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 TO BE ISSUED FOR IMPORT OF DRUGS INTO INDIA UNDER DRUGS AND COSMETICS RULES 1945

Registration Certificate No. **RC/BD-002080**

1. **M/s. Zhejiang Starry Pharmaceutical co., Ltd.,, No. 1 Starry Road of Xianju Modern Industrial Centralization Zone Taizhou - 317300 zhejiang (China)** having factory premises at **M/s. Zhejiang Starry Pharmaceutical Co., Ltd, No. 1 Starry Road of Xianju Modern Industrial Centralization Zone Zhejiang taizhou (China) - 317300 [Manufacturing Site,Batch Release Site]** 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 **14-Dec-2016** to **13-Dec-2019** 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 VITA BIO INTERNATIONAL PVT LTD, 305 , 3RD FLOOR ARENJA CORNER SECTOR 17 , PLOT NO 71 , VASHI , TAL DISST THANE ZONE 7 MAHARASHTRA, Maharashtra, THANE, Thane- 400703 (India)** 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.

GYANENDRA NATH SINGH

Digitally signed by GYANENDRA NATH SINGH
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION....., 2.5.4.20=35b54b42f8a0feb089de52edb5df5d1676cdc2ade3cb54154373fec3389c688d, ou=CDSCO,CID - 4171152, postalCode=110002, st=Delhi, cn=GYANENDRA NATH SINGH
Date: 2016.12.16 11:21:22 +05'30'

LICENSING AUTHORITY

Seal/Stamp

Place: New Delhi
Date:15-Dec-2016

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 License 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.

File No. **IR/16/000111**

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NAME(S) OF DRUGS, WHICH MAY BE IMPORTED UNDER REGISTRATION CERTIFICATE NO. **RC/BD-002080** VALID UP TO **13-Dec-2019**

S.No.	Drug Name
1	Iopamidol U.S.P.

Item(s) (One) Only

GYANENDRA NATH SINGH

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Date: 2016.12.16 11:21:40 +05'30'

Place: New Delhi
Date:15-Dec-2016

LICENSING AUTHORITY
Seal/Stamp