

7-5/2013/EU/WC-0236
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

05 OCT 2021

To,
M/s. IPCA Laboratories Limited,
Plot No. 4722, 4723, 4731 & 4732,
GIDC Estate, Ankleshwar,
Dist- Bharuch, Gujarat

SUB:- Application for amendment of the Written Confirmation of M/s. IPCA Laboratories Limited, Plot No. 4722, 4723, 4731 & 4732, GIDC Estate, Ankleshwar, Dist- Bharuch, Gujarat 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 submitted to this office vide letter Number Nil dated 23/09/2021 for addition of plot No 4372 in the existing WCC.

In this regard, it is stated that your request for address amendment has been approved. Kindly find the enclosed amended Written Confirmation Certificate. The all other conditions of the Written Confirmation Certificate 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,


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


04-10-2021

o/c



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

Amended

CERTIFICATE NO. :

WC-0236

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 Limited
2. Manufacturer's License Number: G/25/946

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0236) granted on date 05.08.2019 is hereby amended as follows:

In place of:

"M/s IPCA Laboratories Limited, Plot No. 4722, 4723 & 4731, GIDC Estate, Ankleshwar, Dist- Bharuch, Gujarat."

Read as:

"M/s IPCA Laboratories Limited, Plot No. 4722, 4723, 4731 & 4732, GIDC Estate, Ankleshwar, Dist- Bharuch, Gujarat"

All other conditions of Written Confirmation Certificate will remain same.

Signature

V. K.
04-10-2021

Stamp of the authority and date



05 OCT 2021