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

Digitally signed by Vidiborschii Vladimir
Date: 2022.12.16 12:58:34 EET
Reason: Qualified Signature
Location: Moldova

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**

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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

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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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Drug License No : AD089 In Form 25,
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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

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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

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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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INDIA

Drug License No : AD089 In Form 25,
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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 ...

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Drug License No : AD089 In Form 25,
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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

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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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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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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

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
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
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

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

... 6 7 8 9 10 11 12 13 14 15

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

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

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**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
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 :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-2659236[illegible]
Fax: +91-22-2659[illegible]

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MYLAN LABORATORIES LIMITED - NEW-WHO-GMP/CERT/AD/106169/[illegible]1/38759

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

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
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

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

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**

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
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

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

1LYM244106169202201l2
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
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

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

...6 7 8 9 10 11 12 13 14 15

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

Health Products Regulatory Authority

CERTIFICATE NUMBER : ***30759***

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

Part 1

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

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

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC .

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-05-14*** , it is considered that it complies with :

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

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

---

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

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

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

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

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

2021-07-19

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

---

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

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

Via E-Mail

March 5, 2020[1]

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

Dear Mr. Devakamma:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Mylan Laboratories Limited, FEI 3010453141, located at Plot Nos. 11, 12, 13 (FDF-3), Indore Special Economic Zone, Pharma Zone, Phase II, Sector III, Pithampur, District Dhar, from October 21, 2019 to October 25, 2019. FDA has determined that the inspection classification of this facility is "voluntary action indicated" (VAI).[2] Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regard to current good manufacturing practice (CGMP).

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

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

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

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

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

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

If you have any questions regarding this letter, you may contact Brooke Higgins via telephone at (301) 796-4171 or email at brooke.higgins@fda.hhs.gov.

Sincerely,

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

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.

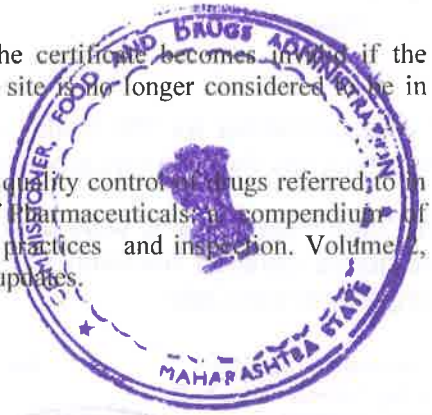
   Example - 2.

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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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
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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

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
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

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

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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/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
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

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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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**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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

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

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

Sr.No.	Name of the Product	Composition
33	Lopinavir and Ritonavir Tablets, USP 100mg/25mg	Each film coated tablet contains Lopinavir USP 100.00 mg Ritonavir USP 25.00 mg
34	Lopinavir and Ritonavir Tablets, USP 200mg/50mg	Each film coated tablet contains Lopinavir USP 200.00 mg Ritonavir USP 50.00 mg
35	Moxifloxacin Tablets 400 mg	Each film coated tablet contains: Moxifloxacin Hydrochloride Ph. Eur. equivalent to Moxifloxacin 400 mg
36	Nevirapine Extended Release Tablets 400 mg	Each Extended Release 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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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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Tel: +91-22-26592363/64
Fax: +91-22-26591959

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

Signature :

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

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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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
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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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**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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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

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

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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
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

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

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

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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
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

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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
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

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

In reply please refer to: HA678-0/MS/ADV

Your reference:

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

31 October 2018

Dear Mr Basade,

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

Application number: HA678-0

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

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

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

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

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

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

ENCLS: (2)

.../...

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

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

- consult the "WHO guidelines on variations to a prequalified product", as adopted in 2012 by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, and published in Annex 3 of the WHO Technical Report Series N° 981 in 2013, and
- submit the respective information about the intended variations and the required additional data in electronic format (CD or DVD or via a file transfer link). The submission (if submitted on CD/DVD), including any packages/containers (if applicable), should be clearly addressed, as follows:

  CONFIDENTIAL
  Attention: Dr Matthias Stahl
  WHO Prequalification Team – Medicines
  Product Ref Number: HA678

  UNICEF Supply Division
  Oceanvej 10-12
  2150 Nordhavn Copenhagen
  Denmark

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

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

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

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

.../...

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

Thank you for your cooperation.

Yours sincerely,

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

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

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

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

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

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

Signed on behalf of Mylan Laboratories Ltd

_____ (Date) Imtiyaz Basade

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

Imtiyaz Basade-Senior Vice President (Name and title)

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

1. Mylan Laboratories Ltd hereby confirms that it:

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

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

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

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

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

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

2. Commitments:

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

FPP

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

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

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

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

Signed on behalf of Mylan Laboratories Ltd.

_____ (Date)

Imtiyaz Basade-Senior Vice President (Name and title)

World Health Organization

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

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

In reply please refer to: P5-447-5

Your reference:

Dear Madam/Sir

World Health Organization Collaborative Procedure for Accelerated Registration of Prequalified Medicines

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

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

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

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

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

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

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

Yours faithfully,

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

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

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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°: HA417

Your reference:

Mr Kameshwar Bhardwaj
General Manger - Regulatory Afairs
Matrix Laboratories Limited
1-1-151/1, 5th Floor
Sairam Towers
Alexander Road
Secunderabad 500 003
Inde

20 October 2010

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:

- Tenofovir disoproxil fumarate /Emtricitabine 300mg/200mg 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 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 2 November 2010 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

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

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.