

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

FDA Bhawan, New Delhi  
Dated

**19 JAN 2011**

To,

M/S. GENERIX LIFESCIENCES PVT. LTD.  
A-101, NESTLE APTS. OPP. TOYOTA SHOW  
ROOM, LINK ROAD, MALAD(W)  
MUMBAI-400064

Sub: -Registration of M/S. HENGKANG PHARMACEUTICAL CO. LTD. ZHEJIANG SANMENT, FENGKENG TANG, HAIYOU TOWN ZHEJIANG 317100 CHINA under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application No. NIL dated 24/12/2010: received by this Office vide diary No : 60171 dated : 24/12/2010 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 conform 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 The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage.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.

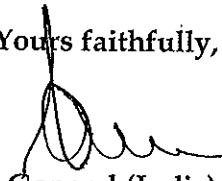
- 8 This registration in no way relieves you of the responsibility of complying with all other provisions of the Drugs & Cosmetics Act and Rules there under, and any other provisions of any other Act and Rules applicable in the matter concerned.
- 9 Each consignment of the drugs to be imported by you 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 ORIGINAL LABELS OF THE DRUGS AS GIVEN IN THE RC SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF THE DRUG.**

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.

OFFICE COPY

Yours faithfully,

  
Drugs Controller General (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, 2<sup>nd</sup> 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)



OFFICE COPY

Form 41

(See Rule 27-A)

REGISTRATION CERTIFICATE

Registration Certificate issued for import of drugs into India

Under Drugs and Cosmetics Rules, 1945

19 JAN 2011

Registration Certificate No. BD-899

Dated

M/S. HENGKANG PHARMACEUTICAL CO. LTD. ZHEJIANG SANMEN, FENGKENG TANG, HAIYOU TOWN ZHEJIANG 317100 CHINA having factory premises at M/s. HENGKANG PHARMACEUTICAL CO. LTD. ZHEJIANG SANMENT, FENGKENG TANG, HAIYOU TOWN ZHEJIANG 317100 CHINA has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.

- Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
- This Registration Certificate shall be in force from 01/01/2011 to 31/12/2013 unless it is sooner suspended or cancelled under the rules.
- This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S GENERIX LIFESCIENCES PVT. LTD. A-101, NESTLE APTS. OPP. TOYOTA SHOW ROOM, LINK ROAD, MALAD(W), MUMBAI-400064 who will be responsible for the business activities of the manufacturer in India in all respects.
- 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: \_\_\_\_\_

19 JAN 2011

LICENSING AUTHORITY

Dr. SURENDER SINGH  
Seal/Stamp  
General of Health Services  
New Delhi - 110002

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-899  
DATED 19 JAN 2011

1. AMIODARONE HCL IP
2. GABAPENTIN USP

OFFICE COPY

ITEMS (TWO) ONLY

Place: New Delhi

Date:

19 JAN 2011



LICENSING AUTHORITY

Seal/Stamp

Handwritten signature and date: 19/1/11



No. 6-3/BD/58/07-DC(RE-REG-2010)

2044  
27/11/2011  
19/11

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

FDA Bhawan, New Delhi  
Dated **19 JAN 2011**

To,

M/S. RUSKIN CHEMIPHARM  
4/A, BHANGWADI SHOPPING ARCADE,  
KALBADEVI ROAD  
MUMBAI-400002

Sub: -Registration of M/S. NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH CO. LTD. NO. 20 YANGZI ROAD SHIJIAZHUANG ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE HEBEI P.R.CHINA under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application No. NIL dated 11/11/2010: received by this Office vide diary No : 53678 dated : 16/11/2010 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.~~ **OFFICE COPY**
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 ORIGINAL LABEL OF THE DRUG AS PER IP SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT.
- 13 SOFT COPY OF MODULE III CTD DOSSIERS SHALL BE SUBMITTED TO THIS OFFICE.

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.

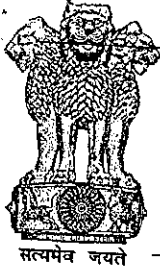
OFFICE COPY

Yours faithfully,

  
Drugs Controller General (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, 2<sup>nd</sup> 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.



सत्यमेव जयते

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

19 JAN 2011

Registration Certificate No. BD-697

Dated

1. M/S. NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH CO. LTD. NO. 20 YANGZI ROAD SHIJIAZHUANG ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE HEBEI P.R.CHINA having factory premises at M/s. NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH CO. LTD. NO. 20 YANGZI ROAD SHIJIAZHUANG ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE HEBEI P.R.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 01/12/2010 to 30/11/2013 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 RUSKIN CHEMIPHARM 4/A, BHANGWADI SHOPPING ARCADE, KALBADEVI ROAD, MUMBAI-400002 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: 19 JAN 2011

LICENSING AUTHORITY

Dr. Arjun Singh  
Seal/Stamp  
Director, Health Services  
FDA Bhawan, Connaught Road,  
New Delhi-110002

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".

OFFICE COPY



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-697  
DATED **19 JAN 2011**

AMOXICILLIN TRIHYDRATE IP

OFFICE COPY

ITEMS (ONE) ONLY

Place: New Delhi

Date: **19 JAN 2011**



LICENSING AUTHORITY

Dr. SURINDER SINGH  
Secretary (Drugs) / Director  
Central of Health Services  
FDA Bhawan, Kala Road,  
New Delhi - 110002



1111 1111 1111

1111 1111 1111

No. 6-3/BD/90/07-DC(RE-REG-2011)

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

FDA Bhawan, New Delhi

Dated **19 JAN 2011**

*Real*  
*[Signature]*  
19/1/11  
(981085555)

To,

M/S. DKSH INDIA PVT LTD  
1001 & 1002, ALPHA, HIRANANDANI  
BUSINESS PARK, POWAI,  
MUMBAI-400076

**Sub: -Registration of M/S. NINGBO RENJIAN PHARMACEUTICAL GROUP CO LIMITED NO.555, CHANGCHI ROAD, CIXI,ZHEJIANG 315 300 P.R.CHINA under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India**

Dear Sir,

Please refer to your application No. NIL dated 08/09/2010: received by this Office vide diary No : 59184 dated : 20/12/2010 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.

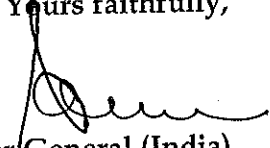
- 8 This registration in no way relieves you of the responsibility of complying with all other provisions of the Drugs & Cosmetics Act and Rules there under, and any other provisions of any other Act and Rules applicable in the matter concerned.
- 9 Each consignment of the drugs to be imported by you 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.

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.

OFFICE COPY

Please acknowledge the receipt.

Yours faithfully,

  
Drugs Controller General (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, 2<sup>nd</sup> 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

19 JAN 2011

Dated

Registration Certificate No. BD-716

1. M/S. NINGBO RENJIAN PHARMACEUTICAL GROUP CO LIMITED NO.555  
CHANGCHI ROAD, CIXI,ZHEJIANG 315 300 P.R.CHINA having factory premises at M/s.  
NINGBO RENJIAN PHARMACEUTICAL GROUP CO LIMITED NO.555 ,CHANGCHI  
ROAD, CIXI,ZHEJIANG 315 300 P.R.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 01/04/2011 to 31/03/2014 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 DKSH INDIA PVT LTD 1001 & 1002, ALPHA,  
HIRANANDANI BUSINESS PARK, POWAL, , MUMBAI-400076  
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: 19 JAN 2011

LICENSING AUTHORITY

Seal/Stamp

92/11  
3/11  
Seal/Stamp  
Director (India)  
Health Services  
Kalla Road,  
110002

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".~~

OFFICE COPY





JOTSINGH

17/1/11

9410389321

From:

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

FDA Bhawan, New Delhi

Dated

19 JAN 2011

To,

M/S. DSM ANTI-INFECTIVES INDIA LTD.  
BHAI MOHAN SINGH NAGAR, TOANSA,  
TEH BALACHAUR,  
DIST. NAWANSHAHR(PUNJAB) INDIA, 144533,

Sub: -Registration of M/S. FERSINSA GB S.A DE C.V P.O BOX 37, CARRETERA SALTILLO-MONETETERREY, ZIP CODE 25900, RAMOS ARIZPO, COAH, MEXICO  
under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application No. NIL dated 26/10/2010: received by this Office vide diary No : 59437 dated : 21/12/2010 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.

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.

OFFICE COPY

Yours faithfully,

  
Drugs Controller General (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, 2<sup>nd</sup> 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

19 JAN 2011

Registration Certificate No. BD-475

Dated

1. M/S. FERSINSA GB S.A DE C.V P.O BOX 37, CARRETERA SALTILLO-MONETETERREY, ZIP CODE 25900, RAMOS ARIZPO, COAH, MEXICO having factory premises at M/s. FERSINSA GB S.A DE C.V P.O BOX 37, CARRETERA SALTILLO-MONETETERREY, ZIP CODE 25900, RAMOS ARIZPO, COAH, MEXICO 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 01/10/2010 to 30/09/2013 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 DSM ANTI-INFECTIVES INDIA LTD. BHAI MOHAN SINGH NAGAR, TOANSA, T EH BALACHAUR., DIST. NAWANSHAHR(PUNJAB) INDIA, 144533, 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: 19 JAN 2011

LICENSING AUTHORITY

Seal/Stamp

90/11/11

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".

OFFICE COPY



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-475  
DATED **19 JAN 2011**

OFFICE COPY

BENZYL PENICILLIN POTASSIUM (PENICILLIN G POTASSIUM)  
IP

ITEMS (ONE) ONLY

Place: New Delhi

Date: **19 JAN 2011**



LICENSING AUTHORITY

Dr. SURENDER Seal/Stamp  
21/1/11

100 731

No. 6-4/FF/19/02 -DC(PT-I) (RE-REG 2008)

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

Recd  
Shobhit  
19/11/11

FDA Bhawan, New Delhi

Dated 19 JAN 2011

To,

M/S. ABBOTT HEALTHCARE PVT. LTD.,  
4 CORPORATE PARK, SION TROMBAY ROAD,  
MUMBAI 400 071

Sub: -Registration of M/S. GILEAD SCIENCES LIMITED, IDA BUSINESS AND TECHNOLOGY PARK, CARRIGTOHILL, CO. CORK, IRELAND under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application no. NIL dated 12/11/2010: received by this Office vide diary No: 55054 dated: 24/11/2010 on the above subject. Fresh Registration Certificate in Form 41 under the Rules due to change in the name of Indian Agent 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 conform 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 **ORIGINAL LABEL AND PACKAGE INSERT OF THE PRODUCT IN NEW NAME OF INDIAN AGENT SHALL BE SUBMITTED TO THIS OFFICE BEFOR IMPORT.**

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.

OFFICE COPY

Please acknowledge the receipt.

Yours faithfully,

  
Drugs Controller General (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, 2<sup>nd</sup> 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



सत्यमेव जयते

## 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

19 JAN 2011

Registration Certificate No. FF-569

Dated

- M/S. GILEAD SCIENCES INC., USA having factory premises at M/s. GILEAD SCIENCES LIMITED, IDA BUSINESS AND TECHNOLOGY PARK, CARRIGTOHILL, CO. CORK, IRELAND has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.
- Name(s) of drug(s) which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
- This Registration Certificate shall be in force from 01/12/2010 to 30/11/2013 unless it is sooner suspended or cancelled under the rules.
- This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S ABBOTT HEALTHCARE PVT. LTD., 4 CORPORATE PARK, SION TROMBAY ROAD, MUMBAI 400 071 who will be responsible for the business activities of the manufacturer in India in all respects.
- 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

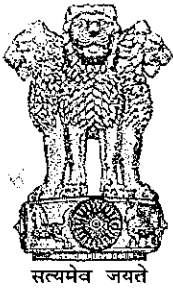
Date: 19 JAN 2011

LICENSING AUTHORITY

Seal/Stamp  
91/1/11  
7/11  
Dte. 19/1/11  
FDA Bhawan, Kala Road,  
New Delhi-110002

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".



GOVERNMENT OF INDIA

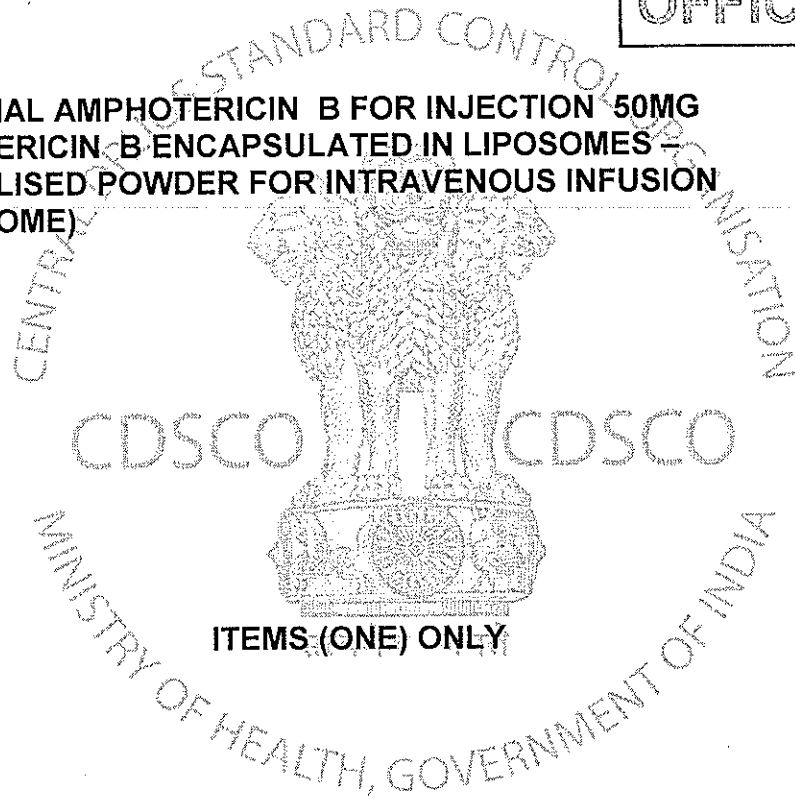
Central Drugs Standard Control Organisation  
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED  
UNDER REGISTRATION CERTIFICATE NO. FF-569  
DATED 19 JAN 2011

OFFICE COPY

LIPOSOMAL AMPHOTERICIN B FOR INJECTION 50MG  
AMPHOTERICIN B ENCAPSULATED IN LIPOSOMES -  
LYOPHILISED POWDER FOR INTRAVENOUS INFUSION  
(AMBIOSOME)



ITEMS (ONE) ONLY

Place: New Delhi

Date: 19 JAN 2011



LICENSING AUTHORITY

*[Signature]*  
Seal/Stamp  
Dr. S. K. ...  
Director, Licensing Services  
Central Drugs Standard Control Organisation  
Ministry of Health & Family Welfare  
New Delhi - 110002

1998 041 91

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

Recd  
Shobh V  
19/1/2011

FDA Bhawan, New Delhi

Dated

19 JAN 2011

To,

M/S. ABBOTT HEALTHCARE PVT. LTD.,  
4 CORPORATE PARK, SION TROMBAY ROAD,  
MUMBAI 400 071

Sub: -Registration of M/S. PIERRE FABRE MEDICAMENT PRODUCTION, ESTABLISSEMENT AQUITAINE PHARM INTERNATIONAL, AVENUE DU BEARN - 64320, IDRON, FRANCE under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India

Dear Sir,

Please refer to your application no. NIL dated 12/11/2010: received by this Office vide diary No: 55055 dated: 24/11/2010 on the above subject. Fresh Registration Certificate in Form 41 under the Rules due to change in the name of Indian Agent 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 conform 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 **ORIGINAL LABEL AND PACKAGE INSERT OF THE PRODUCT IN NEW NAME OF INDIAN AGENT SHALL BE SUBMITTED TO THIS OFFICE BEFOR IMPORT.**

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.

OFFICE COPY

Yours faithfully,

Drugs Controller General (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, 2<sup>nd</sup> 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.



सत्यमेव जयते

# 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

Registration Certificate No. FF-568

19 JAN 2011

1. M/S. PIERRE FABRE MEDICAMENT PRODUCTION, FRANCE having factory premises at M/s. PIERRE FABRE MEDICAMENT PRODUCTION, ESTABLISSEMENT AQUITAINE PHARM INTERNATIONAL, AVENUE DU BEARN - 64320, IDRON, FRANCE 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 01/12/2010 to 30/11/2013 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 ABBOTT HEALTHCARE PVT. LTD., 4 CORPORATE PARK, SION TROMBAY ROAD, MUMBAI 400 071 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: 19 JAN 2011



LICENSING AUTHORITY

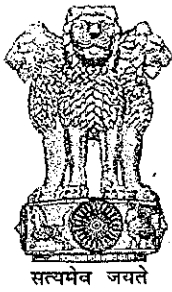
Seal/Stamp

90/11  
19/1/11

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”.

OFFICE COPY



GOVERNMENT OF INDIA

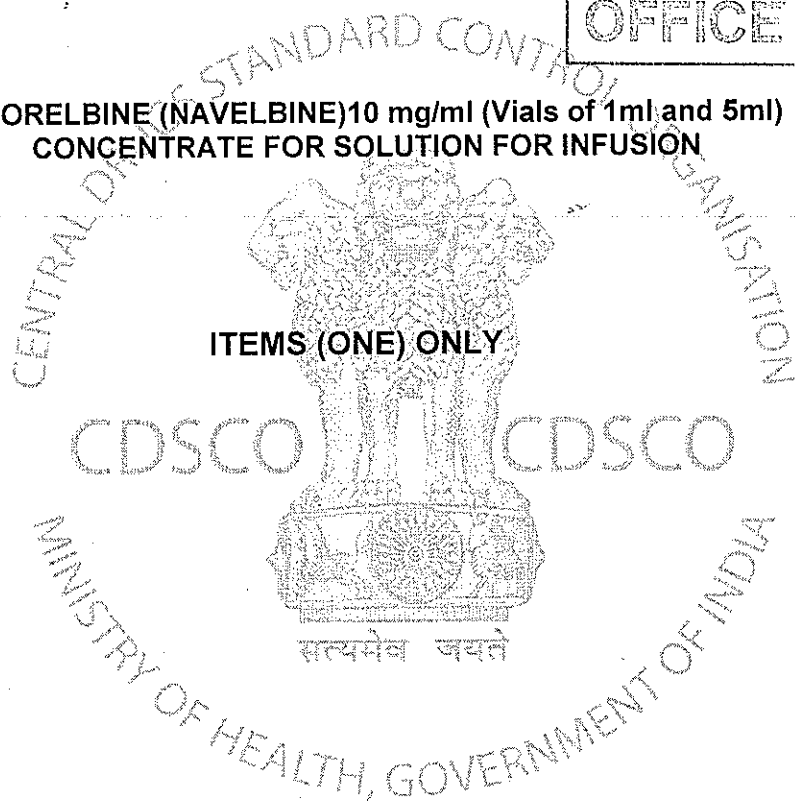
Central Drugs Standard Control Organisation  
Ministry of Health & Family Welfare

FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED  
UNDER REGISTRATION CERTIFICATE NO. FF-568  
DATED **19 JAN 2011**

OFFICE COPY

VINORELBINE (NAVELBINE) 10 mg/ml (Vials of 1ml and 5ml)  
CONCENTRATE FOR SOLUTION FOR INFUSION



ITEMS (ONE) ONLY

Place: New Delhi

Date: **19 JAN 2011**



  
LICENSING AUTHORITY  
Dr. SURINDER SINGH  
Seal/Stamp  
Ministry of Health & Family Welfare  
FDA Bhawan, New Delhi

1952 MAR 21

1952 MAR 21