



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

Product Name : Paclitaxel

Pharmacopoeia : USP

Manufacturing Date : May 2022

Lot No. : 27701

T.O. No. : TO2300984

Batch No. : PAL0222003

Batch Qty. : 9.26KGS

Approved On : 30/06/2022

C.A.S. No. : 33069-62-4

Expiry Date : Apr 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.	-51.91 °
6	Water Content (USP)		
	Water (Colourometric)	Not more than 4.0 %	2.26 %
7	Residue on Ignition (USP)		
	Result	Not more than 0.2%	0.07 %

Office : 304, Town Centre, Andheri Kurla Road, Andheri(E), Mumbai - 400059, India.Tel.: +91 2240939000, Fax: +91 2240939060.

Factory : N-211/2/10, Tarapur MIDC Industrial Area, Boisar, Thane - 401506, India. Tel.: +91 02525661120 /661121.

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	TEST	SPECIFICATION	RESULT
8	Related compounds by HPLC(USP)		
	10-Deacetylbaaccatin III	Not more than 0.1%	0.003 %
	Baccatin III	Not more than 0.2%	0.010 %
	Photodegradant	Not more than 0.1%	Not Detected
	10-Deacetylpaclitaxel	Not more than 0.5%	0.231 %
	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%	0.145 %
	10,13-Bissidechainpaclitaxel	Not more than 0.5%	0.002 %
	7-Acetylpaclitaxel	Not more than 0.6%	0.001 %
	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%	0.59 %
9	Assay By HPLC (USP)		
	Assay on anhydrous and solvent free basis (USP)	Not less than 97.0% and not more than 102.0% of C ₄₇ H ₅₁ NO ₁₄ ,calculated on the anhydrous, solvent- free basis.	100.35 %
10	Bacterial Endotoxins (USP)		
	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	Less than 10
	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	67 ppm
	Acetone	Not more than 5000 ppm	354 ppm
	Methylene chloride	Not more than 600 ppm	351 ppm
	Ethyl acetate	Not more than 5000 ppm	0 ppm
	Cyclohexane	Not more than 3880 ppm	0 ppm

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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 :	22/06/2022	Date :	22/06/2022

Approved By :	Sachin Gapat	Verified By :	maheshy shelke
Designation :	Manager - QC	Designation :	Sr. Manager - QA
Date :	30/06/2022	Date :	30/06/2022

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