

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

(Amended)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 15 JUL 2019

To
M/s Vasudha Pharma Chem Limited-Unit-1,
Plot No. 37/A, 38, 39 A&B, PHASE -1,
IDA,Jeedimetla, Hyderabad-500 055,
Telangana, India.

SUB: Written Confirmation M/s Vasudha Pharma Chem Limited (Unit-1),Plot No. 37/A, 38, 39 A&B, PHASE -1,IDA,Jeedimetla, Hyderabad-500 055,Telangana, India of 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 conform 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	17	05.07 2019	04.07.2022
02	02	05.07. 2019	04.07.2022

Yours faithfully,

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

o/c 12.7.2019.



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

Amended
WC-0070

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

2. Manufacturer's Licence Number: 105/RR/AP/97/B/R

The Address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0070) granted on date 05.07.2019 is hereby amended as follows:

In place of:

M/s Vasudha Pharma Chem Limited (Unit-1)
39 A&B, PHASE -1, IDA, Jeediletla,
Hyderabad-500 055,Telangana, state India

Read as:

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

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

Signature

Stamp of the authority and date



15 JUL 2019

o/c
12-7-19
12-7-19
12/07/19