COPP/18-21/CJR/Unit-1/177

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : **COPP/CERT/KD/79303/2018/11/25743/134237** **Valid Upto :01 Aug 2021**

Exporting Country : INDIA

Importing Country : **MOLDOVA**

1. Name and dosage form of product : **NORADERIN**
STERILE NORADRENALINE CONCENTRATE BP

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each ml contains:

Noradrenaline Acid Tartrate BP 2 mg	(Eq. To Noradrenaline 1mg)	Water for Injection BP qs

For complete qualitative composition including excipients :[4]

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 ☐ Unknown ☐

2A.1 Number of product license:[7] **KD74 In Form 28**
and date of issue: **26 Jul 2012**

2A.2 Product License holder (Name and address) :
CIRON DRUGS & PHARMACEUTICALS PVT. LTD. N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA

2A.3 Status of product-license Holder :[8]
A ☒ B ☐ C ☐

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

2A.4 Is summary basis of Approval appended ?[10]
Yes ☐ No ☒

2A.5 Is the attached, officially approved product information complete and consonant with the license ?[11]
Yes ☐ No ☐ Not Provided ☒

2A.6 Applicant for certificate if different from License holder :[12]
Not Applicable

2B.1 Applicant for certificate (name and address) :

2B.2 Status of applicant :
A ☐ B ☐ C ☐

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ Refused

2B.4 Remarks :[13]

NOTARY GOV. OF MAHARASHTRA Name G. H. Shukla Area Reg.

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced ? if no or not applicable proceed to question 4. **Yes** ☒ **No** ☐ **Not Applicable**[14] ☐

3.1 Periodicity of routine inspections(years) : **Once a year**

3.2 Has the manufacture of this type of dosage form been inspected ? Yes ☒ No ☐

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?[15]
Yes ☒ No ☐ Not Applicable [14] ☐

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

If no, explain :

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64/65
Fax: +91-22-26591959
5RIC183793032018111505 9

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**15 Nov 2018**

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY 1836

A copy of this document / CERTIFICATE has been recorded with the Chamber 15 NOV 2018

MR. SUKHADEO DADU CHAVAN
ASSISTANT MANAGER

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 139232 Date 25 JAN 2019

I. ANEMII NOI, S. RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA
S.R.L. medeferent grup
100260005328 9

Apostillation - Sheet

GENERAL INSTRUCTION :

Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the scheme.The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than hand, written.Additional sheets should be appended, as necessary, to accommodate remarks and explanations .

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 dosages 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 be provided only 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 must be updated or it will cease to be valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from t... This permission must be provided to the author...
13. Please indicate the reason that the applicant...
    (a) the product has been developed excl... ...ical diseases – not endemic in the country of...
    (b) the product has been reformulated with a...
    (c) the product has been reformulated to ex... ...ucts in the country of import:
    (d) the product has been reformulated to me...
    (e) any other reason, please specify.
14. Not applicable means that the manufacture... conducted under ... practices in the n... ...irty- second repor... ...eport Seri... have been ... Report Serie... ...en the produ... of particula... ...se circumste... ...ng parties re... ny controls e...

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 CIRON DRUGS & PHARMACEUTICALS PVT. LTD
has been signed by SUKHADEO DADU CHAVAN
with the seal / stamp of ASSTT. MANAGER, BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
at NEW DELHI, INDIA
on 30-Jan-2019
MHMC0002161019

NOTARY NOTARIAL NOTARIAL NOTARIAL NOTARIAL NOTARIAL
G. H. Shukla Regd. No. 121/04

The layout of this model ... available on diskette in Word Perfect from the Division of Drug Management and World Health Organization, 1211 Geneva 27, Switzerland.

ATTESTED

G. H. SHUKLA,
NOTARY GREATER MUMBAI
Jagdamba Bhavan, Ground Floor,
Ganpatrao Kadam Marg, Lower Parel,
MUMBAI - 400 013.

25 JAN 2019

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
BOMBAY CHAMBER
1836

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :

13 AUG 2018

NOTARY
Name: S. H. Shukla
Area: Mumbai
Reg. No. 121/84
GOV. OF MAHARASHTRA

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).
Certificate No.: **NEW-WHO-GMP/CERT/KD/72365/2018/11/24339**

On the basis of the inspection carried out on **07/06/18 , 08/07/18 and 18/07/2018** ,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 of the Firm : **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.**
   Address : **N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD80 In Form 25, KD74 In Form 28, KD/3 In Form 28B**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Eye / Ear Drops	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Eye Drops / Ophthalmic Preparations	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Inhalation	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Liquid Injection (SVP)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	Liquid Orals	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
1 2			

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

This certificate remains valid until 01 Aug 2021 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai- 400 051.
Maharashtra,INDIA
Tel: +91-22-2659 3363/64
Fax: +91-22-2659 1950

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:09 Aug 2018

09 AUG 2018

A copy of this document / CERTIFICATE has been registered with the Chamber
PRATIK RALE
EXECUTIVE
Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 69558 Date

MOLDOVA, FILIALA IENI NOI, s. RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA
S.R.L. medeferent grup
100260005328

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified, record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product	
Starting material (s)2	
Paracetamol	

Use, whenever r otherwise national nonproprietary n

5. The certificate ecomes invalid if the activities and/o r considered to be in compliance wit

6. The requireme of drugs referred to in the certificate ls: a compendium of guidelines an inspection. Volume 2, 1999. World H

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 CIRON DRUGS & PHARMACEUTICALS PVT. LTD
has been signed by PRATIK RALE
with the seal / stamp of EXEC. BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 18-Sep-2018 at NEW DELHI, INDIA
MHMC0029960818
Seal / Stamp
Signature

BOMBAY CHAMBER OF COMMERCE & INDUSTRY ★1836★ BOMBAY

MAHARASHTRA STATE

S.R.L. medeferent grup IBNO 10026000053289

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 13 AUG 2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

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(General instructions and explanatory notes attached).
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1. Name of the Firm : **CIRON DRUGS & PHARMACEUTICALS PVT. LTD.**
   Address : **N-118,118/1, 119,119/1,119/2,113 MIDC, TARAPUR, BOISAR, DIST. THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD80 In Form 25, KD74 In Form 28, KD/3 In Form 28B**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
7	Lyophilised / Powder injectable	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
1 2			

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

This certificate remains valid until 01 Aug 2021 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 05
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:09 Aug 2018

09 AUG 2018

Explanatory note

1. This certif … nended in point 1 …

2. The certifi… eable … certificate.

3. Where the regulato… ues a licence for the si… ified record "not applicable" in cases where there is no legal frame…

4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

ATTESTED TRUE COPY

G. H. SHUKLA,
NOTARY GREATER MUMBAI
Jagdamba Bhavan, Ground Floor,
Ganpatrao Kadam Marg, Lower Parel,
MUMBAI 400 013.
28 AUG 2018

Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

28 AUG 2018

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

GUVERNUL
REPUBLICII MOLDOVA

CERTIFICAT
DE ÎNREGISTRARE A MEDICAMENTULUI
MARKETING AUTHORIZATION OF MEDICINAL PRODUCT

în baza ordinului AMDM RM (nr. A07.PS-01.Rg04-380 din 26 decembrie 2018)
in accordance with order of MMDA RM (nr. A07.PS-01.Rg04-380 from December 26, 2018)

se decide autorizarea produsului:
has been decided the registration of product:

Denumire comercială:
Name: Rinlaktin

Formă farmaceutică, doză, mărimea ambalajului: soluţie perfuzabilă 500 ml N1
Dosage form, strength and package size:

Compoziţia: 1000 ml conţine
Composition: substanţe active: lactat de sodiu 3,2 g,
clorură de sodiu 6,0 g,clorură de potasiu 0,4 g,
clorură de calciu dihidrat 0,27 g.
excipienţi: anexa 1

Deţinător al Certificatului de Înregistrare:
Marketing Autorization Holder: Jurabek Laboratories IM SRL, Uzbekistan

Producător:
Manufacturer: Jurabek Laboratories IM SRL, Uzbekistan

Clasificare ATC:
ATC classification: B05BB01

Termen de valabilitate:
Shelf life: 36 luni

Număr de înregistrare, data emiterei:
Registration number and date of issue: 25200 din 26 decembrie 2018

Rezumatul caracteristicilor produsului şi prospect anexa 1
Summary of the product and patient information leaflet

sau

Instrucţiunea pentru administrare
Instructions for administration

Informaţii privind etichetarea anexa 2
Information on the labeling

Parametrii de calitate ai produsului sunt cei prevăzuţi în documentaţia care a stat la baza eliberării prezentului Certificat de Înregistrare. Orice modificare a datelor specificate în Certificatul de Înregistrare sau în documentaţia de autorizare trebuie raportată şi aprobată de Agenţia Medicamentului şi Dispozitivelor Medicale. Prezentul Certificat de Înregistrare are o valabilitate de 5 ani de la data emiterii şi nu condiţionează importul.

The quality of the product is that which is stipulated by the documentations which were the basis for giving this particular Marketing Authorization. Any modification of the data stipulated by the Marketing Authorization or documentation must be reported to the Medicines and Medical Devices Agency and have its approval. The Marketing Authorization is valid for 5 years after emission and doesn't guarantee the import of the medicinal product.

Director general **Vladislav Zara**

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ
РОССИЙСКОЙ ФЕДЕРАЦИИ

Регистрационное удостоверение лекарственного препарата для медицинского применения

ЛП-001826
(номер регистрационного удостоверения лекарственного препарата)

Наименование держателя (владельца) регистрационного удостоверения лекарственного препарата	Публичное акционерное общество "Биосинтез" (ПАО "Биосинтез"), Россия
Адрес местонахождения держателя (владельца) регистрационного удостоверения лекарственного препарата	440033, г. Пенза, ул. Дружбы, д. 4
Дата государственной регистрации лекарственного препарата	**10.09.2012**
Срок действия регистрационного удостоверения лекарственного препарата	бессрочно
Дата внесения изменений в регистрационное удостоверение лекарственного препарата (дата замены регистрационного удостоверения лекарственного препарата)	15.01.2018
Информация о зарегистрированном лекарственном препарате:	
Торговое наименование	**Тринальгин**
Международное непатентованное, или группировочное, или химическое наименование	Метамизол натрия + Питофенон + Фенпивериния бромид
Лекарственная форма	раствор для внутривенного и внутримышечного введения
Дозировка	-
Качественный состав и количественный состав действующих веществ и качественный состав вспомогательных веществ	
метамизола натрия моногидрат (анальгин) 500 мг, питофенона гидрохлорид 2.0 мг, фенпивериния бромид 0.02 мг, вспомогательные вещества (натрия дисульфит (натрия метабисульфит), 2 М раствор натрия гидроксида, вода для инъекций)	
Форма выпуска (лекарственная форма, дозировка, первичная упаковка, количество лекарственной формы в первичной упаковке, количество первичной упаковки в потребительской упаковке, комплектность)	раствор для внутривенного и внутримышечного введения (ампула) 2/5 мл х 5/10 (пачка картонная) раствор для внутривенного и внутримышечного введения (ампула) 2 мл х 10 (коробка картонная)
Реквизиты нормативной документации	ЛП 001826-100912

018459

Производственные площадки, участвующие в процессе производства лекарственного препарата, с указанием стадий производства, названий и фактических адресов местонахождения	
Производитель (Все стадии производства)	Публичное акционерное общество "Биосинтез" (ПАО "Биосинтез"), Россия
440033, г. Пенза, ул. Дружбы, д. 4	

Статс-секретарь - заместитель Министра **Д.В. Костенников**

(подпись)

М.П.

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ

ЗАКЛЮЧЕНИЕ
о соответствии производителя (иностранного производителя) лекарственных средств для медицинского применения требованиям Правил надлежащей производственной практики

№ GMP-0023-000350/19

Часть 1

Министерство промышленности и торговли Российской Федерации подтверждает, что

Публичное акционерное общество «Биосинтез» (ПАО «Биосинтез»),

(полное и сокращенное наименование (при наличии) производителя (иностранного производителя) лекарственных средств для медицинского применения)

находящийся по адресу:

440033, г. Пенза, ул. Дружбы, д. 4,

осуществляющий производство лекарственных средств для медицинского применения по адресу:

440033, г. Пенза, ул. Дружбы, д. 4,

прошел инспектирование в рамках лицензионного контроля на соблюдение лицензионных требований при осуществлении деятельности по производству лекарственных средств в соответствии с лицензией от 18 августа 2017 г. № 00290-ЛС в соответствии с законодательством Российской Федерации *или* прошел инспектирование в части регистрационного(-ых) удостоверения(-ий), указывающего(-их) производителей, расположенных за пределами Российской Федерации, в соответствии с требованиями **Правил надлежащей производственной практики,** утвержденных приказом Министерства промышленности и торговли Российской Федерации от 14 июня 2013 г. № 916.

0001328

GMP-0023-000350/19

На основании информации, полученной в ходе инспектирования данного производителя, последнее из которых было проведено 29/12/2018, следует, что он соответствует требованиям Правил надлежащей производственной практики, утвержденных приказом Минпромторга России от 14 июня 2013 г. № 916.

Настоящее заключение отражает статус соответствия производственной площадки производителя (иностранного производителя) лекарственных средств для медицинского применения на момент проведения вышеуказанной инспекции и не должно восприниматься в качестве документа, свидетельствующего о статусе соответствия в случае истечения более 3 (трёх) лет с даты этой инспекции.

Заключение является действующим при предоставлении всех его страниц (как части 1, так и части 2).

Подлинность данного заключения проверяется в реестре заключений о соответствии производителей лекарственных средств для медицинского применения требованиям Правил надлежащей производственной практики, размещенном на официальном сайте http://www.minpromtorg.gov.ru, http://www.минпромторг.рф. При отсутствии настоящего заключения в реестре заключений о соответствии производителей лекарственных средств для медицинского применения требованиям Правил надлежащей производственной практики, сообщите в Минпромторг России.

Настоящее заключение действует в течение 3 лет с даты окончания инспекции.

Первый заместитель Министра _____ **С.А. Цыб**

М.П.

24 января 2019 г.
(дата выдачи заключения)

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/ 12371 **Date:** 26.02.15

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

1. Name and Dosage form of the Product :

A) In Bangladesh : **Veracal 2ml Injection**
B) In Moldova : **Veracal 2ml Injection**

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

Active Ingredient(s)	Amount per unit dose
Verapamil Hydrochloride USP	Each 2 ml injection contains Verapamil Hydrochloride USP 5.00 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. 116-309-022
Date of issue 02-11-2004

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

S.R.L. medeferent grup IDNO 1002600053289

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
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

26 AUG 2015

S.R.L. medeferent grup IDNO 1002600053269 REPUBLICA MOLDOVA, r. ANENII NOI, s. RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA

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

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भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country: 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
Email : dgda.gov@gmail.com
Website : 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 attestor / Signatory is hereby attested
17 AUG 2017
Tamanna Tabassum khan
Assistant Secretary (Consular)
Ministry of Foreign Affairs, Dhaka

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

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 Oushud Shilpa Samity)

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.