

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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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)



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.

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:

Telephone no.:

Fax no.:

dci@nic.in,

+91-11-23236965

+91-11-23236977

Signature

Stamp of the authority and date



06 JUN 2022



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



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.

The Written Confirmation remains valid until: 21.07.2025

Signature

[Handwritten Signature]

Stamp of the authority and date



06 JUN 2022

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:

08 JUN 2022

To

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/2022/3401 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	06.06.2022	21.07.2025
2	01	06.06.2022	21.07.2025
3	05	08 JUN 2022	21.07.2025
4	01	08 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. :

Annexure-3
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.	Dapagliflozin IH	Manufacturing & Packing
2.	Methylcobalamin /Mecobalamin USP/JP	Manufacturing & Packing
3.	Sacubitril/Valsartan IH	Manufacturing & Packing
4.	Nicotine IH	Manufacturing & Packing
5.	Noradrenaline Tartrate EP	Manufacturing & Packing

ITEM(S) FIVE (05) ONLY

The Written Confirmation remains valid until: 21.07.2025

Signature

Stamp of the authority and date



08 JUN 2022



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

CERTIFICATE NO. :

Annexure-4
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.	Succinylcholine Chloride/Suxamethonium Chloride/Suxamethonium Chloride Hydrate USP/EP/JP	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.

The Written Confirmation remains valid until: 21.07.2025

Signature

Stamp of the authority and date



08 JUN 2022

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: **20 NOV 2023**

To,

**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-431007, Maharashtra, India**

SUB:- Written Confirmation of Harman Finochem Limited, Plot No. A-100, A-100/1, A-100/2 & D-1, M.I.D.C. Ind. Area, Shendra, Aurangabad-431007, 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/FR/2023/7009 submitted to CDSCO, West Zone Mumbai 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.

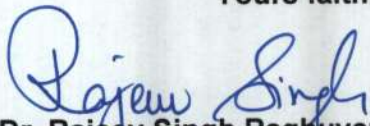
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.
7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt 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.

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	17	06.06.2022	21.07.2025
02	01	06.06.2022	21.07.2025
03	05	08.06.2022	21.07.2025
04	01	08.06.2022	21.07.2025
05	01	20 NOV 2023	21.07.2025

Yours faithfully,


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)



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

Annexure-5

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-431007, Maharashtra, India

List of API(s):

S.No.	Active substance	Activity(ies)
1.	Clofazimine EP/USP/IHS	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 21.07.2025

Signature
Rajeev Singh



20 NOV 2023

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: **23 DEC 2024**

To

**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**

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 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/FR/2024/8809 submitted to CDSCO, West zone office and the recommendation received from DDC(I), West 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.
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 manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

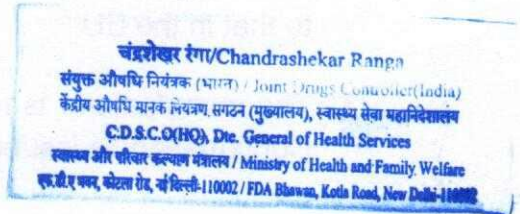
Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	17	06.06.2022	21.07.2025
02	01	06.06.2022	21.07.2025
03	05	08.06.2022	21.07.2025
04	01	08.06.2022	21.07.2025
05	01	20.11.2022	21.07.2025
06	01	23 DEC 2024	21.07.2025

Yours faithfully,

Chandrashekar
23/12/24
(Ranga Chandrashekar)
Joint Drugs Controller (India)





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

Annexure-6
WC-0044

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 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

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	NICOTINE POLACRILEX USP	Manufacturing & Packing

ITEM(S) One (01 ONLY)

The Written Confirmation remains valid until: 21.07.2025

Chandrashekar Ranga

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)

केन्द्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय

C.D.S.C.O(HQ), Dte. General of Health Services

स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare

एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



23 DEC 2024