

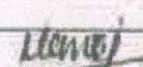
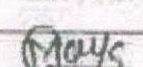

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QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01			
Product Name	AMPHOLIZED B		
Generic Name	Amphotericin B Injection IP 50 mg per vial		
Batch No.	K30225010	A.R. No.	FP/12/25/00008
Mfg. Date	Dec-2025	Sampling Quantity	65 vials
Exp. Date	Nov-2027	Sampling Date	05/12/2025
Batch Size	17000 vials	Date of Analysis	05/12/2025
Pack Quantity	NA	Date of Release	19/12/2025
Ref. Spec. No.	FP/SPC/0002-01	Page No.	Page 1 of 1
Pack Size/Type	1 Vial		

Sr. No.	Test	Specification	Result
1.	Description	A yellow to orange Lyophilized cake.	A yellow Lyophilized cake.
2.	pH	Between 7.2 to 8.0	7.7
3.	Loss on Drying	Not More Than 8.0% w/w	4.5 %
4.	Uniformity of weight	For Information Only.	93.3 mg
5.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container	403 particles per container
	≥ 25 µm	NMT 600 no. of particles per container	23 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 Amphotericin B (C ₁₇ H ₁₇ NO ₁₇)	101.4 %

CONCLUSION: The Finish Product Sample Complies/Does not complies as per HH/IP/BP/USP Specification.

Function	Prepared By	Reviewed By	Approved By
Name	Manoj Borase	Maya Sirsat	Avnish Kumar
Designation- Department	Officer-QC	Executive-QC	Manager-QC
Sign & Date	 21/01/2026	 21/01/2026	 21/01/2026

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