7-5/2013/EU/WC-0084
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

2 9 AUG 2025

To

M/s. Zydus Lifesciences Limited,
Plot no. 26 to 29 & 31, Umraya Road, Vill-Dabhasa,
Tal-Padra, Dist.: Vadodara, Pin-391440, Gujarat

Subject: - Written Confirmation of **M/s. Zydus Lifesciences Limited, Plot no. 26 to 29 & 31, Umraya Road, Vill-Dabhasa, Tal-Padra, Dist.: Vadodara, Pin-391440, Gujarat, 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 application no. **WC/RE/2025/10851 & WC/ED/2025/9995** submitted to CDSCO, Ahmedabad zone office and the recommendation received from DDC(I), Ahmedabad 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

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

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
--	--	29 AUG 2025	Three Year from the Date of Issue
1	25	29 AUG 2025	Three Year from the Date of Issue
2	10	29 AUG 2025	Three Year from the Date of Issue

Yours faithfully,

Chandrashekar
28/08/25

(Ranga Chandrashekar)
Joint Drugs Controller (India)

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

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

CERTIFICATE NO. : **WC-0084**

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. Zydus Lifesciences Limited,**
Plot no. 26 to 29 & 31, Umraya Road,
Vill-Dabhasa, Tal-Padra, Dist.: Vadodara,
Pin-391440, Gujarat

2. Manufacturer's licence number: **G/25/1409**

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 the annexure(s) 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: 31.07.2025

The Written Confirmation remains valid until: **Three Year 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: Ranga Chandrashekar,
Joint Drugs Controller (India)

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

Signature चंद्रशेखर रंगा/Chandrashekar Ranga 28/08/25
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

29 AUG 2025

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

CERTIFICATE NO. : **Annexure-1**
WC-0084

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 Zydus Lifesciences Limited,**
Plot no. 26 to 29 & 31, Umraya Road,
Vill-Dabhasa, Tal-Padra, Dist.: Vadodara,
Pin-391440, Gujarat

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Tamsulosin Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
2.	Pramipexole Dihydrochloride USP	Manufacturing & Packing
3.	Clopidogrel Besilate Ph.Eur.	Manufacturing & Packing
4.	Hydrochlorothiazide IH/USP	Manufacturing & Packing
5.	Atenolol BP/USP/Ph.Eur.	Manufacturing & Packing
6.	Irbesartan IH/USP	Manufacturing & Packing
7.	Clopidogrel Bisulfate USP	Manufacturing & Packing
8.	Paroxetine Hydrochloride Hemihydrate BP/Ph.Eur.	Manufacturing & Packing
9.	Paroxetine Hydrochloride IH/USP	Manufacturing & Packing
10.	Risperidone BP/Ph.Eur.	Manufacturing & Packing
11.	Donepezil Hydrochloride IH	Manufacturing & Packing
12.	Famotidine BP/USP/Ph.Eur.	Manufacturing & Packing
13.	Topiramate IH	Manufacturing & Packing
14.	Fluconazole USP	Manufacturing & Packing
15.	Ziprasidone Hydrochloride Monohydrate Ph.Eur.	Manufacturing & Packing
16.	Olmesartan Medoxomil IH/Ph.Eur.	Manufacturing & Packing
17.	Ivabradine Hydrochloride IH	Manufacturing & Packing
18.	Azelastine Hydrochloride Ph.Eur.	Manufacturing & Packing
19.	Duloxetine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
20.	Clindamycin Phosphate BP/USP/Ph.Eur.	Manufacturing & Packing
21.	Rivastigmine IH/USP	Manufacturing & Packing
22.	Tirofiban Hydrochloride IH	Manufacturing & Packing
23.	Apixaban IH	Manufacturing & Packing
24.	Ethacrynic acid USP	Manufacturing & Packing
25.	Pramipexole Dihydrochloride Monohydrate IH/USP	Manufacturing & Packing

ITEM(S) Twenty-Five (25) ONLY

The Written Confirmation remains valid until: **Three Year from the Date of Issue**

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

29 AUG 2025

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

CERTIFICATE NO. : **Annexure-2**
WC-0084

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

2. **Name and address of site:** **M/s Zydus Lifesciences Limited,**
Plot no. 26 to 29 & 31, Umraya Road,
Vill-Dabhasa, Tal-Padra, Dist.: Vadodara,
Pin-391440, Gujarat

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Warfarin Sodium Ph.Eur.	Manufacturing & Packing
2.	Aripiprazole IH/Ph.Eur.	Manufacturing & Packing
3.	Pitavastatin Calcium IH	Manufacturing & Packing
4.	Vortioxetine Hydrobromide IH	Manufacturing & Packing
5.	Edoxaban Tosylate Monohydrate IH	Manufacturing & Packing
6.	Trazodone Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
7.	Clopidogrel Hydrogen Sulfate Ph.Eur.	Manufacturing & Packing
8.	Midodrine Hydrochloride IH	Manufacturing & Packing
9.	Hydroxychloroquine Sulfate USP/Ph.Eur.	Manufacturing & Packing
10.	Esomeprazole Magnesium Ph.Eur.	Manufacturing & Packing

ITEM(S) Ten (10) ONLY

The Written Confirmation remains valid until: **Three Year from the Date of Issue**

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

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

29 AUG 2025

7-5/2013/EU/WC-0084
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 03 SEP 2025

To

M/s. Zydus Lifesciences Limited,
Plot no. 26 to 29 & 31, Umaraya Road, Vill-Dabhasa,
Tal-Padra, Dist.: Vadodara, Pin-391440, Gujarat

Subject: - Written Confirmation of **M/s. Zydus Lifesciences Limited, Plot no. 26 to 29 & 31, Umaraya Road, Vill-Dabhasa, Tal-Padra, Dist.: Vadodara, Pin-391440, Gujarat, 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 application no. **WC/RE/2025/11152** submitted to CDSCO, Ahmedabad zone office and the recommendation received from DDC(I), Ahmedabad 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.

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

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
--	--	29.08.2025	**28.08.2028**
1	25	29.08.2025	**28.08.2028**
2	10	29.08.2025	**28.08.2028**
3	01	03 SEP 2025	**28.08.2028**

Yours faithfully,

02/09/25

(Ranga Chandrashekar)
Joint Drugs Controller (India)

चंद्रशेखर रेंगा/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

Annexure-3
WC-0084

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

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 Zydus Lifesciences Limited,**
Plot no. 26 to 29 & 31, Umaraya Road,
Vill-Dabhasa, Tal-Padra, Dist.: Vadodara,
Pin-391440, Gujarat

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Eltrombopag Olamine IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: **28.08.2028**

Chandrashekar 02/09/25

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
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

0 3 SEP 2025