F:No: 7-5/2013/EU/WC-0204
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

15 JUN 2022

To

M/s. Zydus Takeda Healthcare Pvt. Ltd.,
C-4, MIDC, Village Pawne, Thane Belapur Road,
Vashi, Navi Mumbai – 400 703.

SUB: Written Confirmation of M/s. Zydus Takeda Healthcare Pvt. Ltd., C-4, MIDC, Village Pawne, Thane Belapur Road, Vashi, Navi Mumbai – 400 703 Maharashtra, 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/2022/2629 & WC/RE/2022/2053 submitted to CDSCO, West Zone, Mumbai and the recommendation received from DDC (I), West 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:-

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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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	08	15 JUN 2022	07.07.2025
02	03	15 JUN 2022	07.07.2025

Yours faithfully,

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

15.6.2022

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

WC-0204

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 Takeda Healthcare Pvt. Ltd.**
C-4, MIDC, Village Pawne, Thane Belapur Road,
Vashi, Navi Mumbai – 400 703

2. **Manufacturer's license Number: 25-KD/716 & 28-KD/512**

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 Annexed

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: 25.04.2022 & 26.04.2022

The Written Confirmation remains valid until: 07.07.2025

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.

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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

Stamp of the authority and date

Signature

15-06-2022

15 JUN 2022

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-01
WC-0204

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 Takeda Healthcare Pvt. Ltd., C-4, MIDC, Village Pawne, Thane Belapur Road, Vashi, Navi Mumbai – 400 703**

List of APIs:

Sl. No.	Name of the Active Substances	Activitie(s)
1.	Alogliptin Benzoate IH	Manufacturing and Packing
2.	Lornoxicam IH	Manufacturing and Packing
3.	Pantoprazole Sodium Sesquihydrate EP	Manufacturing and Packing
4.	Pantoprazole Sodium USP	Manufacturing and Packing
5.	Podophyllotoxin IH	Manufacturing and Packing
6.	Suxamethonium Chloride IH	Manufacturing and Packing
7.	Policresulen 50%w/w IH	Manufacturing and Packing
8.	Azilsartan Medoxomil Potassium (TAK-491) IH	Manufacturing and Packing

ITEM(S) EIGHT (08) Only

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The Written Confirmation remains valid until: 07.07.2025

Signature

15-06-2022

Stamp of the authority and date

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

15 JUN 2022

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

CERTIFICATE NO. :

Annexure-02
WC-0204

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 Takeda Healthcare Pvt. Ltd.,
C-4, MIDC, Village Pawne, Thane Belapur Road,
Vashi, Navi Mumbai – 400 703

List of APIs:

Sl. No.	Name of the Active substance(s)	Activitie(s)
1	Aprindine Hydrochloride IH	Manufacturing & Packing
2	Urapidil IH	Manufacturing & Packing
3	Urapidil Hydrochloride IH	Manufacturing & Packing

ITEM(S) THREE (03) 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: 07.07.2025

O/C

Signature

15-06-2022

Stamp of the authority and date

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

15 JUN 2022