

## **Press Release**

**Drugs Control Administration Telangana officials raided unlicensed manufacturing facilities on the outskirts of Hyderabad – busted manufacturing of drug ‘Diacerein’ in a chemical factory without a drug licence. Seized stocks worth 50.25 lakhs during the raid.**

Brief details are as follows:

Drugs Control Administration, Telangana officials carried out surprise raids at unlicensed manufacturing facilities on the outskirts of Hyderabad on 04<sup>th</sup> and 05<sup>th</sup> January, 2023.

Two special teams have been constituted by DCA, Telangana in this regard.

DCA officers detected unlicensed manufacturing of the drug ‘Diacerein’ at Rakshit Drugs Pvt. Ltd., Unit II, Sy. No. 466, Temple Street, Bonthapally Village, Gummadidala Mandal, Sangareddy District during the raid. Rakshit Drugs manufacturing facility at Bonthapally doesn’t hold any drug manufacturing licence.

DCA officials detected nine drums of yellow coloured powder labelled as ‘CDE-I’ in the production area of the firm. On verification of the Route of Synthesis (ROS) of the material and Batch Manufacturing Records, DCA officials found that the material labelled as CDE-I is a drug by name ‘Diacerein’.

DCA officials also found that Rakshit Drugs Pvt. Ltd., Unit II, Bonthapally Village has manufactured and sold several batches of the drug 'Diacerein' under code name 'CDE-I' without a drug licence.

The firm Rakshit Drugs Pvt. Ltd. Unit-II is an unlicensed manufacturing facility and do not have any 'Good Manufacturing Practices' (GMP) in place. As per Drugs and Cosmetics Act, drugs shall be manufactured in **ISO-8** Clean Rooms adhering to Good Manufacturing Practices. But the firm is manufacturing the drug 'Diacerein' not adhering to GMPs and without a drug licence.

Good Manufacturing Practices (GMP) regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing and packing of a drug. GMPs make sure that a drug is safe for use by patients.

DCA Telangana ensures the quality of drugs manufactured in the State by carefully monitoring drug manufacturers' compliance with Good Manufacturing Practice (GMP) regulations. The licensing process for drug manufacturers itself includes a review of the manufacturer's compliance with the GMPs.

Unlicensed manufacturing facilities do not follow GMPs and lack formal system of controls which prevent instances of contamination, mix-ups, deviations, failures, and errors. **Hence drugs manufactured at unlicensed facilities may not meet quality standards and such drugs may have serious implications on patient's health.**

Officers seized the stock of 236Kgs of the drug 'Diacerein' worth **50.25 lakhs** during the raid.

M. Anish Kalyan, Assistant General Manager of Rakshit Drugs Pvt. Ltd., Unit II is present during the raid.

Diacerein Active Pharmaceutical Ingredient (API) is used to manufacture formulations intended to treat Osteoarthritis.

Assistant Director Sri. P. Ramu and Drugs Inspectors Sri. G. Srikanth, Sri. K. Anvesh, Sri. Ch. Karthik Siva Chaitanya, Sri. A.N. Kranthi Kumar are among the officers who carried out the raid at Rakshit Drugs, Bonthapally Village.

DCA officers seized the stocks and lifted the samples for analysis. Further investigation shall be carried out and action shall be taken as per the law against all the offenders.

Drugs Control Administration, Telangana intensified surveillance on the chemical / intermediate factories in the State to detect unlicensed manufacturing of drugs in the factories.

Manufacturing of drugs without a drug licence is punishable under Drugs and Cosmetics Act with an imprisonment up to five years.

Surprise raids are intensified on the unlicensed manufacturing facilities in the State. Stringent action shall be taken as per the law against violators.

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

**DIRECTOR GENERAL**

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