7-5/2013/EU/WC-0262
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 07 NOV 2024

To

M/s. Farmson Basic Drugs Pvt. Ltd., (Unit-II),
Plot No.14, G.I.D.C Industrial Estate Nandesari,
Dist: Vadodara-391340

SUB:- Application for grant of Written Confirmation in favor of "M/s. Farmson Basic Drugs Pvt. Ltd., (Unit-II), Plot No.14,G.I.D.C Industrial Estate Nandesari, Dist: Vadodara-391340" due to demerge of the company 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 200183/EC from India - Regarding

Sir,

Please refer to your SUGAM Application no. WC/FR/2024/8814 dated 31-JUL-2024 wherein you have applied for grant of WC certificate due to demerge of the company from M/s. Farmson Pharmaceutical Gujarat Pvt. Ltd. into M/s. Farmson Basic Drugs Pvt. Ltd. vide order no. RD(NWR)/233/45/2023-24/5111 of Registrar of companies Ahmedabad dated 13.03.2024.

In this regard, kindly find the enclosed amended certificate. The conditions 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) of directive 2001/83/EC from India will remain same.

Please acknowledge the receipt.

Yours faithfully,

Chandrashekar
07/11/24

(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-0262

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. Farmson Basic Drugs Pvt. Ltd., (Unit-II), Plot No.14,G.I.D.C Industrial Estate Nandesari, Dist: Vadodara-391340**

2. **Manufacturer's License Number: G/25/1974**

Name of the company mentioned in the Written Confirmation Certificate issued on 06.06.2022 is hereby amended as follows.

In place of	*Read as*
M/s. Farmson Pharmaceuticals Guj. Pvt. Ltd., (Unit-II), Plot No. 14, G.I.D.C Industrial Estate Nandesari, City: Nandesari- 391340, Dist: Vadodara, Gujarat, India	**M/s. Farmson Basic Drugs Pvt. Ltd., (Unit-II), Plot No.14,G.I.D.C Industrial Estate Nandesari, Dist: Vadodara-391340**

All other conditions of Written Confirmation Certificate will remain same.

Chandrashekar

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 ★ Ministry of Health & Family Welfare, Govt. of India ★ सत्यमेव जयते

07 NOV 2024

7-5/2013/EU/WC-0262
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated:
21 MAR 2023

To

M/s Farmson Pharmaceuticals Guj. Pvt Ltd. (UNIT-II),
Plot No 14, GIDC Industrial Estate, Nandesari,
City-Nandesari-391340, Dist- Vadodara, Gujarat, India

Sub: Written Confirmation M/s Farmson Pharmaceuticals Guj. Pvt Ltd. (UNIT-II), Plot No 14 , GIDC Industrial Estate, Nandesari, City-Nandesari-391340, Dist-Vadodara, Gujarat, 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/2023/6300 submitted to CDSCO, Ahemdabad Zone office and the recommendation received from DDC (I), Ahemdabad 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 event 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.

Yours faithfully,

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

WC- 0242

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

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 Farmson Pharmaceuticals Guj. Pvt Ltd. (UNIT-II), Plot No 14, GIDC Industrial Estate, Nandesari, City-Nandesari-391340, Dist- Vadodara, Gujarat, India

2. Manufacturer's licence number: G/25/1974

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):

Sr. No.	Active substance (s)	Activity(ies)
1	Paracetamol (BP/Ph. Eur.)	Manufacturing & Packing

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: 21.12.2022 & 22.12.2022

The Written Confirmation remains valid until: 05.02.2026

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

21 MAR 2023

Rajeev Singh
Signature

Stamp of the authority and date

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