HEILSA LIFE SCIENCES PVT. LTD.
KH No. 940, 941, 942, Vill. - Kishanpur, Jamalpur, Bhagwanpur, Roorkee-247668. Distt. - Haridwar, (Uttarakhand) INDIA.

Quality control Department
Certificate of analysis of Finished Product

A.R. No: - HLS/FP/26/CH18

NAME OF PRODUCT	**Amikacin sulphate injection IP 500 mg/2ml (AMIXIN 500)**		
BATCH NO.	**VCH18**	**SAMPLED ON**	**31/08/2026**
MFG. DATE	**08/2026**	**QTY. SAMPLED**	**80 Nos.**
EXP. DATE	**07/2028**	**TESTED BY**	**Haripriya**
BATCH SIZE	**150 Ltr**	**TESTING ON**	**01/09/2026**
REFERENCE	**As per IP**	**COMPLETION ON**	**15/09/2026**

S. No.	Test	Specification	Observation
1.	**Description**	A clear colourless solution.	A clear colourless solution.
2.	**Identification**	**A) By TLC:** The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. **B) By Chemically:** A violet colour is produced. **C) By Chemically:** A bluish-violet colour is produced.	The principal spot in the chromatogram obtained with the test solution corresponds with the reference solution. A violet colour produced. A bluish-violet colour produced.
3.	**pH**	Between 3.5 to 5.5	4.554
4.	**Extractable volume**	Not less than 2.0 ml	2.08 ml
5.	**Bacterial Endotoxins**	Not more than 0.33 Endotoxin Units per mg of Amikacin.	Less than 0.33 Endotoxin Units per mg of Amikacin.
6.	**Sterility**	Complies with the test for sterility	Complies
7.	**Particulate Matter** **Visible Particle** **Sub Visible Particle** **a) ≥10µm** **b) ≥25 µm**	Free from visible particles Not more than 6000 Particles/container Not more than 600 Particles/container	Free from visible particles 92.53 Particles/container 0.27 Particles/container

	Prepared By	Reviewed By	Approved By
Name	Haripriya	Kamal Kishor	[illegible]
Designation	Jr. officer	QC - Executive	[illegible]
Sign.	[signature]	[signature]	[signature]
Date	09/10/26	09/10/26	09/10/26

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BATCH SIZE	150 Ltr	TESTING ON	01/09/2026
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*8.	**Related Substances** **Any Secondary Impurity** **Sum of all secondary Impurities**	 NMT 1.5% NMT 3.0%	 Not Detected Not Detected
9.	**Assay:** **Amikacin sulphate IP 500 mg/2ml**	450.0 mg/2ml to 600.0 mg / 2ml (90.0 % to 120.0 % of label claim)	528.09 mg/2ml. 105.62 %

***This test is analysed by Devansh Lab.**

Conclusion: The sample Complies / ~~doesn't comply~~ as per prescribed standards of IP and specification No: HLS/FPS/022

	Prepared By	Reviewed By	Approved By
Name	Haripriya	Kamal Kishor	Ayush A. Jaiswal
Designation	Jr. officer	QC- Executive	Manager
Sign.			
Date	09/10/26	09/10/26	09/10/26