Biozenta human helping human	**BIOZENTA LIFESCIENCE PVT. LTD.** **KHASRA NO. 59, 60 & 61 BELA BATHRI, HAROLI, UNA, HIMACHAL PRADESH 174301 INDIA**

CERTIFICATE OF ANALYSIS
(The Drugs and Cosmetics act 1940, and the rules therein 1945)

Product Name	Amphotericin B Liposomal Injection 50mg/vial		
Generic Name	Amphotericin B Liposomal Injection 50mg/vial	Page No.	1 of 3
Batch No.	GL23013	**AR No.**	FG23100018
Reference	In House	**Product Code**	AM/001/002
Mfg. Date	10/2023	**Batch Size**	3600 vials
Exp. Date	09/2025	**Sample Qty.**	38 vials
Date of Sampling	21/10/2023	**Date of Release**	04/11/2023

S. No.	Test	Specification	Results
`1.	Description	A yellow colour Lyophilized Cake filled in 20 ml clear moulded glass vial USP Type I, stoppered with 20 mm slotted bromo butyl rubber plug and sealed with 20 mm aluminum flip off seal having yellow colour.	A yellow colour Lyophilized Cake filled in 20 ml clear moulded glass vial USP Type I, stoppered with 20 mm slotted bromo butyl rubber plug and sealed with 20 mm aluminum flip off seal having yellow colour.
2.	Appearance of reconstituted Suspension	After reconstitution with 12 ml water for injection, it gives yellow coloured translucent uniform suspension with no sign of precipitation.	After reconstitution with 12 ml water for injection, it gives yellow coloured translucent uniform suspension with no sign of precipitation.
3.	Identification		
	A. BY UV	The UV absorption spectrum obtained from sample solution shall be corresponds to the UV absorption spectrum obtained from the standard solution.	The UV absorption spectrum obtained from sample solution is corresponds to the UV absorption spectrum obtained from the standard solution.

Remarks: In the opinion of the undersigned the sample complies / ~~does not comply~~ with the ~~IP~~/ BP/USP/In-HouseSpecification.

	Prepared By	Reviewed By	Approved By
Name			
Designation			
Sign			
Date			

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S. No.	Test	Specification	Results
4.	pH	Between 5.0 to 6.0	5.46
5.	Average Fill Weight	1326 mg ± 10%	1372.73 mg
6.	Reconstitution Time	NMT 300 seconds	30 seconds
7.	Uniformity of Dosage Units	For L1, AV = NMT 15 and for L2, AV = NMT 25	AV = 4.23
8.	Related Substances		
	Impurity A	Not more than 2.0%	Not Detected
	Impurity B	Not more than 4.0%	0.48%
	Any other Impurity (at 303nm)	Not more than 1.0%	0.58%
	Any other Impurity (at 383nm)	Not more than 7.0%	6.22%
	Total Impurities (at 303nm and 383nm)	Not more than 15.0%	12.46%
9.	Particle Size		
	Mean Diameter (Z-Average)	50 nm to 150 nm	82 nm
	D10	25 nm to 100 nm	69 nm
	D50	50 nm to 150 nm	90 nm

Remarks: In the opinion of the undersigned the sample complies / ~~does not~~ comply with the ~~IP~~/ BP/USP/In-HouseSpecification.

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S. No.	Test	Specification		Results
10.	Bacterial Endotoxins Test	NMT 5.0EU/mg		Less than 5.0 EU/mg
11.	Sterility	Should be Sterile		Sterile
12.	Moisture Content	Not More Than 5.0%		2.08%
13.	Residual Solvents			
	Chloroform	Not more than 60ppm		Not Detected
	Ethanol	Not more than 5000ppm		Not Detected
14.	**Assay:** Each vial contains	**Claim**	**Limit**	**Limit**
	Amphotericin B USP	50.0 mg	45.0 mg to 55.0 mg (90.0% to 110.0%)	52.30mg (104.60%)

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