Office of the Controller, Food and Drugs Administration

Madhya Pradesh, Idgah Hills, Bhopal (M.P.)-462001

Tel.: 0755-2665385, E-mail : cfdamp@rediffmail.com, fdampbhopal@gmail.com

No.: V/WHO-GMP/M-1/2021 / 5686 **Bhopal; Dated:** 26-10-2021

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This one-page certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).[1]

Certificate No: **07/2014** **Valid Up to : 25/10/2024**

On the basis of the inspection carried out on **08.09.2021 and 09.09.2021,** 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 and address of site: **M/s. Mylan Laboratories Limited, Plot No. 11, 12 & 13, Indore SEZ, Phase-II, Pharma Zone, Sector-III, Pithampur, Dist. Dhar, Madhya Pradesh-454775, INDIA**

2. Manufacturer's licence number: **25/1/2014 & 28/1/2014 in Form - 25 & 28 Dated 17/01/2014.**

CONTROLLER FOOD & DRUGS ADMINISTRATION * M.P., BHOPAL *

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
TABLETS	Hormones	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 **25/10/2024.** 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: **Idgah Hill, Bhopal**

Name and function of responsible person: **Shobhit**
Dy. Drugs Controller & Licensing Authority
Food & Drugs Administration
Idgah Hills, Bhopal (Madhya Pradesh)
Email: cfdamp@rediffmail.com
Telephone No. : 0755-2665385
Fax No. : 0755-2665385

Digitally signed by Dicusar Vladimir
Date: 2022.09.22 17:14:58 EEST
Reason: MoldSign Signature
Location: Moldova

Signature
Stamp and Date: 26 OCT 2021

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

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

Office of the Controller, Food and Drugs Administration

Madhya Pradesh, Idgah Hills, Bhopal (M.P.)-462001

Tel.: 0755-2665385, E-mail : cfdamp@rediffmail.com, fdampbhopal@gmail.com

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.

CONTROLLER FOOD & DRUGS ADMINISTRATION * M.P., BHOPAL *

Example 1

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

[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 the importing state.

[3] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product but excluding packaging materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 90-519

Mylan Pharmaceuticals, Inc.
U.S. Agent for: Matrix Laboratories Limited
Attention: Ronald T. Groman
Director, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 28, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Abacavir Sulfate and Lamivudine Tablets, 600 mg (base)/300 mg.

Reference is also made to your amendments dated April 8, April 10, June 6, July 10, August 1, and December 8, 2008; and February 3, 2009.

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 patent 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 manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug (RLD) upon which you have based your ANDA, Epzicom Tablets, 600 mg (base)/300 mg of SmithKline Beecham Corp. (GlaxoSmithKline), is subject to periods of patent

protection. The following patents with their expiration dates (pediatric exclusivity extensions added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,034,394 (the '394 patent)	June 18, 2012
5,047,407 (the '407 patent)	May 17, 2010
5,089,500 (the '500 patent)	December 26, 2009
5,905,082 (the '082 patent)	November 18, 2016
6,294,540 (the '540 patent)	November 14, 2018
6,417,191 (the '191 patent)	March 28, 2016
7,119,202 (the '202 patent)	August 8, 2009

Your ANDA contains paragraph III certifications to each of these patents under section 505(j)(2)(A)(vii)(III) of the Act stating that Matrix Laboratories Limited will not market Abacavir Sulfate and Lamivudine Tablets, 600 mg/300 mg, in the U.S. prior to the expiration of each of these patents. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until all of these listed patents have expired, currently, November 14, 2018.

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 current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application 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 November 14, 2018, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Laura Longstaff, Project Manager, at 240-276-8500.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
3/30/2009 09:54:34 AM
Deputy Director, for Gary Buehler

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-12 Jan 2022

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/AD/106169/2022/11/38759**

On the basis of the inspection carried out on **10.11.2021 and 11.11.2021** ,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 : **PLOT NO. H-12 & H-13, MIDC, WALUJ, AURANGABAD 431136 MAHARASHTRA STATE, INDIA**
2. Licence No. : **AD089 In Form 25, AD064 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 11 Jan 2025 . 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
1LYM2441061692022011 2
MYLAN LABORATORIES LIMITED, NEW-WHO-GMP/CERT/AD/106169/2022/11/38759

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:**12 Jan 2022**

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.

COMMISSIONER FOOD AND DRUG ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/106169/2022/11/38759 **VALID UP TO :11 Jan 2025**

Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
1	Abacavir (As Sulfate) and Lamivudine Dispersible Tablets 120mg/60mg	Each dispersible tablet contains: Abacavir (as Sulfate) equivalent to Abacavir .... USP 120 mg Lamivudine.... USP 60 mg
2	Acyclovir Tablets USP 200mg	Each tablet contains: Aciclovir Ph.Eur 200 mg
3	Acyclovir Tablets USP 400mg	Each tablet contains: Aciclovir Ph.Eur 400 mg
4	Amlodipine Besylate and Valsartan Tablets 10mg/160mg	Each film coated tablet contains Amlodipine Besylate equivalent to Amlodipine Ph.Eur 10 mg Valsartan Ph.Eur 160 mg Colour:Opadry Brown 03F565041
5	Amlodipine Besylate and Valsartan Tablets 5mg/160mg	Each film coated tablet contains Amlodipine Besylate equivalent to Amlodipine Ph.Eur 5 mg Valsartan Ph.Eur 160 mg Colour:Opadry 03F82965 Yellow
6	Apixaban Film Coated Tablets 2.5 mg	Each film coated tablet contains Apixaban 2.5 mg
7	Apixaban Film Coated Tablets 5 mg	Each film coated tablet contains Apixaban 5 mg
8	Atazanavir (as Sulfate) Capsules 150 mg	Each capsule contains: Atazanavir (as sulfate) equivalent to Atazanavir IH 150 mg Colour:FD&C Blue #2

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

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
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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/106169/2022/11/38759 **VALID UP TO :11 Jan 2025**

Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
9	Atazanavir (as sulfate) Capsules 300mg	Each capsule contains : Atazanavir sulfate equivalent to Atazanavir IH 300.00 mg
10	Atorvastatin Calcium Film Coated Tablets 10 mg	Each film coated tablet contains Atorvastatin Calcium Trihydate. Ph Eur.. equivalent to Atorvastatin 10 mg
11	Atorvastatin Calcium Film Coated Tablets 20 mg	Each film coated tablet contains Atorvastatin Calcium Trihydate. Ph Eur.. equivalent to Atorvastatin.. 20 mg
12	Clarithromycin Tablets, BP 500mg	Each film coated tablet contains: Clarithromycin Ph.Eur 500 mg
13	Clopidogrel and Acetylsalicylic Acid Tablets 75 mg/100 mg	Each film coated tablet contains Clopidogrel Hydrogen Sulfate.... Ph Eur equivalent to Clopidogrel.. 75 mg Acetylsalicylic Acid Ph.Eur 100 mg
14	Clopidogrel and Acetylsalicylic Acid Tablets 75 mg/75 mg	Each film coated tablet contains Clopidogrel Hydrogen Sulfate.... Ph Eur equivalent to Clopidogrel 75 mg Acetylsalicylic Acid Ph.Eur 75 mg
15	Cycloserine Capsules USP 250mg	Each Capsule contains: Cycloserine USP 250 mg
16	Darunavir Tablets 600mg	Each film coated tablet contains : Darunavir Ethanolate equivalent to Darunavir 600 mg

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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:**12 Jan 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/106169/2022/11/38759 **VALID UP TO :11 Jan 2025**

Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
17	Darunavir Tablets 800mg	Each film coated tablet contains Darunavir Ethanolate equivalent to Darunavir 800 mg
18	Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 50 mg / 300 mg /300 mg	Each film coated tablet contains Dolutegravir.... (as Dolutegravir Sodium)... 50 mg Lamivudine .. USP 300 mg Tenofovir Disoproxil Fumarate ....(equivalent to Tenofovir Disoproxil....245 mg) 300 mg
19	Duloxetine Hydrochloride Modified-Release Capsules 30 mg	Each capsule contains Duloxetine Hydrochloride Ph Eur equivalent to Duloxetine 30 mg
20	Duloxetine Hydrochloride Modified-Release Capsules 60 mg	Each capsule contains Duloxetine Hydrochloride Ph Eur equivalent to Duloxetine 60 mg
21	Efavirenz Tablets USP 600mg	Each film coated tablet contains Efavirenz USP 600 mg Colour:Yellow Iron Oxide, Iron Oxide Red
22	Efavirenz,Lamivudine and Tenofovir Disoproxil Fumarate Tablets 400mg/300mg/300mg	Each film coated tablet contains Efavirenz USP 400 mg Lamivudine USP 300 mg Tenofovir Disoproxil Fumarate...(equivalent to Tenofovir Disoproxil...245 mg) 300 mg Colour:Opadry II White 85F18422
23	Etoricoxib Film-Coated Tablets 120mg	Each film coated tablet contains Etoricoxib 120 mg
24	Etoricoxib Film-Coated Tablets 30mg	Each film coated tablet contains Etoricoxib 30 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: +91-22-2659236[illegible]
Fax: +91-22-2659195[illegible]

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:**12 Jan 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
25	Etoricoxib Film-Coated Tablets 60mg	Each film coated tablet contains Etoricoxib 60.000 mg
26	Etoricoxib Film-Coated Tablets 90mg	Each film coated tablet contains Etoricoxib 90 mg
27	Fluconazole Tablets USP 200mg	Each tablet contains Fluconazole Ph.Eur 200 mg Colour:D & C Yellow # 10 Lake Al (15-20%)
28	Fluconazole Tablets USP 50mg	Each tablet contains: Fluconazole Ph.Eur 50 mg Colour:D & C Yellow # 10 Lake Al (15-20%)
29	Isoniazid Tablets BP 100mg	Each tablet contains Isoniazid Ph.Eur 100 mg
30	Isoniazid Tablets BP 300 mg	Each tablet contains : Isoniazid Ph.Eur 300 mg
31	Lamivudine and Zidovudine Dispersible Tablets 30mg/60mg	Each dispersible tablet contains: Lamivudine USP 30 mg Zidovudine USP 60 mg
32	Lamivudine and Zidovudine Tablets USP 150mg/300mg	Each film coated tablet contains Lamivudine USP 150 mg Zidovudine USP 300 mg

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

1 2 3 4 5 6 7 8 9 10 ...

Address of certifying authority :
Food & Drug Administration, M.S.
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Maharashtra,INDIA.
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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:**12 Jan 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
33	Lamivudine, Nevirapine and Zidovudine Dispersible Tablets 30mg/50mg/60mg	Each dispersible tablet contains : Lamivudine USP 30 mg Nevirapine USP 50 mg Zidovudine USP 60 mg
34	Lamivudine, Nevirapine and Zidovudine Tablets 150mg/200mg/300mg	Each film coated tablet contains : Lamivudine USP 150 mg Nevirapine USP 200 mg Zidovudine USP 300 mg Colour:FD&C Blue #2, Aluminum Lake
35	Naratriptan Hydrochloride Tablets 2.5 mg	Each tablet contains Naratriptan Hydrochloride ....2.78 mg equivalent to Naratriptan.. 2.5 mg
36	Nevirapine Tablets USP 200 mg	Each tablet contains : Nevirapine USP 200 mg
37	Olmesartan Medoxomil and Hydrochlorothiazide Tablets 20/12.5mg	Each film coated tablet contains : Olmesartan Medoxomil Ph.Eur 20 mg Hydrochlorothiazide Ph.Eur 12.5 mg
38	Olmesartan Medoxomil and Hydrochlorothiazide Tablets 40/12.5mg	Each film coated tablet contains : Olmesartan Medoxomil Ph.Eur 40 mg Hydrochlorothiazide Ph.Eur 12.5 mg
39	Oseltamivir Phosphate Capsules USP 30mg	Each capsule contains : Oseltamivir Phosphate USP equivalent to Oseltamivir 30 mg Colour:FD&C Yellow 6, D & C Yellow 10
40	Oseltamivir Phosphate Capsules USP 45mg	Each capsule contains : Oseltamivir Phosphate USP equivalent to Oseltamivir 45 mg

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Maharashtra,INDIA.
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Fax: +91-22-26591955

1LYM24410616920220112
MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/AD/106169/2022/11/38759

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

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
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Date:**12 Jan 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
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AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
41	Oseltamivir Phosphate Capsules USP 75mg	Each capsule contains : Oseltamivir Phosphate USP equivalent to Oseltamivir 75 mg Colour:FD&C Yellow 6, D & C Yellow 10
42	Pantoprazole Sodium Delayed-Release Tablets 20mg	Each delayed-release tablets contains Pantoprazole Sodium Sesquihydrate....22.6 mg equivalent to Pantoprazole 20 mg
43	Pantoprazole Sodium Delayed-Release Tablets 40mg	Each delayed-release tablets contains Pantoprazole Sodium Sesquihydrate....45.1 mg equivalent to Pantoprazole 40 mg
44	Pantoprazole Sodium Enteric Coated Tablets 20 mg	Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate....22.6 mg equivalent to Pantoprazole 20 mg
45	Pantoprazole Sodium Enteric Coated Tablets 40 mg	Each enteric coated tablet contains Pantoprazole Sodium Sesquihydrate....45.1 mg equivalent to Pantoprazole 40 mg
46	Pretomanid Tablets 200 mg	Each tablet contains Pretomanid 200 mg
47	Rivaroxaban Tablets, 10 mg	Each film coated tablet contains Rivaroxaban 10 mg
48	Rivaroxaban Tablets, 15 mg	Each film coated tablet contains Rivaroxaban 15 mg

1 2 3 4 5 6 7 8 9 10 ...

Address of certifying authority :
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Name of the Authorised person : **D. R. GAHANE**

Signature :

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Food & Drug Administration, M.S.
Bandra (E), Mumbai.
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Date:**12 Jan 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
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INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
49	Rivaroxaban Tablets, 2.5 mg	Each film coated tablet contains Rivaroxaban 2.5 mg
50	Rivaroxaban Tablets, 20 mg	Each film coated tablet contains Rivaroxaban 20 mg
51	Tenofovir Disoproxil Fumarate and Emtricitabine Tablets 300mg/200mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate... 300 mg Emtricitabine 200 mg
52	Tenofovir Disoproxil Fumarate and Lamivudine Tablets 300mg/300mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Lamivudine USP 300 mg
53	Tenofovir Disoproxil Fumarate Tablets 300 mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate .. 300 mg
54	Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz Tablets 300mg/200mg/600mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Emtricitabine 200 mg Efavirenz USP 600 mg Colour:Iron Oxide Black, Iron Oxide Red
55	Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz Tablets 300mg/300mg/600mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300 mg Lamivudine USP 300 mg Efavirenz USP 600 mg Colour:Opadry II white contains Polyvinyl Alcohol, Titanium dioxide, Polyethylene Glycol & Talc
56	ABAGANIL 150mg Pregabalin Capsules 150mg	Each capsule contains Pregabalin Ph.Eur 150 mg

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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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

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MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/AD/106169/2022/11/38759

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:**12 Jan 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/106169/2022/11/38759 **VALID UP TO :11 Jan 2025**

Name of Manufacturing Firm : MYLAN LABORATORIES LIMITED
PLOT NO. H-12 & H-13, MIDC, WALUJ,
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
57	ABAGANIL 75mg Pregabalin Capsules 75mg	Each capsule contains Pregabalin Ph.Eur 75 mg
58	ANTIXIETY 150 mg Pregabalin Capsules 150 mg	Each capsule contains Pregabalin Ph.Eur 150 mg
59	ANTIXIETY 300 Pregabalin Capsules 300 mg	Each capsule contains Pregabalin 300 mg
60	ANTIXIETY 75mg Pregabalin Capsules 75 mg	Each capsule contains Pregabalin Ph.Eur 75 mg
61	ANZAVIR 150 Atazanavir (as sulfate) Capsules 150mg	Each capsule contains : Atazanavir (as Sulfate) equivalent to Atazanavir 150 mg Colour:FD & C Blue # 2
62	ANZAVIR 300 Atazanavir (as Sulfate) Capsules 300mg	Each capsule contains : Atazanavir (as Sulfate) equivalent to Atazanavir 300 mg Colour:FD & C Blue # 2
63	ATROIZA Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz Tablets 300mg/200mg/600mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Emtricitabine 200 mg Efavirenz USP 600 mg Colour:Iron Oxide Black, Iron Oxide Red
64	AVONZA 300mg/300mg/400mg Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz Tablets 300mg/300mg/400mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate IH 300 mg Lamivudine USP 300 mg Efavirenz USP 400 mg

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1LYM24410616920220112
MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/AD/106169/2022/11/38759

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

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Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
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AURANGABAD 431136 MAHARASHTRA STATE,
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Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
65	CARDISAR HT 160mg/12.5mg Valsartan and Hydrochlorothiazide Tablets 160mg/12.5mg	Each film coated tablet contains : Valsartan Ph.Eur 160 mg Hydrochlorothiazide Ph.Eur 12.5 mg
66	CARDISAR HT 160mg/25mg Valsartan and Hydrochlorothiazide Tablets 160mg/25mg	Each film coated tablet contains : Valsartan Ph.Eur 160 mg Hydrochlorothiazide Ph.Eur 25 mg
67	CARDISAR HT 80mg/12.5mg Valsartan and Hydrochlorothiazide Tablets 80mg/12.5mg	Each film coated tablet contains : Valsartan Ph.Eur 80 mg Hydrochlorothiazide Ph.Eur 12.5 mg
68	Clopidogrel Acide Acetylsalicylique Mylan 75 mg/75 mg Clopidogrel and Acetylsalicylic Acid Tablets 75 mg/75 mg	Each film coated tablet contains Clopidogrel Hydrogen Sulfate.... Ph Eur equivalent to Clopidogrel 75 mg Acetylsalicylic Acid Ph.Eur 75 mg
69	Clopidogrel e Acido Acetilsalicilico Mylan 75 mg/100 mg Clopidogrel and Acetylsalicylic Acid Tablets 75 mg/100 mg	Each film coated tablet contains Clopidogrel Hydrogen Sulfate.... Ph Eur equivalent to Clopidogrel 75 mg Acetylsalicylic Acid Ph.Eur 100 mg
70	Clopidogrel e Acido Acetilsalicilico Mylan 75 mg/75 mg Clopidogrel and Acetylsalicylic Acid Tablets 75 mg/75 mg	Each film coated tablet contains Clopidogrel Hydrogen Sulfate.... Ph Eur equivalent to Clopidogrel 75 mg Acetylsalicylic Acid Ph.Eur 75 mg
71	Diagen-MR-60 mg Gliclazide Modified-Release Tablets 60 mg	Each tablet contains Gliclazide Ph.Eur 60 mg
72	DOVPRELA- 200 mg Pretomanid Tablets 200 mg	Each tablet contains Pretomanid 200 mg

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AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
73	Duloxetine Mylan Gastro-Resistant Capsules 30 mg Duloxetine Hard Gastro-Resistant Capsules 30 mg	Each capsule contains Duloxetine Hydrochloride Ph Eur equivalent to Duloxetine 30 mg
74	Duloxetine Mylan Gastro-Resistant Capsules 60 mg Duloxetine Hard Gastro-Resistant Capsules 60 mg	Each capsule contains Duloxetine Hydrochloride Ph Eur equivalent to Duloxetine 60 mg
75	DURART 600 Darunavir Tablets 600mg	Each film coated tablet contains : Darunavir Ethanolate equivalent to Darunavir.. .. 600 mg
76	DURART 800 Darunavir Tablets 800mg	Each film coated tablet contains : Darunavir Ethanolate equivalent to Darunavir... 800 mg
77	EFAMAT 600 Efavirenz Tablets USP 600mg	Each film coated tablet contains Efavirenz USP 600 mg Colour:Yellow Iron Oxide, Iron Oxide Red
78	ERESTZ 200 mg/25 mg/300 mg Emtricitabine, Rilpivirine and Tenofovir Disoproxil Fumarate Tablets 200 mg/25 mg/300 mg	Each film coated tablet contains Emtricitabine.. 200 mg Rilpivirine Hydrochloride 27.5 mg equivalent to Rilpivirine.. 25 mg Tenofovir Disoproxil Fumarate 300 mg equivalent to Tenofovir Disoproxil. 245 mg
79	Etoricoxib Mylan 120 mg Etoricoxib 120 mg Film Coated Tablets	Each film coated tablet contains Etoricoxib 120 mg
80	Etoricoxib Mylan 30 mg Etoricoxib 30 mg Film-Coated Tablets	Each film coated tablet contains Etoricoxib 30 mg

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INDIA

Drug License No : AD089 In Form 25,
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Sr.No.	Name of the Product	Composition
81	Etoricoxib Mylan 60 mg Etoricoxib 60 mg Film-Coated Tablets	Each film coated tablet contains Etoricoxib 60 mg
82	Etoricoxib Mylan 90 mg Etoricoxib 90 mg Film-Coated Tablets	Each film coated tablet contains Etoricoxib 90 mg
83	ETULOX 120mg Etoricoxib Film-Coated Tablets 120mg	Each film coated tablet contains : Etoricoxib 120 mg
84	ETULOX 30mg Etoricoxib Film-Coated Tablets 30mg	Each film coated tablet contains : Etoricoxib 30 mg
85	ETULOX 60mg Etoricoxib Film-Coated Tablets 60mg	Each film coated tablet contains : Etoricoxib 60 mg
86	ETULOX 90mg Etoricoxib Film-Coated Tablets 90mg	Each film coated tablet contains : Etoricoxib 90 mg
87	Mylan Etoricoxib Film Coated Tablets 120mg Etoricoxib Film Coated Tablets 120mg	Each film coated tablet contains : Etoricoxib 120 mg
88	Mylan Etoricoxib Film Coated Tablets 30mg Etoricoxib Film Coated Tablets 30mg	Each film coated tablet contains : Etoricoxib 30 mg

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

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AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
89	Mylan Etoricoxib Film Coated Tablets 60mg Etoricoxib Film Coated Tablets 60mg	Each film coated tablet contains : Etoricoxib 60 mg
90	Mylan Etoricoxib Film Coated Tablets 90mg Etoricoxib Film Coated Tablets 90mg	Each film coated tablet contains : Etoricoxib 90 mg
91	NEVIMAT Nevirapine Tablets USP 200mg	Each tablet contains : Nevirapine USP 200 mg
92	Pramipexole Mylan ER -0.375 mg Pramipexole Dihydrochloride Monohydrate Extended Release Tablets 0.375 mg	Each tablet contains Pramipexole Dihydrochloride Monohydrate Ph Eur ... 0.375 mg equivalent to Pramipexole..... 0.26 mg
93	Pramipexole Mylan ER -0.75 mg Pramipexole Dihydrochloride Monohydrate Extended Release Tablets 0.75 mg	Each tablet contains Pramipexole Dihydrochloride Monohydrate Ph Eur .... 0.75 mg equivalent to Pramipexole 0.52 mg
94	Pramipexole Mylan ER -1.5 mg Pramipexole Dihydrochloride Monohydrate Extended Release Tablets 1.5 mg	Each tablet contains Pramipexole Dihydrochloride Monohydrate... Ph Eur .... 1.5 mg equivalent to Pramipexole 1.05 mg
95	RICOVIR Tenofovir Disoproxil Fumarate Tablets 300mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Colour:FD & C Blue # 2 / Indigo Carmine Aluminum Lake
96	RICOVIR - EM Tenofovir Disoproxil Fumarate and Emtricitabine Tablets 300mg/200mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Emtricitabine 200 mg

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Address of certifying authority :
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Fax: +91-22-2659[illegible]

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

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AURANGABAD 431136 MAHARASHTRA STATE,
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Drug License No : AD089 In Form 25,
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Sr.No.	Name of the Product	Composition
97	RICOVIR-L Tenofovir Disoproxil Fumarate and Lamivudine Tablets 300mg/300mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Lamivudine USP 300 mg
98	Salpraz 20 mg Pantoprazole Sodium Delayed-Release Tablets 20mg	Each delayed-release tablets contains Pantoprazole Sodium Sesquihydrate....22.6 mg equivalent to Pantoprazole 20 mg
99	Salpraz 40mg Pantoprazole Sodium Delayed-Release Tablets 40mg	Each delayed-release tablets contains Pantoprazole Sodium Sesquihydrate....45.1 mg equivalent to Pantoprazole 40 mg
100	TEEVIR Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz Tablets 300mg/200mg/600mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Emtricitabine 200 mg Efavirenz USP 600 mg Colour:Iron Oxide Black, Iron Oxide Red
101	TELURA Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz Tablets 300mg/300mg/600mg	Each film coated tablet contains : Tenofovir Disoproxil Fumarate 300 mg Lamivudine USP 300 mg Efavirenz USP 600 mg
102	TREZAV Lamivudine, Nevirapine and Zidovudine Tablets 150mg/200mg/300mg	Each film coated tablet contains : Lamivudine USP 150 mg Nevirapine USP 200 mg Zidovudine USP 300 mg Colour:FD&C Blue #2, Aluminum Lake
103	TREZAV PED Lamivudine, Nevirapine and Zidovudine Dispersible Tablets 30mg/50mg/60mg	Each dispersible tablet contains : Lamivudine USP 30 mg Nevirapine USP 50 mg Zidovudine USP 60 mg
104	TREZERT - 150 MG	Each capsule contains : Atazanavir (as Sulfate) equvalent to Atazanavir IH 150.00 mg Colour:FD&C Blue # 2

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MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/AD/106169/2022/11/38759

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

Signature :

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Drug License No : AD089 In Form 25,
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Sr.No.	Name of the Product	Composition
105	TREZERT - 300mg	Each capsule contains : Atazanavir (as Sulfate) equivalent to Atazanavir IH 300 mg Colour:FD & C Blue # 2
106	VALIDIP 10mg/160mg Amlodipine Besylate and Valsartan Tablets 10mg/160mg	Each film coated tablet contains : Amlodipine Besylate... equivalent to Amlodipine Ph.Eur 10 mg Valsartan Ph.Eur 160 mg
107	VALIDIP 5mg/160mg Amlodipine Besylate and Valsartan Tablets 5mg/160mg	Each film coated tablet contains : Amlodipine Besylate... equivalent to Amlodipine Ph.Eur 5 mg Valsartan Ph.Eur 160 mg
108	VALIDIP 5mg/80mg Amlodipine Besylate and Valsartan Tablets 5mg/80mg	Each film coated tablet contains : Amlodipine Besylate..... equivalent to Amlodipine Ph.Eur 5 mg Valsartan Ph.Eur 80 mg
109	XAFARIV - 10 mg Rivaroxaban Tablets 10 mg	Each film coated tablet contains Rivaroxaban 10 mg
110	XAFARIV - 15 mg Rivaroxaban Tablets 15 mg	Each film coated tablet contains Rivaroxaban 15 mg
111	XAFARIV - 2.5 mg Rivaroxaban Tablets 2.5 mg	Each film coated tablet contains Rivaroxaban 2.5 mg
112	XAFARIV - 20 mg Rivaroxaban Tablets 20 mg	Each film coated tablet contains Rivaroxaban 20 mg

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MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/AD/106169/2022/11/38759

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

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
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Date:**12 Jan 2022**

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INDIA

Drug License No : AD089 In Form 25,
AD064 In Form 28

Sr.No.	Name of the Product	Composition
113	XAGULANT - 2.5 mg Apixaban Film Coated Tablets 2.5 mg	Each film coated tablet contains Apixaban 2.5 mg
114	XAGULANT - 5 mg Apixaban Film Coated Tablets 5 mg	Each film coated tablet contains Apixaban 5 mg
115	ZOVILAM 150mg/300mg Lamivudine and Zidovudine Tablets USP 150mg/300mg	Each film coated tablet contains Lamivudine USP 150 mg Zidovudine USP 300 mg
116	ZOVILAM PED DT Lamivudine and Zidovudine Dispersible Tablets 30mg/60mg	Each dispersible tablet contains : Lamivudine USP 30 mg Zidovudine USP 60 mg

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World Health Organization

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In reply please
refer to the WHO product Ref N°: HA456

Your reference:

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

11 November 2009

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 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:

- Abacavir (as sulfate)/Lamivudine 60 mg/30 mg Tablets - HA456

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)

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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 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
HSS/PSM/QSM
20 Avenue Appia
1211 Geneva 27
Switzerland.

We look forward to receiving this information from you by 25 November 2009 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

World Health Organization

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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

NDA 214521

TENTATIVE APPROVAL

Mylan Pharmaceuticals Inc.
Attn: Robert A. Barto
US Agent for Mylan Laboratories Limited, India
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Mr. Barto:

Please refer to your new drug application (NDA) dated and received May 22, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Dolutegravir Tablets for Oral Suspension, 10 mg.

This NDA provides for the use of Dolutegravir Tablets for Oral Suspension in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients at least 4 weeks and weighing at least 3 kg.

This NDA was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR).

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the Prescribing Information, Patient Package Insert, and container labeling**)** submitted on November 2, 2020. Based on the data provided, the expiration dating period is 24 months for Dolutegravir Tablets for Oral Suspension, 10 mg in HDPE bottles containing 30, 60 or 90 tablets with desiccant and non-child-resistant cap when stored below 30ºC (86ºF).

This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be granted before the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the patent(s) protection or (2) date you believe that your

NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data. This amendment should include draft final printed labels and labeling which comply with all U.S. regulations (uniqueness of drug product appearance per 21 CFR 206; child-resistant packaging per 16 CFR 1700, etc.). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved.

Please note that this drug product may not be marketed in the United States without final agency approval under section 505 of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the FD&C Act and 21 U.S.C. 331(d)..

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*[1] and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that if this application is ultimately approved, you will need to meet these requirements.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

OTHER

We also remind you that you are expected to comply with the reporting requirements provided in 21 CFR 314.80 and 314.81. If the product is to be mass distributed in developing countries, a system of collecting and reporting adverse drug reactions by the distributor would be desirable (e.g., through governmental or nongovernmental agencies distributing the products).

If you have any questions, please call David Araojo, Pharm.D., Program Coordinator, at (301) 796-0669 or via email at david.araojo@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

Jeffrey S. Murray, M.D., M.P.H.
Deputy Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
- Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SARITA D BOYD on behalf of JEFFREY S MURRAY
11/19/2020 09:36:19 AM

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
1LYM225103230202107O3
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.

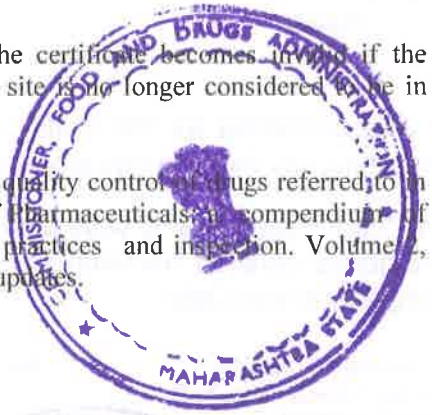
   Example - 2.

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

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Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959

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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
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NASHIK 422113 MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
9	Atazanavir (as Sulfate) Capsules 300mg	Each Capsule Contains Atazanavir [as Sulfate) equivalent to Atazanavir 300.00 mg
10	Atazanavir (as Sulfate)and Ritonavir Tablets 300mg/100mg	Each Film Coated Tablet Contains Atazanavir [as Sulfate) equivalent to Atazanavir 300.00 mg Ritonavir USP 100.00 mg
11	DARUNAVIR AND RITONAVIR TABLETS 400mg/50mg	Each film coated tablet contains Darunavir Ethanolate equivalent to Darunavir 400 mg Ritonavir USP 50 mg
12	Darunavir Tablets 150 mg	Each film coated tablet contains Darunavir 150 mg
13	DARUNAVIR TABLETS 300 mg	Each film coated tablet contains Darunavir 300 mg
14	Darunavir Tablets 400mg	Each film-coated tablet contains Darunavir 400 mg
15	Darunavir Tablets 600 mg	Each film-coated tablet contains Darunavir 600 mg
16	Darunavir Tablets 75 mg	Each film coated tablet contains Darunavir 75 mg

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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NASHIK 422113 MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
17	Efavirenz Tablets, USP 100 mg	Each film coated tablet contains Efavirenz USP 100.00 mg
18	Efavirenz Tablets, USP 200 mg	Each film coated tablet contains Efavirenz USP 200.00 mg
19	Efavirenz Tablets, USP 50 mg	Each film coated tablet contains Efavirenz USP 50.00 mg
20	Efavirenz Tablets, USP 600 mg	Each film coated tablet contains Efavirenz USP 600.00 mg
21	Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200mg / 300mg	Each film coated tablet contains Emtricitabine 200 mg Tenofovir Disoproxil Fumarate 300 mg
22	Entecavir Film Coated Tablets 0.5 mg	Each film coated tablet contains Entecavir Monohydrate equivalent to Entecavir 0.5 mg
23	Entecavir Film Coated Tablets 1mg	Each film coated tablet contains Entecavir Monohydrate equivalent to Entecavir 1 mg
24	Lamivudine and Zidovudine Tablets USP 150mg/300mg	Each film coated tablet Contains Lamivudine USP 150.00 mg Zidovudine USP 300.00 mg

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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NASHIK 422113 MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
25	Lamivudine and Zidovudine Tablets USP 30mg/60mg	Each film coated tablet contains Lamivudine USP 30.00 mg Zidovudine USP 60.00 mg
26	Lamivudine Tablets 100mg	Each Film Coated Tablet Contains Lamivudine USP 100.00 mg
27	Lamivudine Tablets 300mg	Each film coated tablet contains Lamivudine USP 300.00 mg
28	Lamivudine Tablets USP 150mg	Each film coated tablet contains : Lamivudine USP 150.00 mg
29	Lamivudine, Nevirapine and Zidovudine Dispersible Tablets 30mg/50mg/60mg	Each dispersible tablet contains Lamivudine USP 30.00 mg Nevirapine USP 50.00 mg Zidovudine USP 60.00 mg
30	Lamivudine/Nevirapine/Zidovudine Tablets 150mg/200mg/300mg	Each film coated tablet contains Lamivudine USP 150.00 mg Nevirapine USP 200.00 mg Zidovudine USP 300.00 mg
31	Ledipasvir and Sofosbuvir Tablets 90mg/400mg	Each film coated tablet contains Ledipasvir 90 mg Sofosbuvir 400 mg
32	Lopinavir / Ritonavir Oral Granules 40mg / 10mg	Each sachet contains Lopinavir USP 40 mg Ritonavir USP 10 mg

1 2 3 4 5 6 7 8 9 10

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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 Tablet 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

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NASHIK 422113 MAHARASHTRA STATE, INDIA

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

Sr.No.	Name of the Product	Composition
41	Sofosbuvir Tablets 400 mg	Each film coated tablet contains Sofosbuvir 400.00 mg
42	Tenofovir Disoproxil Fumarate and Lamivudine Tablets 300mg/300mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg Lamivudine USP 300.00 mg
43	Tenofovir Disoproxil Fumarate Tablets 300mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300 mg
44	Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz Tablets 300mg/200mg/600mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg Emtricitabine 200.00 mg Efavirenz USP 600.00 mg
45	Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz Tablets 300mg/300mg/600mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg Lamivudine USP 300.00 mg Efavirenz USP 600.00 mg
46	VORICONAZOLE TABLETS 200mg	Each film coated tablet contains: Voriconazole Ph.Eur 200.00 mg
47	VORICONAZOLE TABLETS 50 mg	Each Film coated Tablet contains: Voriconazole Ph.Eur 50 mg
48	Zidovudine Tablets USP 100mg	Each film coated tablet contains Zidovudine USP 100.00 mg

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

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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
49	Zidovudine Tablets USP 300mg	Each film coated tablet Contains Zidovudine USP 300.00 mg
50	ABAMAT Abacavir Tablets USP 300mg	Each film coated tablet contains Abacavir Sulfate USP equivalent to Abacavir 300.00 mg Colour:Iron oxide yellow, Iron oxide red
51	ABAMAT PED Abacavir Tablets USP 60mg	Each film coated tablet contains Abacavir Sulfate USP equivalent to Abacavir 60.00 mg Colour:Iron oxide yellow, Iron oxide red
52	ALLTERA Lopinavir and Ritonavir Tablets, USP 200mg/50mg	Each film coated tablet contains Lopinavir USP 200.00 mg Ritonavir USP 50.00 mg
53	ALLTERA 125 Lopinavir and Ritonavir Tablets USP 100mg/25mg	Each film coated tablet contains Lopinavir USP 100.00 mg Ritonavir USP 25.00 mg
54	ALLTERA 50 Lopinavir / Ritonavir Oral Granules 40mg / 10mg	Each sachet contains Lopinavir USP 40 mg Ritonavir USP 10 mg
55	ANZAVIR-R Atazanavir (as Sulfate) and Ritonavir Tablets 300mg\100mg	Each film coated tablet contains Atazanavir (as Sulfate) equivalent to Atazanavir 300.00 mg Ritonavir USP 100.00 mg
56	EFAMAT Efavirenz Tablets, USP 600mg	Each film coated tablet contains Efavirenz USP 600.00 mg

1 2 3 4 5 6 7 8 9 10

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION 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
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**

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
57	HEPWIN 0.5MG ENTECAVIR TABLETS USP 0.5mg	Each film coated tablet contains Entecavir USP 0.5 mg
58	HEPWIN 1MG ENTECAVIR TABLETS USP 1mg	Each film coated tablet contains Entecavir USP 1 mg
59	KOMEFAN 140 Artemether and Lumefantrine Tablets 20mg/120mg	Each tablet contains: Artemether 20.00 mg Lumefantrine 120.00 mg
60	KOMEFAN 280 Artemether and Lumefantrine Tablets 40mg/240mg	Each tablet contains: Artemether 40.00 mg Lumefantrine 240.00 mg
61	LEDVIR Ledipasvir and Sofosbuvir Tablets 90 mg/400 mg	Each film coated tablet contains Ledipasvir 90 mg Sofosbuvir 400 mg
62	MyDekla 30 Daclatasvir Film-Coated Tablets 30mg	Each film-coated tablet contains Daclatasvir Dihydrochloride equivalent to Daclatasvir 30 mg
63	MyDekla 60 Daclatasvir Film-Coated Tablets 60mg	Each film-coated tablet contains Daclatasvir Dihydrochloride equivalent to Daclatasvir 60 mg
64	MYHEP 400mg Sofosbuvir Tablets 400 mg	Each film coated tablet contains Sofosbuvir 400 mg

1 2 3 4 5 6 7 8 9 10

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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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**

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
65	MyHep ALL Sofosbuvir and Velpatasvir Film Coated Tablets 400mg/100mg	Each film coated tablet contains Sofosbuvir 400 mg Velpatasvir 100 mg
66	MyHep DVIR Daclatasvir and Sofosbuvir Film-Coated Tablets 60mg / 400mg	Each film coated tablet contains Daclatasvir Dihydrochloride equivalent to Daclatasvir 60 mg Sofosbuvir 400 mg
67	MyVelpa Sofosbuvir and Velpatasvir Film-Coated Tablets 400mg/100mg	Each film coated tablet contains Sofosbuvir 400 mg Velpatasvir 100 mg
68	MyVorcon 200 mg VORICONAZOLE TABLETS 200mg	Each film coated tablet contains Voriconazole Ph.Eur 200.00 mg
69	RICOVIR Tenofovir Disoproxil Fumarate Tablets 300 mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg
70	RICOVIR - EM Emtricitabine and Tenofovir Disoproxil Fumarate Tablets 200mg/300mg	Each film coated tablet contains Emtricitabine 200.00 mg Tenofovir Disoproxil Fumarate 300.00 mg
71	RICOVIR - L Tenofovir Disoproxil Fumarate and Lamivudine Tablets 300mg/300mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg Lamivudine USP 300.00 mg
72	TEEVIR Tenofovir Disoproxil Fumarate, Emtricitabine and Efavirenz Tablets (300mg/200mg/600mg)	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg Emtricitabine 200.00 mg Efavirenz USP 600.00 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

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**

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
73	TELURA Tenofovir Disoproxil Fumarate, Lamivudine and Efavirenz Tablets 300mg/300mg/600mg	Each film coated tablet contains Tenofovir Disoproxil Fumarate 300.00 mg Lamivudine USP 300.00 mg Efavirenz USP 600.00 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
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

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

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

Main characteristics of the prequalified medicinal product

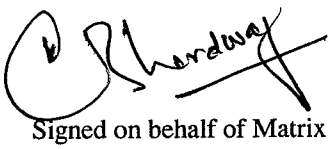
(to be signed by a duly authorized representative of the applicant and returned to WHO)

1. Product WHO Reference number HA467
2. INN of active ingredient(s) Ritonavir
3. Dosage form and strength 100mg, Tablets
4. Trade name(s) of the product (if applicable)* NA
5. Name of applicant and official address Matrix Laboratories Limited 1-1-151/1, 5th Floor Sairam Towers Alexander Road Secunderabad 500 003 India
6. Name of manufacturer of finished product, physical address of manufacturing site(s) (and unit, if applicable) **For Ritonavir Premix:** Matrix Laboratories Limited (Unit-8) G.Chodavaram Village, Pusapatirega (M), Vizianagaram District, Andhra Pradesh, India. **For Ritonavir 100mg Tablets** Matrix Laboratories Limited F-4, F-12, Malegaon M.I.D.C Sinnar Nashik 422113 Maharashtra India
7. Finished product specifications (ref N° and/or version; ref to pharmacopoeia) FPSRTV027R-03 (at release) FPSRTV027S-04 (Shelf life)
8. Finished product batch size (approved) 110,000 tablets
9. Name of API manufacturer, physical address of manufacturing site(s) (and unit, if applicable)
Matrix Laboratories Limited (Unit-8) G.Chodavaram Village, Pusapatirega (M), Vizianagaram District, Andhra Pradesh, India.
10.1. API specifications (ref N° and/or version; ref to pharmacopoeia) Ritonavir: RMSRIT003R-W-07 Premix: RMSRNR005R-W-05
10.2. Retest period of the API(s)
12 months. Preserve in tight, light-resistant containers. Store between 5°C and 30°C
11. Product description (as in finished product specifications, i.e. coated, scored, etc) Yellow coloured, film coated capsule shaped tablets debossed with "M163" on one side and plain on the other side.

12. Pack size(s), primary and secondary packaging material(s) 250 cc white HDPE Purell PE GF 4760 Bassell (colorant 8160) bottle, 36 mm closure with inbuilt desiccant. Pack size: 120 tablets
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 Matrix Laboratories Limited.

28-02-2011 (Date)

Kameshwar Bhardwaj
Associate Vice President - DRA (Name and title)

Undertakings of the applicant

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

1. Matrix Laboratories Limited **hereby confirms that it:**

a) will inform the WHO Prequalification Programme in writing of any variations in the manufacture of Ritonavir 100mg Tablets, 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) will submit the draft WHOPAR for Ritonavir 100mg Tablets according to the current guidance notes (available at www.who.int/prequal);

c) has nominated a responsible employee (as detailed below) in Matrix Laboratories Limited responsible for communication with WHO on any issues related to the prequalified Ritonavir 100mg Tablets, and will inform WHO of any change of contact person;

Name and title of designated contact person
<to be entered by company> Kameshwar Bhardwaj AVP - DRA
E-mail address, telephone number and fax number of contact person
<to be entered by company> kameshwar.bhardwaj@matrixlabsindia.com Ph: +91 8008001460 Fax No: +91 40 30493199

d) authorizes WHO to publish on the WHO Prequalification web site the information as listed in points 1 to 6, point 9 and 11 to 14 of the attached "Main characteristics of 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 inspection reports with the relevant authorities of any interested WHO Member State.

2. Commitments:

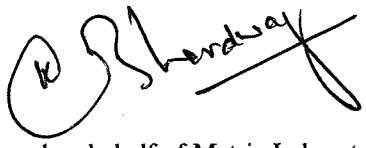
2.1. The applicant committed to continue the long term stability studies at 30±2°C/75±5%RH of batches (1005473, 1005474 and 1005475 in HPDE packs) for a period of time sufficient to cover the whole provisional shelf life (NLT 24 months,) and to report any out-of-specification results or significant change immediately to WHO.

2.2. The Applicant has submitted a commitment letter dated April 14, 2010 to charge the first three batches of Ritonavir 100mg tablets manufactured with batch size larger than 110,000 tablets on long-term stability study (30±2°C/75±5%RH) and shall report to WHO, if any out of specification (OOS) result is observed.

2.3. The Applicant has committed in its submission dated 15 April 2010 to charge one commercial batch per year on long- term stability studies and report to WHO if any out of specification result is observed.

2.4. The applicant has charged two commercial sized batches of Ritonavir 100mg tablets manufactured with premix from Unit-8 and committed (letter dated April 14, 2010) to continue the studies for 6 months at 40±2°C/75±5% and 24 months at 30±2°C/75±5%RH conditions. Any out of specification (OOS) result will be reported to WHO immediately.

2.5. The applicant has committed (letter dated 24 November 2010) to perform the PXRD test on Ritonavir 100 mg tablets at the final stability time point if extension of the shelf-life is proposed in the future.



Signed on behalf of Matrix Laboratories Limited.

28-02-2011
(Date)

Kameshwar Bhardwaj
Associate Vice President - DRA
(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 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