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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.	V00126002	A.R. No.	FP/03/26/00023
Mfg. Date	03/2026	Sampling Quantity	65 vials
Exp. Date	02/2028	Sampling Date	15/03/2026
Batch Size	10000 vials	Date of Analysis	15/03/2026
Pack Quantity	NA	Date of Release	23/03/2026
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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	7.6
3.	Loss on Drying	Not More Than 8.0% w/w	2.0 %
4.	Uniformity of weight	For Information Only.	90.9 mg
5.	Particulate Matter		
	≥ 10 µm	NMT 6000 no. of particles per container	329 particles per container
	≥ 25 µm	NMT 600 no. of particles per container	19 particles per container
6.	Sterility	Should be sterile.	*Under observation
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 ₄₇ H ₇₃ NO ₁₇)	102.9 %

CONCLUSION: The Finish Product Sample Complies/Does not complies as per ~~4H/IP/BPA/USP~~ Specification.

Note: *Sterility test is under observation.

Function	Prepared By	Reviewed By	Approved By
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Designation-Department	Officer-QC	Executive-QC	Manager-QC
Sign & Date	 23/03/2026	 23/03/2026	 23/03/2026

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