Mac-chem Products (India) Pvt Ltd

Quality Control Department

Certificate of Analysis

MAC-CHEM PRODUCTS (INDIA) PVT. LTD.

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
1	**Description (USP)**	White or off white powder.	White powder
2	**Solubility (USP)**	Soluble in alcohol; insoluble in water.	Complies
3	**Identification (USP)**		
a	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%
c	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]	x1	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%
o	Total impurities	Not more than 2.0 %.	0.409%

Office : 304, Town Centre, Andheri-Kurla Road, Andheri (East), Mumbai - 400 059, INDIA
Tel. : + 91 - 22 - 4093 9000 (30 Lines) • Fax : + 91 - 22 - 4093 9060
Factory : N-211/2/10, Tarapur MIDC, Boisar, District Palghar, Pin - 401 506, INDIA
Tel. : + 91 - 7770016606 / 7770016607 / 02525 661120
www.macchemgroup.com
CIN No. : U24239MH1991PTC062948

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Retest Date	**Aug 2020**	**TO. No.**	**TO1803668**
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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
c	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
c	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	Checked By	: Kiran Bhirud	Approved By	: Pinank Raval
Designation	: Executive -QC	Designation	: Sr. Executive - QC	Designation	: Asst. Manager - QC
Date	: 12/10/2017	Date	: 12/10/2017	Date	: 12/10/2017

VERIFIED BY QUALITY ASSURANCE SIGN. & DATE 12/10/2017

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MAC-CHEM PRODUCTS
(INDIA) PVT. LTD.

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..,

21/12/2017

Name : Mr. R. Prem kumar

Designation : Asst. Manager - QA

Company seal:

MAC-CHEM PRODUCTS (INDIA) PVT. LTD.
BOISAR
401506.

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