**7-5/2013/EU/WC-0174**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:- 23 JUN 2023

**To,**

**M/s Pioneer Agro Industries Sanvin Laboratories Private Limited,**
**Plot no. 6,7,8,20 & 24, MIDC Industrial Area, Post Kulgaon,**
**Badlapur, Dist. Thane – 421503, Maharashtra, India.**
**Email : corp@sanvin.co.in**

**Subject :-** Request for Change of Company Name in the Written Confirmation of M/s Pioneer Agro Industries Sanvin Laboratories Private Limited, Plot no. 6,7,8,20 & 24, MIDC Industrial Area, Post Kulgaon, Badlapur, Dist. Thane – 421503, Maharashtra, India - Regarding.

Sir/Madam,

This is with reference to your application no. PAI/Ph/MO/549/2022-23 dated 09/03/2023 and subsequent email correspondences for the name change in the Written Confirmation Certificate. Based on your application and submitted documents please find enclosed Amendment in the Written Confirmation Certificate, all the conditions of the Written Confirmation as required for the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

Rajeev Singh

**(Dr. Rajeev Singh Raghuvanshi)**
**Drugs Controller General (India)**

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

**Amended**

**CERTIFICATE NO. : WC-0174**

**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 Pioneer Agro Industries Sanvin Laboratories Private Limited, Plot no. 6,7,8,20 & 24, MIDC Industrial Area, Post Kulgaon, Badlapur, Dist. Thane – 421503, Maharashtra, India.

2. **Manufacturer's License Number:** 25-KD/323

The Name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0174) granted on date 08.08.2022 and its Annexure no. 01 & 02 valid up 12.09.2025 is hereby amended as follows:

***In place of:***
"M/s. **Pioneer Agro Industries (Pharmaceutical Division)"**.

***Read as:***
"M/s. **Pioneer Agro Industries Sanvin Laboratories Private Limited**".

All other conditions of Written Confirmation Certificate will remain same.

*Signature*

*Stamp of the authority and date*

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

23 JUN 2023

7-5/2013/EU/WC-0174
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

08 AUG 2022

To

M/s Pioneer Agro Industries (Pharmaceutical Division),
Plot No. 6,7,8,20 & 24 MIDC Industrial Area,
Post – Kulgaon, Badlapur, Dist – Thane – 421 503,
Maharashtra, India

**SUB:-** Written Confirmation of M/s Pioneer Agro Industries (Pharmaceutical Division), plot No. 6,7,8,20 & 24 MIDC Industrial Area, Post – Kulgaon, Badlapur, Dist – Thane – 421 503, 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/FR/2022/4289 submitted to CDSCO, West Zone office, 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:-

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 |
|---|---|---|---|
| 1 | 12 | 08 AUG 2022 | 12.09.2025 |
| 2 | 06 | 08 AUG 2022 | 12.09.2025 |

**Yours faithfully,**

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

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

**CERTIFICATE NO. :**

**WC-0174**

**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. Pioneer Agro Industries (Pharmaceutical Division), Plot No. 6, 7, 8, 20 & 24, MIDC Industrial Area, Post Kulgaon, Badlapur, Dist. Thane- 421 503 Maharashtra, India**

2. **Manufacturer's licence number**: 25-KD/323

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 enclosed as Annexure-1 & 2**

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**: 16.06.2022 & 17.06.2022

**The Written Confirmation remains valid until**: 12.09.2025

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

***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

08 AUG 2022

*Signature*

*Stamp of the authority and date*

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

**Annexure-1**

**CERTIFICATE NO. :**

**WC-0174**

**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 Pioneer Agro Industries (Pharmaceutical Division), Plot No. 6,7,8,20 & 24 MIDC Industrial Area, Post – Kulgaon, Badlapur Dist – Thane – 421 503, Maharashtra, India

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Betaxolol Hydrochloride EP/USP | Manufacturing & Packing |
| 2. | Buprenorphine BP/EP | Manufacturing & Packing |
| 3. | Buprenorphine Hydrochloride BP/EP/USP/IP | Manufacturing & Packing |
| 4. | Cyclopentolate Hydrochloride BP/EP/USP/JP | Manufacturing & Packing |
| 5. | Cinchocaine Hydrochloride EP/BP | Manufacturing & Packing |
| 6. | Dexmedetomidine Hydrochloride USP | Manufacturing & Packing |
| 7. | Dibucaine Hydrochloride USP | Manufacturing & Packing |
| 8. | Dibucaine USP | Manufacturing & Packing |
| 9. | Fentanyl Citrate USP | Manufacturing & Packing |
| 10. | Methadone Hydrochloride IP/BP/EP/USP | Manufacturing & Packing |
| 11. | Ropivacaine Hydrochloride Monohydrate EP | Manufacturing & Packing |
| 12. | Ropivacaine Hydrochloride USP | Manufacturing & Packing |

**ITEM(S) Twelve (12) ONLY**

**The Written Confirmation remains valid until: 12.09.2025**

08 AUG 2022

*Signature*

*Stamp of the authority and date*

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-2**

**CERTIFICATE NO. :**

**WC-0174**

**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 Pioneer Agro Industries (Pharmaceutical Division), Plot No. 6,7,8,20 & 24 MIDC Industrial Area, Post – Kulgaon, Badlapur Dist – Thane – 421 503, Maharashtra, India

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Levomethadone Hydrochloride EP | Manufacturing & Packing |
| 2. | Manidipine Hydrochloride JP | Manufacturing & Packing |
| 3. | Proparacaine Hydrochloride USP | Manufacturing & Packing |
| 4. | Remifentanil Hydrochloride EP | Manufacturing & Packing |
| 5. | Levobupivacaine Hydrochloride IH | Manufacturing & Packing |
| 6. | Delapril Hydrochloride IH | Manufacturing & Packing |

**ITEM(S) Six (06) 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: 12.09.2025**

*Signature* 08 AUG 2022

*Stamp of the authority and date*

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

**7-5/2013/EU/WC-0174**

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

**FDA Bhawan, Kotla Road,**
**New Delhi-110002**
**Dated** 27 AUG 2024

To

**M/s. Pioneer Agro Industries Sanvin Laboratories Private Limited,**
**Plot No. 6,7,8,20 & 24, MIDC Industrial Area,**
**Post Kulgaon, Badlapur, Dist. Thane -421503,**
**Maharashtra, India**

**SUB:-** Written Confirmation of **M/s. Pioneer Agro Industries Sanvin Laboratories Private Limited, Plot No. 6,7,8,20 & 24, MIDC Industrial Area, Post Kulgaon, Badlapur, Dist. Thane -421503, 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/FR/2024/8233 submitted to DDC(I), CDSCO, West-Zone Mumbai, and the recommendation received from DDC(I), CDSCO, West-Zone Mumbai 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 |
|---|---|---|---|
| -- | -- | 08.08.2022 | **12.09.2025** |
| 1 | 12 | 08.08.2022 | **12.09.2025** |
| 2 | 06 | 08.08.2022 | **12.09.2025** |
| Amendment | -- | 23.06.2023 | **12.09.2025** |
| 3 | 01 | 27 AUG 2024 | **12.09.2025** |

**Yours faithfully,**

Chandrashekar
27/08/24

**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

Annexure-03
WC-0174

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. Pioneer Agro Industries Sanvin Laboratories Private Limited,**
**Plot No. 6,7,8,20 & 24, MIDC Industrial Area,**
**Post Kulgaon, Badlapur, Dist. Thane -421503,**
**Maharashtra, India**

1. **List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 01 | Nepafenac IH | Manufacturing & Packing |

**ITEM(S) ONE (01) ONLY**

**The Written Confirmation remains valid until: 12.09.2025**

Chandrashekhar 27/8/24

*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 Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, GOI

27 AUG 2024