7-5/2013/EU/WC-0123
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 05 JUL 2019

To,

M/s. Piramal Enterprises Limited,
Sy. Nos. 7-70, 70/1 & 70/2,
Digwal Village, Kohir Mandal,
Sangareddy District, Telangana, India

SUB:- Written Confirmation of M/s. Piramal Enterprises Limited, Sy. Nos. 7-70, 70/1 & 70/2, Digwal Village, Kohir Mandal, Sangareddy District, Telangana, 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, Hyderabad Zone office and the recommendation received from DDC(I), Hyderabad Zonal office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	33	05 JUL 2019	02.07.2022
02	06	05 JUL 2019	02.07.2022

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

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

CERTIFICATE NO. : WC-0123

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. Piramal Enterprises Limited,**
Sy. Nos. 7-70, 70/1 & 70/2,
Digwal Village, Kohir Mandal,
Sangareddy District, Telangana, India

2. **Manufacturer's licence number**: 28220/AP/MD/96/B&F/R

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- 01 and Annexure- 02

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: 03-04/08/2019

The Written Confirmation remains valid until: 02.07.2022

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. S Eswara Reddy,
Drugs Controller General (India)

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

Signature

Stamp of the authority and date

05 JUL 2019

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

WC-0123

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. Piramal Enterprises Limited,
Sy. Nos. 7-70, 70/1 & 70/2,
Digwal Village, Kohir Mandal,
Sangareddy District, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir Sulphate Ph.Eur	Manufacturing & Packing
2.	Acyclovir USP	Manufacturing & Packing
3.	Amiodarone Hydrochloride Ph.Eur	Manufacturing & Packing
4.	Aprepitant IH	Manufacturing & Packing
5.	Armodafinil IH	Manufacturing & Packing
6.	Baclofen USP/Ph.Eur	Manufacturing & Packing
7.	Bisoprolol Fumarate USP/BP/Ph.Eur	Manufacturing & Packing
8.	Brimonidine Tartrate IH/Ph.Eur	Manufacturing & Packing
9.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
10.	Clobazam IP/BP/Ph.Eur	Manufacturing & Packing
11.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
12.	Diltiazem Hydrochloride IP/BP/ Ph.Eur./USP	Manufacturing & Packing
13.	Donepezil Hydrochloride IP/USP	Manufacturing & Packing
14.	Entacapone USP/BP/Ph.Eur	Manufacturing & Packing
15.	Flecainide Acetate USP/Ph.Eur	Manufacturing & Packing
16.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
17.	Isoflurane BP/Ph.Eur./USP	Manufacturing & Packing
18.	Ketoconazole IP/BP/Ph.Eur./USP	Manufacturing & Packing
19.	Levobunolol Hydrochloride BP/USP/Ph.Eur	Manufacturing & Packing
20.	Mebeverine Hydrochloride BP	Manufacturing & Packing
21.	Oxybutynin Hydrochloride BP/USP/IP	Manufacturing & Packing
22.	Perindopril tert-Butylamine Ph.Eur/USP/BP	Manufacturing & Packing
23.	Pramipexole Dihydrochloride USP	Manufacturing & Packing
24.	Memantine Hydrochloride IH	Manufacturing & Packing
25.	Rivaroxaban IH	Manufacturing & Packing
26.	Tramadol Hydrochloride IP/BP	Manufacturing & Packing
27.	Valacyclovir Hydrochloride USP	Manufacturing & Packing
28.	Verapamil Hydrochloride IP/BP/Ph.Eur./USP	Manufacturing & Packing
29.	Halothane Bulk	Manufacturing & Packing
30.	Trazodone Hydrochloride BP/USP	Manufacturing & Packing
31.	Dronedarone Hydrochloride IH	Manufacturing & Packing
32.	Paliperidone Palmitate IH	Manufacturing & Packing
33.	Tetrabenazine IH	Manufacturing & Packing

ITEM(S) Thirty Three (33) ONLY

The Written Confirmation remains valid until: 02.07.2022

Signature

28-6-19

Stamp of the authority and date

05 JUL 2019

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

Annexure-02

CERTIFICATE NO. : WC-0123

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. Piramal Enterprises Limited,
Sy. Nos. 7-70, 70/1 & 70/2,
Digwal Village, Kohir Mandal,
Sangareddy District, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Deferasirox IH	Manufacturing & Packing
2.	Tafenoquine Succinate IH	Manufacturing & Packing
3.	Tolcapone USP	Manufacturing & Packing
4.	Sulindac USP/Ph.Eur	Manufacturing & Packing
5.	Promethazine Teoclate BP/USP/IP	Manufacturing & Packing
6.	Lurasidone Hydrochloride IH	Manufacturing & Packing

ITEM(S) Six (06) ONLY

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

The Written Confirmation remains valid until: 02.07.2022

Signature

Stamp of the authority and date

05 JUL 2019