7-5/2015/EU/WC/0349
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan,Kotla Road,
New Delhi-110002
Dated:

To

M/s. MSN Laboratories Private Limited,
Unit-II, Sy. No. 50, Kardanur (Village),
Patancheru (Mandal), Sangareddy District,
Telangana, 502300, India

02 SEP 2022

Subject:- Written Confirmation of M/s. MSN Laboratories Private Limited (Unit-II), Sy No. 50, Kardanur (Village), Patancheru (Mandal), Sangareddy District, Telangana, 502300, 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 online WC/RE/2022/2021 application submitted to CDSCO, Hyderabad Zone office and the recommendation received from DDC(I), Hyderabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	55	02 SEP 2022	05.05.2025
2	17	02 SEP 2022	05.05.2025

Yours faithfully,

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

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

CERTIFICATE NO. : **WC-0349**

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. MSN Laboratories Private Limited,
Unit-II, Sy. No. 50, Kardanur (Village),
Patancheru (Mandal), Sangareddy District,
Telangana, 502300, India

2. Manufacturer's licence number: 25/MD/AP/2011/B/CC

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

As per List enclosed as Annexure-1 & 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: 04.02.2021 & 05.02.2021

The Written Confirmation remains valid until: **05.05.2025**

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

Signature

02 SEP 2022

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

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

Annexure-1
WC-0349

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

Name and address of site: **M/s. MSN Laboratories Private Limited, Unit-II, Sy. No. 50, Kardanur (Village), Patancheru (Mandal), Sangareddy District, Telangana, 502300, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abiraterone Acetate IH/USP	Manufacturing & Packing
2.	Abiraterone IH	Manufacturing & Packing
3.	Afatinib Dimalate IH	Manufacturing & Packing
4.	Azacitidine IH	Manufacturing & Packing
5.	Axitinib IH	Manufacturing & Packing
6.	Bicalutamide USP/Ph.Eur	Manufacturing & Packing
7.	Bendamustine Hydrochloride IH	Manufacturing & Packing
8.	Bexarotene IH	Manufacturing & Packing
9.	Bimatoprost IH	Manufacturing & Packing
10.	Bortezomib IH	Manufacturing & Packing
11.	Bosutinib Monohydrate IH	Manufacturing & Packing
12.	Cabazitaxel IH	Manufacturing & Packing
13.	Capecitabine USP/Ph.Eur	Manufacturing & Packing
14.	Carboprost Tromethamine USP	Manufacturing & Packing
15.	Carfilzomib IH	Manufacturing & Packing
16.	Carmustine USP	Manufacturing & Packing
17.	Ceritinib IH	Manufacturing & Packing
18.	Cyclophosphamide Monohydrate USP/EP	Manufacturing & Packing
19.	Dasatinib IH	Manufacturing & Packing
20.	Dasatinib (Monohydrate) IH	Manufacturing & Packing
21.	Decitabine IH	Manufacturing & Packing
22.	Docetaxel Anhydrous USP/Ph.Eur	Manufacturing & Packing
23.	Docetaxel Trihydrate USP/Ph.Eur	Manufacturing & Packing

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

02 SEP 2022

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

Annexure-1
WC-0349

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

Name and address of site: **M/s. MSN Laboratories Private Limited, Unit-II, Sy. No. 50, Kardanur (Village), Patancheru (Mandal), Sangareddy District, Telangana, 502300, India**

S. No.	Active substance(s)	Activity(ies)
24.	Enzalutamide IH	Manufacturing & Packing
25	Erlotinib Hydrochloride IH	Manufacturing & Packing
26	Fingolimod IH	Manufacturing & Packing
27	Fingolimod Hydrochloride IH/Ph.Eur	Manufacturing & Packing
28	Gefitinib IH/Ph.Eur	Manufacturing & Packing
29	Gemcitabine Hydrochloride USP	Manufacturing & Packing
30	Ibrutinib IH	Manufacturing & Packing
31	Imatinib Mesylate IH/Ph.Eur	Manufacturing & Packing
32	Latanoprost USP	Manufacturing & Packing
33	Lenalidomide IH	Manufacturing & Packing
34	Nilotinib IH	Manufacturing & Packing
35	Nilotinib Hydrochloride IH	Manufacturing & Packing
36	Nintedanib Esylate IH	Manufacturing & Packing
37	Nintedanib IH	Manufacturing & Packing
38	Olaparib IH	Manufacturing & Packing
39	Paclitaxel USP/EP	Manufacturing & Packing
40	Palonosetron Hydrochloride IH/USP	Manufacturing & Packing
41	Pazopanib Hydrochloride IH	Manufacturing & Packing
42	Pemetrexed Disodium Hemipentahydrate IH	Manufacturing & Packing
43	Pemetrexed Disodium Heptahydrate Ph.Eur	Manufacturing & Packing
44	Plerixafor IH	Manufacturing & Packing
45	Palbociclib IH	Manufacturing & Packing
46	Regorafenib IH	Manufacturing & Packing
47	Ruxolitinib Phosphate IH	Manufacturing & Packing
48	Sorafenib Hemi Tosylate Monohydrate IH	Manufacturing & Packing
49	Sorafenib Tosylate IH	Manufacturing & Packing
50	Sunitinib Malate IH	Manufacturing & Packing
51	Tafluprost IH	Manufacturing & Packing
52	Thiotepa USP	Manufacturing & Packing
53	Trabectedin IH	Manufacturing & Packing
54	Travoprost USP	Manufacturing & Packing
55	Trifluridine USP	Manufacturing & Packing

ITEM(S) Fifty-Five (55) ONLY

The Written Confirmation remains valid until: 05.05.2025

Signature

02 SEP 2022

Stamp of the authority and date

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

Annexure-2
WC-0349

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

Name and address of site: **M/s. MSN Laboratories Private Limited, Unit-II, Sy. No. 50, Kardanur (Village), Patancheru (Mandal), Sangareddy District, Telangana, 502300, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Apalutamide IH	Manufacturing & Packing
2.	Aclidinium Bromide IH	Manufacturing & Packing
3.	Bosutinib IH	Manufacturing & Packing
4.	Belinostat IH	Manufacturing & Packing
5.	Bexarotene IH	Manufacturing & Packing
6.	Cabozantinib (s)-Maleate IH	Manufacturing & Packing
7.	Clofarabine IH	Manufacturing & Packing
8.	Ixazomib Citrate IH	Manufacturing & Packing
9.	Iloprost IH	Manufacturing & Packing
10.	Neratinib Maleate Monohydrate IH	Manufacturing & Packing
11.	Latanoprostene Bunod IH	Manufacturing & Packing
12.	Lenvatinib Base IH	Manufacturing & Packing
13.	Lenvatinib Mesylate DMSO Solvate IH	Manufacturing & Packing
14.	Panobinostat Lactate IH	Manufacturing & Packing
15.	Pomalidomide IH	Manufacturing & Packing
16.	Tipiracil Hydrochloride IH	Manufacturing & Packing
17.	Venetoclax IH	Manufacturing & Packing

ITEM(S) Seventeen (17) 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: 05.05.2025

Signature

Stamp of the authority and date

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

02 SEP 2022