7-5/2014/EU/WC-297
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

01 SEP 2022

To

M/s Naari Pharma Private Limited
Address: Village-Sakhanpur, Po- Pirumadara-244715
Tehsil-Ramnager, Dist- Nainital, Uttarakhand, India

SUB:- Written Confirmation of M/s Naari Pharma Private Limited Address: Village-Sakhanpur, Po- Pirumadara-244715 Tehsil-Ramnager, Dist- Nainital, Uttarakhand, 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/2022/3061 submitted to CDSCO, Zonal office, Ghaziabad and the recommendation received from DDC (I), CDSCO, Zonal office, Ghaziabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	07	01 SEP 2022	05.11.2024

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-297**

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 Naari Pharma Private Limited**
Address: Village-Sakhanpur, Po- Pirumadara-244715
Tehsil-Ramnager, Dist- Nainital, Uttarakhand, India

2. Manufacturer's licence number: 29/UA/SC/P-2010

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

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: 02/03/2022

The Written Confirmation remains valid until: 05.11.2024

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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

01 SEP 2022

Stamp of the authority and date Signature

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

Annexure-1

CERTIFICATE NO. : **WC-297**

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 Naari Pharma Private Limited**
Address: Village-Sakhanpur, Po-Pirumadara-244715
Tehsil-Ramnager, Dist- Nainital, Uttarakhand, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Allylestrenol IH	Manufacturing & Packing
2.	Levonorgestrenol	Manufacturing & Packing
3.	Lynestrenol BP/EP	Manufacturing & Packing
4.	Mifepristone IP/IH	Manufacturing & Packing
5.	Norethisterone IP/BP/USP/EP	Manufacturing & Packing
6.	Norethisterone Acetate BP/USP/EP	Manufacturing & Packing
7.	Norethisterone Enanthate IH	Manufacturing & Packing

ITEM(S) Seven (07) ONLY

The Written Confirmation remains valid until: 05.11.2024

Signature

01 SEP 2022

Stamp of the authority and date

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

7-5/2014/EU/WC-297
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

21 OCT 2022

To,

M/s Naari Pharma Private Limited
Address: Village-Sakhanpur, Po- Pirumadara-244715
Tehsil-Ramnager, Dist- Nainital, Uttarakhand, India

Sub:- Application for amendment of the Written Confirmation of M/s Naari Pharma Private Limited, Address: Village-Sakhanpur, Po- Pirumadara-244715, Tehsil-Ramnager, Dist-Nainital, Uttarakhand, 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 this office vide email dated 15/10/2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended Written Confirmation Certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

VGS

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

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

CERTIFICATE NO. :

Amended Annexure-1

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

WC-0297

1. **Name of site:** M/s. Naari Pharma Private Limited Address: Village-Sakhanpur, Po- Pirumadara-244715 Tehsil-Ramnager, Dist- Nainital, Uttarakhand, India

The product name in the Annexure 1 of Written Confirmation Certificate (WC-0297) issued on date 01.09.2022 is hereby amended as follows:

In place of:

"Levonorgestrenol"

Read as:

"Levonorgestrel IP/BP/Ph. Eur/USP"

All other conditions of Written Confirmation Certificate will remain same.

21 OCT 2022

Signature

Stamp of the authority and date

7-5/2014/EU/WC-0297
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

26 APR 2023

To,

M/s. Naari Pharma Pvt. Ltd.,
Village – Sakhanpur, PO-Pirumadara,
Tehsil- Ramnagar, Dist-Nainital-244715,
Uttarakhand. India.

Subject :- Written Confirmation of M/s. Naari Pharma Pvt. Ltd., Village – Sakhanpur, PO-Pirumadara, Tehsil- Ramnagar, Dist-Nainital-244715, Uttarakhand. 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-Regarding.

Sir,

Please refer to your online application no. WC/ED/2022/5589 submitted to CDSCO, zone office, Ghaziabad and the recommendation received from DDC (I), 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.

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	07	01.09.2022	05.11.2024
02	01	26 APR 2023	05.11.2024

Yours faithfully,

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

Annexure-02

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

CERTIFICATE NO. : WC-0297

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. Naari Pharma Pvt. Ltd., Village – Sakhanpur, PO-Pirumadara, Tehsil-Ramnagar, Dist-Nainital-244715, Uttarakhand. India.**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Dydrogesterone IP/BP/Ph. Eur./USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 05/11/2024

Signature

Stamp of the authority and date

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

26 APR 2023