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: 26 JUN 2019

To

M/s. Symbiotec Pharmalab Private Limited,
385/2, Gram Pigdamber, Rau,
Indore-453 331, 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 application submitted to CDSCO, Sub-Zonal office Indore and the recommendation received from ADC (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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	24	26 JUN 2019	02.07.2022
2	02	26 JUN 2019	02.07.2022

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

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

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.

OIC

Date of Inspection of the plant: 25.04.2019 & 26.04.2019

The Written Confirmation remains valid until: **02nd July, 2022**

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. S. Eswara Reddy,
Drugs Controller General (India)

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

Signature

Stamp of the authority and date

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare, Government of India

26 JUN 2019

18/06/19 18-6-19 19/06/19

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

CERTIFICATE NO. : WC-0161

Annexure-I

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.	Beclomethasone Dipropionate BP/EP/USP	Manufacturing & Packing
2.	Betamethasone BP/EP/USP	Manufacturing & Packing
3.	Betamethasone Dipropionate BP/EP/USP	Manufacturing & Packing
4.	Betamethasone Valerate BP/EP/USP	Manufacturing & Packing
5.	Betamethasone Sodium Phosphate BP/EP/USP	Manufacturing & Packing
6.	Clobetasol Propionate USP/EP	Manufacturing & Packing
7.	Clobetasone Butyrate BP/EP	Manufacturing & Packing
8.	Deflazacort IH	Manufacturing & Packing
9.	Desoximetasone USP	Manufacturing & Packing
10.	Dexamethasone Sodium Phosphate BP/EP/USP	Manufacturing & Packing
11.	Halobetasol Propionate USP	Manufacturing & Packing
12.	Hydrocortisone Acetate BP/EP/USP	Manufacturing & Packing
13.	Hydrocortisone Hemisuccinate BP/USP	Manufacturing & Packing
14.	Hydrocortisone Sodium Succinate USP	Manufacturing & Packing
15.	Hydrocortisone Sodium Succinate for Injection USP for Manufacturer's Use	Manufacturing & Packing
16.	Methylprednisolone Acetate BP/EP/USP	Manufacturing & Packing
17.	Methylprednisolone Hemisuccinate USP	Manufacturing & Packing
18.	Methylprednisolone Sodium Succinate USP	Manufacturing & Packing
19.	Methylprednisolone Sodium Succinate for Injection USP for Manufacturer's Use	Manufacturing & Packing
20.	Mometasone Furoate BP/EP/USP	Manufacturing & Packing
21.	Mometasone Furoate Monohydrate IH	Manufacturing & Packing
22.	Prednisolone Acetate BP/EP/USP	Manufacturing & Packing
23.	Prednisolone Sodium Phosphate BP/EP/USP	Manufacturing & Packing
24.	Triamcinolone Acetonide BP/EP/USP	Manufacturing & Packing

ITEM(S) Twenty Four (24) ONLY

The Written Confirmation remains valid until: 02nd July, 2022

Signature

Stamp of the authority and date

18/06/19 16-6-19 26 JUN 2019

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

Annexure-2

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

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.	Cloprednol IH	Manufacturing & Packing
2.	Prednisolone Hemisuccinate USP	Manufacturing & Packing

ITEM(S) Two (02) 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, 2022

OIC

Signature

Stamp of the authority and date

26 JUN 2019

18/06/19

15-6-19

19/06/19