7-5/2013/EU/WC-0045
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated 22 JUL 2019

To

M/s. Harman Finochem Limited,
Plot No. E-7, E-8, E-9, MIDC Industrial Area,
Chikalthana, Aurangabad-431006.

SUB:- Written Confirmation of M/s. Harman Finochem Limited, Plot No. E-7, E-8, E-9, MIDC Industrial Area, Chikalthana, Aurangabad-431006 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, West Zone , Mumbai office and the recommendation received from DDC(I), West Zone , Mumbai 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 oe 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	23	22 JUL 2019	Three years from the date of issue
02	04	22 JUL 2019	Three years from the date of issue

Yours faithfully,

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

15/07/19.

15.7.19

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

CERTIFICATE NO. : WC-0045

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. Harman Finochem Limited,**
Plot No. E-7, E-8, E-9, MIDC Industrial Area
Chikalthana, Aurangabad-431006

2. Manufacturer's licence number: 25-849

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

As per list enclosed as Annexure-1 & 2

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: 20th & 21st June, 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

15/07/19

15.7.19

Stamp of the authority and date

22 JUL 2019

Annexure-1

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

CERTIFICATE NO. : WC-0045

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. Harman Finochem Limited,
Plot No. E-7, E-8, E-9, MIDC Industrial Area,
Chikalthana, Aurangabad-431006.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Metformin Hydrochloride IP/BP/EP/USP/JP	Manufacturing & Packing
2.	Allopurinol IP/BP/EP/USP/JP	Manufacturing & Packing
3.	Phenobarbital IP/BP/EP/USP	Manufacturing & Packing
4.	Xipamide	Manufacturing & Packing
5.	Glycopyrrolate USP/ Glycopyrronium Bromide EP	Manufacturing & Packing
6.	Oxybutynin Hydrochloride BP/EP/ Oxybutynin Chloride USP	Manufacturing & Packing
7.	Oxiconazole Nitrate	Manufacturing & Packing
8.	Bisoprolol Fumarate EP/USP	Manufacturing & Packing
9.	Methyl Phenidate Hydrochloride EP/USP	Manufacturing & Packing
10.	Riboflavin Phosphate Sodium IP/BP/EP/USP	Manufacturing & Packing
11.	Methadone Hydrochloride BP/EP/USP	Manufacturing & Packing
12.	Phenobarbital Sodium EP/BP/USP	Manufacturing & Packing
13.	Phenytoin Sodium EP/USP	Manufacturing & Packing
14.	Lidocaine EP/USP	Manufacturing & Packing
15.	Lidocaine Hydrohcloride EP/USP	Manufacturing & Packing
16.	Phenytoin EP/USP	Manufacturing & Packing
17.	Sitagliptin Phosphate Monohydrate	Manufacturing & Packing
18.	Torasemide EP/USP	Manufacturing & Packing
19.	Neostigmine Metilsulfate EP/ Neostigmine Methylsulfate USP	Manufacturing & Packing
20.	Linagliptin	Manufacturing & Packing
21.	Sitagliptin Hydrochloride	Manufacturing & Packing
22.	Fenofibric Acid	Manufacturing & Packing
23.	Choline Fenofibrate	Manufacturing & Packing

ITEM(S) Twenty Three (23) ONLY

The Written Confirmation remains valid until: Three years from the date of issue

Signature

Stamp of the authority and date

22 JUL 2019

Annexure-2

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

CERTIFICATE NO. : WC-0045

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. Harman Finochem Limited,
Plot No. E-7, E-8, E-9, MIDC Industrial Area,
Chikalthana, Aurangabad-431006.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Methylphenobarbital BP/EP /Mephobarbital USP	Manufacturing & Packing
2.	Metformin Hydrochloride with 0.50% Aerosil	Manufacturing & Packing
3.	Metformin Hydrochloride with 1.0% Aerosil	Manufacturing & Packing
4.	Levomethadone Hydrochloride EP	Manufacturing & Packing

ITEM(S) Four (04) 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 for sale in India.

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

Signature

Stamp of the authority and date

22 JUL 2019