**7-5/2013/EU/WC-0044**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**
**(International Cell)**

FDA Bhawan,Kotla Road,
New Delhi-110002
**Dated:**

To

06 JUN 2022

**M/s. Harman Finochem Limited,**
**Plot No. A-100, A-100/1, A-100/2 & D-1,**
**M.I.D.C Ind. Area, Shendra,**
**Aurangabad-431 007, Maharashtra, India**

**Subject:- Written Confirmation of M/s. Harman Finochem Limited, Plot No. A-100, A-100/1, A-100/2 & D-1, M.I.D.C Ind. Area, Shendra, Aurangabad-431 007, Maharashtra, 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 online application No. WC/RE/2022/3307 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 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.

9. The firm should submit the stability data in accordance with WHO TRS 1010.

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 |
|---|---|---|---|
| 1 | 17 | 06 JUN 2022 | 21.07.2025 |
| 2 | 01 | 06 JUN 2022 | 21.07.2025 |

**Yours faithfully,**

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

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

**CERTIFICATE NO. :** **WC-0044**

**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. A-100, A-100/1, A-100/2 & D-1,
M.I.D.C Ind. Area, Shendra,
Aurangabad-431 007, Maharashtra, India

**2. Manufacturer's licence number**: 25-AD/065

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 Annexure 1 & Annexure 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**: 02.05.2022 & 03.05.2022

**The Written Confirmation remains valid until**: 21.07.2025

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

O/C 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. V. G. Somani,
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*

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India

06 JUN 2022

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

**CERTIFICATE NO. :** **Annexure-1**
**WC-0044**

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

**Name and address of site:** **M/s. Harman Finochem Limited,**
**Plot No. A-100, A-100/1, A-100/2 & D-1,**
**M.I.D.C Ind. Area, Shendra,**
**Aurangabad-431 007, Maharashtra, India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Allopurinol BP/EP/USP | Manufacturing & Packing |
| 2. | Carisoprodol BP/EP/USP | Manufacturing & Packing |
| 3. | Divalproex Sodium USP | Manufacturing & Packing |
| 4. | Fenofibrate BP/EP/USP | Manufacturing & Packing |
| 5. | Isoproterenol Hydrochloride USP/ Isoprenaline Hydrochloride BP/EP | Manufacturing & Packing |
| 6. | Meprobamate BP/EP/USP | Manufacturing & Packing |
| 7. | Metformin Hydrochloride BP/EP/USP | Manufacturing & Packing |
| 8. | Phenobarbital BP/EP/USP | Manufacturing & Packing |
| 9. | Phenytoin EP | Manufacturing & Packing |
| 10. | Phenytoin Sodium | Manufacturing & Packing |
| 11. | Sodium Valproate EP | Manufacturing & Packing |
| 12. | Valproic Acid BP/EP/USP | Manufacturing & Packing |
| 13. | Phenobarbital Sodium Ph. Eur/USP | Manufacturing & Packing |
| 14. | Valsartan Ph. Eur. | Manufacturing & Packing |
| 15. | Norepinephrine Bitartrate USP/ Noradrenaline Tartrate EP | Manufacturing & Packing |
| 16. | Calcium Gluconate BP/EP/USP | Manufacturing & Packing |
| 17. | Vildagliptin IH | Manufacturing & Packing |

**ITEM(S) SEVENTEEN (17) ONLY**

**The Written Confirmation remains valid until: 21.07.2025**

*Signature*

*Stamp of the authority and date*

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

06 JUN 2022

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

**CERTIFICATE NO. :** **Annexure-2**
**WC-0044**

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

**Name and address of site:** **M/s. Harman Finochem Limited,**
**Plot No. A-100, A-100/1, A-100/2 & D-1,**
**M.I.D.C Ind. Area, Shendra,**
**Aurangabad-431 007, Maharashtra, India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Calcium Saccharate USP | 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 for sale in India.**

OIC

**The Written Confirmation remains valid until: 21.07.2025**

*Signature* V.H.L 06-06-2022

*Stamp of the authority and date*

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

06 JUN 2022