F. No.: 7-5/2013/EU/WC-0091
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

08 JUN 2022

To

M/s. IPCA Laboratories Ltd.,
P.O. Sejavta, Dist. Ratlam,
Madhya Pradesh, India.

SUB: - Written Confirmation of M/s. IPCA Laboratories Ltd., P.O. Sejavta, Dist. Ratlam, Madhya 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/RE/2022/2842 submitted to CDSCO, Indore Sub Zone and the recommendation received from ADC (I), Indore subzone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
01	67	08 JUN 2022	02/07/2025
02	04		02/07/2025

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-0091

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.,
P.O.Sejavta, Dist-Ratlam,
Madhya Pradesh, India.

2. **Manufacturer's license number**: 25/35/83

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

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/ICHQ7):

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 & 14 May 2022

The Written Confirmation remains valid until: 02nd JULY 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

Signature

Stamp of the authority and date

0 8 JUN 2022

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

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

Annexure-01
WC-0091

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. IPCA Laboratories Ltd.,
P.O.Sejavta, Dist. Ratlam,
Madhya Pradesh, INDIA.

List of APIs:

Sl.No.	Name of the active substances	Activitie(s)
1.	Allopurinol BP/Ph.Eur./USP	Manufacturing & Packing
2.	Amlodipine Besylate BP/Ph.Eur./USP	Manufacturing & Packing
3.	Amodiaquine Hydrochloride USP	Manufacturing & Packing
4.	Artemether Int.Ph	Manufacturing & Packing
5.	Artesunate Int.Ph	Manufacturing & Packing
6.	Atenolol BP/Ph.Eur.JPC/USP	Manufacturing & Packing
7.	Bendroflumethiazide BP/Ph.Eur	Manufacturing & Packing
8.	Bisoprolol Fumarate USP/Ph.Eur.	Manufacturing & Packing
9.	Carvedilol BP/Ph.Eur./USP	Manufacturing & Packing
10.	Cetirizine Dihydrochloride BP/Ph.Eur/USP	Manufacturing & Packing
11.	Chloroquine Phosphate BP/Ph.Eur/USP	Manufacturing & Packing
12.	Chlorthalidone / Chlortalidone BP/Ph.Eur/USP	Manufacturing & Packing
13.	Cilostazol USP/JPC	Manufacturing & Packing
14.	Citalopram Hydrobromide BP/USP/Ph.Eur	Manufacturing & Packing
15.	Clopidogrel Bisulphate USP	Manufacturing & Packing
16.	2, 4-Dichlorobenzyl Alcohol IH	Manufacturing & Packing
17.	Etodolac BP/Ph.Eur./USP	Manufacturing & Packing
18.	Eszopiclone USP	Manufacturing & Packing
19.	Famotidine USP/JP/BP/Ph.Eur.	Manufacturing & Packing
20.	Fenofibrate BP/Ph.Eur./USP	Manufacturing & Packing
21.	Fluconazole BP/Ph.Eur./USP/CP	Manufacturing & Packing
22.	Furosemide BP/Ph.Eur./JP/USP	Manufacturing & Packing
23.	Glimepiride BP/Ph.Eur./USP	Manufacturing & Packing
24.	Hydrochlorothiazide BP/Ph.Eur./USP/JP	Manufacturing & Packing
25.	Hydroxy Chloroquine Sulphate BP/Ph.Eur./USP	Manufacturing & Packing
26.	Hydroxyzine Di Hydrochloride BP/USP/Ph.Eur.	Manufacturing & Packing
27.	Indapamide BP/USP/Ph.Eur/CP	Manufacturing & Packing
28.	Losartan Potassium BP/Ph.Eur/USP	Manufacturing & Packing
29.	Lumefantrine Int.Ph./CP	Manufacturing & Packing
30.	Levofloxacin USP	Manufacturing & Packing
31.	Levofloxacin Hydrate JP	Manufacturing & Packing
32.	Lamotrigine BP/Ph.Eur./USP	Manufacturing & Packing
33.	Zopiclone Ph.Eur.	Manufacturing & Packing
34.	Mesalamine/Mesalazine BP/Ph.Eur./USP	Manufacturing & Packing
35.	Metformin Hydrochloride BP/Ph.Eur./USP/CP/JPC	Manufacturing & Packing
36.	Methyl Phenidate Hydrochloride BP/Ph.Eur./USP	Manufacturing & Packing

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

08 JUN 2022

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

CERTIFICATE NO. :

Annexure-01
WC-0091

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

Sl.No.	Name of the Active Substances	Activitie(s)
37.	Metoclopramide Base BP/Ph.Eur./JP	Manufacturing & Packing
38.	Metoclopramide Hydrochloride BP/Ph.Eur./USP	Manufacturing & Packing
39.	Metoprolol Succinate BP/Ph.Eur./USP	Manufacturing & Packing
40.	Metoprolol Tartrate BP/Ph.Eur./USP/JPC	Manufacturing & Packing
41.	Olanzapine Ph.Eur./USP	Manufacturing & Packing
42.	Nabumetone BP/Ph.Eur./USP	Manufacturing & Packing
43.	Nifedipine Ph.Eur./USP	Manufacturing & Packing
44.	Ondansetron Base USP	Manufacturing & Packing
45.	Ondansetron Hydrochloride Dihydrate BP/Ph.Eur./USP	Manufacturing & Packing
46.	Paroxetine HCl Hemihydrate BP/Ph.Eur.	Manufacturing & Packing
47.	Primaquine Phosphate BP/Ph.Eur./USP	Manufacturing & Packing
48.	Proguanil Hydrochloride BP/Ph.Eur.	Manufacturing & Packing
49.	Propranolol Hydrochloride BP/Ph.Eur./USP/JP	Manufacturing & Packing
50.	Promethazine Hydrochloride BP/USP/Ph.Eur	Manufacturing & Packing
51.	Pyrantel Embonate BP/Ph.Eur	Manufacturing & Packing
52.	Pyrimethamine BP/USP/Ph.Eur	Manufacturing & Packing
53.	Ractopamine Hydrochloride IH	Manufacturing & Packing
54.	Risedronate Sodium USP	Manufacturing & Packing
55.	Risperidone Ph.Eur./USP/BP	Manufacturing & Packing
56.	Sodium Alendronate BP/Ph.Eur./USP	Manufacturing & Packing
57.	Sulfadoxine BP/Ph.Eur.	Manufacturing & Packing
58.	Torsemide Ph.Eur./USP	Manufacturing & Packing
59.	Triclabendazole IH	Manufacturing & Packing
60.	Trimethoprim BP/Ph.Eur./USP/JPC	Manufacturing & Packing
61.	Telmisartan Ph.Eur./BP/IP/USP	Manufacturing & Packing
62.	Valsartan BP/USP/Ph.Eur/IP	Manufacturing & Packing
63.	Venlafaxine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
64.	Warfarin Sodium Clathrate BP/USP/Ph.Eur	Manufacturing & Packing
65.	Warfarin Sodium EP/USP	Manufacturing & Packing
66.	Artesunate Sterile IH	Manufacturing & Packing
67.	Quetiapine Fumarate Ph.Eur./USP	Manufacturing & Packing

ITEM(S) Sixty Seven (67) Only

The Written Confirmation remains valid until: 02/07/2023.

Signature

Stamp of the authority and date

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

08 JUN 2022

Annexure- 02
WC-0091

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. IPCA Laboratories Ltd.,
P.O.Sejavta, Dist. Ratlam,
Madhya Pradesh, INDIA.

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Dihydroartemisinin (INP) IH	Manufacturing & Packing
2.	Morantel Citrate IH	Manufacturing & Packing
3.	Atovaquone IH	Manufacturing & Packing
4.	Midodrine Hydrochloride USP	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 not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 02/07/2025.

Signature

Stamp of the authority and date

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

08 JUN 2022