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



Product Name

Paclitaxel

Pharmacopoeia

USP

33069-62-4

CAS. No.

Sep 2017

Mfg. Date **Retest Date**

Aug 2020

Batch No.

PAT0217008

Batch Qty.

5.934 KGS

Approved On

29/09/17

TO. No.

TO1803668

Exp. Date

Aug 2021

NO	TESTS	SPECIFICATIONS	RESULTS
1	Description (USP)	White or off white powder.	White powder
2	Solubility (USP)	Soluble in alcohol; insoluble in water.	Complies
3	Identification (USP)		
а	By Infrared absorption	Test infrared spectrum of the sample should concordant with the infrared spectrum of the Paclitaxel working/ reference standard obtained in same manner.	Complies
b	By HPLC	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.	Complies
4	Specific optical rotation (USP)	Between - 49.0° and - 55.0° at 20°, calculated on the anhydrous, solvent-free basis.	-53.16°
5	Water content (By Coulometric Titration) (USP)	Not more than 4.0%.	1.42%
6	Residue on ignition (USP)	Not more than 0.2 %	0.11%
.7	Heavy metals (USP)	Not more than 0.002%.	Less than 0.002%
8	Related compounds (BY HPLC) (USP)		
a	10-Deacetylbaccatin III	Not more than 0.1%	Not detected
b	Baccatin III	Not more than 0.2%	0.039%
С	Photodegradant ²	Not more than 0.1%.	Not detected
d	10-Deacetylpaclitaxel	Not more than 0.5%.	Not detected
e	2-Debenzoylpaclitaxel-2-pentenoate	Not more than 0.7%.	0.053%
f	Oxetane ring opened, acetyl & benzoyl migrated ²	xl	Not detected
g	10-Acetoacetylpaclitaxel	x2	Not detected
h	10-Deacetyl-7-epipaclitaxel (Paclitaxel Related compound B)	x3 Sum of x1+x2+x3 : Not more than 0.4%	0.012%
i	7-Epipaclitaxel	Not more than 0.4 %.	0.094%
j	10,13-Bissidechainpaclitaxel ²	Not more than 0.5 %.	Not detected
k	7-Acetylpaclitaxel	Not more than 0.6 %.	0.018%
l	13-Tes-baccatin III	Not more than 0.1 %.	0.012%
m	7-Tes-paclitaxel	Not more than 0.3 %	Not detected
n	Any other single impurity	Not more than 0.1 %	0.053%
0	Total impurities	Not more than 2.0 %.	0.409%

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



Certificate of Analysis

Product Name	Paclitaxel		
Pharmacopoeia	USP	Batch No.	PAT0217008
CAS. No.	33069-62-4	Batch Qty.	5.934 KGS
Mfg. Date	Sep 2017	Approved On	29/09/17
Retest Date	Aug 2020	TO. No.	TO1803668
Exp. Date	Aug 2021		

NO	TESTS	SPECIFICATIONS	RESULTS
9	Assay (By HPLC) (USP)	Not less than 97.0% and not more than 102.0% of C47H51NO14 calculated on the anhydrous, solvent-free basis.	100.40%
10	Bacterial Endotoxins (USP)	Not more than 0.4 EU/mg of Paclitaxel.	Less than 0.4 EU/mg
11	Residual solvents (By GCHS) (ICH) (IH)		
a	Methanol	Not more than 3000 ppm.	Not detected
b	Acetone	Not more than 5000 ppm.	Not detected
С	Ethyl acetate	Not more than 5000 ppm.	Not detected
d	Di-isopropyl ether	Not more than 5000 ppm.	36 ppm
e	Methylene chloride	Not more than 600 ppm.	Not detected
12	Microbiological limit test (USP)		
a	Total aerobic microbial count	Not more than 100 cfu / g	10 cfu/g
b	Total combined yeasts and moulds count	Not more than 10 cfu/g	Nil
С	Escherichia coli	Should be absent.	Absent
d	Salmonella species	Should be absent.	Absent
e	Pseudomonas aeruginosa	Should be absent.	Absent
f	Staphylococcus aureus	Should be absent.	Absent

 $Remark: The\ Product\ complies\ the\ prescribed\ standards\ of\ quality\ as\ per\ USP\ specification\ No.\ FPSTP00040-USP-03$

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

Prepared By : Tukaram Badhe

Delle

Checked By : Kiran Bhirud

Approved By : Pinank Raval

Designation : Executive -QC

Designation : Sr. Executive - QC

Tolia

Designation : Asst. Manager - QC

Date : 12/10/2017 Date : 12/10/2017 Date : 12/10/2017



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CIN No.: U24239MH1991PTC062948



Date: 21/12/2017

TO WHOMSOEVER IT MAY CONCERN

Name of Product: Paclitaxel

We, Mac- Chem Products (India) Pvt. Ltd., hereby declare and certify that during packing of our product Paclitaxel no silica gel bags have been put inside the packing.

For M/ac-Chem Products (I) Pvt. Ltd..,

They 21/12/2017

Name

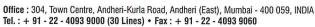
: Mr. R. Prem kumar

Designation

: Asst. Manager - QA

Company seal:





Factory: N-211/2/10, Tarapur MIDC, Boisar, District Palghar, Pin - 401 506, INDIA Tel.: + 91 - 7770016606 / 7770016607 / 02525 661120

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CIN No.: U24239MH1991PTC062948





