

7-5/2013/EU/WC-0093
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 12 NOV 2021

To,

M/s Malladi Drugs and Pharmaceuticals Limited,
Unit-3, 7B & 7C, SIPCOT Industrial Complex,
Ranipet-632403, Ranipet District, Tamilnadu, India

SUB:- Application for amendment of the Written Confirmation of M/s Malladi Drugs and Pharmaceuticals Limited, Unit-3, 7B & 7C, SIPCOT Industrial Complex, Ranipet-632403, Ranipet District, Tamilnadu, 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 application received vide email dated 18.10.2021 and subsequent reply dated 08.11.2021 on the subject cited above.

In this regard, please find the enclosed amended Written Confirmation Certificate. The condition of the 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 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
WC-0093

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 of site:

M/s Malladi Drugs and Pharmaceuticals Limited,

Unit-3, 7B & 7C, SIPCOT Industrial Complex,

Ranipet-632403, Ranipet District, Tamilnadu, India

2. Manufacturer's Licence Number: 704

The name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0093) granted on date 15.07.2019 is hereby amended as follows:

In place of:

"M/s Malladi Drugs and Pharmaceuticals Limited, Unit-3, 7B & 7C, SIPCOT Industrial Complex, Ranipet-632403, Vellore District Tamilnadu, India"

Read as:

"M/s Malladi Drugs and Pharmaceuticals Limited, Unit-3, 7B & 7C, SIPCOT Industrial Complex, Ranipet-632403, Ranipet District Tamilnadu, India"

All the other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date



12 NOV 2021