

7-5/2013/EU/WC-0019
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 13 APR 2020

To,

M/s. Pharmazell (India) Private Limited
Plot No: 115, Ramky Pharma City (India) Ltd. SEZ
Parawada Mandal, Visakhapatnam District
Andhra Pradesh, India, PIN: 531 019

SUB:- Application for address amendment in the issued Written Confirmation Certificate to the M/s. Pharmazell (India) Private Limited, Plot No: 115, Ramky Pharma City (India) Ltd. SEZ, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India, PIN: 531 019 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 No. Nil dated 09/04/2020 on the subject cited above requesting amendment of the address in the issued WC.

In this regard, it is stated that your request for address amendment has been approved. Kindly find the enclosed amended Written Confirmation Certificate. All the 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)



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

Amended
CERTIFICATE NO. :
WC-0019

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 of site: M/s. Pharmazell (India) Private Limited
2. Manufacturer's License Number: 51/VP/AP/2008/B/R

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0019) issued on date 18.03.2019 is hereby amended as follows:

In place of:

M/s. Pharmazell (Vizag) Private Limited, Plot No: 115, Ramky Pharma City (India) Ltd. SEZ, Parawada Mandal, Visakhapatnam District – 531 021, Andhra Pradesh, India

Read as:

M/s. Pharmazell (India) Private Limited, Plot No: 115, Ramky Pharma City (India) Ltd. SEZ, Parawada Mandal, Visakhapatnam District, Andhra Pradesh, India, PIN: 531 019

All other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

13 APR 2020