AMENDED

7-5/2019/EU/WC-0460
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To

M/s. Aparna Pharmaceuticals Pvt. Ltd.,
Sy. No. 78, 79, 80 & 145, Chittivalasa Village,
Padibhimavaram (Panchayat), Ranastalam (M),
Srikakulam District, Andhra Pradesh, India

SUB:- Written Confirmation of **M/s. Aparna Pharmaceuticals Pvt. Ltd., Sy. No. 78, 79, 80 & 145, Chittivalasa Village, Padibhimavaram (Panchayat), Ranastalam (M), Srikakulam District, Andhra Pradesh, 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 application submitted vide email dated 05-10-2024, wherein you had requested for change of company name in the WC valid upto 21.03.2027.

In this regard, your application has been reviewed and considered. Accordingly, amended Written Confirmation Certificate is enclosed.

Please acknowledge the receipt

Yours faithfully,

Chandrashekar
20/12/24

(Sh. Ranga Chandrashekhar)
Joint Drugs Controller (India)

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

AMENDED
WC-0460

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. Aparna Pharmaceuticals Pvt. Ltd., Sy. No. 78, 79, 80 & 145, Chittivalasa Village, Padibhimavaram (Panchayat), Ranastalam (M), Srikakulam District, Andhra Pradesh, India**

The name of the firm mentioned in the Written Confirmation Certificate, WC-0460 along with annexures issued on 21.03.2024, 03.10.2024 and 04.10.2024, which are valid up to 21.03.2027 is hereby amended as follows:

In place of	*Read as*
M/s. Aparna Organics Limited Sy. No. 78, 79, 80 & 145, Chittivalasa Village, Padibhimavaram (Panchayat), Ranastalam (M), Srikakulam District, Andhra Pradesh, India	**M/s. Aparna Pharmaceuticals Pvt. Ltd., Sy. No. 78, 79, 80 & 145, Chittivalasa Village, Padibhimavaram (Panchayat), Ranastalam (M), Srikakulam District, Andhra Pradesh, India**

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

20 DEC 2024

7-5/2019/EU/WC-0460
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

21 MAR 2024

To

M/s.Aparna Organics Limited,
Sy.No.78,79,80 & 145, Chittivalasa Village,
Pydibhimavaram (Panchayat),
Ranastalam Mandal, Srikakulam District-532 409,
Andhra Pradesh, India

SUB:-Written Confirmation ofM/s.Aparna Organics Limited,Sy.No.78,79,80 & 145, Chittivalasa Village,Pydibhimavaram (Panchayat), Ranastalam Mandal, Srikakulam District-532 409, Andhra Pradesh, Indiaas 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/2023/6620** dated 23.02.2023 submitted to CDSCO, Hyderabad Zone office, and the recommendation received from DDC(I), HyderabadZone 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
--	--	21 MAR 2024	Three years from the date of issue
01	01	21 MAR 2024	Three years 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-0460

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. Aparna Organics Limited,**
Sy.No.78, 79, 80 & 145, Chittivalasa Village,
Pydibhimavaram (Panchayat),
Ranastalam Mandal, Srikakulam District-532 409,
Andhra Pradesh, India.

2. Manufacturer's licence number: 43/SK/AP/2010/B/R

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 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: 11.10.2022 & 12.10.2022

The Written Confirmation remains valid until: **Three years 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

21 MAR 2024

Signature

Stamp of the authority and date

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

Annexure-1
WC-0460

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. Aparna Organics Limited,**
Sy.No.78,79,80 & 145, Chittivalasa Village,
Pydibhimavaram (Panchayat),
Ranastalam Mandal, Srikakulam District-532 409,
Andhra Pradesh, India.

List of API(s):

S.No.	Active Substance(s)	Activity(ies)
1	Nitroxoline IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to the 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 years from Date of Issue

Signature

21 MAR 2024

Stamp of the authority and date

7-5/2019/EU/WC-0460

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 03 OCT 2024

To,

M/s. Aparna Organics Limited.,
Sy No. 78, 79, 80 & 145,
Chittivalasa village, Padibhimavaram (Panchayat),
Ranastalam (M), Srikakulam district, Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Aparna Organics Limited., Sy No. 78, 79, 80 & 145, Chittivalasa village, Padibhimavaram (Panchayat), Ranastalam (M), Srikakulam district, Andhra Pradesh, 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/2023/7688 dated 06-NOV-2023 submitted to CDSCO, DDC(I), Hyderabad Zone, and the recommendation received from DDC(I), Hyderabad 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 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 Upto
--	--	21.03.2024	21.03.2027
01	01	21.03.2024	21.03.2027
02	01	03 OCT 2024	21.03.2027

Yours faithfully,

Chandrashekar
03/10/24

(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

Annexure-02

CERTIFICATE NO. : **WC-0460**

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. Aparna Organics Limited.,**
Sy No. 78, 79, 80 & 145,
Chittivalasa village, Padibhimavaram (Panchayat),
Ranastalam (M), Srikakulam district, Andhra Pradesh, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Vildagliptin IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 21.03.2027

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
Health & Family Welfare, Govt. of India

03 OCT 2024

7-5/2019/EU/WC-0460
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 04 OCT 2024

To

M/s. Aparna Organics Limited,
Sy.No.78,79,80 & 145, Chittivalasa Village,
Pydibhimavaram (Panchayat), Ranastalam Mandal,
Srikakulam District-532 409, Andhra Pradesh, India

SUB:-Written Confirmation of M/s. Aparna Organics Limited, Sy.No.78,79,80 & 145, Chittivalasa Village, Pydibhimavaram (Panchayat), Ranastalam Mandal, Srikakulam District-532 409, Andhra Pradesh, 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/2023/6717, dated 16.03.2023 submitted to CDSCO, Sub-Zone Visakhapatnam office, and the recommendation received from ADC (I), CDSCO, Sub-Zone Visakhapatnam 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
--	--	21.03.2024	21.03.2027
01	01	21.03.2024	21.03.2027
02	01	03.10.2024	21.03.2027
03	04	04 OCT 2024	21.03.2027

Yours faithfully,

04/10/24

(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

CERTIFICATE NO. : **Annexure-03**
WC-0460

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.Aparna Organics Limited,**
Sy.No.78,79,80 & 145, Chittivalasa Village,
Pydibhimavaram (Panchayat),
Ranastalam Mandal, Srikakulam District-532 409,
Andhra Pradesh, India.

List of API(s):

S.No.	Active Substance(s)	Activity(ies)
01	Clopidogrel Bisulphate USP	Manufacturing & Packing
02	Clopidogrel Hydrogen Sulfate Ph. Eur.	Manufacturing & Packing
03	Memantine Hydrochloride USP	Manufacturing & Packing
04	Telmisartan USP/Ph. Eur.	Manufacturing & Packing

ITEM(S) Four (04) ONLY

The Written confirmation remains valid until: 21.03.2027

Chandrasekhar

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

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

Stamp of the authority and date

04 OCT 2024