



Nixi Laboratories Pvt. Ltd.
VPO: MouzaOgli, Sadhora Road, Kala Amb Distt. Sirmour (H.P)

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	AMIXIN-100	AR. No.	NL/LV/FG/24/184
Generic Name	Amikacin Injection IP 100 mg/2ml		
Mother Batch No.	V24GG002	Reference	IP
Child Batch No.	V24GG002A	Batch Size	38095 Vials
Mfg. Date	08/2024	Exp. Date	07/2026
Specification No. (STS No)	QC/LV/FG/STS/001-04	Standard Test Procedure No.	QC/LV/FG/STP/001
Sample Quantity	55 Vials	Sampling Date	28/08/2024
Released Date	11/09/2024		

Sr. No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	Clear to pale yellow liquid free from particles filled in transparent glass vial, plugged with grey rubber stopper and sealed with flip off aluminum seal.	Clear liquid free from particles filled in transparent glass vial, plugged with grey rubber stopper and sealed with flip off aluminum.
2.	Identification		
	A. By TLC	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).	Complies
	B. By Chemically	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.	Complies
	C. By Chemically	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
3.	Average Filled Volume	Not less than 2.0 ml	2:08 ml
4.	Extractable Volume	Not less than 2.0 ml	2.08 ml
5.	pH	3.5 to 5.5	4.28
6.	Particulate matter		
	Visible particles:	Should be free from foreign particles	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Signature			
Date	11/09/24	11/09/24	11/09/24



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	For sub visible particles :		
	(i) Equal to or greater than 10µm	Not more than 6000 particles /container	929.0 particles/container
	(ii) Equal to or greater than 25µm	Not more than 600 particles /container	11.0 particles/container
7.	Sterility	Should comply the test of sterility	Complies
8.	Bacterial Endotoxins	Not more than 0.33 EU /mg of Amikacin	Complies
9.	Related Substances		
	The area of secondary peak	NMT 1.5%	Not Detected
	The sum all secondary peak	NMT 3.0%	Not Detected
10.	Assay: Each 2 ml contains: Amikacin Sulfate IP Eq. to Amikacin 100 mg	90.00 mg to 120.00 mg (90.00 % to 120.00 %)	109.68 mg (109.68%)
	Methylparaben (As Preservative) IP 1.8 mg	1.44 mg to 2.16 mg (80% to 120%)	1.75 mg (97.2%)
	Propylparaben (As Preservative) IP 0.2 mg	0.16 mg to 0.24 mg (80 % to 120 %)	0.19 mg (95.0%)

RESULT: The above sample ~~COMPLIES/DOES NOT COMPLY~~ as per Specification No-QC/LV/FG/STS/001-04.

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 here under further.

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Signature			
Date	11/09/24	11/09/24	11/09/24