# 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/25 & 28/M-1/2024/ 253 Bhopal, Dated: 12/01/2024

## TO WHOMSOEVER IT MAY CONCERN

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 has been granted Drugs Manufacturing Licence No. 25/1/2014 in Form 25 & 28/1/2014 in Form 28 which was valid up to 16-01-2024. The licensee has deposited requisite online fee for retention of licence(s) as per office record vide application No. DHR2325R1337 & DHR2328R1338 dated 22-09-2023.

In View of above as per GSR 1337(E) Dated 27-10-2017, the above-mentioned licences are deemed to be valid for a period of 5 years i.e., up to 16-01-2029.

CONTROLLER FOOD & DRUGS ADMINISTRATION M.P. BHOPAL

12/01/2024

(Rajneesh Chowdhary)
Deputy Director &
State Licensing Authority
Food and Drugs Administration
Madhya Pradesh

To,

Mylan Laboratories Limited,
Plot No. 11, 12 & 13, Indore SEZ, Phase-II,
Pharma Zone, Sector-III, Pithampur,
District – Dhar (M.P.) India

# Form 24

[See Rule 69]

*Application for the grant of or renewal of a licence to manufacture for sale [or for distribution of] drugs other than those specified in [Schedules C, C(1) and X]*

(1) I/We **Mr. Rakesh Bamzi S/W/D/O Trilokinath Bamzai Director and Other(s) Of Mylan Laboratories Limited** of **Mylan Laboratories Limited** hereby apply for the grant/renewal of a licence to manufacture on the premises situated at **Plot No. 11,12 and 13, Special Economic Zone, Pharma Zone, Phase-II, Sector- III, Pithampur** the following drugs being drugs other than those specified in [Schedules C, C(1) and X] to the Drugs and Cosmetics Rules, 1945.

(2) Names of drugs categorised according to Schedule M (List enclosed of 1217 Item(s)).

(3) Names, qualifications and experience of technical staff employed for manufacture and testing (List enclosed of 156 Competent/Expert/Technical Staff).

(4) A fee of rupees **363600.00/-** has been credited to Government under the head of account 0210 Medical and Public Health, 04 Public Health, 104 Fees and fines, (5) Lic Fees under Drugs and Cosmetics Rules.

Signature valid
Digitally Signed By PAYAL AMAN BHARGAVA
(INDORE\)
Date : 22-Sep-2023 17:32:38 IST

Date : 22-Sep-2023

**Mylan Laboratories Limited**
(Authorised Signatory)

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|---|---|---|
| 326. | Dolutegravir Sodium, Lamivudine and Tenofovir Disoproxil Fumarate Tablets 50 mg / 300 mg / 300 mg<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film-coated tablet Contains:<br>Dolutegravir Sodium 52.6 mg Equivalent to Dolutegravir 50 mg<br>Lamivudine USP 300 mg<br>Tenofovir Disoproxil Fumarate 300mg Equivalent to Tenofovir Disoproxil 245 mg<br>Excipients q.s. q.s. |
| 327. | ACRIPTEGA (Dolutegravir /Lamivudine / Tenofovir Disoproxil Fumarate Tablets 50mg /300mg /300mg)<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film-coated tablet Contains:<br>Dolutegravir (as Dolutegravir Sodium) 50 mg<br>Lamivudine USP 300 mg<br>Tenofovir Disoproxil Fumarate (equivalent to 245mg of Tenofovir Disoproxil) 300 mg<br>Excipients q.s. q.s. |
| 328. | Lamivudine, Tenofovir Disoproxil Fumarate and Dolutegravir Tablets 300 mg / 300 mg /50 mg [RANEGA]<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film-coated tablet Contains:<br>Tenofovir disoproxil fumarate 300 mg<br>Lamivudine 300 mg<br>Dolutegravir sodium equivalent to dolutegravir 50 mg<br>Excipients q.s. q.s. |
| 329. | Lamivudine, Tenofovir Disoproxil Fumarate and Dolutegravir Tablets 300mg / 300mg / 50mg [ACRIPTEGA]<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film-coated tablet Contains:<br>Lamivudine 300 mg<br>Tenofovir disoproxil fumarate 300 mg<br>Dolutegravir sodium 50 mg<br>Excipients q.s. q.s. |
| 330. | Lamivudine/Tenofovir Disoproxil Fumarate/ Dolutegravir Film-Coated Tablets 300mg/300mg/50mg [ACRIPTEGA] (Trade name given by manufacturer)<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir (as Dolutegravir Sodium) 50 mg<br>Lamivudine USP 300 mg<br>Tenofovir Disoproxil Fumarate (equivalent to 245 mg of Tenofovir Disoproxil) 300 mg<br>Excipients q.s. q.s. |
| 331. | Lamivudine, Tenofovir Disoproxil Fumarate and Dolutegravir tablets 300 mg /300 mg /50 mg<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Lamivudine USP 300 mg<br>Tenofovir disoproxil fumarate 300 mg (equivalent to 245 mg of tenofovir disoproxil)<br>Dolutegravir (as dolutegravir sodium) 50 mg<br>Excipients q.s. q.s. |
| 332. | Abacavir (as Sulfate) / Lamivudine Dispersible Tablets 120 mg / 60 mg<br>Oral Solid Dosage, Tablets, Dispersible<br>**For Export**<br>Form CT-23 (MF-229/2020 Dated 06.10.2020)<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each dispersible tablet Contains:<br>Abacavir (as sulfate) USP equivalent to Abacavir 120 mg<br>Lamivudine USP 60 mg<br>Excipients q.s. q.s. |
| 333. | Abacavir Sulfate and Lamivudine Dispersible Tablets 60 mg / 30 mg<br>Oral Solid Dosage, Tablets, Dispersible<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each tablet Contains:<br>Abacavir Sulfate USP equivalent to Abacavir 60 mg<br>Lamivudine USP 30 mg<br>Excipients q.s. q.s. |

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| 357. | Deferasirox Film Coated Tablets 180 mg [EFERAS<br>Deferasirox 180 mg film-coated tablets]<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>Export NOC/ Mylan/ 2023/ 04; Dated 18.05.2023<br>Name of Countries: Australia<br>Quantity: 8,000,000 Units X 30's Bottle Pack; 8,000,000 Units X 10's Blister Pack; 8,000,000 Units X 500's Bottle Pack and 1,000,000 Units<br>Pack Detail: Blister Pack, Bottle Pack and Bulk Pack | Each film coated tablet Contains:<br>Deferasirox 180 mg<br>Excipients q.s. q.s. |
| 358. | Deferasirox Film Coated Tablets 360 mg [EFERAS<br>Deferasirox 360 mg film-coated tablets]<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>Export NOC/ Mylan/ 2023/ 04; Dated 18.05.2023<br>Name of Countries: Australia<br>Quantity: 8,000,000 Units X 30's Bottle Pack; 8,000,000 Units X 10's Blister Pack; 8,000,000 Units X 500's Bottle Pack and 1,000,000 Units<br>Pack Detail: Blister Pack, Bottle Pack and Bulk Pack | Each film coated tablet Contains:<br>Deferasirox 360 mg<br>Excipients q.s. q.s. |
| 359. | Dolutegravir Tablets 50 mg [MyTegra] (Trade name given by Manufacturer)<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir Sodium 52.6 mg Equivalent to Dolutegravir free acid 50 mg<br>Excipients q.s. q.s. |
| 360. | Dolutegravir (as Sodium) Tablets 50 mg<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir (as Sodium) 50 mg<br>Excipients q.s. q.s. |
| 361. | Dolutegravir Tablets 50 mg [Myltega] (Trade name given by Manufacturer)<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir 50 mg<br>Excipients q.s. q.s. |
| 362. | Dolutegravir Tablets 50 mg [Myltega] (Trade name given by Manufacturer)<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir Sodium equivalent to 50 mg Dolutegravir<br>Excipients q.s. q.s. |
| 363. | Dolutegravir Film coated Tablets 50 mg<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir (as dolutegravir sodium) 50 mg<br>Excipients q.s. q.s. |
| 364. | Dolutegravir Tablets 50 mg<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film coated tablet Contains:<br>Dolutegravir sodium 52.6mg Equivalent to Dolutegravir Free acid 50 mg<br>Excipients q.s. q.s. |

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| 635. | Pantoprazole Sodium Delayed-Release Tablets, USP 40 mg<br>Oral Solid Dosage, Tablets, Film Coated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each film-coated tablet Contains:<br>Pantoprazole 40 mg (equivalent to 45.10 mg of pantoprazole sodium USP)<br>Excipients q.s. q.s. |
| 636. | Piperaquine Tetraphosphate and Dihydroartemisinin Tablets 320 mg / 40 mg<br>Oral Solid Dosage, Tablets, Uncoated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each tablet Contains:<br>Piperaquine tetraphosphate as Piperaquine tetraphosphate tetrahydrate 320 mg<br>Dihydroartemisinin 40 mg<br>Excipients q.s. q.s. |
| 637. | Piperaquine Tetraphosphate and Dihydroartemisinin Tablets 320 mg / 40 mg [PALUACTA] (Trade name given by manufacturer)<br>Oral Solid Dosage, Tablets, Uncoated<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each tablet Contains:<br>Piperaquine tetraphosphate as Piperaquine tetraphosphate tetrahydrate 320 mg<br>Dihydroartemisinin 40 mg<br>Excipients q.s. q.s. |
| 638. | Pomalidomide Capsules 1 mg<br>Oral Solid Dosage, Capsules, Hard Gelatine Capsule<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each capsule Contains:<br>Pomalidomide 1 mg<br>Excipients q.s. q.s. |
| 639. | Pomalidomide Capsules 2 mg<br>Oral Solid Dosage, Capsules, Hard Gelatine Capsule<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each capsule Contains:<br>Pomalidomide 2 mg<br>Excipients q.s. q.s. |
| 640. | Pomalidomide Capsules 3 mg<br>Oral Solid Dosage, Capsules, Hard Gelatine Capsule<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each capsule Contains:<br>Pomalidomide 3 mg<br>Excipients q.s. q.s. |
| 641. | Pomalidomide Capsules 4 mg<br>Oral Solid Dosage, Capsules, Hard Gelatine Capsule<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each capsule Contains:<br>Pomalidomide 4 mg<br>Excipients q.s. q.s. |
| 642. | Pomalidomide Capsules 1 mg [VIAPOM 1 mg] (Trade name given by Manufacturer)<br>Oral Solid Dosage, Capsules, Hard Gelatine Capsule<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each capsule Contains:<br>Pomalidomide 1 mg<br>Excipients q.s. q.s. |
| 643. | Pomalidomide Capsules 2 mg [VIAPOM 2 mg] (Trade name given by Manufacturer)<br>Oral Solid Dosage, Capsules, Hard Gelatine Capsule<br>**For Export**<br>NA<br>Name of Countries: NA<br>Quantity: NA<br>Pack Detail: NA | Each capsule Contains:<br>Pomalidomide 2 mg<br>Excipients q.s. q.s. |

# OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
# MADHYA PRADESH

No. : DHRIN18DML2912 BHOPAL Dated: 19-Apr-2018

To,

Mylan Laboratories Limited,
Plot No. 11,12 and 13, Special Economic Zone, Pharma Zone, Phase-II, Sector- III, Pithampur,
(Dist.) - DHAR,
Madhya Pradesh.

,

Sub : Inclusion of item(s) in the Drug Mfg. Lic. No. : **25/1/2014**

Permission is hereby accorded for inclusion item(s) as per list enclosed in your Drugs Manufacturing Licence No. : **25/1/2014** in the Form No. : **25** Valid upto **16-Jan-2019**

List Enclosed [3 Item(s)]

Please keep this letter with your original Licence for inspection by the authorised concerned.

Signature valid
Digitally Signed By RAJNEESH CHOWDHARY
(Food and Drugs Administration)
Date : 21-Apr-2018 19:22:06 IST

**LICENSING AUTHORITY**
**FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

No. : DHRIN18DML2912 Bhopal, Dated: 19-Apr-2018

Copy forwarded to :

1. The Drugs Inspector C/o Dy. Director, Food And Drugs Administration,Bhopal DHAR for information.

**LICENSING AUTHORITY**
**FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

**OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

Mylan Laboratories Limited, (Dist)-DHAR

UNDER MFG. LIC NO. : 25/1/2014
Valid upto : 16-Jan-2019

LIST OF PRODUCT(S)

| S.No. | Product Name | Composition |
|---|---|---|
| 1. | Dolutegravir (as Dolutegravir Sodium) 50 mg + Lamivudine IP 300 mg + Tenofovir Disoproxil Fumarate IP 300 mg (Eq. to 245 mg of Tenofovir Disoproxil) film coated tablets | Each film coated tablet Contains:<br>Dolutegravir (as Dolutegravir Sodium) 50 mg<br>Lamivudine IP 300 mg<br>Tenofovir Disoproxil Fumarate (Eq. to 245mg of Tenofovir Disoproxil) IP 300 mg<br>Excipients q.s. q.s. |
| 2. | Dolutegravir /Lamivudine / Tenofovir Disoproxil Fumarate Tablets 50mg /300mg /300mg<br>(For Export)<br>NOC Number (with full file No. &Date):-<br>MF-85/2018 Date : 13.03.2018<br>Name of Countries:- NA<br>Quantity:- NA<br>Pack Detail:- NA | Each film coated tablet Contains:<br>Dolutegravir (as Dolutegravir Sodium) 50 mg<br>Lamivudine USP 300 mg<br>Tenofovir Disoproxil Fumarate (equivalent to 245mg of Tenofovir Disoproxil) 300 mg<br>Excipients q.s. q.s. |
| 3. | ACRIPTEGA (Dolutegravir /Lamivudine / Tenofovir Disoproxil Fumarate Tablets 50mg /300mg /300mg)<br>(For Export)<br>NOC Number (with full file No. &Date):-<br>MF-85/2018 Date : 13.03.2018<br>Name of Countries:- NA<br>Quantity:- NA<br>Pack Detail:- NA | Each film coated tablet Contains:<br>Dolutegravir (as Dolutegravir Sodium) 50 mg<br>Lamivudine USP 300 mg<br>Tenofovir Disoproxil Fumarate (equivalent to 245mg of Tenofovir Disoproxil) 300 mg<br>Excipients q.s. q.s. |

**Condition:**

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# OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
# MADHYA PRADESH

No. : DHRIN17DML2554 BHOPAL Dated: 01-Dec-2017

To,

Mylan Laboratories Limited,
Plot No. 11,12 and 13, Special Economic Zone, Pharma Zone, Phase-II, Sector- III, Pithampur,
(Dist.) - DHAR,
Madhya Pradesh.

,

Sub : Inclusion of item(s) in the Drug Mfg. Lic. No. : **25/1/2014**

Permission is hereby accorded for inclusion item(s) as per list enclosed in your Drugs Manufacturing Licence No. : **25/1/2014** in the Form No. : **25** Valid upto **16-Jan-2019**

List Enclosed [2 Item(s)]

Please keep this letter with your original Licence for inspection by the authorised concerned.

Signature valid
Digitally Signed By RAJNEESH CHOWDHARY
(Food and Drugs Administration)
Date : 02-Dec-2017 18:08:20 IST

**LICENSING AUTHORITY**
**FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

No. : DHRIN17DML2554 Bhopal, Dated: 01-Dec-2017

Copy forwarded to :

1. The Drugs Inspector C/o Dy. Director, Food And Drugs Administration,Bhopal DHAR for information.

**LICENSING AUTHORITY**
**FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

**OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

Mylan Laboratories Limited, (Dist)-DHAR

UNDER MFG. LIC NO. : 25/1/2014
Valid upto : 16-Jan-2019

LIST OF PRODUCT(S)

| S.No. | Product Name | Composition |
|---|---|---|
| 1. | Dolutegravir Tablets 50 mg | Each film coated tablet Contains:<br>Dolutegravir sodium 52.6mg Equivalent to Dolutegravir Free acid 50 mg<br>Excipients q.s. q.s. |
| 2. | Dolutegravir Tablets 50 mg<br>(For Export)<br>NOC Number (with full file No. &Date):- NA<br>Name of Countries:- NA<br>Quantity:- NA<br>Pack Detail:- NA | Each film coated tablet Contains:<br>Dolutegravir sodium 52.6mg Equivalent to Dolutegravir Free acid 50 mg<br>Excipients q.s. q.s. |

**Condition:**

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**OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

No. : DHRIN20DML4854 BHOPAL Dated: 16-Feb-2020

To,

Mylan Laboratories Limited,
Plot No. 11,12 and 13, Special Economic Zone, Pharma Zone, Phase-II, Sector- III, Pithampur,
(Dist.) - DHAR,
Madhya Pradesh.

,

Sub : Inclusion of item(s) in the Drug Mfg. Lic. No. : **25/1/2014**

Permission is hereby accorded for inclusion item(s) as per list enclosed in your Drugs Manufacturing Licence No. : **25/1/2014** in the Form No. : **25** Valid upto **16-Jan-2024**

List Enclosed [1 Item(s)]

Please keep this letter with your original Licence for inspection by the authorised concerned.

Signature valid
Digitally Signed By RAJEEV KUMAR AGRAWAL (Food And Drugs Administration)
Date : 18-Feb-2020 11:57:09 IST

**LICENSING AUTHORITY**
**FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

No. : DHRIN20DML4854 Bhopal, Dated: 16-Feb-2020

Copy forwarded to :

1. The Drugs Inspector C/o Dy. Director, Food And Drugs Administration,Bhopal DHAR for information.

**LICENSING AUTHORITY**
**FOOD AND DRUGS ADMINISTRATION**
**MADHYA PRADESH**

# OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
# MADHYA PRADESH

Mylan Laboratories Limited, (Dist)-DHAR

UNDER MFG. LIC NO. : 25/1/2014
Valid upto : 16-Jan-2024

## LIST OF PRODUCT(S)

| S.No. | Product Name | Composition |
|---|---|---|
| 1. | Piperaquine Tetraphosphate and Dihydroartemisinin Tablets 320 mg / 40 mg<br>(For Export)<br>NOC Number (with full file No. &Date):- NA<br>Name of Countries:- NA<br>Quantity:- NA<br>Pack Detail:- NA | Each Tablet Contains:<br>Piperaquine tetraphosphate as Piperaquine tetraphosphate tetrahydrate 320 mg<br>Dihydroartemisinin 40 mg<br>Excipients q.s. q.s. |

**Condition:**

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