

7-5/2016/EU/WC-0453
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated 25 SEP 2023

To

**M/s Ipca Laboratories Ltd.,
Plot NO. E-41, 129 & 128/2,
MIDC Ind. Area, Tarapur, Boisar-401 506
Maharashtra, India**

SUB:- Written Confirmation of M/s Ipca Laboratories Ltd., Plot NO. E-41, 129 & 128/2, MIDC Ind. Area, Tarapur, Boisar-401 506, 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 offline application no. nil dated 24.05.2023 submitted to CDSCO (HQ) vide diary no. 5764 dated 07.06.2023 and your reply submitted with reference no. CQA/CDSCO/357/2023 dated 11.09.2023 received in CDSCO(HQ) vide diary no. 8725 dated 14.09.2023, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
--	03	25 SEP 2023	20.03.2026

Yours faithfully,


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



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

CERTIFICATE NO. : WC-0453

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 Ipca Laboratories Ltd.,
Plot NO. E-41, 129 & 128/2,
MIDC Ind. Area, Tarapur, Boisar-401 506
Maharashtra, India

2. Manufacturer's licence number: 25-KD/442

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)
1	Benzocaine BP/Ph.Eur/USP	Manufacturing & Packing
2	Meloxicam BP/ Ph.Eur /USP	Manufacturing & Packing
3	Piroxicam BP/ Ph.Eur	Manufacturing & Packing

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: 28.06.2021 & 29.06.2021

The Written Confirmation remains valid until: 20.03.2026

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. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

E-mail:
Telephone no.:
Fax no.:

dci@nic.in,
+91-11-23236965
+91-11-2323697

Signature

25 SEP 2023



7-5/2016/EU/WC-0453
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 18 FEB 2025

To

M/s. Ipca Laboratories Ltd.,
Plot No. E-41, 129 & 128/2, MIDC Ind. Area,
Tarapur, Boisar -401506,
Maharashtra, India

Subject: - Written Confirmation of **M/s. Ipca Laboratories Ltd., Plot No. E-41, 129 & 128/2, MIDC Ind. Area, Tarapur, Boisar -401506, 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/ED/2024/8061 submitted to 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 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 Up to
--	03	25.09.2023	20.03.2026
01	02	18 FEB 2025	20.03.2026

Yours faithfully,

Chandrashekar
18/02/25
(Ranga Chandrashekar)
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुंब्यालय), स्वास्थ्य सेवा प्रहानिदेशालय
C.D.S.C.(H.O.), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एन.डी.एच.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. Ipca Laboratories Ltd.,
Plot No. E-41, 129 & 128/2, MIDC Ind. Area,
Tarapur, Boisar -401506,
Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Propranolol Hydrochloride BP/Ph.Eur./USP	Manufacturing & Packing
02	Sacubitril Valsartan IH	Manufacturing & Packing

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 20.03.2026

Chandrashekar Ranga

Signature: Chandrashekar Ranga/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
एक टॉवर, कोटला रोड, नई दिल्ली-110002 / FDA Bldg., Kotla Road, New Delhi-110002

Stamp of the authority and date



18 FEB 2025