

Press Release

Drugs Control Administration, Telangana cancelled the product manufacturing licence of Mylan Laboratories Ltd., Unit-7, Pashamylaram, Patancheru Mandal, Sangareddy District for the drug 'Alprazolam'

The details are as follows:

Mylan Laboratories Ltd., Unit-7, Pashamylaram, Patancheru Mandal, Sangareddy District was issued a licence by the Drugs Control Administration, Telangana, to manufacture the drug '**Alprazolam**' (Active Pharmaceutical Ingredient). The licence issued by DCA includes permission for the activities of manufacturing the bulk drug Alprazolam (API) and supplying the drug exclusively to the formulation (tablets/injections) manufacturing units."

'Alprazolam' is a **psychotropic substance** under Narcotic Drugs and Psychotropic Substances Act (NDPS Act) and is used as a **medicine** to treat anxiety disorders, panic disorders, anxiety associated with depression, insomnia. The addiction / habit-forming potential of Alprazolam is very high. The **abuse** of Alprazolam can lead to various adverse effects including addiction, physical dependence, tolerance and withdrawal symptoms upon discontinuation.

Misuse of Alprazolam can result in sedation, drowsiness, dizziness, confusion, impaired coordination, memory problems, and respiratory depression, **particularly when combined with alcohol** or other central nervous

system depressants. Long-term abuse of Alprazolam can have serious consequences for physical and mental health, including cognitive impairment, mood disturbances, and increased risk of accidents.

There were reported events of 'Alprazolam' drug being mixed with toddy (adulterating toddy) which leads to serious health consequences.

The unauthorized diversion of 21.250 kilograms of the psychotropic substance 'Alprazolam' from the licensed premises of Mylan Laboratories Ltd., Unit-7, through certain employees who were working as chemists and production officers at the site, was detected by Prohibition & Excise Authorities. In connection with this, a seizure of 4.850 kilograms of Alprazolam was carried out in February 2023 by Prohibition & Excise Authorities from the consumables room of Mylan Laboratories Ltd., Unit-7.

The event of unauthorized diversion, which could potentially lead to abuse of the drug 'Alprazolam', came to the notice of the Drugs Control Administration, Telangana, from the Excise Authorities.

DCA Telangana issued a Show Cause Notice to Mylan Laboratories Ltd., Unit-7, upon carrying out an inspection of the site, as the firm failed to notify the Drugs Control Administration, Telangana, regarding the unauthorized diversion of Alprazolam from the licensed premises and for certain violations reported by DCA officers regarding the lack of adequate controls for the prevention and detection of such unauthorized diversion of Alprazolam from the licensed premises.

Considering the nature of the violations reported regarding the drug 'Alprazolam', which is a psychotropic substance, and its unauthorized diversion from Mylan Laboratories Ltd., Unit-7, upon assessment of the existing controls

and practices at the site, **the manufacturing licence for the drug 'Alprazolam' has been cancelled by the Drugs Control Administration, Telangana**, with immediate effect, in the larger public interest.

Manufacturers who are producing narcotic drugs and psychotropic substances must implement stringent measures to prevent unauthorized diversion, pilferage, or theft of the drugs they manufacture, in order to prevent abuse.

Surprise raids shall be intensified on manufacturing units holding licences to manufacture **narcotic drugs and psychotropic substances** to verify reconciliation data. Stringent action shall be taken as per the law against violators.

Date: 14-02-2024

**V.B. KAMALASAN REDDY, IPS
DIRECTOR GENERAL**

Proceedings of the Deputy Director, Nizamabad and Licensing Authority
Present: P. SARALA

Proc. Re. No. 56/DD-NZB/Mfg/2024

Date: -02-2024

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Cancellation of the drug license (product approval) issued for the drug ‘Alprazolam’ in Form-25 under Licence No. 108/MD/AP/97/B/R to M/s. Mylan Laboratories Ltd., Unit-7, Plot No. 213-215, IDA, Phase-II, Pashamylaram, Patancheru Mandal, Sangareddy Dist., Telangana State – **ORDERS – Issued** – Regarding.

Ref: 1. Inspection Report of M/s. Mylan Laboratories Ltd., Unit-7 dated: 03-01-2024 of Drugs Inspector, Pashamylaram.
2. SCN issued vide Re. No. 56/DD-NZB/Mfg/2024 dated: 08-01-2024
3. Interim response of M/s. Mylan Laboratories Ltd., Unit-7 dated: 11-01-2024 requesting for extension of time for submission of response.
4. Letter dated: 17-01-2024 of the Deputy Director, Nizamabad & Licensing Authority allowing an extension of one-week time for submission of explanation.
5. Explanation submitted by M/s. Mylan Laboratories Ltd., Unit-7 vide Letter dated: 22-01-2024.
6. Compliance Verification Report dated: 25-01-2024.

ORDER:

Based on the inspection report dated: 03-10-2024 (reference 1st cited), Show Cause Notice has been issued against your firm (reference 2nd cited) under Rule 85(2) of Drugs Rules for certain violations reported by the Drugs Inspector.

On the basis of your letter dated: 11-01-2024 (reference 3rd cited), one-week extension has been issued vide this office letter dated: 17-01-2024 (reference 4th cited), for submission of the explanation.

Explanation submitted by you (5th reference cited) has been examined by this office, vide reference 6th cited, and is found to be not satisfactory.

In view of the nature of the violations reported regarding the drug ‘Alprazolam’, which is a psychotropic substance and its unauthorized diversion from your site, on assessment of your existing controls and practices at the site regarding the drug ‘Alprazolam’, I, P. Sarala, Deputy Director, Nizamabad & Licensing Authority, Drugs Control Administration appointed under Rule 69(1) and in exercise of the powers vested under Rule 85(2) of the Drugs Rules, 1945 do hereby ‘CANCEL’ the drug manufacturing licence i.e. product approval issued for the drug substance ‘Alprazolam’ under Form-25 bearing Licence No. 108/MD/AP/97/B/R (for all the specification types) with immediate effect in larger public interest.

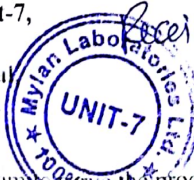
Receipt of this order shall be acknowledged.

K. Kesavaiah
13/2/2024
DEPUTY DIRECTOR, NIZAMABAD
LICENSING AUTHORITY

To
M/s. Mylan Laboratories Ltd., Unit-7,
Plot No. 213-215, IDA, Phase-II,
Pashamylaram, Patancheru Mandal,
Sangareddy Dist., Telangana State.

Copy to:

1. The Drugs Inspector, Pashamylaram to be provided the product licence cancellation order against the firm under acknowledgement and submit compliance report.
2. The Assistant Director, Patancheru, DCA, Telangana State.



Received copy of this cancellation order
Somy 13/02/24
R. SRIPATHY
SR AM – MFG OPERATIONS