



**Nixi Laboratories Pvt. Ltd.,**  
Village MouzaOgli, Sadhaura Road, Kala-Amb, District Sirmour -173030,  
Himachal Pradesh (INDIA).

**CERTIFICATE OF ANALYSIS FINISHED PRODUCTS**

Product Name	AMIXIN 500	AR. No.	NL/LV/FG/25/316
Generic Name	Amikacin Injection IP 500 mg/2ml		
Mother Batch No.	V25DA013	Reference	IP
Child Batch No.	V25DA013	Batch Size	52380 Vials
Mfg. Date	12/2025	Exp. Date	11/2027
Specification No. (STS No)	QC/LV/FG/STS/005-06	Standard Test Procedure No.	QC/LV/FG/STP/005
Sample Quantity	87 Vials	Sampling Date	08/12/2025
Released Date	29/12/2025		

Sr. No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	Clear to pale yellow liquid free from particles filled in 2ml transparent glass vial, plugged with grey rubber stopper and sealed with flip of seal.	Clear to pale yellow liquid free from particles filled in 2ml transparent glass vial, plugged with grey rubber stopper and sealed with flip of seal.
2.	Identification A. By TLC  B. By Chemically  C. By Chemically	A. The principal Pink coloured spot in the chromatogram obtained with the test solution corresponds those in the chromatogram obtained with reference solution (a) and (b).  B. 1.5 ml of the test solution add 1 ml of 2M Sodium hydroxide mix and add 2 ml of a 1.0% solution of cobalt nitrate a violate colour is produced.  C. 1.5 ml of the test solution add 3.5 ml of water mix and add 4 ml of a 0.035 % solution of anthrone in sulphuric acid bluish violate colour is produced.	Complies  Complies  Complies
3.	Average Filled Volume	Not less than 2.0 ml	2.05ml
4.	Extractable Volume	Not less than 2.0 ml	2.05ml
5.	pH	3.5 to 5.5	4.32
6.	Particulate matter Visible particles:	Should be free from foreign particles	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Rahul Singh	Ganesh Jaiswal	Aditya Singh
Designation	Sr. Officer QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	29/12/25	29/12/25	29/12/25



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	For sub visible particles: (i) Equal to or greater than 10µm	NMT 6000 particles /container	1384.0 particles/container
	(ii) Equal to or greater than 25µm	NMT 600 particles /container	278.0 particles/container
7.	<b>Sterility</b>	Should comply the test of sterility	Complies
8.	<b>Bacterial Endotoxins</b>	Not more than 0.33 EU /mg of Amikacin	Complies
9.	<b>Related Substances</b>		
	The area of secondary peak	NMT 1.5%	Not Detected
	The sum all secondary peak	NMT 3.0%	Not Detected
10.	<b>Assay:</b> Each 2 ml contains: Amikacin Sulphate IP Eq. to Amikacin 500 mg Methylparaben IP 0.18%w/v (as preservative) Propylparaben IP 0.02%w/v (as preservative)	450.00 mg to 600.00 mg (90.00 % to 120.00 %) 0.144 % w/v to 0.216 % w/v (80.00 % to 120.00 %) 0.016 % w/v to 0.024 % w/v (80.00 % to 120.00 %)	501.32 mg (100.26%) 0.17 %w/v (94.44%) 0.02%w/v (100.0%)

**RESULT:** The above sample ~~COMPLIES/DOES NOT COMPLY~~ as per Specification No-QC/LV/FG/STS/005-06.

**CONCLUSION:** In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS NOT STANDARD QUALITY** as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

	<b>ANALYSED BY</b>	<b>CHECKED BY</b>	<b>APPROVED BY</b>
<b>Name</b>	Rahul Singh	Ganesh Jaiswal	Aditya Singh
<b>Designation</b>	Sr.Officer QC	Sr.Executive QC	Asst.Manager QC
<b>Signature</b>	<i>Rahul</i>	<i>[Signature]</i>	<i>[Signature]</i>
<b>Date</b>	29/12/25	29/12/25	29/12/25

Format No.:F/QC/013/03-04

**Approved By**  
Name: Aditya Singh  
Designation: Asst. Manager QC  
Qualification: Bsc  
Enrollment No. II-009545  
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