



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 (FINISHED PRODUCT)

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

Generic Name	Propofol Injection IP 200 mg/20ml		
Product Name	Profocan	A. R. No.	MBFP251691
Batch No.	ALV131	Date of Receipt	08/12/2025
Mfg. Date	11/2025	Batch Size	20065 Vials
Exp. Date	10/2027	Sample Qty.	06 Vials

S. No.	Test	Specification	Result
1.	Description	A white to off white colour emulsion filled in clear glass vial.	White colour emulsion filled in clear glass vials.
2.	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	20.8 ml
4.	Uniformity of filled volume	20.0 ml to 22.0 ml	Complies
5.	pH	6.0 to 8.5	7.605
6.	Particulate Matter (By Visual Method)	Should be free from foreign 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%)	9.866 mg (98.66 %)
8.	Free Fatty Acids	NMT 7 mmol/L	Complies
9.	Propofol Quinone and Propofol dimer	Propofol Quinone:NMT 0.1 % Propofol Dimer :NMT 0.25 %	Not Detected Not Detected
10.	Lysolecithin	NMT 0.2 %	Complies
11.	Globule Size ($\geq 2\mu\text{m}$)	NMT 5000 globule/ml	Complies
12.	Sterility	Should be Sterile	Sterile
13.	Bacterial Endotoxin Test	NMT 0.33 Endotoxin Unit per mg of propofol	Less than 0.33 EU/mg of propofol

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

	Analyzed By	Checked By	Approved By
Name	Harsh kumar	Sangeet Kumar	for Neha
Designation	Officer	Executive	Assistant Manager
Sign & Date	 23/12/2025	 23/12/2025	 23/12/2025

Registration No. : PG000581

Name & Place of Institution: AAIDU

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