7-5/2014/EU/WC-0275

Government of India

Directorate General of Health Services

Central Drugs Standard Control Organisation

(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated : 22 JAN 2021

To

M/s Mac-Chem Products (India) Pvt Ltd.,
N-211/2/10, Tarapur, M.I.D.C, Boisar,
District-Thane-401 506 Maharashtra, India

SUB:- Written Confirmation of M/s Mac-Chem Products (India) Pvt Ltd., N-211/2/10, Tarapur, M.I.D.C, Boisar, District-Thane-401 506 Maharashtra, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, West Zone office, and the recommendation received from DDC (I), West Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	33	22 JAN 2021	01.08.2023
2	02	22 JAN 2021	01.08.2023

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

WC-0275

CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Mac-Chem Prodcuts (India) Pvt Ltd., N-211/2/10, Tarapur, M.I.D.C, Boisar, District-Thane-401 506 Maharashtra India**

2. Manufacturer's licence number: KD-715 and KD-506

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

As per Annexure 1 & Annexure 2

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 15/10/2020 & 16/10/2020

The Written Confirmation remains valid until: 01/08/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. V.G.Somani,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

22 JAN 2021

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, Government of India

22 JAN 2021

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **Annexure-1**

WC-0275

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Mac-Chem Products (India) Pvt Ltd., N-211/2/10, Tarapur, M.I.D.C, Boisar, District-Thane-401 506 Maharashtra India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Acyclovir for Injection USP	Manufacturing & Packing
2.	Anastrozole USP	Manufacturing & Packing
3.	Capecitabine USP	Manufacturing & Packing
4.	Carboplatin USP/BP/EP	Manufacturing & Packing
5.	Cytarabine USP/BP/EP	Manufacturing & Packing
6.	Docetaxel USP	Manufacturing & Packing
7.	Erlotinib Hydrochloride IH	Manufacturing & Packing
8.	Esomeprazole Sodium for Injection IH	Manufacturing & Packing
9.	Gefitinib IH/EP	Manufacturing & Packing
10.	Gemcitabine Hydrochloride USP/BP/EP	Manufacturing & Packing
11.	Hydrocortisone Sodium Succinate for Injection (Lyophilized Sterile Bulk) USP	Manufacturing & Packing
12.	Irinotecan Hydrochloride Trihydrate USP/EP	Manufacturing & Packing
13.	Letrozole USP/BP/EP	Manufacturing & Packing
14.	Methotrexate USP/BP/EP	Manufacturing & Packing
15.	Neostigmine Methylsulphate USP/BP	Manufacturing & Packing
16.	Omeprazole Sodium for Injection (Lyophilized Sterile Bulk) IH	Manufacturing & Packing
17.	Oxaliplatin BP	Manufacturing & Packing
18.	Paclitaxel USP	Manufacturing & Packing
19.	Pantoprazole Sodium for Injection (Lyophilized Sterile Bulk) IH	Manufacturing & Packing
20.	Ropivacaine Hydrochloride USP/BP/EP	Manufacturing & Packing
21.	Succinylcholine Chloride USP/BP	Manufacturing & Packing
22.	Zoledronic Acid IH	Manufacturing & Packing
23.	Abiraterone Acetate USP	Manufacturing & Packing
24.	Bendamustine Hycrochloride IH	Manufacturing & Packing
25.	Bicalutamide USP/EP	Manufacturing & Packing
26.	Colistimethate Sodium for Injection (Lyophilized Sterile Bulk) BP	Manufacturing & Packing
27.	Colistimethate for Injection (Lyophilized Sterile Bulk) USP	Manufacturing & Packing
28.	Methylprednisolone Sodium Succinate Sterile for Injection (Lyophilized Sterile Bulk) USP	Manufacturing & Packing
29.	Chloramphenicol Sodium Succinate for Injection (Lyophilized Sterile Bulk) BP	Manufacturing & Packing
30.	Polymyxin B Sulfate USP	Manufacturing & Packing
31.	Succinylcholine chloride for Injection (Lyophilized Sterile Bulk) USP	Manufacturing & Packing
32.	Suxamethonium Choride EP	Manufacturing & Packing
33.	Tenoxicam for Injection (Lyophilized Sterile Bulk) BP	Manufacturing & Packing

ITEM(S) ThirtyThree (33) ONLY

The Written Confirmation remains valid until: 01/08/2023

Signature : 22 JAN 2021 *Stamp of the authority and date*

22 JAN 2021

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-2

CERTIFICATE NO. : WC-0275

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s Mac-Chem Products (India) Pvt Ltd.,
N-211/2/10, Tarapur, M.I.D.C, Boisar,
District-Thane-401 506
Maharashtra India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Dacarbazine USP/BP/EP	Manufacturing & Packing
2.	Pemetrexed Disodium Heptahydrate BP/EP	Manufacturing & Packing

ITEM(S) Two (02) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 01/08/2023

22 JAN 2021

Signature

Stamp of the authority and date

22 JAN 2021