7-5/2013/EU/WC-0070
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 12 FEB 2021

To,

M/s. Vasudha Pharma Chem Limited-Unit-1,
37/A, 38, 39 A&B, PHASE-1, IDA, Jeedimetla
Hyderabad, 500 055, Telangana, India

SUB:- Written Confirmation of M/s. Vasudha Pharma Chem Limited-Unit-1, 37/A, 38, 39 A&B, PHASE-1, IDA, Jeedimetla Hyderabad, 500 055, Telangana, 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 office and the recommendation received from DDC(I), Hyderabad Zonal office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	Valid Upto
01 (Amended)	17	12 FEB 2021	04.07.2022
02 (Amended)	02	12 FEB 2021	04.07.2022

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

08-02-2021

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

CERTIFICATE NO. : WC-0070

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. Vasudha Pharma Chem Limited (Unit-I),**
Plot No. 39 A & B, IDA,
Jeedimetla, Hyderabad, 500055, Telangana

2. Manufacturer's licence number: 105/RR/AP/97/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 and Annexure- 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: 07-08/02/2019

The Written Confirmation remains valid until: 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

05 JUL 2019

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

CERTIFICATE NO. : **Amended Annexure – 01**

WC-0070

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. Vasudha Pharma Chem Limited-Unit-1, 37/A, 38, 39 A&B, PHASE-1, IDA, Jeedimetla Hyderabad, 500 055, Telangana, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Domperidone BP/Ph.Eur	Manufacturing & Packing
2.	Domperidone Maleate BP/Ph.Eur	Manufacturing & Packing
3.	Loratadine USP/Ph.Eur	Manufacturing & Packing
4.	Desloratadine IH/Ph.Eur/USP/BP	Manufacturing & Packing
5.	Amitriptyline Hydrochloride BP/USP/Ph.Eur	Manufacturing & Packing
6.	Cyclobenzaprine Hydrochloride USP	Manufacturing & Packing
7.	Pimozide USP/BP/Ph.Eur	Manufacturing & Packing
8.	Ebastine BP/Ph.Eur	Manufacturing & Packing
9.	Loperamide Hydrochloride BP/Ph. Eur./USP	Manufacturing & Packing
10.	Ketorolac Tromethamine USP	Manufacturing & Packing
11.	Ketorolac Trometamol BP/Ph. Eur.	Manufacturing & Packing
12.	Donepezil Hydrochloride USP	Manufacturing & Packing
13.	Donepezil Hydrochloride Monohydrate USP	Manufacturing & Packing
14.	Cyproheptadine Hydrochloride USP/BP/Ph. Eur	Manufacturing & Packing
15.	Olmesartan Medoxomil USP/BP/Ph.Eur	Manufacturing & Packing
16.	Piribedil IH	Manufacturing & Packing
17.	Nebivolol Hydrochloride IH	Manufacturing & Packing

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ITEM(S) Seventeen (17) ONLY

The Written Confirmation remains valid until: 04.07.2022

Signature

08-02-2021

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health Family Welfare, Government of India
सत्यमेव जयते

12 FEB 2021

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

CERTIFICATE NO. : **Amended Annexure-02**

WC-0070

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. Vasudha Pharma Chem Limited-Unit-1, 37/A, 38, 39 A&B, PHASE-1, IDA, Jeedimetla Hyderabad, 500 055, Telangana, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Cisapride Monohydrate USP	Manufacturing & Packing
2.	Oxatomide IH	Manufacturing & Packing

ITEM(S) Two (02) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: 04.07.2022

Signature

08-2-2021

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Directorate General of Health, Family Welfare, Government of India

12 FEB 2021