IP	C ₁ is between 25.0% and 50.0%	25.4 %
			C _{1a} is between 10.0% and 35.0%	24.3 %
			The sum of the contents of gentamicin C _{2a} and gentamicin C ₂ is between 25.0 % to 55.0%	50.3 %
7	Assay (Each 1 ml of solution contains 40 mg Gentamicin)	IP	NLT 95.0% and NMT 110.0% of the gentamicin	99.31% (39.724 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%	97.7 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	101.0 %

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

	Analysed by	Checked by	Approved by
Signature			
Date	26/10/2024	26/10/2024	26/10/2024