

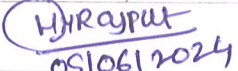
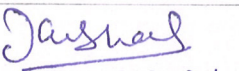
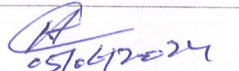
# kaliberr

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.	K30224005	A.R. No.	FP/05/24/00015
Mfg. Date	May-2024	Sampling Quantity	65 vials
Exp. Date	Apr-2026	Sampling Date	14/05/2024
Batch Size	10000 vials	Date of Analysis	15/05/2024
Pack Quantity	NA	Date of Release	29/05/2024
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.	A yellow lyophilized cake.
02	pH	Between 7.2 and 8.0	7.8
03	Loss on Drying	Not more than 8.0% w/w	2.3 % w/w
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.	244 Particles pre container
	≥ 25µm	NMT 600 no. of particle per container.	2 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> )	104.2 %

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

Function	Prepared By	Reviewed By	Approved By
Name	Harshali Rajput	Kushal Deshmukh	Avnish Kumar
Designation-Department	Officer -QC	Asst. Manager-QC	Manager-QC
Sign & Date	 05/06/2024	 05/06/2024	 05/06/2024

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