7-5/2013/EU/WC-0161
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

05 JUL 2022

To

M/s. Symbiotec Pharmalab Private Limited,
385/2, Gram Pigdamber, Rau,
Indore-453331, M.P., India

Subject:- Written Confirmation of M/s Symbiotec Pharmalab Private Limited, 385/2, Gram Pigdamber, Rau, Indore-453 331, M.P., 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/2022/3902 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	28	30.06.2022	**02.07.2025**
2	41	05 JUL 2022	**02.07.2025**

Yours faithfully,

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

Annexure-2

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

WC-0161

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

Name and address of site: **M/s. Symbiotec Pharmalab Private Limited, 385/2, Gram Pigdamber, Rau, Indore-453 331, M.P., India**

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.	Estrone USP	Manufacturing & Packing
15.	Ethinyl Estradiol BP/EP/USP	Manufacturing & Packing
16.	Ethynodiol Diacetate USP	Manufacturing & Packing
17.	Hydrocortisone Acetate BP/EP/USP	Manufacturing & Packing
18.	Hydrocortisone BP/EP/USP	Manufacturing & Packing
19.	Hydrocortisone Hemisuccinate BP/USP	Manufacturing & Packing
20.	Hydroxy Progesterone Caproate USP	Manufacturing & Packing
21.	Levonorgestrel BP/EP/USP	Manufacturing & Packing
22.	Methyl Prednisolone Acetate USP	Manufacturing & Packing
23.	Methyl Prednisolone BP/EP/USP	Manufacturing & Packing
24.	Methylprednisolone Hemisuccinate USP	Manufacturing & Packing
25.	Nandrolone Decanoate EP/USP	Manufacturing & Packing
26.	Nandrolone Phenyl Proplonate BP/USP	Manufacturing & Packing
27.	Norethisterone BP/EP	Manufacturing & Packing
28.	Prasterone (Dihydroepiandrosterone) IH	Manufacturing & Packing

05 JUL 2022

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-2**

WC-0161

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, 385/2, Gram Pigdamber, Rau, Indore-453 331, M.P., India**

29	Prednisolone Acetate BP/EP/USP	Manufacturing & Packing
30	Prednisolone BP/EP/USP	Manufacturing & Packing
31	Prednisolone Sodium Phosphate IP/BP/EP/USP	Manufacturing & Packing
32	Progesterone EP/USP	Manufacturing & Packing
33	Testosterone BP/EP/USP	Manufacturing & Packing
34	Testosterone Cypionate USP	Manufacturing & Packing
35	Testosterone Decanoate BP/EP	Manufacturing & Packing
36	Testosterone Enanthate BP/EP/USP	Manufacturing & Packing
37	Testosterone Isocaproate BP/EP	Manufacturing & Packing
38	Testosterone Phenyl Propionate IH	Manufacturing & Packing
39	Testosterone Propionate BP/EP/USP	Manufacturing & Packing
40	Testosterone Undecanoate IH	Manufacturing & Packing
41	Triamcinolone Acetonide USP	Manufacturing & Packing

ITEM(S) Twenty Four (41) ONLY

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

Signature

Stamp of the authority and date

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

05 JUL 2022