7-5/2013/EU/WC-0197
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated 09 SEP 2019

To

M/s. Olon Active Pharmaceutical Ingredients India Private Limited,
Plot No. L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Mahad,
Taluka: Mahad, District: Raigad-402301.

SUB:- Written Confirmation of M/s. Olon Active Pharmaceutical Ingredients India Private Limited, Plot No. L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Mahad Taluka: Mahad, District: Raigad-402301 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, Mumbai office and the recommendation received from DDC(I), West Zone, Mumbai 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 Confirrnation 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	11	09 SEP 2019	Three years from the date of issue
2	03	09 SEP 2019	Three years from the date of issue

Yours faithfully,

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

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

WC-0197

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. Olon Active Pharmaceutical Ingredients India Private Limited,**
Plot No. L-1, L-21 to L-28 & L-44,
Additional Phase MIDC, Mahad,
Taluka: Mahad, District: Raigad-402301.

2. **Manufacturer's licence number: MH/102992**

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 list enclosed in 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: 11th to 13th June, 2019

The Written Confirmation remains valid until: Three years from the date of issue.

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

30/08/19

Stamp of the authority and date

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

09 SEP 2019

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

Annexure-1

CERTIFICATE NO. : WC-0197

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. Olon Active Pharmaceutical Ingredients India Private Limited, Plot No. L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Mahad, Taluka: Mahad, District: Raigad-402301.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aprepitant IH/Ph.Eur/USP	Manufacturing & Packing
2.	Aripiprazole IH/Ph.Eur/USP	Manufacturing & Packing
3.	Escitalopram Oxalate IH/Ph.Eur/USP	Manufacturing & Packing
4.	Lansoprazole IH/Ph.Eur/USP	Manufacturing & Packing
5.	Moxifloxacin Hydrochloride IH	Manufacturing & Packing
6.	Mycophenolate Mofetil IH/Ph.Eur	Manufacturing & Packing
7.	Posaconazole IH	Manufacturing & Packing
8.	Pramipexole Dihydrochloride Monohydrate IH/Ph.Eur	Manufacturing & Packing
9.	Quetiapine Fumarate IH/Ph.Eur/USP/JP	Manufacturing & Packing
10.	Rifampicin IP/BP/EP	Manufacturing & Packing
11.	Rifampin USP	Manufacturing & Packing

ITEM(S) Eleven (11) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

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

09 SEP 2019

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

Annexure-2

CERTIFICATE NO.WC-0197

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. Olon Active Pharmaceutical Ingredients India Private Limited, Plot No. L-1, L-21 to L-28 & L-44, Additional Phase MIDC, Mahad, Taluka: Mahad, District: Raigad-402301.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Clopidogrel Hydrochloride IH	Manufacturing & Packing
2.	Lactobionic Acid IH/Ph.Eur	Manufacturing & Packing
3.	Tigecycline Hydrochloride IH	Manufacturing & Packing

ITEM(S) Three (03) 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: Three years from the date of issue

Signature

30/08/19.

Stamp of the authority and date

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

09 SEP 2019