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-0128

Dated 06 MAR 2014

To

M/s. Apotex Pharmachem India Pvt. Ltd.,
1A, Bommasandra Industrial Area, 4th Phase,
Bommasandra Industrial Estate (Post Office),
Bangalore-560 099.

SUB:- Written Confirmation M/s. Apotex Pharmachem India Pvt. Ltd., 1A, Bommasandra Industrial Area, 4th Phase, Bommasandra Industrial Estate (Post Office), Bangalore-560 099., 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, South Zone office and the recommendation received from DDC (I), South Zone, Chennai, 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

Annexure-1

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

WC-0128

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. Apotex Pharmachem India Pvt. Ltd.,
Plot No. 1A, Bommasandra Industrial Area, 4th Phase,
Bommasandra Industrial Estate (Post Office),
Bangalore.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Alprazolam (USP)	Manufacturing & Packing
2.	Capecitabine (USP)	Manufacturing & Packing
3.	Dabigatran Etexilate Mesylate	Manufacturing & Packing
4.	Eletriptan Hydrobromide	Manufacturing & Packing
5.	Pramipexole Dihydrochloride Monohydrate (Ph. Eur/USP)	Manufacturing & Packing
6.	Torsemide (USP)	Manufacturing & Packing
7.	Trospium Chloride (USP)	Manufacturing & Packing
8.	Valganciclovir Hydrochloride (USP)	Manufacturing & Packing
9.	Cabergoline (USP/EP)	Manufacturing & Packing
10.	Entecavir	Manufacturing & Packing
11.	Enalapril Maleate (USP/EP)	Manufacturing & Packing
12.	Lansoprazole (USP)	Manufacturing & Packing
13.	Linezolid	Manufacturing & Packing
14.	Mycophenolate Mofetil (USP/EP)	Manufacturing & Packing
15.	Naratriptan Hydrochloride (USP)	Manufacturing & Packing
16.	Raloxifene Hydrochloride (USP/EP)	Manufacturing & Packing
17.	Riluzole (USP)	Manufacturing & Packing
18.	Rizartriptan Benzoate (USP/EP)	Manufacturing & Packing
19.	Tizanidine Hydrochloride (USP)	Manufacturing & Packing
20.	Zolmitriptan	Manufacturing & Packing
21.	Perindopril Arginine	Manufacturing & Packing

ITEM(S) Twenty One (21) ONLY

The Written Confirmation remains valid until: **02nd July, 2016**

Signature

Stamp of the authority and date

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

06 MAR 2014

Annexure-2

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

WC-0128

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. Apotex Pharmachem India Pvt. Ltd.,
1A, Bommasandra Industrial Area, 4th Phase,
Bommasandra Industrial Estate (Post Office),
Bangalore-560 099.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Perindopril tert-Butylamine (EP)	Manufacturing & Packing
2.	Gatifloxacin Hemihydrate (USP)	Manufacturing & Packing

ITEM(S) Two (02) 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: **02nd July, 2016**

Signature

Stamp of the authority and date

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

6 MAR 2014

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	07/10/2013	02/07/2016
1.	21	06 MAR 2014	02/07/2016
2.	02	06 MAR 2014	02/07/2016

Yours faithfully,

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