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.

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

In reply please refer to: HA635/MS/PG

Your reference:

Mr Imtiyaz Basade
Sr. Vice-President, Regulatory Affairs
Mylan Laboratories Ltd
Plot No 34-A
ANRICH Industrial Estate Bollaram
Hyderabad 502 325
Jinnaram Mandal, Medak District
Telangana
Inde

29 March 2016

Dear Mr Basade,

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

Application number: HA635

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:

- **HA635 - Abacavir (as sulfate)/Lamivudine Tablet, Film-coated 600mg/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 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: HA635

  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 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
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

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 – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1LYM22510323020210703
MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/NKD/103230/2021/11/36529

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**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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.

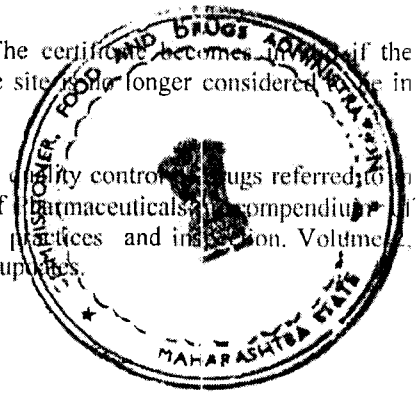
   Example - 2.

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
1	Abacavir and Lamivudine Tablets USP 600mg/300mg	Each film coated tablet contains Abacavir Sulfate USP equivalent to Abacavir 600 mg Lamivudine USP 300 mg
2	Abacavir Sulfate and Lamivudine Dispersible Tablets 60 mg / 30 mg	Each tablet contains Abacavir Sulfate USP equivalent to Abacavir 60 mg Lamivudine USP 30 mg
3	Abacavir Sulfate, Lamivudine and Zidovudine Tablets 300mg/150mg /300mg	Each film coated tablet contains Abacavir Sulfate USP 351.39 mg equivalent to Abacavir 300.00 mg Lamivudine USP 150.00 mg Zidovudine USP 300.00 mg
4	Abacavir Tablets USP 300 mg	Each film coated tablet contains Abacavir Sulfate USP equivalent to Abacavir 300.00 mg
5	Abacavir Tablets USP 60mg	Each Film Coated Tablet Contains Abacavir Sulfate USP equivalent to Abacavir 60.00 mg
6	Artemether and Lumefantrine Tablets 20mg/120mg	Each uncoated tablet contains Artemether 20.00 mg Lumefantrine 120.00 mg
7	Artemether and Lumefantrine Tablets 40mg/240mg	Each uncoated tablet contains Artemether 40.00 mg Lumefantrine 240.00 mg
8	Atazanavir (as Sulfate) Capsules 150mg	Each Capsule Contains Atazanavir [as Sulfate) equivalent to Atazanavir 150.00 mg

1 2 3 4 5 6 7 8 9 10

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
1LYM225103230202107O3
MYLAN LABORATORIES LIMITED - NKD-WHO-GMP/CERT/NKD/103230/2021/11/36529

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**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

OFFICE OF THE CONTROLLER, FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No.: V/WHO-GMP/M-2/2018/ 4979 **Bhopal, Dated:** 11/11/2020

To,

M/s Mylan Laboratories Limited,
Plot No.11, 12 & 13, Indore SEZ, Pharma Zone,
Phase-II, Sector-III, Pithampur-454775, Dist. Dhar

Sub: - Inclusion of additional item in the list of Pharmaceutical Products under WHO-GMP Certification Scheme, under Certificate No. 07/2014, Valid up to 21.11.2021.

Ref: - Letter No. as listed below in a table from Deputy Drugs Controller (India) CDSCO, Sub zonal office, Indore.

On the above cited subject following product is hereby included in the list of pharmaceutical products under WHO-GMP certification scheme, under certificate no. 07/2014 valid up to 21-11-2021 on the basis of recommendation of Assistant Drugs Controller (India) CDSCO, Sub zonal office, Indore vide the referred letter No. in below table;

S. No.	Name of the Product	Composition	CDSCO, Sub zonal office, Indore; Letter No
1.	**Isoniazid / Pyridoxine Hydrochloride / Sulfamethoxazole / Trimethoprim Tablets 300 mg / 25 mg / 800 mg / 160 mg**	Each film coated tablet Contains: Isoniazid Ph. Eur. 300 mg Pyridoxine Hydrochloride Ph. Eur. 25 mg Sulfamethoxazole Ph. Eur. 800 mg Trimethoprim Ph. Eur. 160 mg	SZI/2017/CoPP/Mylan/015/553 dated 14.09.2020
2.	**Dolutegravir Dispersible Tablets 10 mg MYLTEGA DT** *(Trade Name Given By Manufacturer)*	Each tablet Contains: Dolutegravir sodium equivalent to Dolutegravir 10 mg	SZI/2017/COPP/Mylan/015 /588; dated: 12.10.2020

Please keep this letter with your list of Pharmaceutical products for inspection by the authorities concerned.

Dy. Drugs Controller &
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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

Copy forward to:

- The Asst. Drugs 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.
- The Drugs Inspector, C/o Dy. Director, Food and Drugs Administration, for information.

Dy. Drugs Controller &
Licensing Authority
Food & Drugs Administration
Madhya Pradesh

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=U.S., o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000594 62, 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

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: HA678-0/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: HA678-0

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:

- **HA678 – Dolutegravir (Sodium) Tablet, Film-coated 50mg**

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: HA678

  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
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

Main characteristics of the prequalified medicinal product
(to be signed by a duly authorized representative of the applicant and returned to WHO)

1. Product WHO Reference number **HA678**
2. INN of active ingredient(s) Dolutegravir (Sodium)
3. Dosage form and strength Tablet, Film-coated 50mg
4. Trade name(s) of the product (if applicable)* NA
5. Name of applicant and official address Mylan Laboratories Limited Plot No.564/A/22, Road No. 92 Jubilee Hills Hyderabad – 500096 Telangana, India
6. Name of manufacturer of finished product, physical address of manufacturing site(s) (and unit, if applicable) Mylan Laboratories Limited Plot No.11, 12 & 13, Indore Special Economic Zone, Pharma Zone, Phase-II, Sector-III, Pithampur-454775 Dist. Dhar, Madhya Pradesh, India.
7. Finished product specifications (ref N° and/or version; ref to pharmacopoeia) FPSDOL201R-06 FPSDOL201S-06 In-house
8. Finished product batch size (approved) 66.000 Kg eq. to 220,000 tablets 660.000 kg eq. to 2,200,000 tablets
9. Name of API manufacturer, physical address of manufacturing site(s) (and unit, if applicable) Dolutegravir Sodium, Mylan Laboratories Limited WHOAPI-310 Mylan Laboratories Limited (Unit-2) Manufacturing Blocks- MB-01 and MB-06 Survey No. 10/42, Gaddapotharam Kazipally Industrial Area Sangaredddy District – 502319 Telangana, India
10.1. API specifications (ref N° and/or version; ref to pharmacopoeia) RMSDOL104R-W-01 (In-house)
10.2. Retest period of the API(s) 36 months. Do not store above 30oC, protect from light.
11. Product description (as in finished product specifications, i.e. coated, scored, etc) A pink, film coated, round, biconvex, beveled edge tablet debossed with **M** on one side of the tablet and **DT5** on the other side.
12. Pack size(s), primary and secondary packaging material(s) **Alu/PVC/ACLAR blister pack of 10's** Forming Foil: Clear, transparent, PVC laminated with ACLAR. Lidding Foil: Hard tempered aluminium foil coated with heat seal lacquer. **HDPE Bottle (Blue) of 30's, 90's and 180's**

Bottle: Round blue opaque HDPE bottle Closure: Blue opaque polypropylene cap
13. Storage conditions Do not store above 30°C, store in original container.
14. Shelf-life 24 months

* Trade names are not prequalified - completed for WHO administrative purposes only.

I, the undersigned, certify, that the information provided above is correct and true.

Signed on behalf of Mylan Laboratories Ltd

_____ (Date) Imtiyaz Basade

Digitally signed by Imtiyaz Basade
DN: cn=Imtiyaz Basade, o=Mylan Laboratories Ltd, ou, email=imtiyaz.basade@mylan.in, c=IN
Reason: Signed electronically
Date: 2018.11.13 14:01:29 +05'30'

Imtiyaz Basade-Senior Vice President (Name and title)

Undertakings of the applicant

(to be signed by a duly authorized representative of the applicant and returned to WHO)

1. Mylan Laboratories Ltd hereby confirms that it:

a) will inform the WHO Prequalification Team – Medicines, in writing, of any variations in the manufacture of Dolutegravir (Sodium) Tablet, Film-coated 50mg including, in particular (but not limited to), those specified in the "Main characteristics of the prequalified medicinal product", according to *Guidance on variations to a prequalified product dossier*. Geneva, World Health Organization, 2007, Annex 6 (WHO Technical Report Series, No. 943);

b) has nominated a responsible employee (as detailed below) in Mylan Laboratories Ltd responsible for communication with WHO on any issues related to the prequalified Dolutegravir (Sodium) Tablet, Film-coated 50mg, and will inform WHO of any change of contact person;

Name and title of designated contact person
Imtiyaz Basade Senior Vice President
Email address, telephone number and fax number of contact person
Tel. No.: 0091-40-39258109; Fax: 0091-40-39258105 E-mail: imtiyaz.basade@mylan.in

d) authorizes WHO to publish on the WHO Prequalification Team – Medicines website the information as listed in points 1 - 6, point 9 and 11 - 14 of the attached "Main characteristics o the prequalified medicinal product";

e) confirms that, subject to the protection of any confidential and proprietary information of the applicant, manufacturer and/or CRO, WHO shall be entitled to use and publish the product and site evaluation information;

f) furthermore, confirms that WHO shall also be entitled to share the full evaluation and inspecti reports with the relevant authorities of any interested WHO Member State.

2. Commitments:

Important note: The product information is an essential part of the medicinal product. The SmPC and PIL published with the WHOPAR have been quality assured by WHO experts and reflect the situation at the time of publication of the WHOPAR. These texts, i.e. the SmPC and the PIL are prequalified and should be adhered to. Generally, a deviation from the prequalified product information (especially as to contents) means the product can no longer be considered to be prequalified.

FPP

Commitment stability studies

Since stability data on three production scale batches of size 2,200,000 tablets was not provided with the application, the Applicant undertook in writing, (letter dated 13 July 2016) to put three production scale batches on long-term stability testing. Any out-of-specification results or significant changes during the study will immediately be reported to WHO. The approved stability protocol will be used for commitment batches.

Ongoing stability study commitment

The Applicant undertook in writing (letter dated 13 July 2016) a commitment regarding ongoing stability studies. Unless otherwise justified, at least one batch per year of the product manufactured in every primary packaging type will be included in the stability programme (unless none is produced during that year). The stability protocol will be that which was approved for primary batches. Out-of-specification results or significant atypical trends will be investigated. Any confirmed significant change or out-of-

specification result will be reported immediately to WHO. The possible impact on batches on the market will be considered in consultation with WHO inspectors.

Validation of production batches

Validation data on production scale batches of not less than three (3) consecutive batches was not provided with the application. Therefore, the Applicant submitted a written commitment (letter dated 13 July 2016) that three consecutive production batches of size 2,200,000 tablets would be prospectively validated and a validation report —in accordance with the details of the validation protocol provided in the dossier— would be made available as soon as possible for evaluation by assessors or for verification by the WHO inspection team.

Imtiyaz Basade

Digitally signed by Imtiyaz Basade
DN: cn=Imtiyaz Basade, o=Mylan Laboratories Ltd, ou, email=imtiyaz.basade@mylan.in, c=IN
Reason: Signed electronically
Date: 2018.11.13 14:03:08 +05'30'

Signed on behalf of Mylan Laboratories Ltd.

_____ (Date)

Imtiyaz Basade-Senior Vice President (Name and title)

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 1506
Fax direct: +41 22 791 4856
E-mail : azatyans@who.int

In reply please refer to: P5-447-5

Your reference:

Dear Madam/Sir

World Health Organization Collaborative Procedure for Accelerated Registration of Prequalified Medicines

In view of the successfully completed prequalification assessment process for your company's product, we would like to draw your attention to a collaborative procedure developed by the World Health Organization (WHO), which aims to accelerate national registration of prequalified medicines.

Under the current procedure, a manufacturer of a prequalified product can authorise WHO to share its assessment and inspection information relating to that product with National Medicines Regulatory Authorities (NMRAs) in countries where registration is sought. If an NMRA agrees to apply the procedure to the specific product, it commits to issuing its independent decision regarding registration within 90 days and to communicate it within a further 30 days. Therefore, the procedure helps optimise use of the outcomes of the WHO Prequalification Team (WHO PQT) product assessments, as well as accelerate national registration of prequalified products. It also reduces the burden of inspections on manufacturers.

At the beginning of April 2018 a total of 33 NMRAs were already participating in the procedure; we anticipate that additional NMRAs will join them. An updated list, further information and relevant forms for completion can be found at https://extranet.who.int/prequal/content/collaborative-registration-faster-registration.

Should you be interested in seeking accelerated national registration for your product, please familiarise yourself with the principles of the collaborative procedure, inform us about your intention to apply it in specific country/ies and submit registration applications in line with its requirements. Generally, the dossier that was approved by WHO PQT (i.e., including additional data provided during the prequalification process) can be submitted for national registration using the collaborative procedure.

Should you need any additional information or clarification regarding the steps that you should take to prepare your application for accelerated registration, please email Dr Luther Gwaza (gwazal@who.int) or Mrs Dilber Gunlu (gunlud@who.int). Please note that we can facilitate your communication with the relevant NMRAs.

If you are interested in registering your company's product in countries other than those listed on the website, please us know. WHO will then actively encourage these countries to participate in the procedure.

We believe that the procedure aiming to accelerate national registration benefits manufacturers, NMRAs, health care providers and, most importantly to patients. We, therefore, very much hope that you will join us in this initiative.

Yours faithfully,

Dr Samvel Azatyan
Group Lead, Regulatory Networks and Harmonization
Regulatory Systems Strengthening

منظمة الصحة العالمية • 世界卫生组织
Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud

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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: 1300059462, 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