

**7-5/2013/EU/WC-0023**  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(International Cell)

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated:

11 JUL 2025

To,

**M/s. Apitoria Pharma Private Limited (Unit-IV)**  
**Sy. No's. 52,53,58,59,61 to 78, 127 & 128,**  
**Pydibhimavaram Village & Sy. No's. 1,2,4 to 9,11,29,30,31 & 32,**  
**Chittivalasa Village, Ranasthalam Mandal, Srikakulam District,**  
**Andhra Pradesh, India, PIN: 532409**

**SUB: - Written Confirmation of M/s. Apitoria Pharma Private Limited (Unit-IV), Sy. No's. 52,53,58,59,61 to 78, 127 & 128, Pydibhimavaram Village & Sy. No's. 1,2,4 to 9,11,29,30,31 & 32, Chittivalasa Village, Ranasthalam Mandal, Srikakulam District, Andhra Pradesh, India, PIN: 532409, 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/2025/10517** submitted to CDSCO, ADC(I), Vishakhapatnam Sub-Zone, and the recommendation received from ADC(I), Vishakhapatnam 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 conform 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 to the provision 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 Up to
--	--	1 1 JUL 2025	25.06.2028
01	27	1 1 JUL 2025	25.06.2028
02	27	1 1 JUL 2025	25.06.2028
03	25	1 1 JUL 2025	25.06.2028
04	10	1 1 JUL 2025	25.06.2028

Yours faithfully,

*Chandrashekar*  
11/07/25

(Ranga Chandrashekar)  
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga  
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय 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  
केन्द्रीय औषधि मानक नियंत्रण संगठन, 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. Apitoria Pharma Private Limited (Unit-IV)  
Sy. No's. 52,53,58,59,61 to 78, 127 & 128,  
Pydibhimavaram Village & Sy. No's. 1,2,4 to 9,11,29,30,31  
& 32, Chittivalasa Village, Ranasthalam Mandal,  
Srikakulam District, Andhra Pradesh, India, PIN: 532409

2. Manufacturer's licence number: 32/SK/AP/2003/B/CC

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):

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: 15.05.2025 & 16.05.2025

The Written Confirmation remains valid until: 25.06.2028

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: Ranga Chandrashekar,  
Joint Drugs Controller (India)

E-mail: [ranga.cs@cdsco.nic.in](mailto:ranga.cs@cdsco.nic.in);

Telephone no.: +91-11-23236965

Fax no.: +91-11-23236973

  
चंद्रशेखर रंगा/Chandrashekar Ranga  
11/07/25

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
औषधि आयोग प्रमुख 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  
एफ.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date





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. Apitoria Pharma Private Limited (Unit-IV)  
Sy. No's. 52,53,58,59,61 to 78, 127 & 128,  
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& 32, Chittivalasa Village, Ranasthalam Mandal,  
Srikakulam District, Andhra Pradesh, India, PIN: 532409

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir Sulfate Ph.Eur.	Manufacturing & Packing
2.	Alendronate Sodium Ph.Eur.	Manufacturing & Packing
3.	Amoxicillin Trihydrate Ph.Eur.	Manufacturing & Packing
4.	Ampicillin Ph.Eur.	Manufacturing & Packing
5.	Ampicillin Trihydrate Ph.Eur.	Manufacturing & Packing
6.	Apremilast IH	Manufacturing & Packing
7.	Atomoxetine Hydrochloride Ph.Eur.	Manufacturing & Packing
8.	Bilastine IH	Manufacturing & Packing
9.	Carbimazole Ph.Eur.	Manufacturing & Packing
10.	Cariprazine Hydrochloride IH	Manufacturing & Packing
11.	Cefadroxil Monohydrate Ph.Eur.	Manufacturing & Packing
12.	Cefalexin Monohydrate Ph.Eur.	Manufacturing & Packing
13.	Cefixime Ph.Eur.	Manufacturing & Packing
14.	Celecoxib Ph.Eur.	Manufacturing & Packing
15.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
16.	Clindamycin Palmitate Hydrochloride IH	Manufacturing & Packing
17.	Cloxacillin Sodium Ph.Eur.	Manufacturing & Packing
18.	Dabigatran Etexilate Mesylate IH	Manufacturing & Packing
19.	Darifenacin Hydrobromide IH	Manufacturing & Packing
20.	Dicloxacillin Sodium Ph.Eur.	Manufacturing & Packing
21.	Didanosine Ph.Eur.	Manufacturing & Packing
22.	Dimethyl Fumarate IH	Manufacturing & Packing
23.	Dolutegravir Sodium IH	Manufacturing & Packing
24.	Dronedarone Hydrochloride Ph.Eur.	Manufacturing & Packing
25.	Duloxetine Hydrochloride Ph.Eur.	Manufacturing & Packing
26.	Emtricitabine IH	Manufacturing & Packing
27.	Esomeprazole Sodium Ph.Eur.	Manufacturing & Packing

ITEM(S) TWENTY-SEVEN (27) ONLY

The Written Confirmation remains valid until: 25.06.2028

  
Signature  
चंद्रशेखर रंगा/Chandrashekar Ranga  
11/07/25  
केन्द्रीय औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय औषधि मानक नियंत्रण संगठन (मुम्बई), स्वास्थ्य सेवा महानिदेशक  
C.D.S.C.(HQ), Dte. General of Health Services  
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare  
एन.ए. रोड, दिल्ली-110002

  
Stamp of the authority and date  
11 JUL 2025



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. Apitoria Pharma Private Limited (Unit-IV)  
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Pydibhimavaram Village & Sy. No's. 1,2,4 to 9,11,29,30,31  
& 32, Chittivalasa Village, Ranastharam Mandal,  
Srikakulam District, Andhra Pradesh, India, PIN: 532409

List of API(s):

S. No.	Active substance(s)	Activity(ies)
28.	Esomeprazole Magnesium Dihydrate Ph.Eur.	Manufacturing & Packing
29.	Esomeprazole Magnesium Trihydrate IH	Manufacturing & Packing
30.	Ezetimibe IH	Manufacturing & Packing
31.	Felodipine Ph.Eur.	Manufacturing & Packing
32.	Hydralazine Hydrochloride Ph.Eur.	Manufacturing & Packing
33.	Lacosamide Ph.Eur.	Manufacturing & Packing
34.	Lamivudine Crystalline Polymorph Form II Ph.Eur.	Manufacturing & Packing
35.	Lamotrigine Ph.Eur.	Manufacturing & Packing
36.	Levetiracetam Ph.Eur.	Manufacturing & Packing
37.	Linagliptin IH	Manufacturing & Packing
38.	Lopinavir Ph.Eur.	Manufacturing & Packing
39.	Lurasidone Hydrochloride IH	Manufacturing & Packing
40.	Macitentan IH	Manufacturing & Packing
41.	Mirabegron IH	Manufacturing & Packing
42.	Montelukast Sodium Ph.Eur.	Manufacturing & Packing
43.	Naproxen Ph.Eur.	Manufacturing & Packing
44.	Naproxen Sodium Ph.Eur.	Manufacturing & Packing
45.	Nevirapine Ph.Eur.	Manufacturing & Packing
46.	Olmesartan Medoxomil Ph.Eur.	Manufacturing & Packing
47.	Omeprazole Magnesium Ph.Eur.	Manufacturing & Packing
48.	Omeprazole Ph.Eur.	Manufacturing & Packing
49.	Pioglitazone Hydrochloride Ph.Eur.	Manufacturing & Packing
50.	Pitavastatin Calcium IH	Manufacturing & Packing
51.	Pregabalin Ph.Eur.	Manufacturing & Packing
52.	Quetiapine Fumarate Ph.Eur.	Manufacturing & Packing
53.	Raloxifene Hydrochloride Ph.Eur.	Manufacturing & Packing
54.	Ranolazine IH	

ITEM(S) TWENTY-SEVEN (27) ONLY

The Written Confirmation remains valid until: 25.06.2028

*Chandrashekar Ranga*  
Signature of Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केन्द्रीय 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  
भारत सरकार, केंद्र, बिल्डिंग 110002 / FDA Bhawan, Kofa Road, New Delhi-110002

Stamp of the authority and date





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

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Pydibhimavaram Village & Sy. No's. 1,2,4 to 9,11,29,30,31  
& 32, Chittivalasa Village, Ranasthalam Mandal,  
Srikakulam District, Andhra Pradesh, India, PIN: 532409

List of API(s):

S. No.	Active substance(s)	Activity(ies)
55.	Repaglinide Ph.Eur.	Manufacturing & Packing
56.	Risedronate Sodium Hemipentahydrate/Risedronate Sodium 2.5 Hydrate Ph.Eur.	Manufacturing & Packing
57.	Rivaroxaban Ph.Eur.	Manufacturing & Packing
58.	Rizatriptan Benzoate Ph.Eur.	Manufacturing & Packing
59.	Rosuvastatin Calcium Ph.Eur.	Manufacturing & Packing
60.	Sertraline Hydrochloride Ph.Eur.	Manufacturing & Packing
61.	Sevelamer Carbonate IH	Manufacturing & Packing
62.	Sevelamer Hydrochloride IH	Manufacturing & Packing
63.	Saxagliptin Monohydrate IH	Manufacturing & Packing
64.	Sildenafil Citrate Ph.Eur.	Manufacturing & Packing
65.	Sildenafil IH	Manufacturing & Packing
66.	Sitagliptin Phosphate IH	Manufacturing & Packing
67.	Solifenacin Succinate Ph.Eur.	Manufacturing & Packing
68.	Sultamicillin Tosylate Dihydrate Ph.Eur.	Manufacturing & Packing
69.	Tenofovir Alafenamide Fumarate IH	Manufacturing & Packing
70.	Tenofovir Disoproxil Fumarate IH	Manufacturing & Packing
71.	Teriflunomide Ph.Eur.	Manufacturing & Packing
72.	Tramadol Hydrochloride Ph.Eur.	Manufacturing & Packing
73.	Valacyclovir Hydrochloride Hydrate Ph.Eur.	Manufacturing & Packing
74.	Valganciclovir Hydrochloride IH	Manufacturing & Packing
75.	Valsartan Ph.Eur.	Manufacturing & Packing
76.	Voriconazole Ph.Eur.	Manufacturing & Packing
77.	Zidovudine Ph.Eur.	Manufacturing & Packing
78.	Ziprasidone Hydrochloride Monohydrate Ph.Eur.	Manufacturing & Packing
79.	Zolmitriptan Ph.Eur.	Manufacturing & Packing

ITEM(S) TWENTY-FIVE (25) ONLY

The Written Confirmation remains valid until: 25.06.2028

*Chandrashekar*  
Signature of Chandrashekar Ranga

संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)  
केंद्रीय 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  
एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date  
11 JUL 2025



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& 32, Chittivalasa Village, Ranasthalam Mandal,  
Srikakulam District, Andhra Pradesh, India, PIN: 532409

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Brivudine IH	Manufacturing & Packing
2.	Docosanol IH	Manufacturing & Packing
3.	Darunavir Propylene Glycolate IH	Manufacturing & Packing
4.	Fampridine IH	Manufacturing & Packing
5.	Galantamine Hydrobromide Ph.Eur.	Manufacturing & Packing
6.	Lumacaftor IH	Manufacturing & Packing
7.	Methenamine Hippurate IH	Manufacturing & Packing
8.	Nirmatrelvir IH	Manufacturing & Packing
9.	Safinamide Mesylate IH	Manufacturing & Packing
10.	Sitagliptin Hydrochloride Monohydrate IH	Manufacturing & Packing

ITEM(S) Ten (10) 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: 25.06.2028

*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

