



KAMLA
LIFESCIENCES LTD.

Inspired Medicine

G - 84/1, TARAPUR, M.I.D.C., BOISAR, DISTRICT- PALGHAR- 401506.

CERTIFICATE OF ANALYSIS

Product Name	:	PROFOCAN 1 %			
Generic Name	:	Propofol Injection IP 10 mg/ml			
Batch No.	:	KV24007B	AR No.	:	FP02/24/021
Batch Size	:	9,900 Nos	Released Date	:	21/02/24
Mfg. Date	:	02/2024	Sampled Date	:	21/02/24
Exp. Date	:	01/2026	Packed Qty.	:	2120 Nos

Sr. No.	Test	Specification	Observation
1.	Description	A milky white solution	A milky white solution
2.	Identification		
	A. BY IR	The infra-red absorption spectrum of residue of sample should concordant with that of the reference spectrum of Propofol.	Complies
3.	Acidity or Alkalinity (pH)	Not less than 6.0 and not more than 8.5.	8.00
4.	Extractable volume	The Content of each containers is not less than 20 ml and the average content of 3 containers should not more than 23.0 ml.	Average Volume : 20.2 ml
5.	Bacterial Endotoxins	Not more than 1.65 IU/ml of propofol.	Less than 1.65 IU/ml of propofol.
6.	Sterility	To be sterile	Sterile
7.	Globule size	Not more than 5000 globules more than or equal to 2 µm per ml of a 0.01% v/v solution in filtered 0.9% w/v solution of sodium chloride	1971
8.	Propofol quinine and propofol dimer A. Propofol impurity E. B. Propofol impurity J	Not more than 0.25% Not more than 0.10%	0.015 % 0.004 %
9.	Free fatty acid	Not more than 7 milimoles per litre	2.595 milimoles per litre
10.	Lysolecithin	Not greater than 0.2%	0.072 %
11.	Assay Propofol IP 10 mg/ml	Not less than 95.0 % and Not more than 105.0 % of the stated amount.	102.64 %



KAMLA
LIFESCIENCES LTD.
Inspired Medicine

G - 84/1, TARAPUR, M.I.D.C., BOISAR, DISTRICT- PALGHAR- 401506.

CERTIFICATE OF ANALYSIS

Product Name	:	PROFOCAN 1 %			
Generic Name	:	Propofol Injection IP 10 mg/ml			
Batch No.	:	KV24007B	AR No.	:	FP02/24/021
Batch Size	:	9,900 Nos	Released Date	:	21/02/24
Mfg. Date	:	02/2024	Sampled Date	:	21/02/24
Exp. Date	:	01/2026	Packed Qty.	:	2120 Nos

Conclusion: The above mentioned sample complies/ ~~does not comply~~ with prescribed standard quality as per IP/ ~~BP/ USP/ JP~~ specification.

	Analyzed by:	Checked by:	Approved by:
Sign & Date	 21/02/24	 21/02/24	 21/02/24
Name	Nitesh Yadav	Ankush R. Rout	Vijay Yadav
Designation	QC Officer	SR. EXECUTIVE O.C.	BDT-Manager