7-5/2013/EU/WC-0009
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

16 SEP 2022

To

M/s Coral Drugs Pvt. Ltd.
Address: Plot No. 55, 56 & 57, HSIIDC Industrial Estate,
Murthal, Sonipat-131029, Haryana India

SUB:- Written Confirmation of M/s Coral Drugs Pvt. Ltd. Address: Plot No. 55, 56 & 57, HSIIDC Industrial Estate, Murthal, Sonipat-131029, Haryana 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/2022/1649 submitted to CDSCO, Zonal office, Ghaziabad and the recommendation received from DDC (I), CDSCO, Zonal office, Ghaziabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	18	16 SEP 2022	05.07.2025

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-0009**

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 Coral Drugs Pvt. Ltd. Address: Plot No. 55, 56 & 57, HSIIDC Industrial Estate, Murthal, Sonipat-131029, Haryana India**

2. Manufacturer's licence number: 473-B(H) & 785-OSP(H)

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: 07/03/2022

The Written Confirmation remains valid until: 05.07.2025

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

16 SEP 2022

Stamp of the authority and date Signature

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

CERTIFICATE NO. :

Annexure-1

WC-0009

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 Coral Drugs Pvt Ltd Address: Plot No. 55, 56 & 57, HSIIDC Industrial Estate, Murthal, Sonipat-131029, Haryana India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Azelastine Hydrochloride BP/EP/USP/IP	Manufacturing & Packing
2.	Budesonide BP/EP/USP/IP	Manufacturing & Packing
3.	Ciclesonide IP/EP	Manufacturing & Packing
4.	Clobetasol Propionate BP/USP/IP	Manufacturing & Packing
5.	Danazol USP/IP	Manufacturing & Packing
6.	Estramustine Sodium Phosphate BP	Manufacturing & Packing
7.	Exemestane BP/EP/USP/IP	Manufacturing & Packing
8.	Flucinolone Acetonide USP	Manufacturing & Packing
9.	Flutamide BP/EP/USP/IP	Manufacturing & Packing
10.	Fluticasone Furoate IH	Manufacturing & Packing
11.	Fluticasone Propionate BP/EP/USP/IP	Manufacturing & Packing
12.	Formoterol Fumarate Dihydrate BP/EP/USP/IP	Manufacturing & Packing
13.	Isoflupredone Acetate IP/USP	Manufacturing & Packing
14.	Mometasone Furoate BP/EP/USP/IP	Manufacturing & Packing
15.	Mometasone Furoate Monohydrate IH/EP	Manufacturing & Packing
16.	Salmeterol Xinafoate BP/EP/USP/IP	Manufacturing & Packing
17.	Triamcinolone BP/EP/USP/IP	Manufacturing & Packing
18.	Triamcinolone Acetonide BP/EP/USP/IP	Manufacturing & Packing

ITEM(S) Eighteen (18) ONLY

The Written Confirmation remains valid until: 05.07.2025

Signature VHL

16 SEP 2022

Stamp of the authority and date

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

7-5/2013/EU/WC-0009
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 18 SEP 2023

To,

M/s.Coral Drugs Pvt.Ltd,
Address: Plot No. 55, 56, 57, HSIIDC Industrial Estate,
Murthal, Sonipat – 131 029, Haryana, India

SUB:- Written Confirmation to M/s.Coral Drugs Pvt.Ltd, Address: Plot No. 55, 56, 57, HSIIDC Industrial Estate, Murthal, Sonipat – 131 029, Haryana, 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/ED/2022/5921 dated 23.12.2023 submitted to CDSCO, DDC(I), North Zone, Ghaziabad, and the recommendation received from DDC(I), North Zone, Ghaziabad, 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	18	16.09.2022	05.07.2025
2	01	18 SEP 2023	05.07.2025

Yours faithfully,

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

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

Annexure-02

CERTIFICATE NO. : WC-0009

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.Coral Drugs Pvt.Ltd,**
Address: Plot No. 55, 56, 57,
HSIIDC Industrial Estate, Murthal,
Sonipat – 131 029, Haryana, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Fluticasone Furoate EP/BP	Manufacturing & Packing

ITEM ONE (01) ONLY

The Written Confirmation remains valid until: 05.07.2025

Signature

18 SEP 2023

Stamp of the authority and date