

# kaliberr

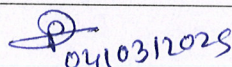
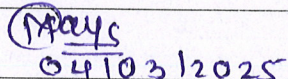
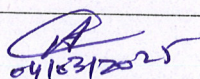
## QUALITY CONTROL CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL/QC/030/F03-01

Product Name	AMPHOLIZED B		
Generic Name	Amphotericin B Injection IP 50 mg per vial		
Batch No.	K30225001	A.R. No.	FP/02/25/00017
Mfg. Date	Feb-2025	Sampling Quantity	80 vials
Exp. Date	Jan-2027	Sampling Date	17/02/2025
Batch Size	17000 vials	Date of Analysis	18/02/2025
Pack Quantity	NA	Date of Release	04/03/2025
Ref. Spec. No.	FP/SPC/0002-00	Page No.	Page 1 of 1
Pack Size/Type	1 Vial		

Sr. No.	Test	Specification	Result
01	Description	A yellow to orange Lyophilized cake/powder.	A yellow lyophilized cake
02	pH	Between 7.2 and 8.0	7.4
03	Loss on Drying	Not more than 8.0% w/w	2.5 %
04	Clarity of solution	The solid dissolves completely, leaving no visible residue as undissolved matter; The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injection contained in a similar container and examined in the same manner.	Complies
05	Particulate Matter		
	≥10µm	NMT 6000 no. of particle per container.	2059 Particles pre container
	≥ 25µm	NMT 600 no. of particle per container.	81 Particle per container
06	Sterility	Should be Sterile.	Sterile
07	Bacterial Endotoxins	It contains not more than 5.0 Endotoxin Units per mg of amphotericin B	Less than 5.0 EU/mg
08	Assay (Microbiological)	Not less than 90.0% and not more than 120.0% of Amphotericin B (C <sub>47</sub> H <sub>73</sub> NO <sub>17</sub> )	102.5 %

**CONCLUSION:** The Finish Product Sample ~~Does not complies~~ Complies as per ~~HI/IP/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	 04/03/2025	 04/03/2025	 04/03/2025

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