

From :
The Drugs Controller General (India)
Directorate General of Health Services

FDA Bhawan, New Delhi
Dated

To,

01 OCT 2015

M/s. P.K.Pharmatech Pvt. Ltd.
001, Ground Floor, B-21,
Zarina Park, Mankhurd, Mumbai,
Tal: Mankhurd (Mumbai-Zone3)-400088

Sub: -Registration of M/S. Henan Lihua Pharmaceutical Co. Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan, China under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India.

BD-1391

Dear Sir,

Please refer to your application no. PKPPL:2015-16 dated 07.08.2015, received by this Office vide Diary no. 27397 dated 19.08.2015 on the above subject. Registration Certificate in Form 41 under the Rules is issued for the manufacturing site along with the name (s) of drug (s) imported under the said Certificate subject to the condition:

1. The drugs shall confirm to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
3. Dispute, if any, in respect of the payment of fees and submission of TR6 challan, shall have to be settled between the bank and the applicant.
4. The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage. This Directorate should be informed of adverse reports on the drug, if any.
5. The drugs shall be marketed for indications for which they have been approved.
6. If any claim is made for these drugs in future other than those approved, prior permissions from this Directorate will be necessary before such claim is made.
7. The drugs shall be supplied and marketed as per the provisions of the existing Drugs & Cosmetics Act and Rules thereunder.

8. This registration in no way relieves you of the responsibility of complying with all other provisions of the Drugs & Cosmetics Act and Rules there under, and any other provisions of any other Act and Rules applicable in the matter concerned.
9. Each consignment of the drugs to be imported by you shall be accompanied by a test / analysis reports.
10. Based on this registration, import applications for the drug (s) endorsed in the enclosed Registration Certificate shall be considered for the issue of Form 10 Licence under the Rules.
11. This Registration Certificate is being issued under the condition that during the pendency of Registration, the applicant may be required to deposit inspection fee as stipulated under Clause (5) of Rule 24-A and enable inspection of manufacturing site by the officials authorised for this purpose. Non-compliance to this condition as and when so directed would result in cancellation of Registration Certification.
12. **The shelf life of the drug Betamethasone IP shall be 24 months.**
13. **Long term stability data as per Indian climatic condition zone IVb shall be submitted for proposed shelf life, according to WHO guideline, duly notarized.**

Please note that Registration Certificate issued is liable to be suspended / cancelled, if any of the condition stipulated above is not complied with, apart from any other condition that may be taken under the provisions of the Drugs & Cosmetics Act, 1940 and the Rules there under.

Please acknowledge the receipt.

Yours faithfully,

Joint Drugs Controller (India)

Copy forwarded to:

1. The Assistant Drug Controller (I), New Custom House, Annexe, Ballard Estate, Fort, Mumbai-400038.
2. The Assistant Drug Controller (I), 15/1, Strand Road, Custom House, Kolkata-700001.
3. The Assistant Drug Controller (I), Room No. 66, 2nd Floor, Custom House, Chennai-600001.
4. The Assistant Drug Controller (I), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.

GOVERNMENT OF INDIA



Central Drugs Standard Control Organisation Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

Registration Certificate issued for import of drugs into India

Under Drugs and Cosmetics Rules, 1945

01 OCT 2015

Registration Certificate No. BD-1391

Dated

1. M/S. Henan Lihua Pharmaceutical Co. Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan, China having factory premises at M/S. Henan Lihua Pharmaceutical Co. Ltd., Middle of Huanghe Street, Anyang Hi-Tech Industry Development Zone, Henan, China has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.
2. Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
3. This Registration Certificate shall be in force from 01/09/2015 to 31/08/2018 unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S P.K.Pharmatech Pvt. Ltd., 001, Ground Floor, B-21, Zarina Park, Mankhurd, Mumbai, Tal: Mankhurd (Mumbai-Zone3)-400088 who will be responsible for the business activities of the manufacturer in India in all respects.
5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.

Place: New Delhi

Date: _____



V-hz

LICENSING AUTHORITY

Seal/Stamp

Dr. V. G. SOMANI

Joint Drugs Controller (India)

Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi-110002

01 OCT 2015

Conditions of the Registration Certificate

1. The Registration Certificate shall be displayed at a prominent place by the authorised agent.
2. No drug shall be registered unless it has a free sale approval in the country of origin, and/or in other major countries.
3. The manufacturer or his authorised agent in India shall comply with the conditions of the import licence issued under the Drugs and Cosmetics Rules, 1945.
4. The manufacturer or his authorised agent in India shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. market withdrawal, regulatory restrictions, or cancellation of authorisation, and/or not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed. The despatch and marketing of the drug in such cases shall be stopped immediately, and the licensing authority shall be informed immediately. Further action in respect of such stopped marketing of drug shall be followed as per the direction of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned drug in the country of origin or in the country of marketing shall be followed in India also, in consultation with the licensing authority. The licensing authority may, however, direct any further modification to this course of action, including the withdrawal of the drug from Indian market within 48 hours time period.
5. The manufacturer or his authorised agent in India shall inform the licensing authority within 30 days in writing in the event of any change in manufacturing process, or in packaging, or in labelling or in testing, or in documentation of any of the drug pertaining to this Registration Certificate. In such cases, where there shall be any major change/modification in manufacturing, or in processing or in testing, or in documentation as the case may be, at the discretion of the licensing authority, the manufacturer or his authorised agent in India shall obtain necessary approval within 30 days by submitting a separate application along with the registration fee, as specified in clause (ii) of sub rule (3) of rule 24-A.
6. The manufacturer or his authorised agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and /or address of the registered office/ factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises".



सत्यमेव जयते

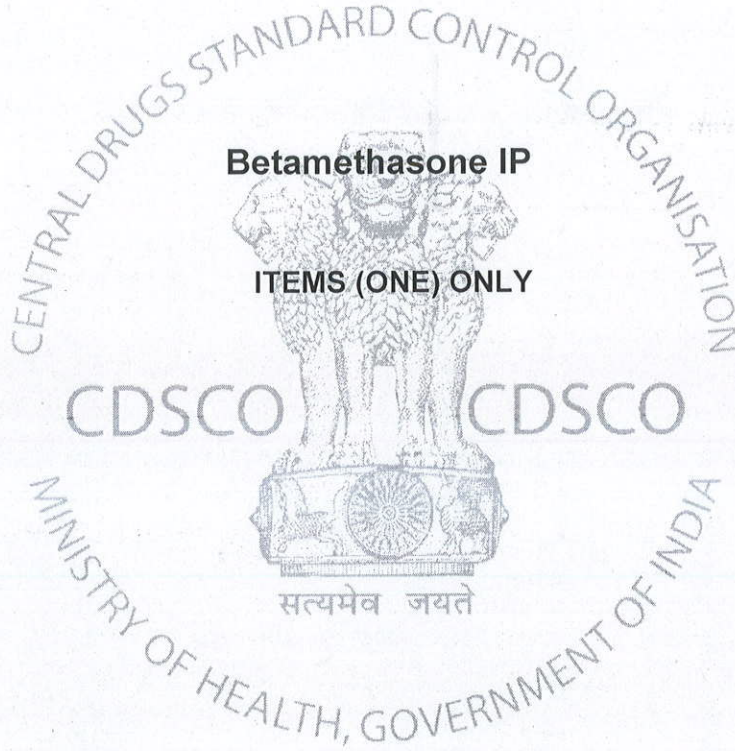
GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
UNDER REGISTRATION CERTIFICATE NO. BD-1391
DATED

01 OCT 2015



Betamethasone IP

ITEMS (ONE) ONLY

Place: New Delhi

Date:

01 OCT 2015



V.G.S

LICENSING AUTHORITY

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Dr. V. G. SOMANI
Joint Drugs Controller (India)
Directorate General of Health Services
FOA Bhawan, Kotla Road, New Delhi-110002

