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/90019/2019/11/29867/152435 Valid Upto :26 Sep 2022

Exporting Country : INDIA

Importing Country : ALGERIA

1. Name and dosage form of product : Darunavir Tablets 600 mg (Export to Algeria)

1.1 Active ingredient(s)[2] and amount (s) per unit dose [3]: Each film-coated tablet contains:

Darunavir Ethanolate equivalent to Darunavir 600 mg

Colour:Titanium Dioxide, Sunset Yellow FCF

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] KD620 In Form 25
and date of issue 27 Nov 2017

2A.2 Product License holder (Name and address) :
CIPLA LTD. PLOT NO. A-42, M.I.D.C., PATALGANGA, RAIGAD
410220 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]

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

SPIC1559001920191022059

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:22 Oct 2019

22 OCT 2019

REPUBLICA MOLDOVA, ANENII NOI, RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA «MEDEFERENT GRUP» S.R.L. IDNO 1002600053289

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 the product Licence holder. This permission must 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 that 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 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. The 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.

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

MOLDOVA, ANENII NOI, RUSENI SOCIETATEA CU RASPUNDERE LIMITATA REPUBLICA MEDEFERENT GRUP IDNO 1002600053289 «MEDEFERENT GRUP» S.R.L.

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 37 17
Fax direct: +41 22 791 47 30
E-mail : prequalassessment@who.int

In reply please refer to: HA628-0/MS/CS

Your reference:

Ms Vaishali Shridhankar
Regulatory Affairs
Cipla Ltd
Building No.5, 7th Floor, North Block Cipla
R&D Centre
L.B.S. Marg Vikhroli (West)
Mumbai 400 083
Maharashtra
Inde

6 January 2017

Dear Ms Shridhankar,

WHO Prequalification Team – Medicines Assessment
FPP Prequalification – Letter of Prequalification

Application number: HA628-0

I refer to your letter expressing Cipla Ltd's interest to participate in the "Procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by United Nations agencies", as adopted in 2001 by the Thirty-seventh World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and published in the WHO Technical Report Series No. 908, and amended subsequently in the Forty-fifth report, as published in the WHO Technical Report Series No. 961 in 2011.

Thank you for submitting the data and information requested and for your voluntary participation in this quality assessment procedure. The review of your company's product dossier on:

- **HA628 - Darunavir (as ethanolate) Tablet, Film-coated 600mg**

has been completed and following inspection of the facilities used for the manufacture and testing of this product, it has been found to meet the norms and standards recommended by WHO and is acceptable, in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at the current time, i.e. the information in the submitted dossier and on the status of current good manufacturing, clinical and laboratory practices at the facilities used for the manufacture and testing of the product. Please note, however, that this decision may change based on new information that may become available to us. Therefore, in accordance with and subject to the Guiding Principles of Prequalification, the product will now be included in the list of medicinal products, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at www.who.int/prequal.

Please note that inclusion in the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

ENCLS: (2)

.../...

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacture of the product, you should:

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and
- submit the respective information about the intended variations and the required additional data by email to **prequalassessment@who.int**, and in hard copy, clearly marked as indicated, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref Number: HA628

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO will, at regular intervals, arrange for the products and manufacturing sites included in the list to be re-evaluated. If, as a result of this reassessment, it is found that a product and/or specified manufacturing site no longer complies with the WHO recommended standards, such products and manufacturing sites will be removed from the list. The failure of an applicant or a manufacturer to participate in the reassessment procedure (as set out in the aforementioned Guiding Principles) will also lead to removal from the list.

WHO welcomes your company's voluntary participation in this Programme. In order to meet the terms established for monitoring and re-evaluation of prequalified medicinal products, as well as to foster communication between Cipla Ltd and the WHO Prequalification Team – Medicines, please complete the two forms enclosed (*"Main characteristics of the prequalified medicinal product"* and *"Undertakings of the applicant"*) and return these, signed by a duly authorized representative of Cipla Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
HIS/EMP/RHT/PQT Room 613
20 Avenue Appia
1211 Geneva 27
Switzerland

.../...

I look forward to receiving this information from within two weeks of the date of this letter at the latest. For further information please use the email address **prequalassessment@who.int** and kindly ensure that any communication quotes the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Group Lead, Medicines Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 207189

ANDA TENTATIVE APPROVAL

Cipla USA, Inc.
U.S. Agent for Cipla Limited
1560 Sawgrass Corporate Parkway, Suite 130
Sunrise, FL 33323
Attention: Michele Crawley

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Darunavir Tablets, 75 mg, 150 mg, 400 mg, and 600 mg.

Reference is also made to your amendments dated June 6 and September 26, 2014; May 6, 2015; March 11, March 23, April 25, June 3, June 23, September 23, 2016; and March 3, 2017.

This ANDA was reviewed under the expedited review provisions of the President's Emergency Plan for AIDS Relief (PEPFAR).

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the exclusivity issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. Furthermore, based on data provided, the expiration dating period is 24 months for Darunavir Tablets, 75 mg, 150 mg, 400 mg, and 600 mg, in the following packaging configuration when store below 30°C (86°F): HDPE bottle packs of 480 with a non-child-resistant closure for the 75 mg tablets, HDPE bottle packs of 240 with a non-child-resistant closure for the 150 mg tablets, HDPE bottle packs of 60 with a non-child-resistant closure for the 400 mg and 600 mg tablets.

The RLD upon which you have based your ANDA, Janssen's Prezista, 75 mg, 150 mg, 400 mg, and 600 mg of Janssen Products LP, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the "Orange Book":

U.S. Patent Number	Expiration Date
7,470,506 (the '506 patent)	December 23, 2019
7,700,645 (the '645 patent)	June 26, 2027

8,518,987 (the '987 patent)	August 16, 2024
8,597,876 (the '876 patent)	December 23, 2019
RE42,889 (the '889 patent)	April 19, 2017
RE43,596 (the '596 patent)	November 9, 2017
RE43,802 (the '802 patent	April 19, 2017

Your ANDA contains paragraph III certifications to each of the patents under section 505(j)(2)(A)(vii)(III) of the Act stating that Cipla Limited will not market Darunavir Tablets, 75 mg, 150 mg, 400 mg, and 600 mg prior to the expiration of the patents. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until the patents have expired, currently.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book." Should you believe that there are grounds for issuing the final approval letter prior to , you should amend your ANDA accordingly.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

Additionally, we note that the failure of any facility referenced in the application to self-identify and pay applicable fees means that FDA will not consider the GDUFA application review goal dates to apply to that application.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs and Drug Master Files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Lakeeta Carr, Regulatory Project Manager, at (240) 402-1391.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
Date: 3/16/2017 05:29:31PM
GUID: 508da712000293e0f6d8acfd3c5e67fe

MOLDOVA, ANENII NOI, RUSENI, SOCIETATEA CU RASPUNDERE LIMITATA "MEDEFERENT GRUP"
IDNO 1002600053289
«MEDEFERENT GRUP»
S.R.L.

FDA MAHARASHTRA

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

03 OCT 2019

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/83192/2019/11/29628**

On the basis of the inspection carried out on **06/05/2019, 07/05/2019, 08/05/2019 and 26/08/2019** ,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 : **CIPLA LTD.**
   Address : **PLOT NO. A-42, M.I.D.C., PATALGANGA, RAIGAD 410220 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD620 In Form 25, KD435 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
2	Suppositories / Pessaries	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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 26 Sep 2022 . 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: +91-22-26592363/64
Fax: +91-22-26591959
1PIC1558319220190927
CIPLA LTD. - NEW-WHO-GMP/CERT/KD/83192/2019/11/29628

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:27 Sep 2019

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

27 SEP 2019

IDNO 1002600053289 «MEDEFERENT GRUP» S.R.L.

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.

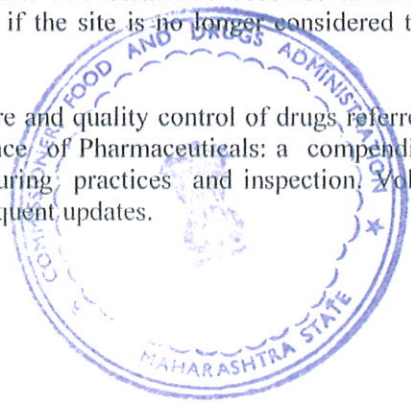
   Example - 2.

Pharmaceutical Product (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.



Dinesh Kashikar/SQA/PTG

From: Vijay L Thange/Technical/PTG
Sent: 20.01.2020 09:17
To: Manoj D Dorlikar/Technical/PTG; Dinesh Kashikar/SQA/PTG; Vijay Divecha/CQA/VKH
Subject: FW: [WARNING: MESSAGE ENCRYPTED]FDA FMD145 EIR
Attachments: EIR for Cipla.pdf

Dear All,

Copy of EIR for your reference.

Thanks
Vijay

From: Deryl.Richardson@FDA.HHS.GOV [mailto:Deryl.Richardson@FDA.HHS.GOV]
Sent: Saturday, January 18, 2020 8:37 AM
To: Vijay L Thange/Technical/PTG <Vijay.Thange@Cipla.com>
Subject: [WARNING: MESSAGE ENCRYPTED]FDA FMD145 EIR

12/16/2019

Mr. Vijay Thange
Site Head
Cipla, Ltd.
Midc Industrial Area Patalganga
Plot No A-2, A-33, A-37/2/2, A-42
Raigad, Maharashtra, 410220 India

Dear Mr. Thange:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Cipla, Ltd., FEI 3002806710, located at Midc Industrial Area Patalganga, Plot No A-2, A-33, A-37/2/2, A-42, Raigad, Maharashtra from 11/04/2019 to 11/13/2019. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action

indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER's Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact me at (949) 608-3519 or email at Katherine.Jacobitz@fda.hhs.gov.

Sincerely,

CAPT Katherine E. Jacobitz
Investigations Branch Director, Division IV
Office of Pharmaceutical Quality Operations

FDA U.S. FOOD & DRUG ADMINISTRATION

Medicines and Healthcare Products Regulatory Agency

CERTIFICATE NUMBER: ***UK GMP 14694 Insp GMP 14694/441687-0005***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of United Kingdom confirms the following:
The manufacturer: ***CIPLA LIMITED (UNIT II)***
Site address: ***UNIT II, PLOT NO A-42, MIDC, PATALGANGA, DISTRICT RAIGAD, MAHARASHTRA, IN-410 220, India***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:
The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-02-19*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

---

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2018-05-22

Name and signature of the authorised person of the Competent Authority of United Kingdom

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