AMENDED

7-5/2013/EU/WC-0092

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 18 FEB 2025

To

M/s. Jubilant Pharmova Limited
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud, 571 302, Dist: Mysore, Karnataka

SUB: - Amendment in the Written Confirmation certificate of **M/s. Jubilant Pharmova Limited, Plot No. 18, 56, 57, 58, KIADB Industrial Area Nanjangud, 571 302, Dist: Mysore, Karnataka** 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 email dated 17.02.2025, wherein, you have requested this office for the amendments in WC-0092 issued on dated 14.02.2025.

In this regard, please find the enclosed amended certificate.

Yours faithfully,

18/02/25

(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.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-0092

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. Jubilant Pharmova Limited**
Plot No. 18, 56, 57, 58, K.I.A.D.B. Industrial Area
Nanjangud, 571 302, Dist: Mysore, Karnataka

The written confirmation certificates of M/s. Jubilant Pharmova Limited, is hereby amended as follows:

List of APIs:

Certificate Name	In place of	Read as
Sr. no. 2 of the main certificate	KTK/25/489/2003	**KTK/25/489/2003 & KTK/28/335/2003**
Annexure-02	M/s. Jubilant Generics Limited	**M/s. Jubilant Pharmova Limited**

All other conditions of Written Confirmation Certificate will remain same.

The Written Confirmation remains valid until: 04.11.2027

Chandrashekar 18/02/25

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

18 FEB 2025

7-5/2013/EU/WC-0092
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 14 FEB 2025

To

M/s. Jubilant Pharmova Limited
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud, 571 302, Dist: Mysore, Karnataka

SUB:- Written Confirmation of **M/s. Jubilant Pharmova Limited, Plot No. 18, 56, 57, 58, KIADB Industrial Area Nanjangud, 571 302, Dist: Mysore, Karnataka** 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 application no. WC/RE/2024/9127 submitted to CDSCO, Bangalore Sub-Zone office, and the recommendation received from DDC (I), Bangalore 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 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
--	--	14 FEB 2025	**04.11.2027**
01	27	14 FEB 2025	**04.11.2027**
02	01	14 FEB 2025	**04.11.2027**

Yours faithfully,

Chandrashekar 14/02/25

(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.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. : **WC-0092**

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. Jubilant Pharmova Limited**
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud, 571 302, Dist: Mysore, Karnataka

2. Manufacturer's licence number: **KTK/25/489/2003**

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: 02.12.2024 & 03.12.2024

The Written Confirmation remains valid until: **04.11.2027**

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;***
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

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

14 FEB 2025

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

CERTIFICATE NO. :

Annexure -01
WC-0092

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. Jubilant Pharmova Limited**
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud, 571 302, Dist: Mysore, Karnataka

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Aprepitant Ph. Eur.	Manufacturing & Packing
2.	Aripiprazole Ph. Eur.	Manufacturing & Packing
3.	Azithromycin Dihydrate Ph. Eur.	Manufacturing & Packing
4.	Azithromycin Monohydrate Ph.Eur.	Manufacturing & Packing
5.	Carbamazepine Ph. Eur./USP/BP	Manufacturing & Packing
6.	Cetirizine Dihydrochloride USP	Manufacturing & Packing
7.	Citalopram Hydrobromide Ph. Eur.	Manufacturing & Packing
8.	Escitalopram Oxalate USP	Manufacturing & Packing
9.	Eslicarbazepine Acetate IH	Manufacturing & Packing
10.	Esomeprazole Magnesium Ph. Eur./USP	Manufacturing & Packing
11.	Esomeprazole Magnesium Trihydrate Ph. Eur.	Manufacturing & Packing
12.	Esomeprazole Sodium IH	Manufacturing & Packing
13.	Irbesartan Ph.Eur.	Manufacturing & Packing
14.	Lamotrigine Ph. Eur.	Manufacturing & Packing
15.	Losartan Potassium Ph.Eur.	Manufacturing & Packing
16.	Olmesartan Medoxomil IH	Manufacturing & Packing
17.	Oxcarbazepine IH/Ph. Eur.	Manufacturing & Packing
18.	Pantoprazole Sodium Ph. Eur.	Manufacturing & Packing
19.	Pinaverium Bromide IH	Manufacturing & Packing
20.	Quetiapine Fumarate IH	Manufacturing & Packing
21.	Risperidone Ph. Eur.	Manufacturing & Packing
22.	Sitagliptin Phosphate USP	Manufacturing & Packing
23.	Tadalafil Ph. Eur.	Manufacturing & Packing
24.	Tramadol Hydrochloride Ph. Eur	Manufacturing & Packing
25.	Valsartan Ph.Eur.	Manufacturing & Packing
26.	Zoledronic acid IH	Manufacturing & Packing
27.	Zolmitriptan IH	Manufacturing & Packing

ITEM(S) TWENTY SEVEN (27) ONLY

The Written Confirmation remains valid until: 04.11.2027

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

14 FEB 2025

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

Annexure -02

CERTIFICATE NO. : WC-0092

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. Jubilant Generics Limited
Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area
Nanjangud – 571302, Mysore District, Karnataka

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Meclizine Hydrochloride Ph. Eur.	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: 04.11.2027

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

14 FEB 2025

7-5/2013/EU/WC-0092

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 24 APR 2025

To

M/s. Jubilant Pharmova Limited
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud-571302, Dist: Mysore, Karnataka

SUB:- Written Confirmation of **M/s. Jubilant Pharmova Limited, Plot No. 18, 56, 57, 58, KIADB Industrial Area Nanjangud-571302, Dist: Mysore, Karnataka** 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 application no. WC/FR/2025/9972 dated 19-FEB-2025 submitted to CDSCO, Bangalore Zone office, and the recommendation received from DDC (I), Bangalore 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.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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
--	--	14.02.2025	**04.11.2027**
01	27	14.02.2025	**04.11.2027**
02	01	14.02.2025	**04.11.2027**
Amendment	--	18.02.2025	**04.11.2027**
03	07	24 APR 2025	**04.11.2027**

Yours faithfully,

(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 -03
WC-0092

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. Jubilant Pharmova Limited**
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud-571302, Dist: Mysore, Karnataka

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Donepezil Hydrochloride IH	Manufacturing & Packing
2.	Escitalopram Oxalate Ph.Eur.	Manufacturing & Packing
3.	Olanzapine Ph.Eur.	Manufacturing & Packing
4.	Oxcarbazepine USP	Manufacturing & Packing
5.	Quetiapine Fumarate Ph.Eur.	Manufacturing & Packing
6.	Tramadol Hydrochloride USP	Manufacturing & Packing
7.	Zoledronic Acid Monohydrate Ph.Eur.	Manufacturing & Packing

ITEM(S) SEVEN (07) ONLY

The Written Confirmation remains valid until: 04.11.2027

Chandrashekar

Signature

24/04/25

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

24 APR 2025

7-5/2013/EU/WC-0092

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 29 MAY 2025

To

M/s. Jubilant Pharmova Limited
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud-571302, Dist: Mysore, Karnataka

SUB:- Written Confirmation of **M/s. Jubilant Pharmova Limited, Plot No. 18, 56, 57, 58, KIADB Industrial Area Nanjangud-571302, Dist: Mysore, Karnataka** 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 application no. WC/FR/2025/10063 dated 03-MAR-2025 submitted to CDSCO, Bangalore Zone office, and the recommendation received from DDC (I), Bangalore 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.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under Unapproved/Banned/ New drug in India.

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
--	--	14.02.2025	**04.11.2027**
01	27	14.02.2025	**04.11.2027**
02	01	14.02.2025	**04.11.2027**
Amendment	--	18.02.2025	**04.11.2027**
03	07	24.04.2025	**04.11.2027**
04	01	29 MAY 2025	**04.11.2027**

Yours faithfully,

29/05/25

(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.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 -04
WC-0092

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. Jubilant Pharmova Limited**
Plot No. 18, 56, 57, 58, KIADB Industrial Area
Nanjangud-571302, Dist: Mysore, Karnataka

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Dalfampridine IH	Manufacturing & Packing

ITEM(S) SEVEN (07) ONLY

The Written Confirmation remains valid until: 04.11.2027

Chandrashekar 29/05/25

Signature
चंद्रशेखर रंगा/Chandrashekar Ranga
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Stamp of the authority and date

29 MAY 2025