



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
ILYM22510323020210703
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**



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

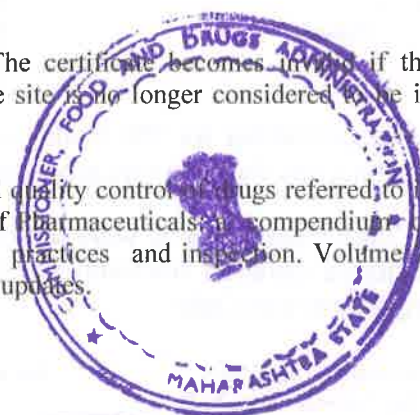
Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

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 1, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

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/2021/11/36529
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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
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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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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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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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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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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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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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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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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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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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

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