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 3717
Fax direct: +41 22 791 4730
E-mail : prequalassessment@who.int

In reply please
refer to the WHO product Ref N°: HA467

Your reference:

Mr Kameshwar Bhardwaj
Senior General Manager - Regulatory Affairs
Matrix Laboratories Limited
1-1-151/1, 4th floor
Sairam Towers
Alexander Road
Secunderabad 500 003
Inde

11 February 2011

Dear Mr Bhardwaj,

WHO Prequalification of Medicines Programme

This is in reference to your letter expressing Matrix Laboratories 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 amended subsequently in the Forty-first report, as published in the WHO Technical Report Series N° 943 in 2007.

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

- Ritonavir 100mg Tablets

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 this 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.

Thus, 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 listed. 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.

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

ENCL: (2)

.../...

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

- consult the "Guidance on variations to a prequalified product dossier", as adopted in 2006 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 6 of the WHO Technical Report Series N° 943 in 2007, 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 below, to the following address:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification of Medicines Programme

  UNICEF Supply Division
  UNICEF Plads – Freeport
  2100 Copenhagen
  Denmark

Finally, we should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. In this regard 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. Failure of an applicant or a manufacturer to participate in the reassessment procedure (as set forth in the above-mentioned 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 Matrix Laboratories Ltd. and the WHO Prequalification of Medicines Programme, 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 Matrix Laboratories Ltd., to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification of Medicines Programme
HSS/PSM/QSM
20 Avenue Appia
1211 Geneva 27
Switzerland.

We look forward to receiving this information from you by 25 February 2011 at the latest. For further information please use the e-mail address – prequalassessment@who.int – and kindly ensure that any correspondence mentions the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

Dr Matthias Stahl
Head of Assessments
Prequalification Programme
Quality Assurance and Safety: Medicines

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-03 Jul 2021

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/NKD/103230/2021/11/36529**

On the basis of the inspection carried out on **27.05.2021 & 28.05.2021 , 22.06.2021** ,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 : **MYLAN LABORATORIES LIMITED**
   Address : **F-4 & F-12, MIDC, MALEGAON, TAL.. SINNAR, NASHIK 422113 MAHARASHTRA STATE, INDIA**
2. Licence No. : **NKD89 In Form 25, NKD43 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	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 02 Jul 2024 . 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: +91-22-26592363/6
Fax: +91-22-26591959
1LYM225103230202107O3
MYLAN LABORATORIES LIMI... NEW-WHO-GMP/CERT/NKD/103230/20...1/36529

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Name of the Authorised person : **D. R. GAHANE**
Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**03 Jul 2021**

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.

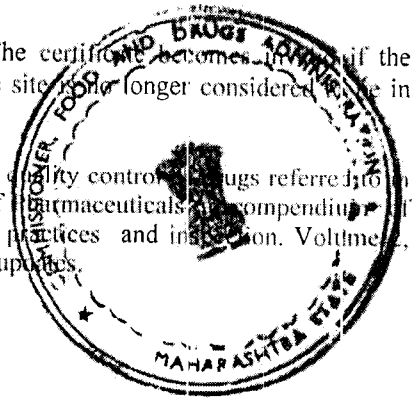
   Example - 2.

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.



LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/NKD/103230 /2021/11/36529 **VALID UP TO :02 Jul 2024**

Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
F-4 & F-12, MIDC, MALEGAON, TAL. SINNAR,
NASHIK 422113 MAHARASHTRA STATE, INDIA

Drug License No : NKD89 In Form 25,
NKD43 In Form 28

Sr.No.	Name of the Product	Composition
33	Lopinavir and Ritonavir Tablets, USP 100mg/25mg	Each film coated tablet contains Lopinavir USP 100.00 mg Ritonavir USP 25.00 mg
34	Lopinavir and Ritonavir Tablets, USP 200mg/50mg	Each film coated tablet contains Lopinavir USP 200.00 mg Ritonavir USP 50.00 mg
35	Moxifloxacin Tablets 400 mg	Each film coated tablet contains: Moxifloxacin Hydrochloride Ph. Eur. equivalent to Moxifloxacin 400 mg
36	Nevirapine Extended Release Tablets 400 mg	Each Extended Release Tab et Contains Nevirapine USP 400.00 mg
37	Nevirapine Tablets USP 200mg	Each tablet Contains Nevirapine USP 200.00 mg
38	Ritonavir Tablets 25 mg	Each tablet contains Ritonavir USP 25 mg
39	Ritonavir Tablets USP 100mg	Each film coated tablet contains Ritonavir USP 100.00 mg
40	Sofosbuvir and Velpatasvir Film Coated Tablets 400mg/100mg	Each film coated tablet contains Sofosbuvir 400 mg Velpatasvir 100 mg

1 2 3 4 5 6 7 8 9 10

FOOD AND DRUGS ADMINISTRATION COMMISSIONER MAHARASHTRA STATE

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

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**03 Jul 2021**

Health Products Regulatory Authority

CERTIFICATE NUMBER : *30759*

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 Ireland confirms the following:
The manufacturer :***MYLAN LABORATORIES LIMITED***
Site address :***F-4 and F-12, Malegaon MIDC, Sinnar Nashik District, 422113, Maharashtra State, 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 .

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-05-14*** , 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) 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Activities listed on the certificate were reviewed by distant assessment; an on-site inspection was not conducted. Live video footage was used to assess relevant manufacturing processes, facilities and equipment. The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.

2021-07-19

Name and signature of the authorised person of the Competent Authority of Ireland

---

Confidential
Health Products Regulatory Authority
Tel:***Confidential***
Fax:***Confidential***

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 3717
Fax direct: +41 22 791 4730
E-mail : prequalassessment@who.int

In reply please refer to: P5-447-3-LoPQ/HA392/MS/SC

Your reference:

Mr Kameshwar Bhardwaj
General Manager - Regulatory Affairs
Matrix Laboratories Ltd
1-1-151/1, 5th Floor
Sairam Towers, Alexander Road
Secunderabad 500 003
Andhra Pradesh
Inde

16 July 2008

Dear Mr Bhardwaj,

WHO Prequalification of Medicines Programme

This is in reference to your letter expressing Matrix Laboratories Limited '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 37th World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently in the forty first report, as published in the WHO Technical Report Series N° 943 in 2007.

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

- Lamivudine/Zidovudine - 150/300 mg - Tablets - HA392

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

This conclusion is based on information available to WHO at this 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 the new information that may become available to us.

Thus, 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 can not be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers listed. 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.

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

ENCLS: (2)

.../...

Prior to implementation of any changes in any parts of the approved dossier and/or in the manufacturing of the product, please:

- consult the "Guidance on variations to a prequalified product dossier", as adopted in 2006 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 6 of the WHO Technical Report Series N° 943 in 2007; 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 below, to the following address:

CONFIDENTIAL
Attention: Dr Matthias Stahl
WHO Prequalification of Medicines Programme
Product Name:

UNICEF Supply Division
UNICEF Plads – Freeport
2100 Copenhagen
Denmark

Finally, we should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. In this regard, 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. Failure of an applicant or a manufacturer to participate in the reassessment procedure (as set forth in the above-mentioned 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 Matrix Laboratories Limited and the WHO Prequalification of Medicines Programme, 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 Matrix Laboratories Limited, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification of Medicines Programme
HTP/PSM/QSM
20 Avenue Appia
1211 Geneva 27
Switzerland.

We look forward to receiving this information from you by 31 July 2008 at the latest. For further information please use the e-mail address – prequalassessment@who.int – and kindly ensure that any such e-mail mentions the corresponding WHO product reference number.

Thank you for your cooperation.

Yours sincerely,

S. Uoyt

Dr Raul Kiivet
Manager, Prequalification Programme
Quality Assurance and Safety: Medicines
Department of Medicines Policy and Standards

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: CPH47/MS/TC/HA392-404V12b

Your reference:

Mr Kameshwar Bhardwaj
General Manager - Regulatory Affa rs
Matrix Laboratories Ltd
1-1-151/1, 5th floor
Sairam Towers, Alexander Road
Secunderabad 500 003
Andhra Pradesh
Inde

17 February 2009

Dear Mr Bhardwaj,

WHO Prequalification of Medicines Programme
Variation to a product dossier

Thank you for submitting the data for the assessment of the variation to your prequalified product dossier within the WHO Prequalification of Medicines Programme. A team of evaluators recently assessed the data submitted for

HA392: *Lamivudine/Zidovudine 150/300mg tablets*
HA404: *Zidovudine 300mg tablets*

Nature of the Variation: Additional manufacturer for Zidovudine API (Variation No. 12b).

As a result of this assessment, you are kindly informed that the variation submitted is considered acceptable:

Since all the conditions of the variation were fulfilled and the required supportive documentation was submitted and found satisfactory, the proposal to use Smurthi Organics Ltd (unit II), Plot No. A-27, Chincholi Mohol, 413 255 Solapur, Maharashtra India (Contract manufacturer for Astrix Laboratories Ltd) as additional source of Zidovudine API is accepted for the following products:

HA392: *Lamivudine/Zidovudine 150/300mg tablets*
HA404: *Zidovudine 300mg tablets*

However, item 6.2 of the contract agreement should state the contract accepter (M/s. Smurthi Organics limited) not the contract giver (Astrix) who should not pass on to a third party any of the work entrusted to them under the contract. Please revise the agreement accordingly.

.../...

For further communication regarding the variations to your prequalif ed product dossier please use the e-mail address – **prequalassessment@who.int** – and kindly ensure that any such e-mail mentions the corresponding WHO product reference number.

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Head of Assessment
Prequalification of Medicines Programme
Quality Assurance and Safety: Medicines

U.S. FOOD & DRUG
ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via E-Mail

March 5, 2020[1]

Mr. Venugopal Reddy Devakamma
Head of OSD-Site Operations
Mylan Laboratories Limited
Plot Nos. 11, 12, 13 (FDF-3), Indore Special Economic Zone
Pharma Zone, Phase II, Sector III, Pithampur
District Dhar, Madhya Pradesh, 454775 India

Dear Mr. Devakamma:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Mylan Laboratories Limited, FEI 3010453141, located at Plot Nos. 11, 12, 13 (FDF-3), Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, from October 21, 2019 to October 25, 2019. FDA has determined that the inspection classification of this facility is "voluntary action indicated" (VAI).[2] Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regard 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 applications referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

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[1] Original 90-day inspection classification letter was issued in accordance with established procedures and timeframes on January 17, 2020. Due to an inadvertent typographical error in the year of issuance (2019 instead of 2020), letter is being reissued.

[2] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.

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 Brooke Higgins via telephone at (301) 796-4171 or email at brooke.higgins@fda.hhs.gov.

Sincerely,

Carmelo R. Rosa -S

Digitally signed by Carmelo R. Rosa -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000019462, cn=Carmelo R. Rosa -S
Date: 2020.03.05 10:19:25 -05'00'

Carmelo Rosa, Psy.D.
Director, Division of Global Quality I
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

OFFICE OF THE CONTROLLER, FOOD AND DRUGS ADMINISTRATION MADHYA PRADESH

No. :V/WHO-GMP/M-2/2018/ 5862 **Bhopal, dated:** 26-11-18

To,

M/s Mylan Laboratories Limited,

Plot No.11, 12 & 13, Indore SEZ, Pharma Zone,

Phase-II, Sector-III, Pithampur-454775, Dist. Dhar

Madhya Pradesh

Sub. : Revalidation of Certificate of Pharmaceutical Products.

****

Please find enclosed herewith the Certificate of Pharmaceutical products under WHO-GMP Certification Scheme under **Certificate No. 7/2014**, Valid up 25 NOV 2021 in respect of finished Drugs granted as per list enclosed under license no. **25/1/2014** in **Form 25** and **28/1/2014** in **Form 28** as per recommendation by the office of the Deputy Drugs Controller (I) CDSCO Sub Zone, Indore vide letter No. **SZI/2017/COPP/Mylan/001/1063-64 dated 12.10.2018.**

Total No. of Items: 43

Enclosed; As Above.

22/11/18

LICENSING AUTHORITY
FOOD & DRUGS ADMINISTRATION
MADHYA PRADESH

Endt. No. :V/WHO-GMP/M-2/2018/ **Bhopal, dated:**

Copy to;

1. The Asst. Drug Controller (India)Sub zonal office, 67-72, Type-I Griffins Colony, M.Y. Hospital to Piplyahana Main Road, Near St. Raphael's School – Indore -452 001
2. Drug Inspector, Food and Drugs Administration, District – Dhar (M.P.) for Information.

LICENSING AUTHORITY
FOOD & DRUG ADMINISTRATION
MADHYA PRADESH

OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No.: V/WHO-GMP/M-2/2018/ **Bhopal, dated**

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This one page certificate conforms to the format recommended by the World Health Organization (general instruction and explanatory notes attached)

Certificate No. 07/2014

On the basis of the inspection carried out on dated 22/09/2018, 24/09/2018 & 25/09/2018, 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 and address of site: **M/s Mylan Laboratories Limited, Plot No.11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II, Sector-III, Pithampur-454775, Dist. Dhar, Madhya Pradesh.**

2. Manufacturer's License Number: **25/1/2014 & 28/1/2014 in form 25 & 28 dated 17/01/2014**

3. Table 1:

Dosage form (s)	Category (ies)	Activity (ies)
TABLETS, CAPSULES & DRY POWDER / GRANULES FOR ORAL SUSPENSION	General (Other than Penicillin, Cephalosporin, Hormones & Cytotoxic)	Production, Packing & Labeling, Quality Control

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 **21/11/2021**. 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: **Idgah Hills, Bhopal**

Name and function of responsible person:

Licensing Authority
Food & Drugs Administration,
Idgah Hills, Bhopal (M.P.)
Email: cfdamp@rediffmail.com
Telephone No. 0755-2666058
Fax No.0755-2665385

6.12.18
Shobhit Koshta
Licensing Authority
Food & Drugs Adminstration
Madhya Pradesh

Signature

Stamp and date

[1] This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

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 case 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 give below.

Example 1

Pharmaceutical Product(s)[2]	*Category(ies)*	*Activity(ies)*
Dosage form(s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labeling
Injectables	Cefalosporin	Aseptic preparation, packaging, labelling

Example 2

Pharmaceutical Product(s)[2]	*Category(ies)*	*Activity(ies)*
Starting material(s)[3]*:*		
Paracetamol	Analgesic	Synthesis, purification, packing, labeling

[2] Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and importing state.
[3] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

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 in 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.

Annexure I

Mylan Laboratories Limited
Plot No. 11, 12 & 13, Indore SEZ, Pharma Zone, Phase-II,
Sector- III, Pithampur- 454775, Dist.: Dhar, Madhya Pradesh, INDIA

Certificate No. 07/2014

11	**Sulfamethoxazole and Trimethoprim Tablets USP 800mg/160mg**	Each tablet Contains: Sulfamethoxazole Ph. Eur. 800 mg Trimethoprim Ph. Eur. 160 mg
12	**Sulfamethoxazole and Trimethoprim Tablets USP 400mg/80mg**	Each tablet Contains: Sulfamethoxazole Ph. Eur. 400 mg Trimethoprim Ph. Eur. 80 mg
13	**Tenofovir Alafenamide Tablets 25mg [HepBest]** (Trade Name Given by Manufacturer)	Each tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25mg
14	**Lamivudine and Zidovudine Tablets USP 150mg/300mg [ZOVILAM] (Trade Name Given by Manufacturer)**	Each film coated tablet Contains: Lamivudine USP 150 mg Zidovudine USP 300 mg
15	**Emtricitabine, Tenofovir Alafenamide and Dolutegravir Tablets 200mg/ 25mg/50mg[KOCITAF]** (Trade Name Given by Manufacturer)	Each film coated tablet Contains:Emtricitabine 200 mgTenofovir Alafenamide Fumarate equivalent toTenofovir Alafenamide 25 mgDolutegravir Sodium equivalent to Dolutegravir 50 mg
16	**Emtricitabine and Tenofovir Alafenamide Tablets 200mg/25mg**	Each tablet Contains: Emtricitabine 200 mg Tenofovir Alafenamide Fumarate Equivalent to Tenofovir Alafenamide 25 mg

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P., BHOPAL

Laboratories Ltd.

24/11/18

SHOBHIT KOSHTA
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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: HA685-0/MS/EG

Your reference:

Mr Imtiyaz Basade
Sr. Vice-President, Regulatory Affairs
Mylan Laboratories Ltd
Plot No.564/A/22 Road No. 92
Jubilee Hills
Hyderabad 500096
Telangana
Inde

11 June 2019

Dear Mr Basade,

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

Application number: HA685-0

I refer to your letter expressing Mylan Laboratories 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:

- **HA685 - Darunavir (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 prequ4alified 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 in electronic format (CD or DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref Number: HA685

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

  Please send the link to **FPPassessment@who.int,** if you prefer to submit the response via a file transfer link.

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 Mylan Laboratories 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 Mylan Laboratories Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
MVP/EMP/RHT/PQT Room 615
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

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: HA688-0/MS/FV

Your reference:

Mr Imtiyaz Basade
Sr. Vice-President, Regulatory Affairs
Mylan Laboratories Ltd
Plot No. 564/A/22 Road No. 92
Jubilee Hills
Hyderabad 500096
Telangana
Inde

18 December 2018

Dear Mr Basade,

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

Application number: HA688-0

I refer to your letter expressing Mylan Laboratories 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:

- **HA688 - Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg**

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 in electronic format (CD or DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref Number: HA688

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

  Please send the link to **FPPassessment@who.int**, if you prefer to submit the response via a file transfer link.

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 Mylan Laboratories 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 Mylan Laboratories Ltd, to the following address:

World Health Organization
Attention: Prequalification Secretariat
WHO Prequalification Team – Medicines
MVP/EMP/RHT/PQT Room 617
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

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: HA721-0/MS/ADV

Your reference:

Mr Imtiyaz Basade
Sr. Vice-President, Regulatory Affairs
Mylan Laboratories Ltd
Plot No.564/A/22 Road No 92
Jubilee Hills
Hyderabad 500096
Telangana
Inde

31 October 2018

Dear Mr Basade,

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

Application Number: HA721-0

I refer to your letter expressing Mylan Laboratories 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:

- **HA721 - Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg (SYMFILO)**

has been completed according to the "WHO Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities", and the product has been found to be acceptable in principle, for procurement by UN agencies.

This conclusion is based on information available to WHO at this time, i.e. the Certificate of Pharmaceutical Product (CPP) and Assessment report issued by the regulatory agency of USFDA. 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.

.../...

Since the product has been licensed by drug regulatory authorities (DRAs) of the ICH region and associated countries, subsequent variation applications are also to be approved by these DRAs and WHO should be notified about the approval of the changes. The applicants are required to submit the respective information about the variations and a copy of the regulatory acceptance letter of the changes issued by the regulatory agency of USFDA in electronic format (on a CD/DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

CONFIDENTIAL
Attention: Group Lead – Medicines Assessment
WHO Prequalification Team – Medicines

UNICEF Supply Division
Oceanvej 10-12
2150 Nordhavn, Copenhagen
Denmark

Please send the link to **FPPassessment@who.int**, if you prefer to submit the response via a file transfer link.

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 Mylan Laboratories 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 Mylan Laboratories Ltd, to the following address:

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

I look forward to receiving this information from you 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 such communication mentions 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