F. No: 7-5/2013/EU/WC-003
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

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

To,

M/s Ind-Swift Laboratories Limited,
Village –Bhagwanpur, Barwala road,
Derabassi, Dist – S.A.S Nagar,
(Mohali), Punjab,INDIA.

03 JUN 2022

SUB: Written confirmation M/s Ind-Swift Laboratories limited, Village –Bhagwanpur, barwla road, Derabassi, Dist – S.A.S Nagar, (Mohali), 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 online application no. WC/RE/2022/3374 submitted to CDSCO, Baddi Sub Zonal office and the recommendation received from DDC (I), Baddi 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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
01.	22	03 JUN 2022	27.05.2025
02.	03	03 JUN 2022	27.05.2025

Yours faithfully,

(Dr. V.G Somani)
Drugs Controller General (India).

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

CERTIFICATE NO. : **WC-003**

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 Ind Swift Laboratories Limited,**
Village –Bhagwanpur,
Barwala Road, Derabassi,
Dist: SAS Nagar, (Mohali),
Punjab, INDIA

2. Manufacturer's license number: 1610-OSP &1615 B dated 11.03.1997

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

As per List enclosed as Annexure- 01 & 02

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: 23 & 24 May 2022

The Written Confirmation remains valid until: 27th May 2025

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. V.G Somani
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

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

03 JUN 2022

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

Annexure – 01
WC-003

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 Ind Swift Laboratories Limited,**
Village –Bhagwanpur,
Barwala Road, Derabassi,
Dist: SAS Nagar, (Mohali),
Punjab, INDIA.

List of APIs:

Sl.No	Active substance(s)	Activity(ies)
1.	Acamprosate Calcium Ph.Eur	Manufacturing & Packing
2.	Anastrozole USP/Ph.Eur/IH	Manufacturing & Packing
3.	Aripiprazole USP/Ph.Eur/IH	Manufacturing & Packing
4.	Atorvastatin Calcium Trihydrate USP/Ph.Eur/JP	Manufacturing & Packing
5.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
6.	Clarithromycin USP/PH.Eur/JP	Manufacturing & Packing
7.	Clarithromycin Citrate IH	Manufacturing & Packing
8.	Clarithromycin Granules 27.5%, 33 %, 42 % (IH)	Manufacturing & Packing
9.	Clopidogrel Hydrogen Sulphate or Clopidogrel Bisulfate (USP/Ph.Eur)	Manufacturing & Packing
10.	Donepezil Hydrochloride USP/IH/JP	Manufacturing & Packing
11.	Ezetmibe IH/USP	Manufacturing & Packing
12.	Fexofenadine Hydrochloride USP/Ph.Eur/JP	Manufacturing & Packing
13.	Imatinib Mesylate IH	Manufacturing & Packing
14.	Letrozole USP/Ph.Eur	Manufacturing & Packing
15.	Nateglinide USP	Manufacturing & Packing
16.	Pioglitazone Hydrochloride USP/Ph.Eur/JP/IH	Manufacturing & Packing
17.	Quetiapine Fumarate USP/Ph.Eur/IH/JP	Manufacturing & Packing
18.	Risedronate Sodium 2.5 Hydrate USP/Ph.Eur/JP	Manufacturing & Packing
19.	Temozolomide USP	Manufacturing & Packing
20.	Ropinirole Hydrochloride USP/IH/Ph.Eur	Manufacturing & Packing
21.	Ivabradine Hydrochloride IH	Manufacturing & Packing
22.	Valganciclovir Hydrochloride USP	Manufacturing & Packing

ITEM(S) Twenty Two (22) Only

The Written Confirmation remains valid until: 27th May 2025

Stamp of the authority and date

Central Drugs Standard Control Organization, Ministry of Health & Family Welfare, Govt. of India

Signature

03 JUN 2022

Annexure – 02

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

CERTIFICATE NO. : WC-003

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 Ind-Swift Laboratories Limited, Village –Bhagwanpur, Barwala road, Derabassi, Dist – S.A.S Nagar, (Mohali), Punjab, INDIA.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Ivabradine Oxalate IH	Manufacturing & Packing.
2	Lisdexamfetamine Dismesylate IH	Manufacturing &Packing
3	Mecloxamine Citrate IH	Manufacturing & Packing.

ITEM(S) Three (03) 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 or sale in India.

The Written Confirmation remains valid until: 27th May 2025

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

02 JUN 2022