F.No:7-5/2013/EU/WC-0030
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 17 JUN 2019

To
M/s Divi's Laboratories Limited, Unit –II
Annavaram (Post), Chippada Village,
Bheemunipatanam Mandal,
Visakhapatnam District -531162,
Andhra Pradesh, INDIA.

SUB: Written Confirmation of M/s Divi's Laboratories Limited, Unit –II, Annavaram (Post), Chippada Village, Bheemunipatanam Mandal, Visakhapatnam District - 531162,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.

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3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

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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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	26	17 JUN 2019	Three years from the date of issue
02	01	17 JUN 2019	Three years from the date of issue

Yours faithfully,

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

O/c

13.6.19

13-6-19

13/06/19

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

CERTIFICATE NO. : **WC-030**

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 Divi's Laboratories Limited, Unit –II
Annavaram (Post), Chippada Village,
Bheemunipatanam Mandal,
Visakhapatnam District -531162,
Andhra Pradesh, INDIA.

2. Manufacturer's license number: 02/VP/AP/2003/B/R

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per list enclosed as Annexure -01 & 02

The issuing Regulatory Authority hereby confirms that:
The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU(= GMP of WHO/ICH Q7):

The manufacturing plant 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 at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 12th & 13th APRIL 2019.

The Written Confirmation remains valid until: (03) Three years from the date of issue.

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority**: Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002,India.

Name and function of responsible person: Dr. S. Eswara Reddy.
Drugs Controller General (India).

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

o/c 13.06.19

13-6-19

13/06/19

17 JUN 2019

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

Annexure- 01
CERTIFICATE NO. : WC 030

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 Divi's Laboratories Limited, Unit –II
Annavaram (Post), Chippada Village,
Bheemunipatanam Mandal,
Visakhapatnam District -531162,
Andhra Pradesh, INDIA.

List of APIs:

Sl.No	Name of the active substances	Activities
1.	Naproxen IP/BP/USP/Ph.Eur	Manufacturing & Packing
2.	Naproxen Sodium Ph. Eur./USP/BP	Manufacturing & Packing
3.	Levodopa IP/BP/USP/Ph. Eur	Manufacturing & Packing
4.	Carbidopa IP/BP/USP/Ph. Eur	Manufacturing & Packing
5.	Gabapentin USP/Ph. Eur.	Manufacturing & Packing
6.	Irbesartan USP/Ph. Eur.	Manufacturing & Packing
7.	Phenylephrine HCl IP/BP/USP/Ph. Eur.	Manufacturing & Packing
8.	Venlafaxine Hydrochloride Ph. Eur./USP/BP	Manufacturing & Packing
9.	Triprolidine Hydrochloride IP/USP/BP	Manufacturing & Packing
10.	Valsartan USP/ Ph. Eur./IP	Manufacturing & Packing
11.	Capecitabine USP/Ph. Eur/IP	Manufacturing & Packing
12.	Lamotrigine Ph. Eur/IP/USP	Manufacturing & Packing
13.	Olmesartan Medoxomil USP/Ph. Eur	Manufacturing & Packing
14.	Bosentan Monohydrate IH	Manufacturing & Packing
15.	Pregabalin IH/USP/Ph.Eur	Manufacturing & Packing
16.	Losartan Potassium Ph. Eur/IP/USP	Manufacturing & Packing
17.	Simvastatin Ph. Eur/IP/USP	Manufacturing & Packing
18.	Sumatriptan IP	Manufacturing & Packing
19.	Sumatriptan Succinate Ph.Eur/BP/IP/USP	Manufacturing & Packing
20.	Bupropion Hydrochloride USP	Manufacturing & Packing
21.	Sitagliptin Phosphate IP/IH	Manufacturing & Packing
22.	Mesalamine IP/USP/BP/Ph.Eur	Manufacturing & Packing
23.	Entacapone Ph.Eur.	Manufacturing & Packing
24.	Raltegravir Potassium IH	Manufacturing & Packing
25.	Orlistat USP	Manufacturing & Packing
26.	Carbamazepine IH	Manufacturing & Packing

ITEM(S) Twenty Six (26) ONLY

The Written Confirmation remains valid until: <u>(03) Three years from the date of issue.</u>

Signature

13.06.19

o/c

Stamp of the authority and date

17 JUN 2019

13-6-19

13/06/19

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

Annexure – 02
WC-030

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 Divi's Laboratories Limited, Unit –II
Annavaram (Post), Chippada Village,
Bheemunipatanam Mandal,
Visakhapatnam District -531162,
Andhra Pradesh, INDIA.

List of APIs:

S. No.	**Active substance(s)**	**Activity(ies)**
1	Vigabatrin	Manufacturing & Packing.

ITEM(S) ONE (01) 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: (03) Three years from the date of Issue

Signature

Stamp of the authority and date

17 JUN 2019

O/c 13.06.19

13-6-19

13/06/19