

7-5/2022/EU/WC-0518
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

10 JUL 2023

To,

**'M/s. Anmol Chemicals Private Limited,
Plot No. J-63,Road No.U-6, MIDC Taloja,
Tal.Panvel Raigad-410208, Maharashtra State, India'**

SUB:- Application for amendment of the Written Confirmation of "M/s. Anmol Chemicals Private Limited, Plot No. J-63,Road No.U-6, MIDC Taloja, Tal.Panvel Raigad-410208, Maharashtra State, 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 letter no nil dated 20.06.2023 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.s

Yours faithfully,


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



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

CERTIFICATE NO. : **Amended
WC-0518**

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 of site: **M/s. Anmol Chemicals Private Limited,
Plot No. J-63, Road No.U-6,
MIDC Taloja, Tal.Panvel Raigad-410208,
Maharashtra State, India**

2. Manufacturer's Licence Number: **KD/504**

Name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0002) granted on date 22.05.2023 is hereby amended as follows:

In place of:

Manufacturer's Name: **'M/s. Anmol Chemicals, Plot No. J-63, Road No.U-6, MIDC, Taloja, Tal.Panvel Raigad-410208, Maharashtra State, India'**

Read as:

Manufacturer's Name: **'M/s. Anmol Chemicals Private Limited, Plot No. J-63, Road No.U-6, MIDC Taloja, Tal.Panvel Raigad-410208, Maharashtra State, India'**

All the other conditions of Written Confirmation Certificate will remain same.


Signature

Stamp of the authority and date



10 JUL 2023

7-5/2022/EU/WC-0518
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. Anmol Chemicals,
Plot No. J-63, Road No. U-6,
MIDC Talaja, Tal. Panvel Raigad-410 208,
Maharashtra State, India**

03 FEB 2022

Subject:- Written Confirmation of M/s. Anmol Chemicals, Plot No. J-63, Road No. U-6, MIDC Talaja, Tal. Panvel Raigad-410 208, Maharashtra State, 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/2021/1363 submitted to CDSCO, West Zone office and the recommendation received from DDC(I), West zone office 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	06	03 FEB 2022	Three (03) years from date of issue

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-0518

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. Anmol Chemicals,
Plot No. J-63, Road No. U-6,
MIDC Taloja, Tal. Panvel Raigad-410 208,
Maharashtra State, India

2. Manufacturer's licence number: KD504

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

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: 23.09.2021 to 24.09.2021

The Written Confirmation remains valid until: Three (03) years from date of issue.

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:

Telephone no.:

Fax no.:

dci@nic.in,
+91-11-23236965
+91-11-23236972

Signature

Vh

Stamp of the authority and date



03 FEB 2022



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

CERTIFICATE NO. :

Annexure-1
WC-0518

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. Anmol Chemicals,
Plot No. J-63, Road No. U-6,
MIDC Talaja, Tal. Panvel Raigad-410 208,
Maharashtra State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Lithium Carbonate USP	Manufacturing & Packing
2.	Magnesium Sulfate Hepta Hydrate BP	Manufacturing & Packing
3.	Boric Acid BP	Manufacturing & Packing
4.	Magnesium Citrate USP	Manufacturing & Packing
5.	Zinc Gluconate USP	Manufacturing & Packing
6.	Zinc Acetate USP	Manufacturing & Packing

ITEM(S) Six (06) ONLY

The Written Confirmation remains valid until: Three (03) years from date of issue.

Signature

Stamp of the authority and date



03 FEB 2022

7-5/2022/EU/WC-0518
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

27 MAY 2023

To

**M/s. Anmol Chemicals,
Plot No. J-63, Road No. U-6,
MIDC Talaja, Tal. Panvel Raigad-410 208,
Maharashtra State, India**

Subject:- Written Confirmation of M/s. Anmol Chemicals, Plot No. J-63, Road No. U-6, MIDC Talaja, Taluka. Panvel Raigad-410 208, Maharashtra State, 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/FR/2023/6631 submitted to CDSCO, West Zone office and the recommendation received from DDC(I), West zone office 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	06	03.02.2022	02.02.2025
2	11	27 MAY 2023	02.02.2025

Yours faithfully,


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



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

CERTIFICATE NO. :

Annexure-2
WC-0518

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

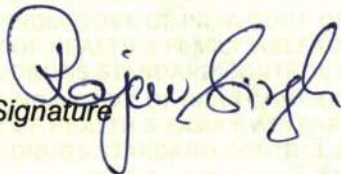
Name and address of site: M/s. Anmol Chemicals,
Plot No. J-63, Road No. U-6,
MIDC Taloja, Tal. Panvel Raigad-410 208,
Maharashtra State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Aluminium Chloride Hexahydrate BP	Manufacturing & Packing
2.	Aluminium Chloride USP	Manufacturing & Packing
3.	Calcium Glycerophosphate BP	Manufacturing & Packing
4.	Calcium Saccharate USP	Manufacturing & Packing
5.	Dried Aluminium Phosphate BP	Manufacturing & Packing
6.	Lithium Carbonate BP	Manufacturing & Packing
7.	Magnesium Sulfate Heptahydrate BP	Manufacturing & Packing
8.	Magnesium Glycerophosphate BP	Manufacturing & Packing
9.	Sodium Acetate USP	Manufacturing & Packing
10.	Sodium Hydroxide BP	Manufacturing & Packing
11.	Zinc Oxide BP	Manufacturing & Packing

ITEM(S) Eleven (11) ONLY

The Written Confirmation remains valid until: 03.02.2025.


Signature

Stamp of the authority and date



22 MAY 2023

