



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.	:	KV24008A	AR No.	:	FP02/24/031
Batch Size	:	9,900 Nos	Released Date	:	28/02/24
Mfg. Date	:	02/2024	Sampled Date	:	28/02/24
Exp. Date	:	01/2026	Packed Qty.	:	7900 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.	7.89
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 μ m per ml of a 0.01% v/v solution in filtered 0.9% w/v solution of sodium chloride	1991
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 millimoles per litre	2.485 millimoles per litre
10.	Lysolecithin	Not greater than 0.2%	0.082 %
11.	Assay Propofol IP 10 mg/ml	Not less than 95.0 % and Not more than 105.0 % of the stated amount.	100.43 %






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

	Analyzed by:	Checked by:	Approved by:
Sign & Date	 28/02/24	 28/02/24	 28/02/24
Name	Nilesh Yadar	Ashit Jha	Vijay Yadar
Designation	QC Officer	Asst. D. Manager	Dist. Manager