Amended

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

To

M/s. Symbiotec Pharmalab Pvt. Ltd.
385/2, Gram Pigdamber,
Rau , Indore-453331, Madhya Pradesh, India

30 SEP 2022

SUB:- Written Confirmation of M/s M/s. Symbiotec Pharmalab Pvt. Ltd. 385/2, Gram Pigdamber, Rau , Indore-453331, Madhya Pradesh, 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/2022/3596 submitted to CDSCO, Indore Sub-Zone office, and the recommendation received from DDC (I), Indore Sub-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.

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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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

Yours faithfully,

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

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

CERTIFICATE NO. : 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

1. Name and address of site: Symbiotec Pharmalab Pvt. Ltd.
385/2, Gram Pigdamber, Rau , Indore-453331,
Madhya Pradesh, India

2. Manufacturer's licence number: 28/2/2004

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: 25/10/2021 and 26/10/2021

The Written Confirmation remains valid until: 02.07.2025

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

30 SEP 2022

Stamp of the authority and date of signature

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

Amended

Annexure-1

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

CERTIFICATE NO. : 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

1. Name and address of site: **M/s Symbiotec Pharmalab Pvt. Ltd.**
385/2, Gram Pigdamber,
Rau , Indore-453331, Madhya Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Cloprednol IH	Manufacturing & Packing
2.	Betamethasone Acetate USP	Manufacturing & Packing
3.	Beclomethasone Dipropionate BP/EP/USP	Manufacturing & Packing
4.	Betamethasone BP/EP/USP	Manufacturing & Packing
5.	Betamethasone Dipropionate BP/EP/USP	Manufacturing & Packing
6.	Betamethasone Valerate BP/EP/USP	Manufacturing & Packing
7.	Betamethasone Sodium Phosphate BP/EP/USP	Manufacturing & Packing
8.	Clobetasol Propionate USP/EP	Manufacturing & Packing
9.	Clobetasone Butyrate BP/EP	Manufacturing & Packing
10.	Deflazacort IH	Manufacturing & Packing
11.	Desoximetasone USP	Manufacturing & Packing
12.	Prednisolone Hemisuccinate USP	Manufacturing & Packing
13.	Methylprednisolone Hydrogen Succinate EP	Manufacturing & Packing
14.	Hydrocortisone Acetate BP/EP/USP	Manufacturing & Packing
15.	Hydrocortisone Sodium Succinate for Injection USP for Manufacturer's use (Hydrocortisone Sodium Succinate Buffered 5% Sterile)	Manufacturing & Packing
16.	Methylprednisolone Sodium Succinate for Injection USP for Manufacturer's use (Methylprednisolone Sodium Succinate Buffered 3% Sterile)	Manufacturing & Packing
17.	Prednisolone Acetate BP/EP/USP	Manufacturing & Packing
18.	Triamcinolone Acetonide BP/EP/USP	Manufacturing & Packing
19.	Halobetasol Propionate USP	Manufacturing & Packing
20.	Mometasone Furoate BP/EP/USP	Manufacturing & Packing
21.	Hydrocortisone Hydrogen Succinate EP	Manufacturing & Packing
22.	Hydrocortisone Hemisuccinate BP/USP	Manufacturing & Packing
23.	Hydrocortisone Sodium Succinate USP	Manufacturing & Packing
24.	Methylprednisolone Acetate BP/EP/USP	Manufacturing & Packing
25.	Methylprednisolone Hemisuccinate USP	Manufacturing & Packing
26.	Methylprednisolone Sodium Succinate USP	Manufacturing & Packing
27.	Mometasone Furoate Monohydrate IH	Manufacturing & Packing
28.	Prednisolone Sodium Phosphate BP/EP/USP	Manufacturing & Packing

ITEM(S) TWENTY EIGHT (28) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature 30 SEP 2022

Stamp of the authority and date

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