F. No: 7-5/2016/EU/WC-0369
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 27 MAY 2019

To,

M/s Apothecon Pharmaceuticals Pvt Ltd.,
Plot No. 1134,1135, 1136, 1137,1143B,
1144 A&B, 1138 A&B, Padra -Jambusar Highway,
Tal-Padra,Village- Dabhasa -391 440
Dist-Vadodara, Gujarat, India.

Sub:- Written Confirmation M/s. Apothecon Pharmaceuticals Pvt Ltd., Plot No.1134, 1135, 1136, 1137, 1143B, 1144 A&B, 1138A&B Padra-Jambusar Highway,Tal-Padra Village-Dabhasa -391440,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 application submitted to CDSCO, Ahmedabad Zonal 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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	Valid up to
00	02	11.07.2016	28.06.2019
01	01	03.08.2017	28.06.2019
02	02	09.08.2017	28.06.2019
03	01	29.10.2018	28.06.2019
04	09	18.03.2019	28.06.2019
05	03	27 MAY 2019	28.06.2019

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India).

Annexure – 05

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

CERTIFICATE NO. : **WC-0369**

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 Apothecon Pharmaceuticals Pvt Ltd.,**
Plot No.1134,1135,1136,1137,
1143B,1144 A&B,1138 A&B,
Padra -Jambusar Highway, Tal- Padra,
Village- Dabhasa -391440
Vadodara, Gujarat, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Ropivacaine IH	Manufacturing & Packing
2.	Fosaprepitant Dimeglumine IH	Manufacturing &Packing
3.	Bendamustine Hydrochloride Monohydrate IH	Manufacturing &Packing

ITEM(s) Three (03) Only

The Written Confirmation remains valid until: 28.06.2019.

Signature

Stamp of the authority and date

27 MAY 2019

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No.: 7-5/2013/EU/WC-0369 Dated 29 JUN 2016

To

M/s. Apothecon Pharmaceuticals Pvt. Ltd,
Plot No. 1134,1135,1136,1137, 1143B, 1144 A&B,
1138 A&B, Padara Jambusar Highway, PO- Dabhasa-391440
Tal-Padara, Dist.-Vadodara, Gujarat, India.

SUB: - Written Confirmation of M/s. Apothecon Pharmaceuticals Pvt. Ltd, Plot No. 1134,1135,1136,1137, 1143B, 1144 A&B, 1138 A&B, Padara Jambusar Highway, PO- Dabhasa-391440, Tal-Padara, 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 application 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 noncompliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

Recived orcignal Copy
Sawleak
12/7/2016
9310022412

7. In the event of any noncompliance 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. G. N Singh)
Drugs Controller General (India)

c/c Ashok ... AG. DCG

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

CERTIFICATE NO. : **WC-0369**

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. Apothecon Pharmaceuticals Pvt. Ltd,
Plot No. 1134,1135,1136,1137, 1143B, 1144 A&B,
1138 A&B, Padara Jambusar Highway, PO- Dabhas 391440
Tal-Padara, Dist.-Vadodara, Gujarat, India.

2. Manufacturer's licence number: G/25/1904 & G/28/1358 dated 03.12.2010.

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

S. No.	Active substance(s)	Activity(ies)
1	Melphalan Hydrochloride(IH)	Manufacturing & Packing
2	Nicardipine Hydrochloride (IH)	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: 20.10.2015, 21.10.2015 & 05.12.2015

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 Organization**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. G.N. Singh,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Stamp of the authority, and date

29 JUN 2016

Signature

o/c
Avinash

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No.: 7-5/2013/EU/WC-0369 Dated 03 AUG 2016

To

M/s. Apothecon Pharmaceuticals Pvt. Ltd,
Plot No. 1134,1135,1136,1137, 1143B, 1144 A&B,
1138 A&B, Padra Jambusar Highway, PO- Dabhasa-391440
Tal-Padra, Dist.-Vadodara, Gujarat, India.

SUB: - Written Confirmation of M/s. Apothecon Pharmaceuticals Pvt. Ltd, Plot No. 1134,1135,1136,1137, 1143B, 1144 A&B, 1138 A&B, Padra Jambusar Highway, PO- Dabhasa-391440, 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 application 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 noncompliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

o/c

Sourab 9310022412
3/8/2016

7. In the event of any noncompliance 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.

S.No.	Annexure no.	Issue date	Valid upto
01	01	03 AUG 2016	28.06.2019

Yours faithfully,

(Dr. G. N Singh)
Drugs Controller General (India)

o/c
Ashwani
AO. d

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

Annexure-1

CERTIFICATE NO. : WC-0369

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. Apothecon Pharmaceuticals Pvt. Ltd,
Plot No. 1134,1135,1136,1137, 1143B, 1144 A&B, 1138 A&B, Padra Jambusar Highway, PO- Dabhasa-391440Tal-Padra, Dist. Vadodara, Gujarat, India.

List of APIs:

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

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 28th June, 2019

Signature

o/c Arinesh

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health Family Welfare Government of India •

03 AUG 2016

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No.: 7-5/2013/EU/WC-0369

Dated 09 AUG 2017

To

M/s. Apothecon Pharmaceuticals Pvt. Ltd,
Plot No. 1134,1135,1136,1137, 1143 B, 1144 A & B,
1138 A & B, Padra-Jambusar Highway, Tal-Padra,
Village – Dabhasa – 391 440, Dist.-Vadodara, Gujarat, India.

SUB: - Written Confirmation of M/s. Apothecon Pharmaceuticals Pvt. Ltd, Plot No. 1134,1135,1136,1137, 1143 B, 1144 A & B, 1138 A & B, Padra Jambusar Highway, Tal-Padra, Village – Dabhasa – 391440, 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 application 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 noncompliance 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 noncompliance 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 up to
0	02	11.07.2016	28.06.2019
1	01	03.08.2017	28.06.2019
2	02	09 AUG 2017	28.06.2019

Yours faithfully,

(Dr. G. N Singh)
Drugs Controller General (India)

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

Annexure-2

CERTIFICATE NO. : WC-0369

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. Apothecon Pharmaceuticals Pvt. Ltd,
Plot No. 1134,1135,1136,1137, 1143 B, 1144 A & B,
1138 A & B, Padra-Jambusar Highway, Tal-Padra,
Village – Dabhasa – 391 440, Dist.-Vadodara, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Argatroban	Manufacturing & Packing
2.	Ropivacaine Hydrochloride	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 28th June, 2019

Signature

Stamp of the authority and date

09 AUG 2017

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

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated: 29 OCT 2018

No.: 7-5/2017/EU/WC-0369

To

M/s. Apothecon Pharmaceuticals Private Limited,
Plot No. 1134, 1135, 1136, 1137, 1143B, 1144 A & B,
1138 A & B, Padra-Jambussar Highway, Tal- Padra,
Vill.- Dabhasa- 391 440, Dist. Vadodara, Gujarat.

Sub: - Written Confirmation of M/s. Apothecon Pharmaceuticals Private Limited, Plot No. 1134, 1135, 1136, 1137, 1143B, 1144 A & B, 1138 A & B, Padra-Jambussar Highway, Tal- Padra, Vill.- Dabhasa- 391 440, Dist. Vadodara, 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 Directive2001/83/EC from India-reg.

Sir,

Please refer to your application submitted to CDSCO, 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
00	02	11.07.2016	28.06.2019
01	01	03.08.2017	28.06.2019
02	02	09.08.2017	28.06.2019
03	01	29 OCT 2018	28.06.2019

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

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

Annexure-3

CERTIFICATE NO. : WC-0369

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. Apothecon Pharmaceuticals Private Limited, Plot No. 1134, 1135, 1136, 1137, 1143B, 1144 A & B, 1138 A & B, Padra-Jambussar Highway, Tal- Padra, Vill.- Dabhasa- 391 440, Dist. Vadodara, Gujarat.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Sevelamer Carbonate	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: .28.06.2019

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health Family Welfare, Government of India

29 OCT 2018

F. No: 7-5/2016/EU/WC-0369
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 18 MAR 2019

To,

M/s Apothecon Pharmaceuticals Pvt Ltd.,
Plot No: 1134,1135, 1136, 1137,1143B,
1144 A&B, 1138 A&B, Padra -Jambusar Highway,
Tal-Padra,Vill- Dabhasa -391 440
Dist-Vadodara, Gujarat,INDIA.

Sub:- Written Confirmation M/s Apothecon Pharmaceuticals Pvt Ltd., Plot No.1134, 1135, 1136, 1137, 1143B, 1144 A&B, 1138A&B Padra-Jambusar Highway,Tal-Padra Vill-Dabhasa -391440,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 application submitted to CDSCO, Ahmedabad Zonal 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 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.

o/c

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 up to
00	02	11.07.2016	28.06.2019
01	01	03.08.2017	28.06.2019
02	02	09.08.2017	28.06.2019
03	01	29.10.2018	28.06.2019
04	09	18 MAR 2019	28.06.2019

Yours faithfully,

(Dr.S.Eswara Reddy)
Drugs Controller General (India).

O/C
25.03.19.

05/03/19

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

Annexure – 04
WC-0369

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 Apothecon Pharmaceuticals Pvt Ltd.,
Plot No.1134,1135,1136,1137,
1143B,1144 A&B,1138 A&B,
Padra -Jambusar Highway,Tal-Padra,
Vill- Dabhasa -391440
Vadodara, Gujarat,INDIA.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Carglumic Acid	Manufacturing & Packing
2.	Sodium Phenyl Acetate	Manufacturing &Packing
3.	Hydralazine Hydrochloride USP	Manufacturing &Packing
4.	Benzoic acid USP-NF	Manufacturing & Packing
5.	Trientine Hydrochloride USP	Manufacturing &Packing
6.	Phenoxy Benzamine Hydrochloride USP	Manufacturing &Packing
7.	Benztropine Mesylate USP	Manufacturing & Packing
8.	Carmustine	Manufacturing &Packing
9.	Vitamin K1 (Phytonadione) USP	Manufacturing &Packing

ITEM(s) Nine (09) ONLY

The Written Confirmation remains valid until: 28.06.2019.

Signature

Stamp of the authority and date

18 MAR 2019

D/C
05.03.19.
05-03-19
05/03/19