7-5/2013/EU/WC-0041
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 09 AUG 2019

To
M/s Hetero Labs Limited., Unit-1 Sy No.10,
I.D.A, Gaddapotharam(V),Jinnaram(M),
Sangareddy Dist, Telangana State.

SUB: Written Confirmation of M/s Hetero Labs Limited., Unit-1, Sy No.10,I.D.A, Gaddapotharam (V), Jinnaram (M), Sangareddy Dist, Telangana State 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, Hyderabad Zone and the recommendation received from DDC (I), Hyderabad 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Validity
01	87	09 AUG 2019	Three years from the date of issue
02	08	09 AUG 2019	Three years from the date of issue

Yours faithfully,

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

o/c 5.08.19

5-8-19

06/08/19

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

WC-0041

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 Hetero Labs Limited.,
Unit-1, Sy. No.10,I.D.A,
Gaddapotharam(V),Jinnaram(M),
Sangareddy Dist,Telangana State.

2. Manufacturer's license Number: 25/MD/AP/97/B/R

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 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: 17th,18th ,19th June 2019.

The Written Confirmation remains valid until: (03) 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 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

09 AUG 2019

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

Annexure-01
WC-0041

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 Hetero Labs Limited.,**
Unit-1 Sy No.10,I.D.A,
Gaddapotharam(V),Jinnaram(M),
Sangareddy Dist, Telangana State.

List of APIs:

Sl. No.	Name of the active substances	Activitie(s)
1	Abacavir IH	Manufacturing and Packing
2	Abacavir Sulfate IH/Ph Eur/USP	Manufacturing and Packing
3	Abiraterone Acetate IH/USP	Manufacturing and Packing
4	Anastrozole IH/USP/Ph Eur	Manufacturing and Packing
5	Aripiprazole USP/Ph. Eur/IH	Manufacturing and Packing
6	Atazanavir Sulphate IH	Manufacturing and Packing
7	Atomoxetine Hydrochloride USP/Ph. Eur/IH	Manufacturing and Packing
8	Atorvastatin Calcium Trihydrate Ph. Eur	Manufacturing and Packing
9	Busulfan USP/EP	Manufacturing and Packing
10	Bendamustine Hydrochloride IH	Manufacturing and Packing
11	Bicalutamide IH/ USP/Ph Eur	Manufacturing and Packing
12	Bortezomib IH	Manufacturing and Packing
13	Cabazitaxel IH	Manufacturing and Packing
14	Candesartan Cilexetil BP/Ph Eur/USP/IH	Manufacturing and Packing
15	Capecitabine Ph. Eur/USP/IH	Manufacturing and Packing
16	Carboplatin BP/USP/Ph.Eur	Manufacturing and Packing
17	Cilazapril Ph.Eur	Manufacturing and Packing
18	Cisplatin BP/USP/Ph Eur	Manufacturing and Packing
19	Crizotinib IH	Manufacturing and Packing
20	Darunavir Amorphous IH	Manufacturing and Packing
21	Darunavir Ethanolate IH	Manufacturing and Packing
22	Dasatinib IH	Manufacturing and Packing
23	Desloratadine IH/Ph Eur	Manufacturing and Packing
24	Didanosine USP/Ph.Eur	Manufacturing and Packing
25	Dutasteride IH/USP/Ph.Eur	Manufacturing and Packing
26	Efavirenz USP/IH	Manufacturing and Packing
27	Emtricitabine IH/USP	Manufacturing and Packing

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06/08/14

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

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

Sl.No.	Name of the Active Substances	Activitie(s)
28	Entecapone BP/IH/USP/Ph.Eur	Manufacturing and Packing
29	Erlotinib Hydrochloride IH	Manufacturing and Packing
30	Escitalopram Oxalate IH/USP	Manufacturing and Packing
31	Etoricoxib IH	Manufacturing and Packing
32	Ezetimibe IH/USP	Manufacturing and Packing
33	Finasteride IH/USP/Ph.Eur	Manufacturing and Packing
34	Gefitinib IH/BP/EP	Manufacturing and Packing
35	Gemcitabine Hydrochloride USP/Ph.Eur	Manufacturing and Packing
36	Hydralazine Hydrochloride BP/USP/Ph.Eur	Manufacturing and Packing
37	Imatinib Mesilate Ph.Eur	Manufacturing and Packing
38	Imatinib Mesylate IH	Manufacturing and Packing
39	Irbesartan BP/USP/Ph.Eur	Manufacturing and Packing
40	Irinotecan HydrochloideUSP	Manufacturing and Packing
41	Lamivudine BP/USP/Ph.Eur	Manufacturing and Packing
42	Lapatinib Ditosylate Monohydrate IH	Manufacturing and Packing
43	Letrozole USP/Ph.Eur	Manufacturing and Packing
44	Levetiracetam IH/BP/USP/Ph.Eur	Manufacturing and Packing
45	Lopinavir USP/IH/Ph.Eur	Manufacturing and Packing
46	Loratadine BP/USP/Ph.Eur	Manufacturing and Packing
47	Lenalidomide IH	Manufacturing and Packing
48	Maraviroc IH	Manufacturing and Packing
49	Melphalan Hydrochloride IH	Manufacturing and Packing
50	Milnacipran Hydrochloride IH	Manufacturing and Packing
51	Nevirapine Anhydrous BP/USP	Manufacturing and Packing
52	Nevirapine Hemihydrate USP	Manufacturing and Packing
53	Nilotinib Hydrochloride IH	Manufacturing and Packing
54	Oxaliplatin USP/Ph.Eur	Manufacturing and Packing
55	Olmesartan Medoxomil USP/Ph.Eur/IH	Manufacturing and Packing
56	Oseltamivir Phosphate USP/Ph.Eur/BP	Manufacturing and Packing
57	Paclitaxel USP/Ph.Eur	Manufacturing and Packing
58	Pazopanib Hydrochloride IH	Manufacturing and Packing
59	Eplerenone IH/EP	Manufacturing and Packing

O/C

5-8-19

06/08/19

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

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

Sl.No.	Name of the Active Substances	Activitie(s)
60	Cyclophosphamide Monohydrate USP/Ph.Eur	Manufacturing and Packing
61	Daclatasvir Dihydrochloride IH	Manufacturing and Packing
62	Dolutegravir sodium IH	Manufacturing and Packing
63	Irinotecan Hydrochloride Trihydrate EP	Manufacturing and Packing
64	Pemetrexed Disodium IH	Manufacturing and Packing
65	Pioglitazone Hydrochloride IH/USP/Ph.Eur	Manufacturing and Packing
66	Quetiapine Fumarate USP/Ph.Eur/IH	Manufacturing and Packing
67	Ramipril BP/USP/Ph.Eur	Manufacturing and Packing
68	Saquinavir Mesylate USP	Manufacturing and Packing
69	Saquinavir Mesilate BP/Ph.Eur	Manufacturing and Packing
70	Simvastatin Ph.Eur/USP	Manufacturing and Packing
71	Sorafenib Tosylate IH	Manufacturing and Packing
72	Stavudine BP/USP/Ph.Eur	Manufacturing and Packing
73	Sunitinib Malate IH	Manufacturing and Packing
74	Telmisartan BP/USP/Ph.Eur	Manufacturing and Packing
75	Temozolomide USP/IH	Manufacturing and Packing
76	Tenofovir Disop[illegible] IH	Manufacturing and Packing
77	Tenofovir Disoproxil Fumarate IH	Manufacturing and Packing
78	Terbinafine Hydrochloride BP/USP/Ph.Eur	Manufacturing and Packing
79	Thalidomide USP	Manufacturing and Packing
80	Torsemide Anhydrous Ph.Eur	Manufacturing and Packing
81	Torsemide USP	Manufacturing and Packing
82	Valsartan BP/USP/Ph.Eur	Manufacturing and Packing
83	Velpatasvir IH	Manufacturing and Packing
84	Voriconazole IH/USP/BP/Ph.Eur	Manufacturing and Packing
85	Zidovudine USP/Ph.Eur/BP	Manufacturing and Packing
86	Zoledronic Acid Monohydrate IH	Manufacturing and Packing
87	Zonisamide IH/USP	Manufacturing and Packing

ITEM(s) Eight Seven (87) Only

The Written Confirmation remains valid until (03)Three Years from the date of Issue

Stamp of the authority and date

Signature

09 AUG 2019

o/c 5.08.19. 5-8-19

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

CERTIFICATE NO. :

Annexure – 02
WC-0041

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 Hetero Labs Limited., Unit-1 Sy No.10, I.D.A,Gaddapotharam(V),Jinnaram(M), Sangareddy (Dist) Telangana State.**

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1	Bexarotene IH	Manufacturing & Packing.
2	Cilazapril Ph.Eur	Manufacturing & Packing
3	Etravirine IH	Manufacturing & Packing
4	Enzalutamide IH	Manufacturing & Packing
5	Plerixafor IH	Manufacturing & Packing.
6	Pomalidomide IH	Manufacturing & Packing
7	Pralatrexate IH	Manufacturing & Packing
8	Regorafenib IH	Manufacturing & Packing

ITEM(S) Eight (08) 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: (03) Three years from the date of Issue

Signature

Stamp of the authority and date

09 AUG 2019

O/C 5.08.2019.

5-8-19

06/08/19