



KAMLA
LIFESCIENCES LTD.
Inspired Medicine

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

CERTIFICATE OF ANALYSIS

Product Name	:	PROFOCAN 10 INJECTION			
Generic Name	:	Propofol Injection IP 10 mg/ml			
Batch No.	:	KV24073A	AR No.	:	FP11/24/017
Batch Size	:	19607 Vials	Released Date	:	18/11/24
Mfg. Date	:	10/2024	Sampled Date	:	18/11/24
Exp. Date	:	09/2026	Packed Qty.	:	18400 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.	7.53
4.	Extractable volume	The content of each container is not less than 10 ml and the average content of 3 containers should not more than 11.5 ml	Average Volume : 10.1 ml
5.	Bacterial Endotoxins	Not more than 1.65 EU/mg of propofol.	Less than 1.65 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	1312
8.	Propofol quinine and propofol dimer A. Propofol impurity E. B. Propofol impurity J	Not more than 0.25% Not more than 0.10%	0.043 % 0.008 %
9.	Lysolecithin	Not greater than 0.2%	0.069 %



KAMLA
LIFESCIENCES LTD.
Inspired Medicine

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

CERTIFICATE OF ANALYSIS

Product Name	:	PROFOCAN 10 INJECTION			
Generic Name	:	Propofol Injection IP 10 mg/ml			
Batch No.	:	KV24073A	AR No.	:	FP11/24/017
Batch Size	:	19607 Vials	Released Date	:	18/11/24
Mfg. Date	:	10/2024	Sampled Date	:	18/11/24
Exp. Date	:	09/2026	Packed Qty.	:	18400 Vials

Sr. No.	Test	Specification	Observation
10.	Free fatty acid	Not more than 7 milimoles per litre	2.486 milimoles per litre
11.	Assay Propofol IP 10 mg/ml	Not less than 95.0 % and Not more than 105.0 % of the stated amount.	101.92 %
12.	Content Uniformity	For Information Only	Average Assay : 101.61 %, Minimum Assay : 101.33 % Maximum Assay : 101.86 %
13.	Particulate Contamination		
	i. Greater than or equal to 10 microns	Not more than 3000 particles/container	29 Particles/vial
	ii. Greater than or equal to 25 microns	Not more than 300 particles/container	8 Particles/vial

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

	Analyzed by:	Checked by:	Approved by:
Sign & Date	<i>SPP</i> 18/11/24	<i>SA</i> 18/11/24	<i>y</i> 18/11/24
Name	Sachin Patil	NITHY Dhanuvade	Vijay yadav
Designation	Trainee Officer ce	Executive ce	Asst-Manager