



MAYA BIOTECH PRIVATE LIMITED

Works: Village- Kondi, P.O.- Thana, Baddi, Distt.- Solan, (H.P.)-173205

Corp. Office: Plot No-46/A, First Floor, Industrial Area Phase-2, Chandigarh-160002

CERTIFICATE OF ANALYSIS (SEMI FINISHED PRODUCT)

(The Drugs and cosmetics Act 1940 and the rules there under)

Generic Name	Propofol Injection IP		
A. R. No.	MBSF251054		
Batch No.	ALV111	Date of Receipt	17/10/2025
Mfg. Date	10/2025	Batch Size	10087 Vials
Exp. Date	09/2027	Sample Qty.	10 Vials

S. No.	Test	Specification	Result
1.	Description	A white to off white colour emulsion filled in clear glass vial.	Off white colour emulsion filled in clear glass vials.
2.	Identification a) By IR	Compare the spectrum with that obtained with propofol IPRS or with the reference spectrum of propofol.	Complies
	b) By HPLC	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies
3.	Nominal fill volume	NLT 20.0 ml	20.1 ml
4.	Uniformity of filled volume	20.0 ml to 23.0 ml	Complies
5.	pH	6.0 to 8.5	7.044
6.	Particulate Matter (By Visual Method)	When emulsion examined under suitable conditions of visibility are free from particles.	Complies
7.	Assay (By HPLC) Each ml contains: Propofol IP 10 mg	NLT 9.5 mg to NMT 10.5 mg (95.0% to 105.0%)	9.833 mg (98.33%)
8.	Free Fatty Acids	NMT 7 mmol/L	Complies
9.	Propofol Quinone and Propofol dimer a)Area of Propofol Quinine	NMT 0.1%	Not Detected
	b)Area of Propofol Dimer	NMT 0.25%	Not Detected
10.	Lysolecithin	NMT0.2%	Complies
11.	Globule Size	Meets the requirements	Complies
12.	Sterility	Should be Sterile	Sterile
13.	Bacterial Endotoxin Test	NMT 0.33 EU/mg	Less than 0.33 EU/mg

Remarks: The product referred to above complies / does not comply with IP Specifications.

	Analyzed By	Checked By	Approved By
Name	Vikas Kumar	Ranjit Kumar	for Meha
Designation	Sr. officer	Executive	Assistant Manager
Sign & Date	 06/11/2025	 06/11/2025	 06/11/2025

Registration No. : 51811

Name & Place of Institution: Punjab Technical University Jalandhar.

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