



MEDION BIOTECH PVT LIMITED
VILL. KAUNDI, BADDI, DISTT. - SOLAN-173205 (H.P.)

FINISH PRODUCT CERTIFICATE OF ANALYSIS

Product Name	Paclitaxel(Protein Bound Particle) for Injection Suspension 100 mg/Vial		
Generic Name	Paclitaxel(Protein Bound Particle) for Injection Suspension 100 mg/Vial		
Batch No.	L25PA06A14	A. R. No.	FG250454
Mfg. Date	06/2025	Sampling Date	20/06/2025
Exp. Date	05/2027	Date of Analysis	20/06/2025
Batch size	600 Vials.	Released Date	04/07/2025
Sampled Qty.	35 vials	Test As Per	IHS
S.No.	Test	Specification	Results
1.	Description	A white color Lyophilized powder filled in a 50 ml clear tubular glass vial	A white color Lyophilized powder filled in a 50 ml clear tubular glass vial
2.	Identification (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution correspond to the peak in the chromatogram obtained with the reference solution	Complies
3.	Particulate matter	The solution is practically free from any visible particle	Complies
4.	pH (20 ml 0.9% Nacl Injection USP)	5.50 to 7.50	6.85
5.	Chloroform	NMT 60 ppm	Not detected
6.	Particle Size	Z- Avg. (mean): 150 nm to 250 nm	218.7 nm
7.	Moisture Content	NMT 5.0%	3.29%
8.	Assay (By HPLC) Each vial contains: Paclitaxel 100mg/vial Albumin 900 mg/Vial	NLT-90mg/Vial (90.0%) NMT-110mg/Vial (110.0%) NLT 810 mg /Vial (90.0%) NMT 990 mg/Vial (110 %)	98.95mg/Vial (98.95 %) 923.92 mg/Vial (102.66 %)
9.	BET	NMT 1.3 EU/mg of Paclitaxel	LT 1.3 EU/mg of Paclitaxel
10.	Sterility	Must be sterile	Sterile

Remark: - The above sample confirms to ~~Does not confirms to~~ IP/ BP/USP/IHS

	Prepared by	Checked by	Approved by
Signature			
Date	04/07/2025	04/07/2025	04/07/2025
Name	MUKESH KUMAR	Kush Singh	
Designation	QC Analyst	QC Manager	QA Manager

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