**AMENDED**

**7-5/2023/EU/WC-0551**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organisation**
**(International Cell)**

FDA Bhawan, Kotla Road,
New Delhi-110002
**Dated:** 12 SEP 2024

To

**M/s. Meha Pharma Private Limited,**
**Plot Nos. 281, Kundaim Industrial Estate,**
**Kundaim – Goa 403115, India**

**SUB:-** Written Confirmation of **M/s. Meha Pharma Private Limited, Plot Nos. 281, Kundaim Industrial Estate, Kundaim – Goa 403115, 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,

This is with reference to your online application no. WC/ED/2024/8617 dated 17.06.2024, submitted on Sugam Portal, wherein, you had requested for amendment in the ***Activity(ies)*** of Annexure-01 for the product sr. no. 4. in the WCC valid upto 19.05.2027.

In this regard, the firm's request for the said amendment has been considered and accordingly, amended Written Confirmation Certificate is enclosed.

Please acknowledge the receipt

Yours faithfully,

Chandrashekar
12/09/24

**(Ranga Chandrashekar)**
**Joint Drugs Controller (India)**

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

**AMENDED**
**WC-0551**

**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**

**1. Name and address of site:** **M/s. Meha Pharma Private Limited,**
**Plot Nos. 281, Kundaim Industrial Estate,**
**Kundaim – Goa 403115, India**

The **activity(ies) column** for the product sr. no. 4 (Dried Aluminium Phosphate BP) in written Confirmation Certificate, WC-0551 valid up to 19.05.2027 is hereby amended as follows:

| S. No. | Active Substance(s) | Activity(ies) |
|---|---|---|
| 4. | Dried Aluminium Phosphate BP | **Manufacturing & Packing** |

All other conditions of Written Confirmation Certificate will remain same.

*Signature*

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ डी ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

*Stamp of the authority and date*

Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, Govt. of India

12 SEP 2024

**7-5/2023/EU/WC-0551**

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
**Dated:** 20 MAY 2024

**To,**

**M/s. Meha Pharma Private Limited,**
**Plot Nos. 281, Kundaim Industrial Estate,**
**Kundaim – Goa 403115, India**

**SUB:-** Written Confirmation of M/s. **Meha Pharma Private Limited**, **Plot Nos. 281, Kundaim Industrial Estate, Kundaim – Goa 403115, 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/2023/7640 dated 19.10.2023 submitted to CDSCO, ADC(I), Goa Sub-Zone, and the recommendation received from ADC(I), Goa 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.

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.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

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 |
|---|---|---|---|
| -- | 04 | 20 MAY 2024 | **Three Year from the Date of Issue** |
| 01 | 08 | 20 MAY 2024 | **Three Year from the Date of Issue** |

**Yours faithfully,**

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

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

WC-0551

**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**

**1. Name and address of site:** **M/s. Meha Pharma Private Limited,**
**Plot Nos. 281, Kundaim Industrial Estate,**
**Kundaim – Goa 403115, India**

**2. Manufacturer's licence number**: **599 in Form 25**

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):**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Dried Aluminium Hydroxide GEL USP | Manufacturing & Packing |
| 2. | Dried Aluminium Hydroxide IP/BP | Manufacturing & Packing |
| 3. | Hydrotalcite BP | Manufacturing & Packing |
| 4. | Simethicone USP | Manufacturing & Packing |

**ITEM(S) FOUR (04) ONLY**
**and as per list enclosed as Annexures**

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**: 11.12.2023 & 12.12.2023

**The Written Confirmation remains valid until**: **Three Year from the 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. Rajeev Singh Raghuvanshi,
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*

20 MAY 2024

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

**CERTIFICATE NO. :**

**Annexure-01**
**WC-0551**

**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. Meha Pharma Private Limited,**
**Plot Nos. 281, Kundaim Industrial Estate,**
**Kundaim – Goa 403115, India**

**List of APIs:**

| S. No. | Active substance(s) | Activity(ies) |
|---|---|---|
| 1. | Almagate BP | Manufacturing & Packing |
| 2. | Aluminium Phosphate GEL BP/USP | Manufacturing & Packing |
| 3. | Calcium Silicate USP | Manufacturing & Packing |
| 4. | Dried Aluminium Phosphate BP | |
| 5. | Magaldrate IP/USP/BP | Manufacturing & Packing |
| 6. | Magnesium Hydroxide Paste USP | Manufacturing & Packing |
| 7. | Magnesium Trisilicate BP/USP | Manufacturing & Packing |
| 8. | Simethicone Powder | Manufacturing & Packing |

**ITEM(S) EIGHT (08) 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: Three Year from the Date of Issue**

*Signature*

*Stamp of the authority and date*

20 MAY 2024