

7-5/2013/EU/WC-0067
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 26 JUL 2019

To

M/s Dr.Reddy's Laboratories Limited
Chemical Technical Operations Unit-VI,
APIIC Industrial Esatate, Pydibhimavaram Village,
Ranasthalam Mandal, Srikakulam District -532409,
Andhra Pradesh, India

SUB: Written Confirmation of M/s Dr.Reddys Laboratories Limited, Chemical Technical Operations Unit-VI, APIIC Industrial Esatate, Pydibhimavaram Village, Ranasthalam Mandal, Srikakulam District -532409, Andhra 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 application submitted to CDSCO, Hyderabad Zone and the recommendation received from DDC (I), Hyderabad Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Validity
01	39	08 July 2019	07.07.2022
02	09	08.JULY 2019	07.07.2022
03	04	26 JUL 2019	07.07.2022
04	02	26 JUL 2019	07.07.2022

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

o/c
25.07.2019

25-7-19

25-7-19



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 Dr.Reddy's Laboratories Limited
Chemical Technical Operations Unit-VI,
APIIC Industrial Estate, Pydibhimavaram Village,
Ranasthalam Mandal, Srikakulam District-532 409,
Andhra Pradesh, India.

List of APIs:

Sl.No	Name of the active substances	Activities
1.	Decitabine IH	Manufacturing & Packing
2.	Esomeprazole Magnesium USP	Manufacturing & Packing
3.	Eslicarbazepine Acetate IH	Manufacturing & Packing
4.	Nilotinib Hydrochloride IH	Manufacturing & Packing

ITEM(S) Four (04) ONLY

The Written Confirmation remains valid until: 07.07.2022


Signature

Stamp of the authority and date



26 JUL 2019

o/c  25.07.2019


25-7-19


25/07/19



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 Dr.Reddy's Laboratories Limited
Chemical Technical Operations Unit-VI,
APIIC Industrial Estate, Pydibhimavaram Village,
Ranasthalam Mandal, Srikakulam District-532 409,
Andhra Pradesh, India.

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1	Enzaiutamide	Manufacturing & Packing.
2	Pomalidomide	Manufacturing & Packing

ITEM(S) Two (02) 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 or sale in India.

The Written Confirmation remains valid until: 07.07.2022

Signature

Stamp of the authority and date



26 JUL 2019

o/c

25.07.2019

25-7-19

25/07/19