



KAMLA
LIFESCIENCES LTD.
Inspired Medicine

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

CERTIFICATE OF ANALYSIS

Product Name	:	PROFOCAN 1% INJECTION			
Generic Name	:	Propofol Injection IP 10 mg/ml			
Batch No.	:	KV24066A	AR No.	:	FP10/24/040
Batch Size	:	9900 Vials	Released Date	:	31/10/24
Mfg. Date	:	10/2024	Sampled Date	:	28/10/24
Exp. Date	:	09/2026	Packed Qty.	:	9550 Vials

Sr. No.	Test	Specification	Observation
1.	Description	A milky white solution	A milky white solution
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.	pH	Not less than 6.0 and not more than 8.5.	7.74
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 : 20.1 ml
5.	Bacterial Endotoxins	Not more than 0.33 EU/mg of propofol.	Less than 0.33 EU/mg 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	1357
8.	Propofol quinine and propofol dimer		
	A. Propofol impurity E.	Not more than 0.25%	0.032 %
	B. Propofol impurity J	Not more than 0.10%	0.023 %
9.	Lysolecithin	Not greater than 0.2%	0.075 %



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Sr. No.	Test	Specification	Observation
10.	Free fatty acid	Not more than 7 millimoles per litre	2.483 millimoles per litre
11.	Assay Propofol IP 10 mg/ml	Not less than 95.0 % and Not more than 105.0 % of the stated amount.	101.83 %

Conclusion: The above mentioned sample complies does not comply with prescribed standard quality as per (P) BP/ USP/ IH specification.

	Analyzed by:	Checked by:	Approved by:
Sign & Date	<i>SPP</i> 31/10/24	<i>[Signature]</i> 31/10/24	<i>[Signature]</i> 31/10/24
Name	sachin patil	NHN Dhanavade	Vijay yadar
Designation	Pradnee officer ce	Executive ce	Asst - Manager