

GOVERNMENT OF TELANGANA DRUGS CONTROL ADMINISTRATION



Press Release

Drugs Control Administration, Telangana seized medicines which are being falsely manufactured and sold in the guise of 'food products/ nutraceuticals'.

The product 'Pregabalin and Methylcobalamin Capsules', which is a medicine used to treat Peripheral Neuropathy, is being manufactured falsely under a food licence at Akshar Molecules, Haryana and being marketed illegally by Elion Health Care Pvt. Ltd., Tarnaka, Secunderabad as a food product/nutraceutical.

Brief details are as follows:

Drugs Control Administration, Telangana officials, on intelligence gathered, raided premises of Elion Health Care Pvt. Ltd., Tarnaka, Secunderabad, on 23rd January, 2024, which is marketing the product 'Pregabalin and Methylcobalamin Capsules' under brand name 'eneuron-P'.

The firm Elion Health Care Pvt. Ltd., Secunderabad, who is the marketer of the product as per the product's label, is getting the product 'eneuron-P' manufactured illegally at Akshar Molecules, 268, Phase-I, HSIIDC, Barhi, Haryana under a 'food licence (FSSAI licence)' falsely claiming it as a food product/nutraceutical.

The product 'Pregabalin and Methylcobalamin Capsules' containing 75 mg of Pregabalin and 750 mcg of Methylcobalamin is a 'drug' as per Drugs and Cosmetics Act. The said product composition was approved as a 'drug' by the

Drugs Controller General (India) to treat 'Peripheral Neuropathy in adult patients'.

The product 'Pregabalin and Methylcobalamin Capsules' shall be manufactured only under a 'drug licence' issued under Drugs and Cosmetics Act adhering to the 'Good Manufacturing Practices' (GMP) prescribed under Schedule-M of Drugs Rules and shall meet the quality standards prescribed in 'Indian Pharmacopoeia' (IP) mandatorily.

During the raid at Elion Health Care Pvt. Ltd., Secunderabad, DCA officers found 'eneuron-P' capsules, Quantity: 4900, Batch No. AMS-103007, labelled with composition 'Each soft gelatin capsule contains: Pregabalin 75 mg, Methylcobalamin 750 mcg along with other ingredients, bearing food licence / FSSAI Licence No. 10018064001600 and seized stocks worth Rs. 93,000/during the raid and lifted the samples for analysis.

Sri. M. Srinivasulu, Assistant Director, Karimnagar, Smt. D. Saritha, Assistant Director, Secunderabad, Sri. B. Govind Singh, Drugs Inspector, Secunderabad and Smt. A. Rashmi, Drugs Inspector, Amberpet are among the officers who carried out the raid.

The product 'eneuron-P', falsely manufactured and sold under food licence and moving in the market, was initially detected by Sri. P. Karthik Bharadwaj, Drugs Inspector, Karimnagar on 18th January, 2024 at Karimnagar and 30 boxes were seized at Karimnagar along with Sri. M. Srinivasulu, Assistant Director, Karimnagar.

DCA officers of Karimnagar zone alerted DCA Secunderabad officers who raided the premises of the marketer Elion Health Care Pvt. Ltd., located at Tarnaka, Secunderabad on Tuesday and seized the stocks. A similar case of a 'drug' manufactured under a 'food licence' was detected earlier by DCA, Telangana in November, 2023. The product Nalcobal-PG Capsules (claimed to contain Pregabalin 75 mg, Methylcobalamin 750 mcg), Manufactured by Yaxon Biocare Pvt. Ltd., Plot No. 7, HSIIDC, Industrial Area, Sonipat, Haryana <u>under a 'Food Licence/FSSAI licence'</u> was detected and seized by Sri. P. Karthik Bharadwaj, Drugs Inspector, Karimnagar and was <u>declared as</u> <u>'Spurious'</u> by Drugs Control Laboratory, Hyderabad as the content of Pregabalin and Methylcobalamin was found to be 'NIL' (i.e. zero drug) in the said product.

The drugs which are falsely manufactured and sold under a food licence are not manufactured in accordance with 'Good Manufacturing Practices' (GMPs) and also fail to meet the quality standards prescribed in Indian Pharmacopoeia (IP) and such products may have serious implications on patient's health.

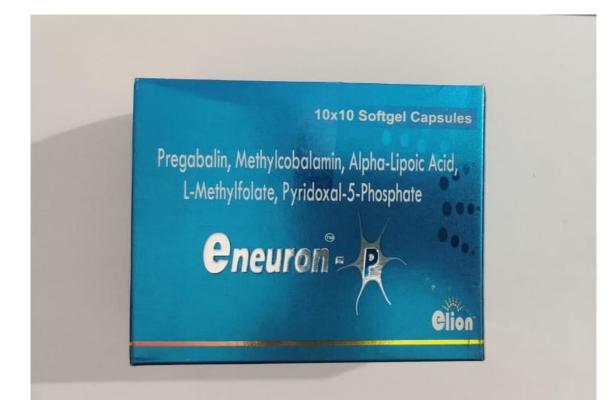
Manufacturing and selling of 'drugs' without a valid 'drug licence' is punishable under Drugs and Cosmetics Act, with an imprisonment up to five years.

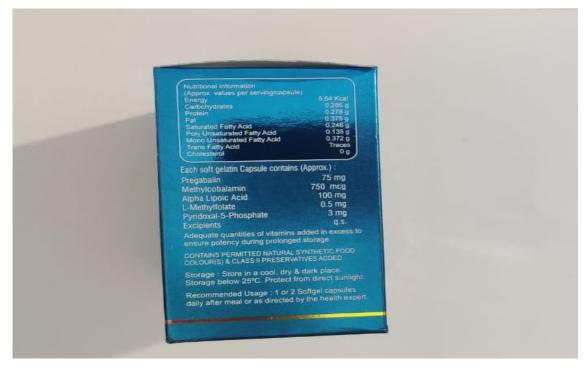
24-01-2024

V.B. KAMALASAN REDDY, IPS

DIRECTOR GENERAL

Photographs of the product seized







Seizure at Tarnaka, Secunderabad

