

7-5/2013/EU/WC-0082
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

To

17 JUN 2022

**M/s Alembic Pharmaceuticals Limited, API Division
Karakhadi, Plot No. 842-843, At – Karakhdi,
Tal. – Padra, Dist – Vadodara, Gujarat**

SUB:- Written Confirmation of M/s Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No. 842-843, At – Karakhdi, Tal. – Padra, Dist – Vadodara 391 450, Gujarat 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/2022/3220 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

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
01	55	17 JUN 2022	02.07.2025
02	26	17 JUN 2022	02.07.2025

Yours faithfully,



(Dr. V. G. Somani)
Drugs Controller General (India)



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 Alembic Pharmaceuticals Limited
API Division, Karakhadi
Plot No. 842-843, At – Karakhdi, Tal. – Padra,
Dist – Vadodara 391 450, Gujarat

2. Manufacturer's licence number: G/25/1826 & G/28/1283

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 & Annexure 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.

Date of Inspection of the plant: 12.07.2021 & 13.07.2021

The Written Confirmation remains valid until: 02.07.2025

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:

Telephone no.:

Fax no.:

dcic@nic.in,

+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date



17 JUN 2022



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 Alembic Pharmaceuticals Limited, API Division
Karakhadi, Plot No. 842-843, At – Karakhdi,
Tal. – Padra, Dist – Vadodara, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Afatinib Dimaleate IH	Manufacturing & Packing
2.	Agomelatine IH	Manufacturing & Packing
3.	Apixaban	Manufacturing & Packing
4.	Aripiprazole Ph. Eur.	Manufacturing & Packing
5.	Asenapine Maleate IH	Manufacturing & Packing
6.	Axitinib IH	Manufacturing & Packing
7.	Azilsartan Medoxomil Monopotassium IH	Manufacturing & Packing
8.	Bosentan	Manufacturing & Packing
9.	Canagliflozin IH	Manufacturing & Packing
10.	Dabigatran Etxilate Mesylate IH	Manufacturing & Packing
11.	Dapagliflozin IH	Manufacturing & Packing
12.	Darifenacin Hydrobromide	Manufacturing & Packing
13.	Dasatinib IH	Manufacturing & Packing
14.	Deferasirox	Manufacturing & Packing
15.	Deferasirox Ph.Eur.	Manufacturing & Packing
16.	Donepezil Hydrochloride	Manufacturing & Packing
17.	Dronedaron Hydrochloride U.S.P.	Manufacturing & Packing
18.	Duloxetine Hydrochloride Ph.Eur	Manufacturing & Packing
19.	Empagliflozin IH	Manufacturing & Packing
20.	Erlotinib Hydrochloride IH	Manufacturing & Packing
21.	Etoricoxib IH	Manufacturing & Packing
22.	Febuxostat	Manufacturing & Packing
23.	Felodipine Ph.Eur	Manufacturing & Packing
24.	Fenofibrate PH. Eur.	Manufacturing & Packing
25.	Gefitinib Ph. Eur	Manufacturing & Packing
26.	Ibrutinib IH	Manufacturing & Packing
27.	Iloperidone	Manufacturing & Packing
28.	Lacosamide Ph. Eur.	Manufacturing & Packing
29.	Lenalidomide IH	Manufacturing & Packing
30.	Linagliptin IH	Manufacturing & Packing



17 JUN 2022



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

31.	Solifenacin Succinate Ph.Eur.	Manufacturing & Packing
32.	Modafinil Ph.Eur	Manufacturing & Packing
33.	Pirfenidone IH	Manufacturing & Packing
34.	Pirfenidone Ph. Eur.	Manufacturing & Packing
35.	Pramipexole Dihydrochloride Monohydrate EP	Manufacturing & Packing
36.	Prasugrel IH	Manufacturing & Packing
37.	Prasugrel Hydrochloride	Manufacturing & Packing
38.	Prasugrel Hydrochloride EP	Manufacturing & Packing
39.	Pregabalin Ph.Eur	Manufacturing & Packing
40.	Rivaroxaban	Manufacturing & Packing
41.	Rivaroxaban Ph. Eur.	Manufacturing & Packing
42.	Ropinirole Hydrochloride USP	Manufacturing & Packing
43.	Sofosbuvir IH	Manufacturing & Packing
44.	Solifenacin Succinate IH	Manufacturing & Packing
45.	Sorafenib Tosylate IH	Manufacturing & Packing
46.	Tadalafil Ph. Eur.	Manufacturing & Packing
47.	Telmisartan Ph. Eur.	Manufacturing & Packing
48.	Ticagrelor IH	Manufacturing & Packing
49.	Ticagrelor Ph. Eur.	Manufacturing & Packing
50.	Venlafaxine Hydrochloride Ph. Eur.	Manufacturing & Packing
51.	Vilazodone Hydrochloride IH	Manufacturing & Packing
52.	Vildagliptin IH	Manufacturing & Packing
53.	Warfarin Sodium Ph. Eur	Manufacturing & Packing
54.	Zolmitriptan	Manufacturing & Packing
55.	Zolmitriptan Ph. Eur.	Manufacturing & Packing

ITEM(S) FIFTY FIVE (55) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date



Page 2 of 2

7 JUN 2022



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 Alembic Pharmaceuticals Limited, API Division
Karakhadi, Plot No. 842-843, At – Karakhdi,
Tal. – Padra, Dist – Vadodara, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alogliptin Benzoate	Manufacturing & Packing
2.	Vortioxetine Hydrobromide	Manufacturing & Packing
3.	Warfarin Sodium Clathrate Ph. Eur.	Manufacturing & Packing
4.	Vardenafil Hydrochloride Trihydrate EP	Manufacturing & Packing
5.	Tenofovir Alafenamide Hemifumarate IH	Manufacturing & Packing
6.	Sacubitril Valsartan Trisodium Hemipentahydrate IH	Manufacturing & Packing
7.	Selexipag IH	Manufacturing & Packing
8.	Ribociclib Succinate IH	Manufacturing & Packing
9.	Riociguat IH	Manufacturing & Packing
10.	Nisoldipine	Manufacturing & Packing
11.	Obeticholic Acid IH	Manufacturing & Packing
12.	Olaparib IH	Manufacturing & Packing
13.	Osimertinib Mesylate IH	Manufacturing & Packing
14.	Palbociclib IH	Manufacturing & Packing
15.	Minodronic Acid Hydrate IH	Manufacturing & Packing
16.	Lurasidone Hydrochloride	Manufacturing & Packing
17.	Macitentan IH	Manufacturing & Packing
18.	Ivacaftor IH	Manufacturing & Packing
19.	Fingolimod Hydrochloride IH	Manufacturing & Packing
20.	Fingolimod Hydrochloride Ph. Eur.	Manufacturing & Packing
21.	Fesoterodine Fumarate	Manufacturing & Packing
22.	Elvitegravir IH	Manufacturing & Packing
23.	Bosutinib	Manufacturing & Packing
24.	Brexipiprazole IH	Manufacturing & Packing
25.	Bazedoxifene Acetate IH	Manufacturing & Packing
26.	Apremilast IH	Manufacturing & Packing

ITEM(S) Twenty Six (26) 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: 02.07.2025

Signature

Stamp of the authority and date



17 JUN 2022

7-5/2013/EU/WC-0082
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.

Dated:

To

**M/s Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No 842-843, At –Karakhdi,
Tal - Padra, Dist - Vadodara, Gujarat, India**

15 JUL 2022

Subject :- Written Confirmation M/s Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No 842-843, At –Karakhdi, Tal - Padra, 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/RE/2022/4639 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.

Annexure No	No. of Products	Date of Issue	Validity
01	55	17.06.2022	02.07.2025
02	26	17.06.2022	02.07.2025
03	04	15 JUL 2022	02.07.2025

Yours faithfully,



(Dr. V.G. Somani)
Drugs Controller General (India)



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 Alembic Pharmaceuticals Limited, API Division
Karakhadi, Plot No 842-843, At -Karakhdi,
Tal-Padra, Dist-Vadodara, Gujarat, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Donepezil Hydrochloride Monohydrate Ph.Eur.	Manufacturing & Packing
2.	Fluphenazine Dihydrochloride Ph. Eur.	Manufacturing & Packing
3.	Mexiletine Hydrochloride Ph.Eur.	Manufacturing & Packing
4.	Theophylline Ph. Eur.	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

The Written Confirmation remains valid until: 02.07.2025

Signature

Stamp of the authority and date



15 JUL 2022

7-5/2013/EU/WC-0082
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. Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No. 842-843, At-Karakhadi,
Tal-Padra, Dist – Vadodara, Gujarat, India**

SUB:- Written Confirmation M/s. Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No. 842-843, At-Karakhadi, Tal-Padra, 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/2023/7284 dated 26-JUN-2023 submitted to CDSCO, DDC(I), Ahmedabad Zone, and the recommendation received from DDC(I), Ahmedabad 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.

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
01	55	17.06.2022	02.07.2025
02	26	17.06.2022	02.07.2025
03	04	15.07.2022	02.07.2025
04	10	8 SEP 2023	02.07.2025

Yours faithfully,


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



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

Annexure-04

CERTIFICATE NO. :

WC-0082

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. Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No. 842-843, At-
Karakhadi, Tal-Padra, Dist – Vadodara, Gujarat,
India

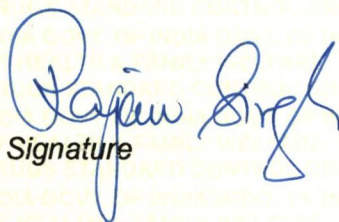
List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Sorafenib Tosilate Ph.Eur	Manufacturing & Packing
2.	Clofarabine IHS	Manufacturing & Packing
3.	Plerixafor IHS	Manufacturing & Packing
4.	Dexlansoprazole IHS	Manufacturing & Packing
5.	Apalutamide IHS	Manufacturing & Packing
6.	Silodosin IHS	Manufacturing & Packing
7.	Venetoclax IHS	Manufacturing & Packing
8.	Tegaserod Maleate IHS	Manufacturing & Packing
9.	Chlordiazepoxide Hydrochloride Ph.Eur	Manufacturing & Packing
10.	Methotrexate Sodium IHS	Manufacturing & Packing

ITEM(S) TEN (10) ONLY

The Written Confirmation remains valid until: 02.07.2025

18 SEP 2023


Signature

Stamp of the authority and date



7-5/2013/EU/WC-0082
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated **29 JAN 2025**

To

**M/s. Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No. 842-843,
At -Karakhadi, Tal -Padra,
Dist.-Vadodara -391450, Gujarat, India**

SUB:- Written Confirmation of **M/s. Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No. 842-843, At -Karakhadi, Tal -Padra, Dist.-Vadodara -391450, 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/2024/8170 submitted to CDSCO, Ahmedabad Zone Office, and the recommendation received from DDC(I), CDSCO, Ahmedabad 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.
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
--	--	17.06.2022	02.07.2025
01	55	17.06.2022	02.07.2025
02	26	17.06.2022	02.07.2025
03	04	15.07.2022	02.07.2025
04	10	18.09.2023	02.07.2025
05	01	29 JAN 2025	02.07.2025

Yours faithfully,

Chandrashekar
27/1/25

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.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



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. Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No. 842-843,
At -Karakhadi, Tal -Padra,
Dist.-Vadodara -391450, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Teriparatide IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 02.07.2025

Chandrashekar

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि पत्रक निबंधन 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
कडवा रोड, कोटा रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date



29 JAN 2025

7-5/2013/EU/WC-0082

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

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated **25 FEB 2025**

To

**M/s. Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No. 842-843,
At -Karakhadi, Tal -Padra,
Dist.-Vadodara -391450, Gujarat, India**

SUB:- Written Confirmation of **M/s. Alembic Pharmaceuticals Limited, API Division, Karakhadi, Plot No. 842-843, At -Karakhadi, Tal -Padra, Dist.-Vadodara -391450, 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/2024/9570 submitted to CDSCO, Ahmedabad Zone Office, and the recommendation received from DDC(I), CDSCO, Ahmedabad 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.
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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
--	--	17.06.2022	02.07.2025
01	55	17.06.2022	02.07.2025
02	26	17.06.2022	02.07.2025
03	04	15.07.2022	02.07.2025
04	10	18.09.2023	02.07.2025
05	01	29.01.2025	02.07.2025
06	01	25 FEB 2025	02.07.2025

Yours faithfully,

Chandrashekar Ranga
25/02/25

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत)

केन्द्रीय औषधि प्राधिकरण, नई दिल्ली

C.D.S.C. (India), Dir. General of Health

स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare

एन.टी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / PDA Bhawan, Kotha Road, New Delhi-110002



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. Alembic Pharmaceuticals Limited,
API Division, Karakhadi, Plot No. 842-843,
At -Karakhadi, Tal -Padra,
Dist.-Vadodara -391450, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Ruxolitinib Hemifumarate IH	Manufacturing & Packing

ITEM(S) ONE (01) 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: 02.07.2025

Signature

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

Stamp of the authority and date



25 FEB 2025