7-5/2013/EU/WC-0162
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 31 AUG 2022

To

M/s. Symbiotec Pharmalab Private Limited,
Plot No. 5,6,7 & 8, Special Economic Zone,
Phase II, Pharma Zone, Pithampur,
District-Dhar (M.p)-454774

Subject:- Written Confirmation of M/s. Symbiotec Pharmalab Private Limited, Plot No. 5,6,7 & 8, Special Economic Zone, Phase II, Pharma Zone, Pithampur, District-Dhar (M.p)-454774 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/2022/3902 submitted to CDSCO, Sub-Zonal office Indore and the recommendation received from DDC (I), Sub-Zone Indore 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	36	31 AUG 2022	**02.07.2025**
2	05	31 AUG 2022	**02.07.2025**

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-0162

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. Symbiotec Pharmalab Private Limited, Plot No. 5,6,7 &8, Special Economic Zone, Phase II, Pharma Zone, Pithampur, District-Dhar (M.p)-454774**

2. Manufacturer's licence number: 28/8/2009

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 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: 08.11.2021 & 09.11.2021

The Written Confirmation remains valid until: **02nd July, 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature VGS

Stamp of the authority and date

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

31 AUG 2022

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

CERTIFICATE NO. :

Amended Annexure-1 WC-0162

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. Symbiotec Pharmalab Private Limited, Plot No. 5,6,7 &8, Special Economic Zone, Phase II, Pharma Zone, Pithampur, District-Dhar (M.p)-454774**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abiraterone Acetate USP	Manufacturing & Packing
2.	Betamethasone BP/EP/USP	Manufacturing & Packing
3.	Betamethasone Dipropionate BP/EP/USP	Manufacturing & Packing
4.	Betamethasone Sodium Phosphate BP/EP/USP	Manufacturing & Packing
5.	Betamethasone Valerate BP/EP/USP	Manufacturing & Packing
6.	Clobetasol Propionate USP/EP	Manufacturing & Packing
7.	Conjugated Estrogens USP	Manufacturing & Packing
8.	Desogestrel BP/EP	Manufacturing & Packing
9.	Dexamethasone BP/EP/USP	Manufacturing & Packing
10.	Dexamethasone Sodium Phosphate USP	Manufacturing & Packing
11.	Drosperinone EP/USP	Manufacturing & Packing
12.	Estradiol Hemihydrate BP/EP/USP	Manufacturing & Packing
13.	Estradiol USP	Manufacturing & Packing
14.	Ethinyl Estradiol BP/EP/USP	Manufacturing & Packing
15.	Ethynodiol Diacetate USP	Manufacturing & Packing
16.	Hydrocortisone Acetate BP/EP/USP	Manufacturing & Packing
17.	Hydrocortisone BP/EP/USP	Manufacturing & Packing
18.	Hydrocortisone Hemisuccinate BP/USP	Manufacturing & Packing
19.	Hydroxy Progesterone Caproate USP	Manufacturing & Packing
20.	Levonorgestrel BP/EP/USP	Manufacturing & Packing
21.	Methyl Prednisolone Acetate USP	Manufacturing & Packing
22.	Methyl Prednisolone BP/EP/USP	Manufacturing & Packing
23.	Nandrolone Decanoate EP/USP	Manufacturing & Packing
24.	Nandrolone Phenylpropionate BP/USP	Manufacturing & Packing
25.	Norethisterone BP/EP	Manufacturing & Packing
26.	Prednisolone Acetate BP/EP/USP	Manufacturing & Packing
27.	Prednisolone BP/EP/USP	Manufacturing & Packing
28.	Prednisolone Sodium Phosphate IP/BP/EP/USP	Manufacturing & Packing
29.	Progesterone EP/USP	Manufacturing & Packing
30.	Testosterone BP/EP/USP	Manufacturing & Packing

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

31 AUG 2022

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

CERTIFICATE NO. :

Amended
Annexure-1
WC-0162

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. Symbiotec Pharmalab Private Limited, Plot No. 5,6,7 &8, Special Economic Zone, Phase II, Pharma Zone, Pithampur, District-Dhar (M.p)-454774**

List of APIs:

31	Testosterone Cypionate USP	Manufacturing & Packing
32	Testosterone Decanoate BP/EP	Manufacturing & Packing
33	Testosterone Isocaproate BP/EP	Manufacturing & Packing
34	Testosterone Propionate BP/EP/USP	Manufacturing & Packing
35	Testosterone Undecanoate IH	Manufacturing & Packing
36	Triamcinolone Acetonide USP	Manufacturing & Packing

ITEM(S) Thirty Six (36) Only

The Written Confirmation remains valid until: 02nd July, 2025

Signature
date

Stamp of the authority and

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

31 AUG 2022

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

CERTIFICATE NO. :

Amended
Annexure-2
WC-0162

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. Symbiotec Pharmalab Private Limited, Plot No. 5,6,7 &8, Special Economic Zone, Phase II, Pharma Zone, Pithampur, District-Dhar (M.p)-454774**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Estrone USP	Manufacturing & Packing
2.	Methylprednisolone Hemisuccinate USP	Manufacturing & Packing
3.	Prasterone (Dihydroepiandrosterone) IH	Manufacturing & Packing
4.	Testosterone Enanthate BP/EP/USP	Manufacturing & Packing
5.	Testosterone Phenyl Propionate IH	Manufacturing & Packing

ITEM(S) Five (05) 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: 02nd July, 2025

Signature VKL

Stamp of the authority and date

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

31 AUG 2022