

Product Name	AMPHOLIZED B		
Generic Name	Amphotericin B Injection IP 50 mg per vial		
Batch No.	V00126007	A.R. No.	FP/08/26/00036
Mfg. Date	08/2026	Sampling Quantity	65 vials
Exp. Date	07/2028	Date of Sampling	16/08/2026
Batch Size	17000 vials	Date of Analysis	16/08/2026
Pack Quantity	NA	Date of Release	31/08/2026
Ref. Spec. No.	FP/SPC/0002-01	Pack Size/Type	NA

Sr. No.	Test	Specification	Result
1.	Description	A yellow to orange Lyophilized cake.	Orange Lyophilized cake.
2.	pH	Between 7.2 to 8.0	7.5
3.	Loss on Drying	Not More Than 8.0% w/w	5.7 %
4.	Uniformity of weight	For Information Only.	82.5 mg
5.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container	4268 particles per container
	≥ 25 µm	NMT 600 no. of particles per container	74 particles per container
6.	Sterility	Should be sterile.	Sterile
7.	Bacterial Endotoxins test	Not more than 5.0 Endotoxin Units per mg of amphotericin B	Less than 5.0 Endotoxin Units per mg
8.	Assay	Not less than 90.0% and not more than 120.0% of Amphoteracin B (C ₄₇ H ₇₃ NO ₁₇)	102.2 %

Remark: The Finish Product test results are Complies / Does not complies as per H/P/BP/USP Specification.

Function	Prepared By	Reviewed By	Approved By
Name	Pranita Wadje	Maya Sirsat	Avnish Kumar
Designation-Department	Officer - QC	Executive – QC	Manager – QC
Sign & Date	<i>P. 31/08/2026</i>	<i>P. 31/08/2026</i>	<i>P. 31/08/2026</i>

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