

No. 6-4/FF/124/08-DC(REREG2008) ENDORSEMENT

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

FDA Bhawan, New Delhi

Dated

02 JUN 2011

To,

M/S. ALLERGAN INDIA PVT LIMITED
LEVEL 2, PRESTIGE OBELISK, NO.3,
KASTURBA ROAD, BANGALORE-560001

Sub: -Registration of M/S. ALLERGAN PHARMACEUTICALS IRELAND
CASTLEBAR ROAD WESTPORT, CO, MAYO, 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 10/09/2010: received by this Office vide diary No : 22596 dated : 18/05/2011 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 The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage.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 DRUG IS 24 MONTHS.**

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,

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, 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.



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. FF-120
DATED 29/12/2008 VALID UPTO 31/12/2011

ENDORSEMENT No.2

*BIMATOPROST OPTHALMIC SOLUTION
EACH VIAL CONTAINS:
BIMATOPROST EQUIVALENT TO BIMATORROST
.....0.01%W/V

ITEMS (ONE) ONLY



CDSCO CDSCO

*COPY OF RULE 122A PERMISSION SHALL BE SUBMITTED AT TIME
OF APPLICATION OF IMPORT LICENSE. सत्यमेव जयते

MINISTRY OF HEALTH, GOVERNMENT OF INDIA

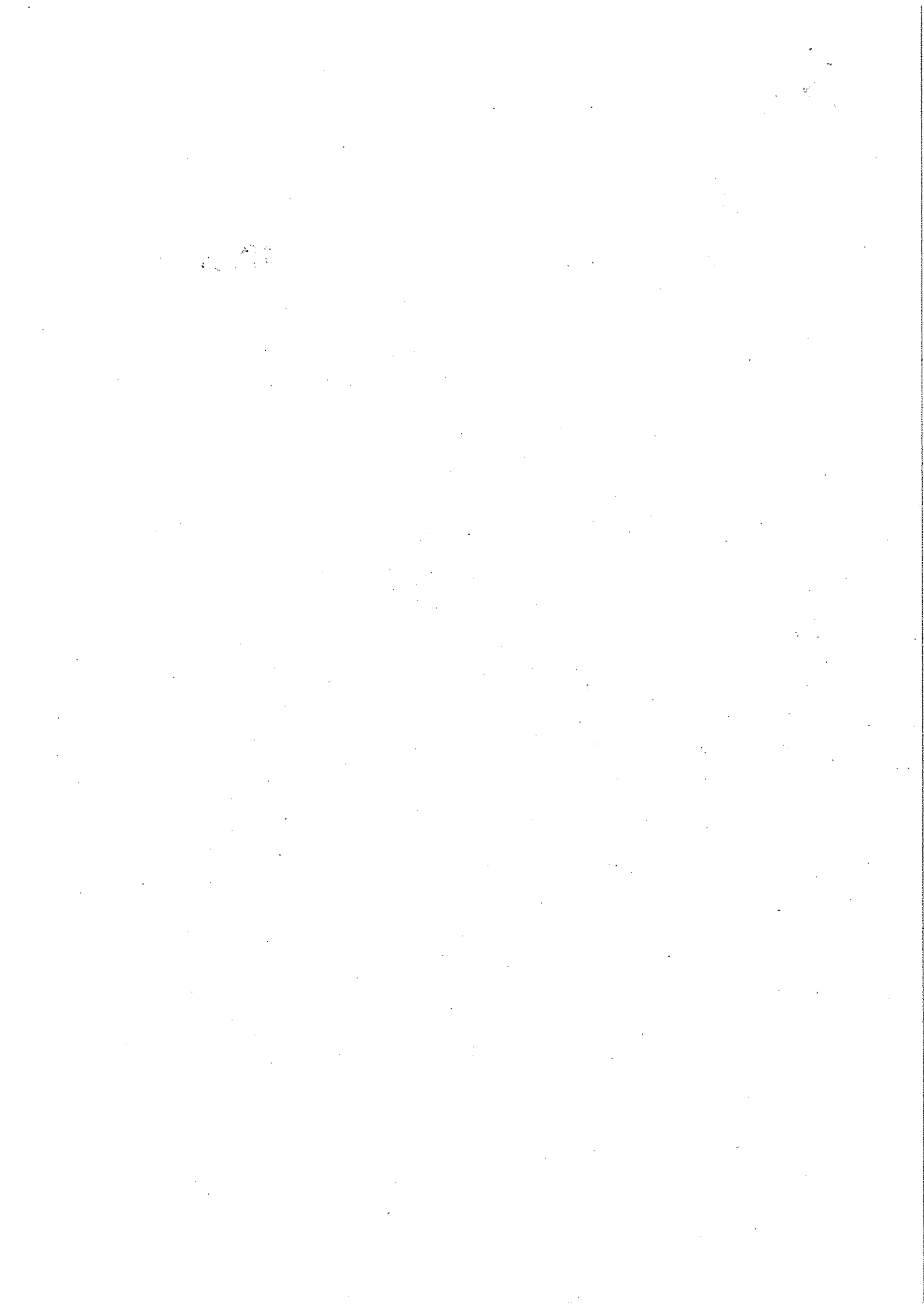
Place: New Delhi

Date: 02 JUN 2011



LICENSING AUTHORITY

डा. सुरिन्द्र सिंह Seal/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महाविदेशालय
Dte. General of Health Services
FDA Bhawan, Kotla Road,
New Delhi-110002



No. 6-4/FF/14/09-DC (RE-REGISTRATION - 2009)

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

FDA Bhawan, New Delhi
Dated 02 JUN 2011

To,

M/S. COVIDIEN HEALTHCARE INDIA PVT. LTD.,
NO. 156, DGSJI TOWERS, 6th FLOOR,
POONAMALLEE HIGH ROAD, KILPAUK,
CHENNAI - 600 010

Sub: -Registration of M/S. MALLINCKRODT INC., RALEIGH PARENTERAL PLANT, 8800 DURANT ROAD, RALEIGH, NC 27616, USA 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 07/04/2011, received by this Office vide diary no. 16478 dated 07/04/2011 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:**

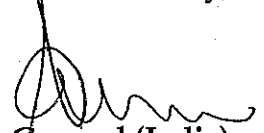
1. The drugs shall confirm to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
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. **Amended labels and package inserts of the products in new name of Indian Agent shall be submitted to this office at the time of application for import license.**

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.

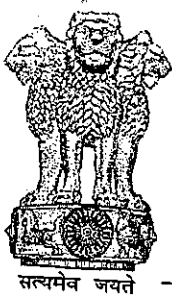
Yours faithfully,



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, 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.



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-585

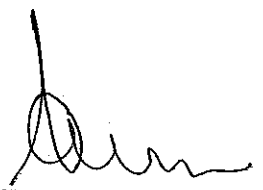
Dated
02 JUN 2011

1. M/S. MALLINCKRODT INC., USA having factory premises at M/s. MALLINCKRODT INC. RALEIGH PARENTERAL PLANT, 8800 DURANT ROAD, RALEIGH, NC 27616, USA 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 01/05/2011 to 30/04/2014 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 COVIDIEN HEALTHCARE INDIA PVT. LTD., NO. 156, DOSHI TOWERS, 6th FLOOR, POONAMALLEE HIGH ROAD, KILPAUK, CHENNAI - 600 010 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: 02 JUN 2011




LICENSING AUTHORITY

Seal/Stamp
डॉ. सुरिंदर सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महाविद्यालय
Dte. General of Health Services
FDA Bhawan, Kotla 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”.



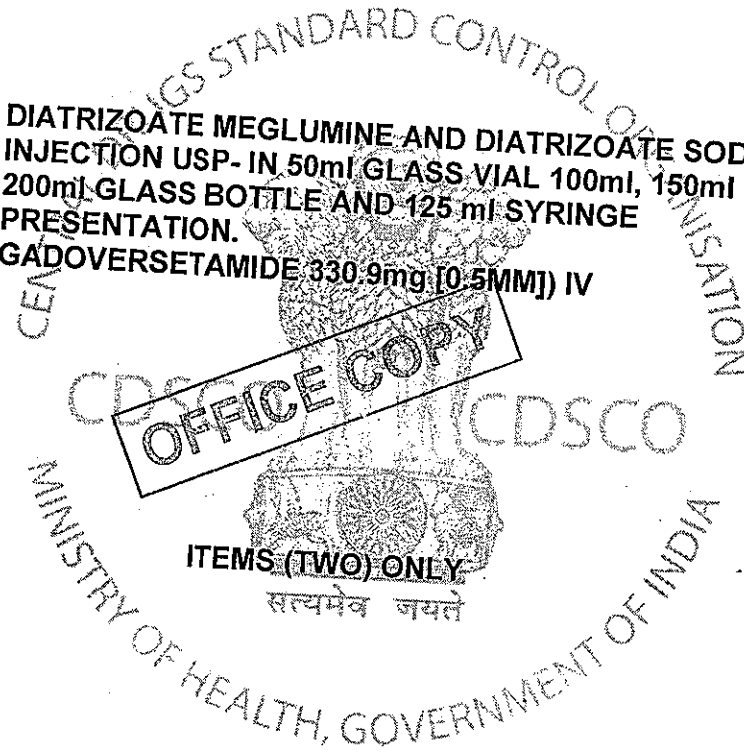
सत्यमेव जयते

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. FF-585
DATED 02 JUN 2011

1. DIATRIZOATE MEGLUMINE AND DIATRIZOATE SODIUM INJECTION USP- IN 50ml GLASS VIAL 100ml, 150ml AND 200ml GLASS BOTTLE AND 125 ml SYRINGE PRESENTATION.
2. GADOVERSETAMIDE 330.9mg (0.5MM) IV



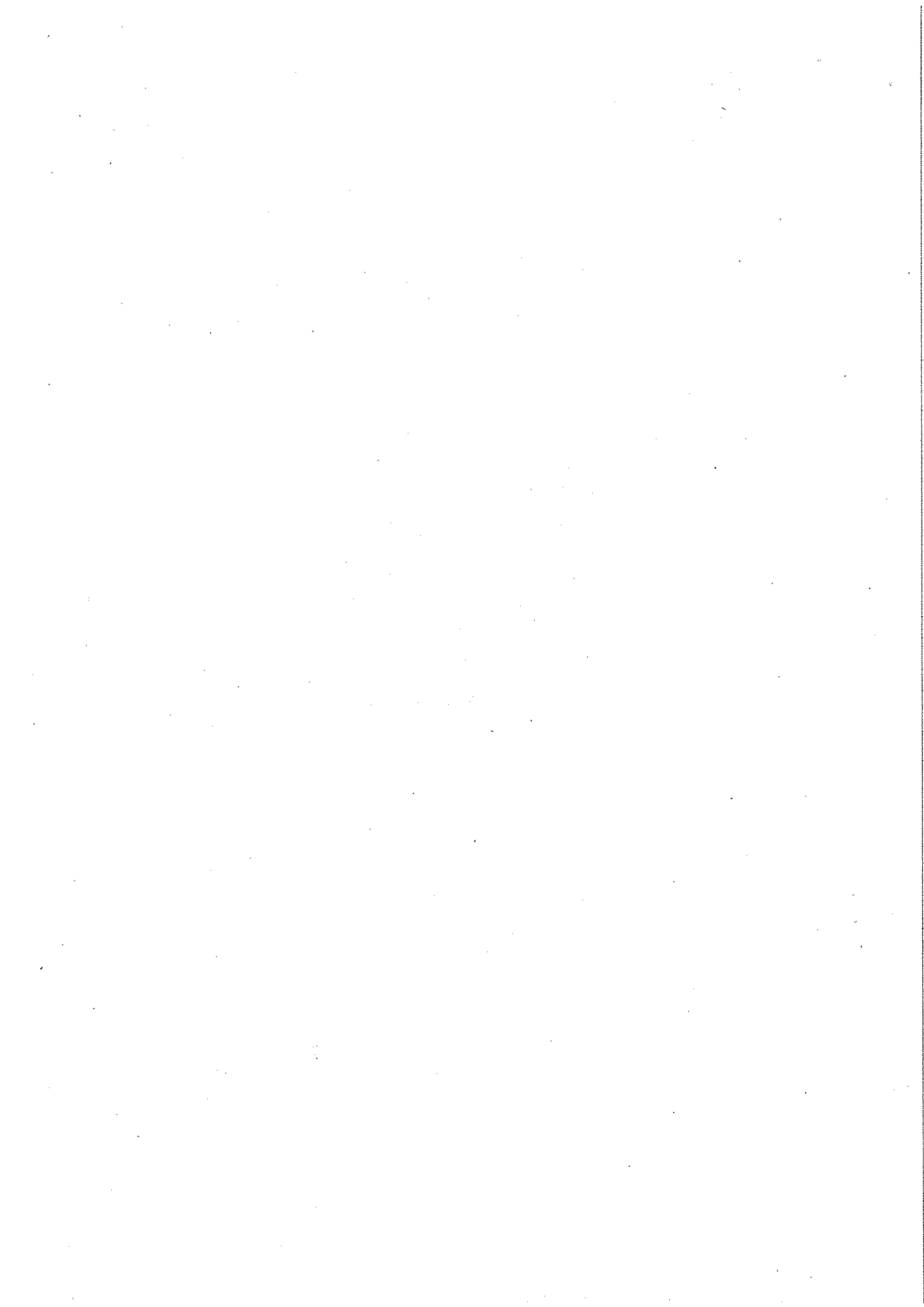
Place: New Delhi

Date: 02 JUN 2011

LICENSING AUTHORITY

Seal/Stamp

डा. सुरिन्द्र सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kotla Road,
New Delhi-110002



No. 6-3/BD/49/07-DC(REREG2011)

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

FDA Bhawan, New Delhi

Dated 02 JUN 2011

To,

M/S. RUSHI CORPORATION,
B-102, PARSIAN APARTMENT, V.P. ROAD,
OFF S.V. ROAD, ANDHERI(WEST)
MUMBAI400058

Sub: -Registration of M/S. QIDONG DONGYUE PHARMACEUTICAL CO LIMITED
HEHE TOWN QIDONG CITY,JIANGSU PROVINCE ,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 24/05/2011, received by this Office vide diary no. 24466 dated 20/05/2011 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:

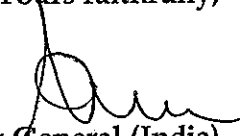
1. The drugs shall confirm to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
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. ORIGINAL LABEL OF THE DRUG AS GIVEN IN RC WITH STORAGE CONDITIONS SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF DRUG.
13. PRODUCT REGISTRATION CERTIFICATE ATTESTED BY CCPIT SHALL BE SUBMITTED TO THIS OFFICE BEFORE IMPORT OF 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.

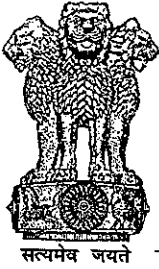
Please acknowledge the receipt.

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, 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.



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. BD-715

Dated

1. M/S. QIDONG DONGYUE PHARMACEUTICAL CO LIMITED HEHE TOWN QIDONG CITY JIANGSU PROVINCE CHINA having factory premises at M/s. QIDONG DONGYUE PHARMACEUTICAL CO LIMITED HEHE TOWN QIDONG CITY JIANGSU PROVINCE 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 RUSHI CORPORATION, B-102, PARSIAN APARTMENT, V.P. ROAD, OFF S.V. ROAD, ANDHERI (WEST) MUMBAI 400058 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: 02 JUN 2011



LICENSING AUTHORITY

Seal/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kotla 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. BD-715
DATED 02 JUN 2011

DIPYRIDAMOLE USP



Place: New Delhi

Date: 02 JUN 2011

LICENSING AUTHORITY

डा. सुरिन्द्र सिंह Seal/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kotta Road,
New Delhi-110002

1911

No. 6-4/FF/31/08-DC

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

FDA Bhawan, New Delhi
Dated 02 JUN 2011

To,

M/S. INDOCOAR PHARMA PVT LIMITED NO.32
1ST MAIN ROAD LOWER PALACE
ORCHARDS
BANGALORE 560003

Sub: -Registration of M/S. ICURE PHARMACEUTICAL INC 221-4 SINNEUNG-RI SEOUN-MYEON ANSEOUNG-SI GYEONGGI-DO 456-853 KOREA 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 16/06/2011, received by this Office vide diary no. 23135 dated 16/05/2011 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 ~~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 OF THE DRUGS ALONG WITH PACKAGE INSERT SHALL BE SUBMITTED BEFORE IMPORT OF DRUGS.**

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,


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, 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.

100 403125 0



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-591

Dated
02 JUN 2011

1. M/S. ICURE PHARMACEUTICAL INC 221-4 SINNEUNG-RI SEOUN-MYEON ANSEOUNG-SI GYEONGGI-DO 456-853 KOREA having factory premises at M/s. ICURE PHARMACEUTICAL INC 221-4 SINNEUNG-RI SEOUN-MYEON ANSEOUNG-SI GYEONGGI-DO 456-853 KOREA 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 INDOCOAR PHARMA PVT LIMITED NO.32 IST MAIN ROAD LOWER PALACE ORCHARDS BANGALORE 560003 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: 02 JUN 2011



LICENSING AUTHORITY

Seal/Stamp
डा. सुरिंदर सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kofla 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".

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सत्यमेव जयते

GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

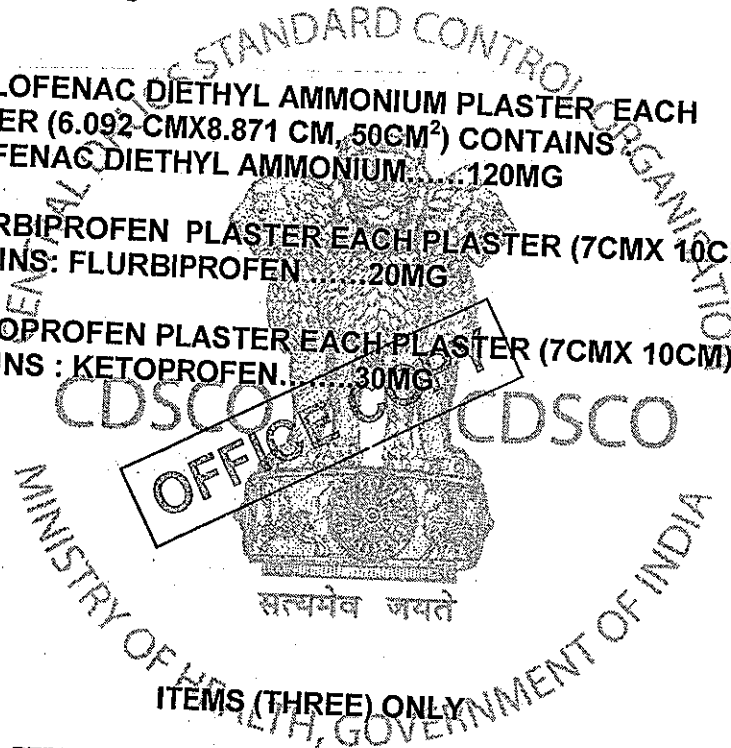
FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED
UNDER REGISTRATION CERTIFICATE NO. FF-591
DATED **02 JUN 2011**

*1) DICLOFENAC DIETHYL AMMONIUM PLASTER EACH
PLASTER (6.092-CMX8.871 CM, 50CM²) CONTAINS
DICLOFENAC DIETHYL AMMONIUM 120MG

*2) FLURBIPROFEN PLASTER EACH PLASTER (7CMX 10CM)
CONTAINS: FLURBIPROFEN 20MG

*3). KETOPROFEN PLASTER EACH PLASTER (7CMX 10CM).
CONTAINS : KETOPROFEN. 30MG



ITEMS (THREE) ONLY

*COPY OF RULE 122A PERMISSION SHALL BE SUBMITTED AT TIME OF APPLICATION OF
FORM TEN.

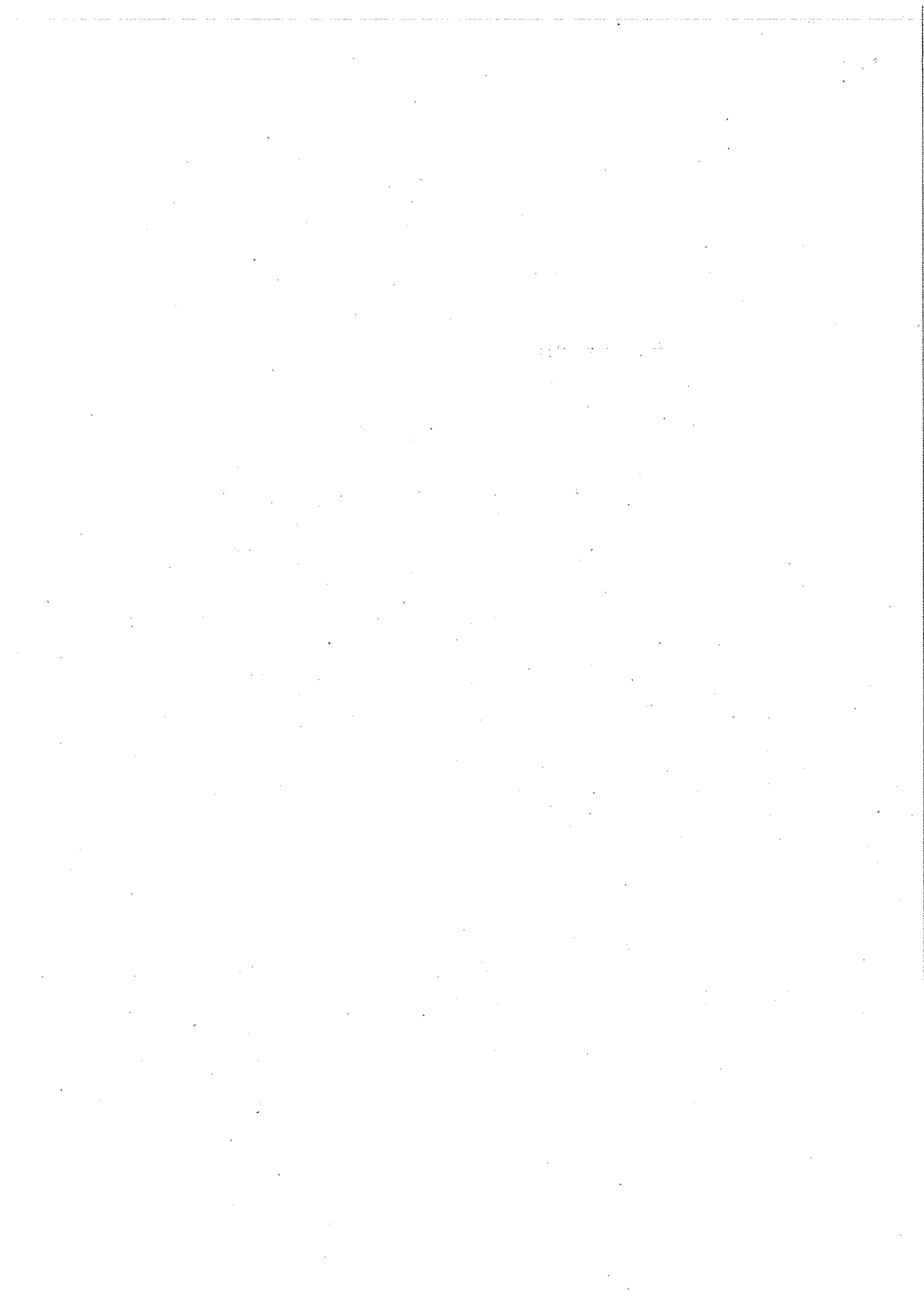
Place: New Delhi

Date: **02 JUN 2011**



LICENSING AUTHORITY

डा. सुरिन्द्र सिंह Seal/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Koda Road,
New Delhi-110002



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

FDA Bhawan, New Delhi
Dated

02 JUN 2011

To,

M/S. BASF INDIA LTD.
1ST FLOOR, VIBGYOR TOWERS, PLOT
NO.C-62, G BLOCK, BANDRA KURLA
COMPLEX
MUMBAI-400051

Sub: -Registration of M/S. BASF CORPORATION HIGHWAY 77 SOUTH BISHOP TEXAS 78343 USA 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 16/05/2011, received by this Office vide diary no. 22976 dated 05/05/2011 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:

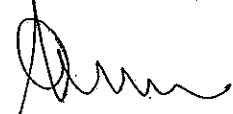
1. The drugs shall conform to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
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. **THE SHELF LIFE OF DRUG IS 5 YEARS AND BATCH SIZE IS 1370KG.**

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,



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, 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

Registration Certificate No. BD-937


02 JUN 2011
Dated

1. M/S. BASF CORPORATION HIGHWAY 77 SOUTH BISHOP, TEXAS 78343 USA having factory premises at M/s. BASF CORPORATION HIGHWAY 77 SOUTH BISHOP, TEXAS 78343 USA 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 01/05/2011 to 30/04/2014 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 BASF INDIA LTD, 1ST FLOOR, VIBGYOR TOWERS, PLOT NO.C-62, G BLOCK, BANDRA KURLA COMPLEX, MUMBAI-400051 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: 02 JUN 2011




LICENSING AUTHORITY

डा. सुरिन्दर सिंह
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत) / Drugs Controller (India)
स्वास्थ्य सेवा महानिदेशालय
Dte. General of Health Services
FDA Bhawan, Kotla Road,
New Delhi-110002

Conditions of the Registration Certificate

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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-937
DATED 02 JUN 2011

IBUPROFEN IP



Place: New Delhi

Date: 02 JUN 2011



LICENSING AUTHORITY

डा. सुरिन्द्र सिंह Seal/Stamp
Dr. SURINDER SINGH
औषधि नियंत्रक (भारत)/Drugs Controller (India)
स्वास्थ्य सेवा महाविदेशालय
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