

**Office of the Controller Food and Drugs Administration  
Madhya Pradesh**

No. V/25 & 28/M-1/2019 | 296

Bhopal, dated 18-1-19



**TO WHOMSOEVER IT MAY CONCERN**

M/s Mylan Laboratories Limited, Plot No. 11, 12 & 13, Indore SEZ, Phase-II, Pharma Zone, Sector-III, Pithampur, District - Dhar (M.P.) has been granted Drugs Manufacturing Licence No. 25/1/2014 in Form 25 & 28/1/2014 in Form 28 which was valid up to 16-01-2019. The licensee has deposited requisite online fee for retention of licence(s) as per office record vide application No. DHR1825R617 & DHR1825R618 dated 19-11-2018.

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 16-01-2024.

  
18/01/19

(Rajneesh Chowdhary)

State Licensing Authority

Food and Drugs Administration

Madhya Pradesh



✓ To,

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

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



No. : DHRIN17DML2616

BHOPAL Dated: 15-Nov-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 [6 Item(s)]

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

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

No. : DHRIN17DML2616

Bhopal, Dated: 15-Nov-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.	Tenofovir Alafenamide Tablets 25mg	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25 mg Excipients q.s. q.s.
2.	Tenofovir Alafenamide Tablets 25mg [HepBest]Marketed by: MPPL (Mylan Pharmaceuticals Pvt. Ltd.)	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25 mg Excipients q.s. q.s.
3.	Tenofovir Alafenamide Tablets 25mg [TAFNAT] Marketed by: NATCO (Natco Pharma Limited)	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate Equivalent to Tenofovir Alafenamide 25 mg Excipients q.s. q.s.
4.	Tenofovir Alafenamide Tablets 25mg (For Export) NOC Number (with full file No. &Date):- NA Name of Countries:- NA Quantity:- NA Pack Detail:- NA	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25 mg Excipients q.s. q.s.
5.	Tenofovir Alafenamide Tablets 25mg [HepBest] (For Export) NOC Number (with full file No. &Date):- NA Name of Countries:- NA Quantity:- NA Pack Detail:- NA	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25 mg Excipients q.s. q.s.
6.	Tenofovir Alafenamide Tablets 25mg [HepBest]Marketed by: MPPL (Mylan Pharmaceuticals Pvt. Ltd.)	Each film coated tablet Contains: Tenofovir Alafenamide Fumarate equivalent to Tenofovir Alafenamide 25 mg Excipients q.s. q.s.

**Condition:**

Firm has to comply with the conditions imposed by DCG(I)vide permission no MF-ND-258/2017, Date 10.11.2017