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: 27 JUN 2025

To,

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

Subject: - Written Confirmation of **M/s. Piramal Pharma Limited, Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V), Kohir (M), Sangareddy (Dist.), 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 no. **WC/RE/2024/9565** dated 26-DEC-2024 submitted to CDSCO, Zonal office Hyderabad, and the recommendation received from DDC(I), Zonal office Hyderabad, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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
--	--	27 JUN 2025	02.07.2028
01	19	27 JUN 2025	02.07.2028
02	10	27 JUN 2025	02.07.2028

Yours faithfully,

Chandrashekar
27/06/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(Ind
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेश
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family W
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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 Pharma Limited,**
Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V),
Kohir (M), Sangareddy (Dist.), Telangana, India

2. Manufacturer's licence number: **220/AP/MD/96/BF/R**

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

List of APIs:

As per Annexures Enclosed

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: **13.05.2025 & 15.05.2025**

The Written Confirmation remains valid until: **02.07.2028**

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: Ranga Chandrashekar,
Joint Drugs Controller (India)

E-mail: ***ranga.cs@cdsco.nic.in;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar

Signature 27/06/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

27 JUN 2025

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

Annexure – 01

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 Pharma Limited,
Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V),
Kohir (M), Sangareddy (Dist.), Telangana, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir Sulphate Ph.Eur.	Manufacturing & Packing
2.	Amiodarone Hydrochloride Ph.Eur.	Manufacturing & Packing
3.	Aprepitant IH/USP/Ph.Eur.	Manufacturing & Packing
4.	Baclofen USP/Ph.Eur.	Manufacturing & Packing
5.	Bisoprolol Fumarate USP/BP/Ph.Eur.	Manufacturing & Packing
6.	Brimonidine Tartrate IH/Ph.Eur.	Manufacturing & Packing
7.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
8.	Dabigatran Etexilate Mesylate IH/Ph.Eur.	Manufacturing & Packing
9.	Dapagliflozin Propanediol Monohydrate IH	Manufacturing & Packing
10.	Diltiazem Hydrochloride BP/ Ph.Eur./USP	Manufacturing & Packing
11.	Flecainide Acetate USP/Ph.Eur.	Manufacturing & Packing
12.	Fosaprepitant Dimeglumine IH	Manufacturing & Packing
13.	Isoflurane BP/Ph.Eur./USP	Manufacturing & Packing
14.	Ketoconazole BP/Ph.Eur./USP	Manufacturing & Packing
15.	Mebeverine Hydrochloride BP/Ph. Eur.	Manufacturing & Packing
16.	Tetrabenazine IH	Manufacturing & Packing
17.	Trazodone Hydrochloride BP/USP	Manufacturing & Packing
18.	Verapamil Hydrochloride BP/Ph.Eur./USP	Manufacturing & Packing
19.	Varenicline Tartrate IH	Manufacturing & Packing

ITEM(S) NINETEEN (19) ONLY

The Written Confirmation remains valid until: 02.07.2028

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

27 JUN 2025

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

CERTIFICATE NO. : Annexure-02 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 Pharma Limited,
Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V),
Kohir (M), Sangareddy (Dist.), Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Bexagliflozin IH	Manufacturing & Packing
2.	Droxidopa IH	Manufacturing & Packing
3.	Lurasidone Hydrochloride IH	Manufacturing & Packing
4.	Metyrapone IH/JP	Manufacturing & Packing
5.	Mirabegron IH/Ph.Eur.	Manufacturing & Packing
6.	Promethazine Teoclate BP	Manufacturing & Packing
7.	Rimegepant Sulphate (BHV-)/FCI IH	Manufacturing & Packing
8.	Tafenoquine Succinate IH	Manufacturing & Packing
9.	Tolcapone USP	Manufacturing & Packing
10.	Vortioxetine Hydrobromide IH	Manufacturing & Packing

ITEM(S) TEN (10) 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(s) for the purpose of export only, as the above-mentioned active substance(s) is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 02.07.2028

Chandrashekar

Signature 27/06/25

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation * Ministry of Health & Family Welfare, Govt. of India *

27 JUN 2025

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:

10 DEC 2025

To,

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

Subject: - Written Confirmation of **M/s. Piramal Pharma Limited, Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V), Kohir (M), Sangareddy (Dist.), 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 no. **WC/ED/2025/11213** submitted to CDSCO, Zonal office Hyderabad, and the recommendation received from DDC(I), Zonal office Hyderabad, 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.

9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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
--	--	27.06.2025	**02.07.2028**
01	19	27.06.2025	**02.07.2028**
02	10	27.06.2025	**02.07.2028**
03	01	10 DEC 2025	**02.07.2028**

Yours faithfully,

Chandrashekar 9/12/25

Dr. Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानि
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. : Annexure – 03 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 Pharma Limited,**
Sy. Nos. 7-70, 70/1 & 70/2, Digwal (V),
Kohir (M), Sangareddy (Dist.), Telangana, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Sevoflurane USP/Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02.07.2028

Chandrashekar
09/12/25
Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

10 DEC 2025