



Mac-chem Products (India) Pvt Ltd  
Quality Control Department  
Certificate of Analysis

Product Name :	Paclitaxel	Batch No. :	PAL0222006
Pharmacopoeia :	USP	Batch Qty. :	7.70KGS
Manufacturing Date :	Dec 2022	Approved On :	30/12/2022
Lot No. :	30520	C.A.S. No. :	33069-62-4
T.O. No. :	TO2302539	Expiry Date :	Nov 2027

	TEST	SPECIFICATION	RESULT
1	Description (USP)		
	Observations	White to off-white powder.	White powder
2	Solubility (USP)		
	Observation 1	Insoluble in Water.	Insoluble in Water.
	Observation 3	Soluble in alcohol	Soluble in alcohol
3	Identification by Infrared Absorption (USP)		
	Observation	The infrared spectrum of the sample should concord with the infrared spectrum of the paclitaxel working standard obtained in same manner.	The infrared spectrum of the sample is concord with the infrared spectrum of the paclitaxel working standard obtained in same manner.
4	Identification by HPLC (USP)		
	Observation	The retention time of the major peak in the chromatogram of the Assay preparation should correspond to that in the chromatogram of the standard preparation in the Assay.	The retention time of the major peak in the chromatogram of the Assay preparation is correspond to that in the chromatogram of the standard preparation in the Assay.
5	Specific optical rotation at 20°C(USP)		
	SOR on anhydrous & solvent free basis	Between - 49.0° and - 55.0°, calculated on the anhydrous and solvent free basis.	-51.97 °
6	Water Content (USP)		
	Water (Colourometric)	Not more than 4.0 %	1.59 %
7	Residue on Ignition (USP)		
	Result	Not more than 0.2%	0.06 %

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TEST	SPECIFICATION	RESULT
<b>8 Related compounds by HPLC(USP)</b>		
10-Deacetylbaaccatin III	Not more than 0.1%	Not Detected
Baccatin III	Not more than 0.2%	0.006 %
Photodegradant	Not more than 0.1%	Not Detected
10-Deacetylpaclitaxel	Not more than 0.5%	0.143 %
2-Debenzoypaclitaxel-2-pentenoate	Not more than 0.7%	Not Detected
Sum of x 1 + x 2 + x 3	Not more than 0.4%	0.000 %
7-Epipaclitaxel	Not more than 0.4%	0.107 %
10,13-Bissidechainpaclitaxel	Not more than 0.5%	0.001 %
7-Acetylpaclitaxel	Not more than 0.6%	0.002 %
13-Tes-baccatin III	Not more than 0.1%	Not Detected
7-Tes-paclitaxel	Not more than 0.3%	Not Detected
Any other single impurity	Not more than 0.1%	0.038 %
Total impurities	Not more than 2.0%	0.40 %
<b>9 Assay By HPLC (USP)</b>		
Assay on anhydrous and solvent free basis (USP)	Not less than 97.0% and not more than 102.0% of C <sub>47</sub> H <sub>51</sub> NO <sub>14</sub> ,calculated on the anhydrous, solvent- free basis.	100.07 %
<b>10 Bacterial Endotoxins (USP)</b>		
BET Result	Not more than 0.4 EU/mg.	Less than 0.4 EU/mg

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	TEST	SPECIFICATION	RESULT
11	Microbial enumeration test (USP)		
	Total bacterial count	Not more than 100 CFU/g	10 CFU/g
	Total yeast and fungal count	Not more than 10 CFU/g	Less than 10
	Escherichia coli per gram	Should be absent	Absent
	Salmonella abony per gram	Should be absent	Absent
	Pseudomonas aerugionosa per gram	Should be absent	Absent
	Staphylococcus aureus per gram	Should be absent	Absent
12	Residual solvents by GCHS (IH)		
	Methanol	Not more than 3000 ppm	91 ppm
	Acetone	Not more than 5000 ppm	277 ppm
	Methylene chloride	Not more than 600 ppm	0 ppm
	Ethyl acetate	Not more than 5000 ppm	0 ppm
	Cyclohexane	Not more than 3880 ppm	36 ppm

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Pharmacopoeia : USP

Manufacturing Date : Dec 2022

Lot No. : 30520

T.O. No. : TO2302539

Batch No. : PAL0222006

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Expiry Date : Nov 2027

Remarks : The Product meets the prescribed standards of quality as per USP specification

Storage Condition : Store in airtight containers, protected from light & moisture, not exceeding 25°C.

Analysed By : sharad thorat

Checked By : Sandip Bhirud

Designation : Officer - QC

Designation : Sr. Executive - Quality Control

Date : 22/12/2022

Date : 23/12/2022

Approved By : Sachin Gapat

Verified By : Mahendra Yadav

Designation : Manager - QC

Designation : Assistant Manager-QA

Date : 29/12/2022

Date : 30/12/2022

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