GOVERNMENT OF ANDHRA PRADESH DRUGS CONTROL ADMINISTRATION

From:

M B R Prasad, M.Pharm, M.Phill, A.IC. Director & Licensing Authority, O/o. The Director General, Drugs Control Administration, Chuttugunta, Guntur-522 004.

To

Dr.Reddy's Laboratories Ltd, CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, AndhraPradesh-532 409.

Sir,

Sub:- Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organization Good Manufacturing Practice Certificate – Reg.

Ref:- 1. Your applications dated: 14.08.2020.

2. Joint Inspection dated 20.08.2019 and 21.08.2019.

I forward herewith **W.H.O. Good Manufacturing Practice Certificate** for the products mentioned by the Joint Inspection team consisting of Officers of Drugs Control Administration, Andhra Pradesh, INDIA for **Export** purpose.

This certificate is valid up to 20.10.2022.

Yours faithfully

and

Digitally signed by Meesala Babu Rajendra Prasad Date: 2020.11.17 18:47:27 +05'30'

DIRECTOR & LICENSING AUTHORITY DRUGS CONTROL ADMINISTRATION

GOVERNMENT OF ANDHRA PRADESH DRUGS CONTROL ADMINISTRATION

Office of the Director General, Drugs control Administration, Chuttugunta, Guntur-522 004.

CERTIFICATE OF PHARMACEUTICALS PRODUCTS FOR EXPORT

S.No	Name of the product
1.	Dasatinib IH

(One Product Only)

Manufacturer : M/s Dr Reddy's Laboratories Limited.,

CTO-VI,

APIIC Industrial Estate,

Pydibhimavaram, Ranasthalam Mandal Srikakulam District, Andhra Pradesh-532 409,

INDIA.

When applicable : Placing the product on the market as detail

below:

It is certified that the above products have been authorized to be placed on the market for use in the Country.

Drug Licence Nos. : 165/SK/AP/95/B/R in Form-25 dated 14.11.1991

Validity up to 31.12.2022.

It is also certified that (a) the manufacturing plant in which the products are produced is subject to inspection at suitable intervals.

The Unit M/s.Dr Reddy's Laboratories Ltd., at the premises situated at M/s Dr Reddy's Laboratories Limited, CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal,Srikakulam District, Andhra Pradesh-532 409, INDIA. Was inspected jointly by Mr. R.Srinivasan, ADC(I),CDSCO, Visakhapatnam, MrA.Lavanya, Drugs Inspector, Drugs Control Administration, Srikakulam of this Department.

B B

Digitally signed by Meesala Babu Rajendra Prasad Date: 2020.11.17 18:47:49

DIRECTOR & LICENSING AUTHORITY DRUGS CONTROL ADMINISTRATION

WHO GMP CERTIFICATE APPROVED FOR ONE PRODUCTS TO M/s Dr Reddy's Laboratories Limited, CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh.. UNDER DRUG LICENCE BEARING No. 165/SK/AP/95/B/R in Form-25 dated 14.11.1991 Validity up to 31.12.2022.

The manufacturer conforms to requirement for Good Manufacturing Practices in the manufacture and quality control (As recommended by the World Health Organization) in respect of products mentioned above(One Product) for export in the international market.

This certificate is valid up to 20.10.2022.

Yours faithfully

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Digitally signed by Meesala Babu Rajendra Prasad Date: 2020.11.17 18:46:50 +05'30'

DIRECTOR & LICENSING AUTHORITY DRUGS CONTROL ADMINISTRATION

TO, M/s Dr Reddy's Laboratories Limited., CTO-VI, APIIC Industrial Estate, Pydibhimavaram, Ranasthalam Mandal Srikakulam District, Andhra Pradesh-532 409, INDIA.