



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/ 20 ml		
Product Name	Profocan 1% Injection	A. R. No.	MBFP260346
Batch No.	ALV185	Date of Receipt	04/02/2026
Mfg. Date	01/2026	Batch Size	20065 Vials
Exp. Date	12/2027	Sample Qty.	06 Vials

Sr. 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 vial.
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	20.1 ml
4.	Uniformity of filled volume	20.0 ml to 22.0 ml	Complies
5.	pH	6.0 to 8.5	6.719
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%)	10.322 mg (103.22%)
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.

	Prepared By	Checked By	Approved By
Name	Harsh Kumar	Ankit Kumar	for Neha
Designation	Officer	Executive	Assistant Manager
Sign & Date	19/02/2026	19/02/2026	19/02/2026

Registration No. : PG000581

Name & Place of Institution: AAIDU Allahabad.