МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

СЕРТИФИКАТ

соответствия производства лекарственного средства требованиям Надлежащей производственной практики (GMP)

№ 030/2016/GMP

Настоящий сертификат выдан открытому акционерному обществу "Борисовский завод медицинских препаратов"
222518, Минская область, г. Борисов, ул. Чапаева, 64, Республика Беларусь

осуществляющему деятельность по промышленному производству лекарственных средств по адресу:
Минская область, г. Борисов, ул. Чапаева, 64/3, Республика Беларусь

и является подтверждением того, что производство лекарственных средств на производственных участках:

производства антибиотиков в форме порошков для инъекций во флаконах (участки № 1 и № 2 цеха № 5)
в лекарственной форме: **порошки для приготовления раствора для инъекций**

соответствует требованиям Надлежащей производственной практики (GMP), утвержденной постановлением Министерства здравоохранения Республики Беларусь от 17 января 2013 г. № 6 (ТКП 030-2013 (02040) «Надлежащая производственная практика»)

Информация о лекарственных формах и производственном процессе представлена в приложении к настоящему сертификату.

Дата выдачи
05 сентября 2016 г.

Действителен до
05 сентября 2019 г.

Заместитель Министра
здравоохранения
Республики Беларусь

В.Д. Шило

GMP

№ 0000071

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

СЕРТИФИКАТ

Приложение
к сертификату
соответствия производства
лекарственного средства
требованиям Надлежащей
производственной практики (GMP)

№ 030/2016/GMP

Информация о лекарственных формах и производственном процессе

Производство стерильных лекарственных средств
Твердая лекарственная форма:
порошки для приготовления растворов для инъекций во флаконах

S.R.L. medeferent grup

GMP

№ 0000072

Реестры УП «Центр экспертиз и испытаний в здравоохранении»

- Государственный реестр лекарственных средств Республики Беларусь
- Государственный реестр предельных отпускных цен производителей на лекарственные средства
- Ход рассмотрения заявок по лекарственным средствам
- Перечень лекарственных средств, забракованных контрольно-аналитическими лабораториями
- Государственный реестр медицинской техники и изделий медицинского назначения Республики Беларусь
- Государственный реестр биомедицинских клеточных продуктов
- Государственный гигиенический регистр Республики Беларусь
- Согласование рекламы
- Реестр сертификатов GMP
- Реестр сертификатов GMP ЕАЭС

Поиск в «Государственный реестр лекарственных средств Республики Беларусь»

справка по поиску

Наименование лекарственного средства:	Анаприлин	с любой частью	исключить
Международное наименование:		с любой частью	исключить
Тип лекарственного средства:			исключить
Производитель:		с любой частью	исключить
Формы выпуска:		с любой частью	исключить
Заявитель:		с любой частью	исключить
Номер регистрационного удостоверения:		с любой частью	исключить
Дата регистрации:	дд.мм.гггг	по дате	дд.мм.гггг
Срок действия:	дд.мм.гггг	по дате	дд.мм.гггг

Поиск | Очистить форму

Найдено 2 записей - 1 страниц **Записей на странице** 20 50 100 **Сортировка по** Торговое наименование а-я я-а

Отображать: ✔ Инструкции ☐ Формы выпуска

№ п/п	Торговое наименование	Международное наименование	Производитель	Заявитель	Номер удостоверения	Дата регистрации	Срок действия	Оригинальное
1	АНАПРИЛИН инструкция: специалиста пациента	Propranolol	Открытое акционерное общество Борисовский завод медицинских препаратов. Республика Беларусь	Открытое акционерное общество Борисовский завод медицинских препаратов. Республика Беларусь	17/11/555	27.04.2016	бессрочно	генерик
2	АНАПРИЛИН-ЗДОРОВЬЕ инструкция: по применению	Propranolol	Фармацевтическая компания Здоровье ООО. Украина	Фармацевтическая компания Здоровье ООО. Украина	2565/97/02/07/07/12/17	10.08.2017	бессрочно	генерик

Страница 1 из 1

Официальные интернет-ресурсы

- Официальный интернет-портал Президента Республики Беларусь
- Официальный интернет-портал Министерства здравоохранения Республики Беларусь
- Национальный правовой интернет-портал Республики Беларусь
- Официальный интернет-портал Евразийской экономической комиссии
- Официальный интернет-портал Администрации Партизанского района г. Минска
- Белорусский профессиональный союз работников здравоохранения

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Отдел информации, информатики и анализа info@rceth.by

S.R.L. medeferent grup REPUBLICA MOLDOVA, r. ANENII NOI, s. RUSENII, SOCIETATEA CU RASPUNDERE LIMITATA 1002600003289

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE OF DRUG ADMINISTRATION

CERTIFICATE OF A PHARMACEUTICAL PRODUCT (1)

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of Certificate: DA/6-91/04/ 12368 **Date:** 26.08.15

Exporting (Certifying) Country : **BANGLADESH**
Importing (Requesting) Country : **MOLDOVA**

1. Name and Dosage form of the Product :

A) In Bangladesh : **Dobutin Injection**
B) In Moldova : **Dobutin Injection**

1.1 Active Ingredient(s) (2) and amount(s) per unit dose(3) :

Active Ingredient(s)	Amount per unit dose
Dobutamine Hydrochloride USP	Each vial contains Dobutamine Hydrochloride USP 280.20 mg equivalent Dobutamine 250 mg.

1.2 Is this product licensed to be placed on the market for use in the exporting country? (5) Yes [√] No [ ]

1.3 Is this product actually on the market in the exporting country? Yes [√] No [ ]

2A.1 Number of product licence (7) and date of issue: DAR No. 116-782-001
Date of issue 06-12-2009

2A.2 Product licence holder (name and address): Name: ***INCEPTA PHARMACEUTICALS LTD.***

Plant Address: Dewan Idris Road, Zirabo, Savar, Dhaka Bangladesh.
Office Address: 40, Shahid Tajuddin Ahmed Sarani; Tejgaon I/A, Dhaka-1208; Bangladesh

2A.3 Status of the Product License Holder (8) : a) **Manufactures the dosage form.**

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is (9) : N/A

2A.4 Is a summary basis of approval appended? [10] Yes [ ] No [√]

2A.5 Is the attached, officially approved product information complete and consonant with the license? [11] **Not Provided.**

2A.6 Applicant for certificate, if different from license holder (name and address) [12] : N/A

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14] Yes [√] No [ ]

3.1 Periodicity of routine inspection (years) : **Every two years**

3.2 Has the manufacture of this type of dosage form been inspected? Yes [√] No [ ]

3.3 Do the facilities and operation conform to GMP as recommended by the World Health Organization? [15] Yes [√] No [ ]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ? [16] Yes [√] No [ ]

Name of Authorized Person : **Major General Md Mustafizur Rahman**
Address of certifying authority : **Directorate General of Drug Administration**
105 – 106 Motijheel C/A, Dhaka-1000
Telephone : +880-(2) - 9556126
Fax : +880-(2) -9568166
E-mail : drugs@citech.net
Web-site : www.dgda.gov.bd

Stamp and Date:

MINISTRY OF HEALTH & FAMILY WELFARE ★ GOVT. OF THE PEOPLE'S REPUBLIC OF BANGLADESH ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ DHAKA

Major General Md Mustafizur Rahman
Director General 26 AUG 2015
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

S.R.L. MEDEFERENT GRUP S.R.L. REPUBLICA MOLDOVA, r. AMENII NOI, s. RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA IDNO 1002600053289 medeferent grup

MOLDOVA + APOS

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd

CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) FOR PHARMACEUTICAL (PRODUCT(S)

This certificate conforms to the format recommended by the World Health Organization (WHO)

Certificate Number : DA/6-91/04/ 10567 **Date :** 31.07.2017

It is hereby certified that M/s **Incepta Pharmaceuticals Ltd**, a drug (Pharmaceutical Products) manufacturing and marketing organization, has been given license to manufacture and sell its products freely in the People's Republic of Bangladesh as lawfully required and granted in pursuance of **The Drugs Act, 1940 (XXIII of 1940) and The Drugs (Control) Ordinance, 1982.**

On the basis of inspection carried out on 22-04-2017 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name & address of site : **Incepta Pharmaceuticals Ltd**
   Dewan Idris Road, Zirabo, Savar, Dhaka
2. Manufacturer's License No: Non-Biological 193 Date of Issue: 27.6.1967
   Biological 108 Date of Issue: 27.6.1989
3. Table: 1

Dosage Form(s)	Category (ies)	Activity (ies)
Tablet (Uncoated, coated, delayed-release, extended-release, effervescent, orodispersible, Vaginal Tablets), Capsule (Hard-shell, Liquid filled capsules), Powders, Coated Granules, Oral drops, Powder for oral Drops, Nasal drops, Eye drops, Nasal sprays, Syrup, Injectables (Injections – IV, IM, SC; Pre-filled syringes, Lyophilized Injections, powder for injections, intravenous infusions), Oral solution, Powder for oral solution, Nebulized solution, Oral suspension, Powder for oral suspension, Elixir, Respiratory Solution, Ointment, Cream, Shampoo, Gel, Vaginal Gel, Topical Solution, Mouthwash, Buccal Tablet, Chewable Tablet, Dry Powder for Inhalation.	Antibiotics and Chemotherapeutics, Antihypertensive and Cardioprotectives, Analgesics and Antipyretics, Antidiarrhoe Antiulcerants and Minerals, Antidiabetics, Antiamebics, Laxatives, Antispasmodi Antiallergics, Antiasthmatics Anxiolytics, A Antimigraine, Gynaecologica Antipsychotic, Opthalmics, An Anticonvulsants Antiplatelets, Di Lipid lowering a for Hepatitis B & Immunosuppress Antifibrinolytics, Antigout	• Procurement of raw materials from approved sources/vendors • Stability studies

continued to page-2

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to INCEPTA PHARMACEUTICALS LTD.
has been signed by MOSHARAF HOSSAIN
with the seal / stamp of MINISTER (CONSULAR), BANGLADESH HIGH COMMISSION, NEW DELHI
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 24-Nov-2017 *at* NEW DELHI, INDIA
with reference no. EIEI0042033917
Seal / Stamp
Signature

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

The manufacturing plant in which the pharmaceutical products are produced is subject to inspection at suitable intervals.

The manufacturer conforms to the requirements for good practices in the manufacture and quality control (GMP) of drugs, as required under law in this country, as well as recommended by the World Health Organization (WHO) in respect of pharmaceutical products to be manufactured, sold or distributed within the country of origin or to be exported.

This certificate remains valid for a period of 2 (Two) years from the date of issue. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name of Authorized Person : **Major General Md Mustafizur Rahman**
Address of certifying authority : **Directorate General of Drug Administration**
Mohakhali, Dhaka - 1212
Telephone : +880-(2) - 9880803
Fax : +880-(2) - 9880854
E-mail : dgda.gov@gmail.com
Web : www.dgda.gov.bd

Stamp and Date:

Major General Md Mustafizur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

Attested
Rasel Ahamed
Assistant Secretary
Board Affairs & Membership
Dhaka Chamber of Commerce & Industry
65-66, Motijheel C/A; Dhaka-1000, Bangladesh

The seal & signature of the attester is hereby attested
17 AUG 2017
Tamanna Tabassum khan
Assistant Secretary (Consular)
Ministry of Foreign Affairs, Dhaka

Attested
Shamima Begum
Deputy Secretary
Ministry of Commerce
Govt. of the People's Republic of Bangladesh

NOTARIZED BY ME
Md. Lukman Hussain
Advocate, Judge Court, Dhaka
Notary Public Whole of Bangladesh
Chamber: New Al-Asad Translation Centre
60, Rahman Mansion (1st Floor), Farmgate, Dhaka
Mobile : 01711-481551

ATTESTED BY
Ziaul Huq
Secretary
Bangladesh Association of Pharmaceuticals Industries
(Bangladesh Aushad Shilpa Samity)

The Seal & Signature of the attester / Signatory is hereby attested
Tamanna Tabassum khan
(Mosharaf Hossain)
Minister (Consular)
Bangladesh High Commission
New Delhi

Explanatory notes

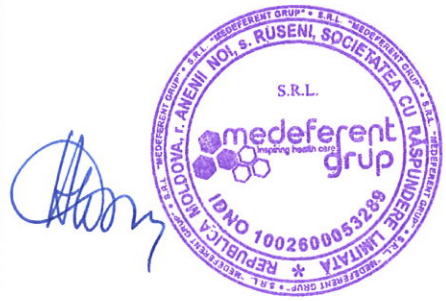
1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:

a. manufactures the dosage form;
b. packages and/or labels a dosage form manufactured by an independent company; or
c. is involved in none of the above.

9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.

a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
b. the product has been reformulated with a view to improving its stability under tropical conditions;
c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
e. any other reason, please specify.

14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.



GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE OF DRUG ADMINISTRATION

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of Certificate: DA/6-91/04/ 12369 **Date:** 26.08.15

Exporting (Certifying) Country : **BANGLADESH**
Importing (Requesting) Country : **MOLDOVA**

1. Name and Dosage form of the Product :

A) In Bangladesh : **Firmac 250 Tablet**
B) In Moldova : **Firmac 250 Tablet**

1.1 Active Ingredient(s) [2] and amount(s) per unit dose[3] :

Active Ingredient(s)	Amount per unit dose
Erythromycin Stearate BP	Each tablet contains Erythromycin Stearate BP 346.90 mg equivalent to Erythromycin 250 mg.

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5] Yes [√] No [ ]

1.3 Is this product actually on the market in the exporting country? Yes [√] No [ ]

2A.1 Number of product licence [7] and date of issue: DAR No. 116-229-60
Date of issue 15-07-2003

2A.2 Product licence holder (name and address): Name: ***INCEPTA PHARMACEUTICALS LTD.***

Plant Address: Dewan Idris Road, Zirabo, Savar, Dhaka Bangladesh.
Office Address: 40, Shahid Tajuddin Ahmed Sarani; Tejgaon I/A, Dhaka-1208; Bangladesh

2A.3 Status of the Product License Holder [8] : a) **Manufactures the dosage form.**

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is [9]: N/A

2A.4 Is a summary basis of approval appended? [10] Yes [ ] No [√]

2A.5 Is the attached, officially approved product information complete and consonant with the license? [11]

Not Provided.

2A.6 Applicant for certificate, if different from license holder (name and address) [12] : N/A

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14] Yes [√] No [ ]

3.1 Periodicity of routine inspection (years) :

Every two years

3.2 Has the manufacture of this type of dosage form been inspected? Yes [√] No [ ]

3.3 Do the facilities and operation conform to GMP as recommended by the World Health Organization? [15] Yes [√] No [ ]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ? [16] Yes [√] No [ ]

Name of Authorized Person : **Major General Md Mustafizur Rahman**
Address of certifying authority : **Directorate General of Drug Administration**
105 – 106 Motijheel C/A, Dhaka-1000
Telephone : +880-(2) - 9556126
Fax : +880-(2) -9568166
E-mail : drugs@citech.net
Web-site : www.dgda.gov.bd

Stamp and Date:

MINISTRY OF HEALTH & FAMILY WELFARE ★ GOVT. OF THE PEOPLE'S REPUBLIC OF BANGLADESH ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ DHAKA

Major General Md Mustafizur Rahman
Director General 26 AUG 2015
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

S.R.L. medeferent grup IDNO 1002600063289 REPUBLICA MOLDOVA, r. ANENII NOI, s. RUSENI, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

MOLDOVA & AFG

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd

CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) FOR PHARMACEUTICAL (PRODUCT(S)

This certificate conforms to the format recommended by the World Health Organization (WHO)

Certificate Number : DA/6-91/04/ 10567 **Date :** 31.07.2017

It is hereby certified that M/s **Incepta Pharmaceuticals Ltd**, a drug (Pharmaceutical Products) manufacturing and marketing organization, has been given license to manufacture and sell its products freely in the People's Republic of Bangladesh as lawfully required and granted in pursuance of **The Drugs Act, 1940 (XXIII of 1940) and The Drugs (Control) Ordinance, 1982.**

On the basis of inspection carried out on 22-04-2017 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name & address of site : **Incepta Pharmaceuticals Ltd**
   Dewan Idris Road, Zirabo, Savar, Dhaka
2. Manufacturer's License No: Non-Biological 193 Date of Issue: 27.6.1967
   Biological 108 Date of Issue: 27.6.1989
3. Table: 1

Dosage Form(s)	Category (ies)	Activity (ies)
Tablet (Uncoated, coated, delayed-release, extended-release, effervescent, orodispersible, Vaginal Tablets), Capsule (Hard-shell, Liquid filled capsules), Powders, Coated Granules, Oral drops, Powder for oral Drops, Nasal drops, Eye drops, Nasal sprays, Syrup, Injectables (Injections – IV, IM, SC; Pre-filled syringes, Lyophilized Injections, powder for injections, intravenous infusions), Oral solution, Powder for oral solution, Nebulized solution, Oral suspension, Powder for oral suspension, Elixir, Respiratory Solution, Ointment, Cream, Shampoo, Gel, Vaginal Gel, Topical Solution, Mouthwash, Buccal Tablet, Chewable Tablet, Dry Powder for Inhalation.	Antibiotics and Chemotherapeutics, Antihypertensive and Cardioprotectives, Analgesics and Antipyretics, S… Antidiarrhoe… Antiulcerants… and Minerals… Antidiabetics… Antiamebics, Laxatives, Antispasmodi… Antiallergics, … Antiasthmatics… Anxiolytics, A… Antimigraine, … Gynaecologica… Antipsychotic, … Opthalmics, An… Anticonvulsants… Antiplatelets, Di… Lipid lowering a… for Hepatitis B &… Immunosuppress… Antifibrinolytics, Antigout…	• Procurement of raw materials from approved sources/vendors … • Stability studies

continued to page-2

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to INCEPTA PHARMACEUTICALS LTD.
has been signed by MOSHARAF HOSSAIN
with the seal / stamp of MINISTER (CONSULAR), BANGLADESH HIGH COMMISSION, NEW DELHI
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 24-Nov-2017 *at* NEW DELHI, INDIA
with reference no. EIEI0042033917
seal / Stamp
Signature

S.R.L. "MEDEFERENT GRUP" S.R.L. MOLDOVA, r. ANENII NOI, s. RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA * REPUBLICA MOLDOVA IDNO 1002600053289 medeferent grup

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

The manufacturing plant in which the pharmaceutical products are produced is subject to inspection at suitable intervals.

The manufacturer conforms to the requirements for good practices in the manufacture and quality control (GMP) of drugs, as required under law in this country, as well as recommended by the World **Health Organization (WHO)** in respect of pharmaceutical products to be manufactured, sold or distributed within the country of origin or to be exported.

The Seal & Signature of the attestor / Signatory Tamanna Tabassum Khan is hereby attested

This certificate remains valid for a period of 2 (Two) years from the date of issue. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

(Mosharaf Hossain)
Minister (Consular)
Bangladesh High Commission
New Delhi

Dhaka Chamber of Commerce & Industry
01 NOV 2017
65-66, Motijheel C/A, Dhaka-1000, Bangladesh

Name of Authorized Person	: **Major General Md Mustafizur Rahman**
Address of certifying authority	: **Directorate General of Drug Administration** Mohakhali, Dhaka - 1212
Telephone	: +880-(2) - 9880803
Fax	: +880-(2) - 9880854
E-mail	: dgda.gov@gmail.com
Website	: www.dgda.gov.bd

Attested
Rasel Ahamed
Assistant Secretary
Board Affairs & Membership
Dhaka Chamber of Commerce & Industry
65-66, Motijheel C/A, Dhaka-1000, Bangladesh

Stamp and Date:

The seal & signature of the attestor is hereby attested
17 AUG 2017
Tamanna Tabassum khan
Assistant Secretary (Consular)
Ministry of Foreign Affairs, Dhaka

Directorate General of Drug Administration, Ministry of Health & Family Welfare, Govt. of the People's Republic of Bangladesh, DHAKA

Major General Md Mustafizur Rahman
Director General 31 JUL 2017
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

Attested
Shamima Begum
Deputy Secretary
Ministry of Commerce
Govt. of the People's Republic of Bangladesh

Consular & Welfare Wing, Ministry of Foreign Affairs, Govt. of Bangladesh

NOTARIZED BY ME
07/8/17
Md. Lukman Hossain
Advocate. Judge Court, Dhaka
Notary Public Whole of Bangladesh
Chamber: New Al-Asad Translation Centre
60, Rahman Mansion (1st Floor), Farmgate, Dhaka
Mobile : 01711-481551

ATTESTED BY
Ziaul Huq
Secretary
Bangladesh Association of Pharmaceuticals Industries
(Bangladesh Aushad Shilpa Samity)

Medeferent Grup S.R.L., Republica Moldova, IDNO 1002600053289

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:

a. manufactures the dosage form;
b. packages and/or labels a dosage form manufactured by an independent company; or
c. is involved in none of the above.

9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.

a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
b. the product has been reformulated with a view to improving its stability under tropical conditions;
c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
e. any other reason, please specify.

14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.