

**Certificate of Analysis**

Product Name	Paclitaxel Protein Bound Particles For Injectable Suspension, 100 mg		
Batch No.	23APP01	A.R. No.	FP2301002
Batch Size	70.0 L	Exp/Retest. Date	12/2024
Mfg. Date	01/2023	Date of Analysis	28/01/2023
Spec. No.	FPIN126-S-06	Date of Report	28/01/2023
STP No.	FPIN126-T-05		

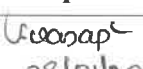
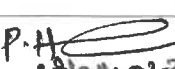
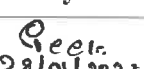
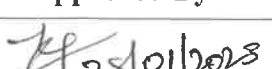
S.No	Test	Result	Specification
1.	Description	Light yellow colored lyophilized cake in 50 mL clear glass vial along with 20 mm grey colored single slotted rubber stoppers and 20mm Raymond blue with matte finish flip-off seals	White to light yellow or yellow colored lyophilized cake in 50 mL clear glass vial along with 20 mm grey colored single slotted rubber stoppers and 20mm Raymond blue with matte finish flip-off seals
2.	Description of reconstituted suspension	Off white colored suspension	Off white to light yellow colored suspension
3.	Volume after reconstitution	20.1 mL	Not less than 20.0 mL
4.	Average filled content	1.01g	1.00 g $\pm$ 10.0% (Between 0.90 g to 1.10 g)
5.	Uniformity of weight	- 8.27% to + 5.71%	$\pm$ 10.0 % of Average Weight
6.	Identification by HPLC		
	A) Limit of degradation products	The retention time of the major peak in the chromatogram of the test solution corresponds to that in the chromatogram of the Standard solution, as obtained in the limit of degradation products	The retention time of the major peak in the chromatogram of the test solution corresponds to that in the chromatogram of the Standard solution, as obtained in the limit of degradation products

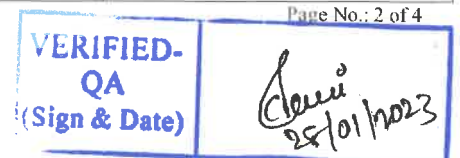
	Prepared by	Reviewed By		Approved By
Sign & Date	<i>Varaprasad</i> 28/01/2023	<i>P.H.</i> 28/01/2023	<i>Spec.</i> 28/01/2023	<i>P.K.</i> 28/01/2023
Name	S. Varaprasad	P.Harish Kumar	M. Srikanth	P.Kotaiah
Department	Quality Control	Quality Control	Quality Assurance	Quality Control

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STP No.	FPIN126-T-05	Date of Report	28/01/2023

S.No	Test	Result	Specification
	B) Assay	The retention time of the major peak in the chromatogram of the test preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay	The retention time of the major peak in the chromatogram of the test preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay
	C) Identification for Human serum albumin	The retention time of the major peak in the chromatogram of the test preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in Human serum albumin (HSA) content by HPLC test	The retention time of the major peak in the chromatogram of the test preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in Human serum albumin (HSA) content by HPLC test
7.	pH of the reconstituted suspension	6.9	Between 5.0 to 7.5
8.	Reconstitution time	2 minutes 10 seconds	Not more than 15 minutes
9.	Osmolality	319mOsm/Kg	300 to 360 mOsm/Kg
10.	Water content	1.2% w/w	Not more than 1.5% w/w

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S.No	Test	Result	Specification
11.	Limit of Degradation products		
	a) Baccatin III	0.001%	Not more than 0.4 %
	b) Ethyl ester side chain	Not Detected	Not more than 0.4 %
	c) 10-Deacetylpaclitaxel	0.03 %	Not more than 0.4 %
	d) 10-Deacetyl-7-epipaclitaxel (Paclitaxel related compound B)	Not Detected	Not more than 0.4 %
	e) 7-Epipaclitaxel	0.008 %	Not more than 0.4 %
	f) Any other Paclitaxel degradation product	0.05 %	Not more than 0.1%
	g) Total Paclitaxel degradation products	0.16 %	Not more than 1.5 %
12.	Assay By HPLC	100.2%	Not less than 95.0 % and not more than 105.0 % of Labeled amount of Paclitaxel (C <sub>47</sub> H <sub>51</sub> NO <sub>14</sub> )
13.	Human serum albumin (HSA) content by HPLC	102.5%	Not less than 90.0% and not more than 110.0%
14.	Residual solvents by GC Ethanol	1647.73 ppm	Not more than 5000 ppm
15.	Bound and unbound paclitaxel content	100.2 %	Not less than 90% of bound paclitaxel content
		Not Detected	Not more than 10% of unbound paclitaxel content

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Sign & Date	<i>S. Varaprasad</i> 28/01/2023	<i>P. Harish Kumar</i> 28/01/2023	<i>M. Srikanth</i> 28/01/2023	<i>P. Kotaiah</i> 28/01/2023
Name	S. Varaprasad	P. Harish Kumar	M. Srikanth	P. Kotaiah
Department	Quality Control	Quality Control	Quality Assurance	Quality Control

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**VERIFIED-  
QA  
(Sign & Date)**

*S. Varaprasad*  
28/01/2023

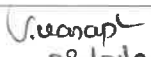
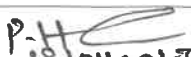
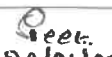

\* Wrong entry 28/01/2023

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S.No	Test	Result	Specification
16.	Uniformity of dosage units by HPLC (Assay)	AV (L1) = 1.02	The acceptance value of the first 10 dosage units is less than or equal to L1. (L1 is 15.0, L2 is 25.0)
17.	Average particle size by zeta sizer	150.8 nm	Less than 165 nm
18.	Zeta potential by Zeta sizer	-28.7 mV	-25 to -35 mV
19.	Bacterial Endotoxins	Less than 0.75 EU per mg of paclitaxel protein bound	Not more than 0.75 EU per mg of paclitaxel protein bound
20.	Sterility	No microbial growth was observed in the sample preparation during 18 days of incubation.	No microbial growth shall be observed in the sample preparation during 18 days of incubation.
21.	Particulate matter A. $\geq 10 \mu$ B. $\geq 25 \mu$	30 00	Not more than 3000 particles per container Not more than 300 particles per container

Remarks: The product **Complies** / **Does Not Comply** with above specification.

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Sign & Date	 28/01/2023	 28/01/2023	 28/01/2023	 28/01/2023
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