7-5/2013/EU/WC-0171
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 13 AUG 2019

To

M/s Saurav Chemicals Ltd.,
Derabassi- Barwala Road, Village Bhagwanpura,
Tehsil Derabassi, District Sahibzada Ajit Singh Nagar,
Punjab, India

SUB: - Written Confirmation of M/s Saurav Chemicals Ltd., Derabassi- Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab,, 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, Sub zone Baddi and the recommendation received from DDC (I), Sub zone Baddi, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	22	13 AUG 2019	Three Years from date of issue
02	01	13 AUG 2019	

Yours faithfully,

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

o/c 07.08.19

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

CERTIFICATE NO. : **WC-0171**

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 Saurav Chemicals Ltd., Derabassi- Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India**

2. Manufacturer's licence number: 1784-OSD & 1864-B

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 annexed

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: 19th – 20th July, 2019

The Written Confirmation remains valid until: Three years from 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. S. Eswara Reddy,
Drugs Controller General (India)

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

Signature

Stamp of the authority and date

13 AUG 2019

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

Annexure-01

CERTIFICATE NO. : WC-0171

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 Saurav Chemicals Ltd., Derabassi- Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atropine Sulfate USP/Ph.Eur	Manufacturing & Packing
2.	Celecoxib USP/ Ph.Eur	Manufacturing & Packing
3.	Chlorzoxazone USP	Manufacturing & Packing
4.	Clopidogrel Bisulfate USP	Manufacturing & Packing
5.	Clopidogrel Hydrogen Sulfate EP	Manufacturing & Packing
6.	Cycloserine USP	Manufacturing & Packing
7.	Dexketoprofen Trometamol IH	Manufacturing & Packing
8.	Dexrabeprazole Sodium IH	Manufacturing & Packing
9.	Diethylcarbamazine Citrate USP/ Ph.Eur	Manufacturing & Packing
10.	Febuxostat IH	Manufacturing & Packing
11.	Homatropine Hydrobromide USP/BP/ Ph.Eur	Manufacturing & Packing
12.	Homatropine Methylbromide USP/BP/ Ph.Eur	Manufacturing & Packing
13.	Ketoprofen USP/ Ph.Eur	Manufacturing & Packing
14.	Ketorolac Tromethamine USP	Manufacturing & Packing
15.	Ketorolac Trometamol BP/ Ph.Eur	Manufacturing & Packing
16.	Levofloxacin Hydrate JP	Manufacturing & Packing
17.	Levofloxacin Hemihydrate USP/IH	Manufacturing & Packing
18.	Loxoprofen Sodium Hydrate JP	Manufacturing & Packing
19.	Pregabalin EP/IH	Manufacturing & Packing
20.	Rebamipide JP	Manufacturing & Packing
21.	Thioctic Acid Ph.Eur	Manufacturing & Packing
22.	Vildagliptin IH	Manufacturing & Packing

ITEM(S) Twenty Two (22) ONLY

The Written Confirmation remains valid until: Three years from date of issue

Signature

Stamp of the authority and date

13 AUG 2019

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

Annexure-02

CERTIFICATE NO. : WC-0171

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 Saurav Chemicals Ltd., Derabassi- Barwala Road, Village Bhagwanpura, Tehsil Derabassi, District Sahibzada Ajit Singh Nagar, Punjab, India

List of APIs:

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

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: Three years from date of issue

Signature

Stamp of the authority and date

13 AUG 2019