7-5/2023/EU/WC-0561

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 26 JUN 2023

To

M/s Shakti Lifescience Private Limited
(Formerly known as M/s Shakti Industries)
Plot No K-2, MIDC, Tarapur, Boisar-401506,
Tal. & Dist-Palghar, Maharashtra, India

SUB: Written Confirmation of M/s Shakti Lifescience Private Limited (Formerly known as M/s Shakti Industries) Plot No K-2, MIDC, Tarapur, Boisar-401506, Tal. & Dist-Palghar, Maharashtra, India as per requirement of EU for import of active substances imported into the European Union (EU) for edicinal 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/2023/6396 submitted to CDSCO, West Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

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	10	26 JUN 2023	Three years from the date of issue

Yours faithfully,

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

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

WC-0561

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 Shakti Lifescience Private Limited**
(Formerly known as M/s Shakti Industries)
Plot No K-2, MIDC, Tarapur, Boisar-401506,
Tal. & Dist-Palghar, Maharashtra, India

2.Manufacturer's license Number: 28-MH/102834

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

As per list Annexed

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: 06.10.2021 & 07.10.2021

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. Rajeev Singh Raghuvanshi
Drugs Controller General (India)

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

26 JUN 2023

Signature

Stamp of the authority and date

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

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

CERTIFICATE NO. : Annexure-01 WC-0561

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 Shakti Lifescience Private Limited (Formerly known as M/s Shakti Industries) Plot No K-2, MIDC, Tarapur, Boisar-401506, Tal. & Dist-Palghar, Maharashtra, India**

List of APIs:

Sr. No	Name of the Active Substances	Activitie(s)
1.	Dutasteride BP/EP/USP	Manufacturing and Packing
2.	Estradiol Cypionate USP	Manufacturing and Packing
3.	Mometasone Furoate Monohydrate BP/EP	Manufacturing and Packing
4.	Nandrolone Decanoate BP/EP/USP	Manufacturing and Packing
5.	Nandrolone Phenyl Propionate USP	Manufacturing and Packing
6.	Prednisolone Sodium Phosphate BP/EP/USP	Manufacturing and Packing
7.	Testosterone BP/EP/USP	Manufacturing and Packing
8.	Testosterone Phenyl Propionate BP	Manufacturing and Packing
9.	Testosterone Propionate BP/EP/USP	Manufacturing and Packing
10.	Tibolone BP/EP	Manufacturing and Packing

ITEM(S) TEN (10) Only

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

Signature

Stamp of the authority and date

26 JUN 2023

7-5/2023/EU/WC-0561

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 04 DEC 2024

To,

M/s Shakti Lifescience Private Limited,
Plot. No. K-2 ,M.I.D.C, Tarapur, Boisar – 401506,
Taluka & Dist: Palghar, Maharashtra, India.

SUB:- Written Confirmation of M/s Shakti Lifescience Private Limited, Plot. No. K-2 ,M.I.D.C, Tarapur, Boisar – 401506, Taluka & Dist: Palghar, 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/2024/8390 dated 28-MAY-2024 submitted to CDSCO, West Zone, Mumbai and the recommendation received from DDC(I), CDSCO, 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 manufacturer is required to comply with the provisions 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
--	--	26.06.2023	**25.06.2026**
1	10	26.06.2023	**25.06.2026**
2	16	04 DEC 2024	**25.06.2026**

Yours faithfully,

Chandrashekar
04/12/24

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय 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
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

Annexure-02
WC-0561

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 Shakti Lifescience Private Limited, Plot. No. K-2 ,M.I.D.C, Tarapur, Boisar – 401506, Taluka & Dist: Palghar, Maharashtra, India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Methyl Testosterone- BP	Manufacturing & Packing
02	Methyl Testosterone- EP	Manufacturing & Packing
03	Methyl Testosterone- USP	Manufacturing & Packing
04	Ethinyl Estradiol- BP	Manufacturing & Packing
05	Ethinyl Estradiol- EP	Manufacturing & Packing
06	Ethinyl Estradiol-USP	Manufacturing & Packing
07	Testosterone Cypionate-USP	Manufacturing & Packing
08	Finasteride –BP	Manufacturing & Packing
09	Finasteride -EP	Manufacturing & Packing
10	Finasteride - USP	Manufacturing & Packing
11	Testosterone Decanoate- BP	Manufacturing & Packing
12	Testosterone Decanoate- EP	Manufacturing & Packing
13	Testosterone Isocaproate-BP	Manufacturing & Packing
14	Testosterone Isocaproate-EP	Manufacturing & Packing
15	Dienogest- BP	Manufacturing & Packing
16	Dienogest -EP	Manufacturing & Packing

ITEM(S) ONE (16) ONLY

The Written Confirmation remains valid until: 25.06.2026

Signature 04/12/24

Stamp of the authority and date

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
CDSCO(HQ), Dte. General of Health Services
स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

04 DEC 2024