

**7-5/2021/EU/WC-0511**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(International Cell)**

FDA, BhawanKotla Road,  
New Delhi-110002

Dated: **27 FEB 2025**

To

**M/s. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021,  
Andhra Pradesh, India**

**Subject:** -Written Confirmation of **M/s. Biophore India Pharmaceuticals Pvt. Ltd., Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City, E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021, Andhra Pradesh, 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/ED/2024/9389** dated **26.11.2024** submitted to ADC(I), CDSCO, Sub-Zone office, Vishakhapatnam and the recommendation received from ADC (I), CDSCO, Sub Zone office, Vishakhapatnam 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
--	01	27 FEB 2025	Three Years from the Date of Issue

Yours faithfully,

*Chandrashekar*  
27/2/25  
(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.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare  
एन.डी.ए. भवन, कोल्हा रोड, नई दिल्ली-110002 / FDA Bhawan, Kofla 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. Biophore India Pharmaceuticals Pvt. Ltd., Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City, E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021, Andhra Pradesh, India.

**2. Manufacturer's licence number:** 07/VSP/AP/2019/B/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 API(s):**

S. No.	Active substance(s)	Activity(ies)
01	Cannabidiol IH	Manufacturing & Packing

**ITEM ONE (01) ONLY**

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:** 13.07.2023 & 14.07.2023

**The Written Confirmation remains valid until: Three Years 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**

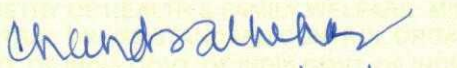
FDA Bhawan, Kotla Road,  
New Delhi- 110 002, India

**Name and function of responsible person:** Ranga Chandrashekar,  
Joint Drugs Controller (India)

**E-mail:** [ranga.cs@cdsco.nic.in](mailto:ranga.cs@cdsco.nic.in);

**Telephone no.:** +91-11-23236965

**Fax no.:** +91-11-23236973

  
Signature 27/02/25

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय 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



27 FEB 2025

**7-5/2021/EU/WC-0511**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated: 25 APR 2025

To,

**M/s. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021,  
Andhra Pradesh, India**

**SUB:-** Written Confirmation of **M/s. Biophore India Pharmaceuticals Pvt. Ltd., Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City, E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021, Andhra Pradesh, 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/ED/2025/9710 and WC/ED/2024/8800 submitted to ADC(I), CDSCO, Sub-Zone office, Vishakhapatnam and the recommendation received from ADC (I), CDSCO, Sub Zone office, Vishakhapatnam 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 with the provisions 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
--	01	27.02.2025	26.02.2028
01	02	25 APR 2025	26.02.2028
02	09	25 APR 2025	26.02.2028

Yours faithfully,

  
21/04/25  
**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.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare  
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla 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. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D),  
Visakhapatnam-531021, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Mexiletine Hydrochloride IH	Manufacturing & Packing
02	Ramelteon IH	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 26.02.2028

Chandrashekar  
21/04/25

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  
एन.एच. कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



25 APR 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

1. Name and address of site: M/s. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D),  
Visakhapatnam-531021, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Dichlorphenamide IH	Manufacturing & Packing
02	Fenoprofen Calcium IH	Manufacturing & Packing
03	Gadoteridol IH	Manufacturing & Packing
04	Favipiravir IH	Manufacturing & Packing
05	Molnupiravir IH	Manufacturing & Packing
06	Naphazoline Hydrochloride IH/USP/Ph.Eur	Manufacturing & Packing
07	Safinamide Mesylate IH	Manufacturing & Packing
08	Sapropterin Dihydrochloride IH/USP	Manufacturing & Packing
09	Urapidil Hydrochloride IH	Manufacturing & Packing

ITEM(S) NINE (09) 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 substances for the purpose of export only, as the above-mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 26.02.2028

*Chandrashekar Ranga*  
21/04/25

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 विभाग / Ministry of Health and Family Welfare  
एफ़ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



25 APR 2025

**7-5/2021/EU/WC-0511**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated: 15 JAN 2026

To,

**M/s. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021,  
Andhra Pradesh, India**

**SUB:-** Written Confirmation of **M/s. Biophore India Pharmaceuticals Pvt. Ltd., Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City, E. Bonangi (V), Parawada (M), Anakapalli (D), Visakhapatnam-531021, Andhra Pradesh, 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/ED/2025/9099 submitted to ADC (I), CDSCO, Sub-Zone office, Visakhapatnam and the recommendation received from ADC (I), CDSCO, Sub Zone office, Visakhapatnam 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.
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5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.

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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 with the provisions 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
--	01	27.02.2025	26.02.2028
01	02	25.04.2025	26.02.2028
02	09	25.04.2025	26.02.2028
03	03	15 JAN 2026	26.02.2028
04	04	15 JAN 2026	26.02.2028

Yours faithfully,

*Chandrashekar*  
15/01/26

**Dr. Ranga Chandrashekar**  
**Joint Drugs Controller (India)**

चंद्रशेखर रंगा/Chandrashekar Ranga  
एजेंट ऑफ नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक निरीक्षण संगठन (मुम्बई/स्वास्थ्य), स्वास्थ्य सेवा महानिदेशालय  
C.D.S.C. (HQ), Dte. General of Health Services  
स्वास्थ्य और 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. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D),  
Visakhapatnam-531021, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Dibasic Potassium Phosphate IH/USP	Manufacturing & Packing
02	Monobasic Potassium Phosphate IH/USP	Manufacturing & Packing
03	Prucalopride Succinate IH	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 26.02.2028

Chandrashekar Ranga

Signature

15/01/26

चंद्रशेखर रंगा/Chandrashekar Ranga

जॉइंट ड्रग्स कंट्रोलर (भारत) / Joint Drugs Controller (India)

डिप्टी जॉइंट ड्रग्स कंट्रोलर (मुख्यालय), 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.डी.एच. भवन, कोला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



Stamp of the authority and date

15 JAN 2026



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. Biophore India Pharmaceuticals Pvt. Ltd.,  
Plot No. 80A, Road No.5, Jawaharlal Nehru Pharma City,  
E. Bonangi (V), Parawada (M), Anakapalli (D),  
Visakhapatnam-531021, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Bempedoic Acid IH	Manufacturing & Packing
02	Cenobamate IH	Manufacturing & Packing
03	Risdiplam IH	Manufacturing & Packing
04	Tafamidis IH	Manufacturing & Packing

ITEM(S) FOUR (04) 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 substances for the purpose of export only, as the above-mentioned active substances are either new drug or not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 26.02.2028

*Chandrashekar Ranga*  
15/01/26

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)

केन्द्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), 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.डी.ए. भवन, बहेला रोड, सं दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



15 JAN 2026