

7-5/2015/EU/WC-0340
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

To

03 DEC 2025

**M/s. BDR Lifesciences Pvt. Ltd.,
R.S. No. 578, Near Effluent Channel Road,
At & Post -Luna, Taluka -Padra,
Dist. -Vadodara -391440, Gujarat, India**

SUB:- Written Confirmation of **M/s. BDR Lifesciences Pvt. Ltd., R.S. No. 578, Near Effluent Channel Road, At & Post -Luna, Taluka -Padra, Dist. -Vadodara -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 application no. **WC/RE/2025/9962** submitted to CDSCO, DDC(I), Ahmedabad zone office, and the recommendation received from DDC(I), Ahmedabad zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.
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 |
|--------------|-----------------|---------------|------------|
| -- | -- | 03 DEC 2025 | 14.04.2028 |
| 1 | 11 | 03 DEC 2025 | 14.04.2028 |
| 2 | 02 | 03 DEC 2025 | 14.04.2028 |

Yours faithfully,



Ranga Chandrashekar
Joint Drugs Controller (India)

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
 केंद्रीय औषधि प्राधिकार निबंधन संगठन (मुख्यालय), स्वास्थ्य सेवा महाविभाग
 C.D.S.C.(HQ), Dir. General of Health Services
 स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
 एन.डी.ए. भवन, कोला रोड, नई दिल्ली-110002 / FDA Bhawan, Kola Road, New Delhi-110002



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. BDR Lifesciences Pvt. Ltd.,
R.S. No. 578, Near Effluent Channel Road,
At & Post -Luna, Taluka -Padra,
Dist. -Vadodara -391440, Gujarat, India

2. Manufacturer's licence number: G/25/1584 & G/28/957

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: 26.07.2023 & 27.07.2023

The Written Confirmation remains valid until: 14.04.2028

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


03/12/25

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

Stamp of the authority and date



03 DEC 2025



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

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List of API(s):

| S. No. | Active Substance (s) | Activity (ies) |
|--------|--|-------------------------|
| 1. | Lapatinib Ditosylate Monohydrate IP | Manufacturing & Packing |
| 2. | Pazopanib Hydrochloride IH | Manufacturing & Packing |
| 3. | Erlotinib Hydrochloride IH | Manufacturing & Packing |
| 4. | Bortezomib IH | Manufacturing & Packing |
| 5. | Abiraterone Acetate IP | Manufacturing & Packing |
| 6. | Dapagliflozin Propanediol Monohydrate IH | Manufacturing & Packing |
| 7. | Nintedanib Esylate IH | Manufacturing & Packing |
| 8. | Olaparib IH | Manufacturing & Packing |
| 9. | Fulvestrant IP | Manufacturing & Packing |
| 10. | Dasatinib Monohydrate IH | Manufacturing & Packing |
| 11. | Enzalutamide IH | Manufacturing & Packing |

ITEM(S) ELEVEN (11) ONLY

The Written Confirmation remains valid until: 14.04.2028

Chandrashekhar
03/12/25
Signature चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केन्द्रीय औषधि मानक नियंत्रण संगठन (मुंबई/मद्रास), स्वास्थ्य सेवा परामर्शदाता
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
एन.डी.ए. रोड, कोटला, नई दिल्ली-110002 / FDA Bldg., Kotla Road, New Delhi-110002





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List of API(s):

| S. No. | Active Substance (s) | Activity (ies) |
|--------|----------------------------|-------------------------|
| 1. | Cabozantinib (s) Malate IH | Manufacturing & Packing |
| 2. | Rucaparib Camsylate IH | Manufacturing & Packing |

ITEM(S) TWO (02) 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 14.04.2028


Signature 03/12/25
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केन्द्रीय औषधि मानक नियंत्रण संगठन (सुब्कालय), स्वास्थ्य सेवा महाविद्यालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
एन.टी.ए. भवन, कोटरा रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

