

GOVERNMENT OF TELANGANA DRUGS CONTROL ADMINISTRATION



Press Note

A) Drugs Control Administration, Telangana seized 'Zinfe-SR Capsules' in Karimnagar which were falsely manufactured and sold under the guise of 'food products/nutraceuticals'.

B) In a separate event, Drugs Control Administration, Telangana seized overpriced antifungal medicine 'Candinex-200 Capsules' (Itraconazole Capsules 200 mg) in Khammam – The MRP indicated is very high compared to the Ceiling Price fixed for the product by the Central Government

A) Seizure of drugs falsely manufactured and sold under the guise of 'food products/nutraceuticals'

The details are as follows:

During the raids carried out on 22nd and 23rd August, DCA officials detected drugs falsely manufactured and sold under the guise of 'food products/nutraceuticals'.

Drugs Control Administration officials of Karimnagar Zone have detected the product 'Zinfe-SR Capsules' (Sustained release Haematinic & Zinc Capsules with Vitamins) circulating in the market. The product has been claimed to contain Dried Ferrous Sulphate (in Sustained Release form) 150 mg, Zinc Sulphate Monohydrate (in Sustained Release form) 61.8 mg, Folic Acid 1.5 mg, Cyanocobalamin 15 mcg, Pyridoxine HCl 3 mg. These tablets were falsely manufactured under a 'food license (FSSAI license)' and falsely claimed to be a food product/nutraceutical.

The tablets were found to be illegally manufactured at Ruby Organics Pvt.

Ltd., Navi Mumbai and were being marketed by Karnataka Antibiotics &

Pharmaceuticals Ltd., Bengaluru as a food product/nutraceutical.

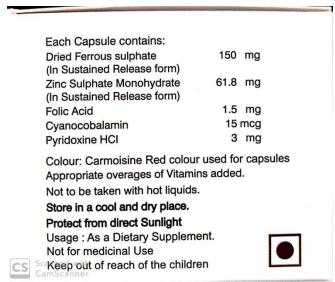
As per the label claim of the product, it is classified as a 'drug' according to the Drugs and Cosmetics Act.

The product 'Zinfe-SR Capsules' must be manufactured only under a 'drug license' issued under the Drugs and Cosmetics Act, adhering strictly to the 'Good Manufacturing Practices' (GMP) outlined in Schedule-M of the Drugs Rules. Additionally, it must meet the quality standards prescribed in the 'Indian Pharmacopoeia' (IP) as mandated.

Sri. M. Srinivasulu, Assistant Director, Karimnagar and Sri. P. Karthik Bharadwaj, Drugs Inspector, Karimnagar are among the officers who carried out the raid at a medical shop in Karimnagar. Samples were lifted for analysis during the raids.

Photographs of the product falsely manufactured and sold under the guise of 'food products/nutraceuticals'





The drugs that are falsely manufactured and sold under a food license are not produced in accordance with 'Good Manufacturing Practices' (GMPs) and often fail to meet the quality standards prescribed in the Indian Pharmacopoeia (IP). Such products pose serious risks to patients' health and may have severe implications.

Manufacturing and selling 'drugs' without a valid 'drug license' is punishable under the Drugs and Cosmetics Act, with imprisonment for up to five years.

B) Seizure of Anti-fungal Drugs in Khammam for Price Violation

During the raids carried out on 22nd and 23rd August, Drugs Control Administration officials seized 'Candinex-200 Capsules' (Itraconazole Capsules 200 mg) at a medical shop located in Khammam.

The product Itraconazole Capsules 200 mg sold under brand name 'Candinex-200 Capsules' is under price control as per Drugs (Prices Control) Order, 2013 and the price of product shall be in accordance with the 'Ceiling Price' fixed by National Pharmaceutical Pricing Authority (NPPA), Government of India.

The product 'Candinex-200 Capsules' (Itraconazole Capsules 200 mg) of B. No: KPC230280, Mfg. Dt: 07/2023; Exp Dt: 06/2025, Manufactured by: Nexkem Pharmaceuticals Pvt. Ltd., Chandigarh and Marketed by: Kusmed Pharmaceuticals, Baddi, Solan, Himachal Pradesh bears MRP as Rs. 300/- for 10 capsules i.e. Rs. 30/- per one capsule, on the label of the product which is a violation of the Drugs (Prices Control) Order, 2013.

The <u>Ceiling price fixed by the Central Government</u> including Wholesale Price Index (WPI) for the product "Itraconazole Capsules 200 mg" is **Rs. 22.12 for one capsule (Ceiling Price).**

Hence Maximum Retail Price (MRP) i.e. including GST 12 % should not be more than **Rs. 24.77 for one capsule** (MRP=Ceiling Price+GST)

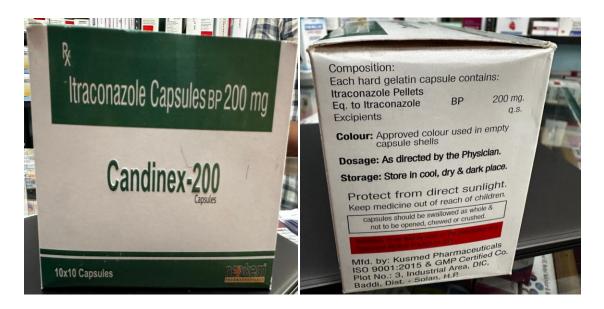
The firm overpriced the product. Firm charged excess of Rs. 52.20/- for 10 capsules which is a violation of Drugs (Prices Control) Order, 2013.

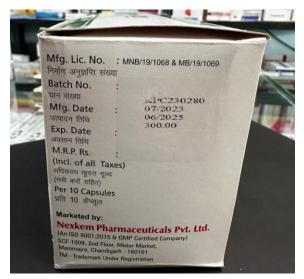
Sri. Ch. Anil Kumar, Drugs Inspector, Khammam Urban carried out the raid under the supervision of Dr. G. Rajyalakshmi, Assistant Director, Khammam.

Further investigation shall be carried out and action shall be taken as per the law against all the offenders.

The prices of Essential Medicines shall be in accordance with the Ceiling Prices fixed by the Central Government. Overpricing of essential medicines is a violation under Drugs (Prices Control) Order, 2013 and stringent action shall be taken as per the law against violators.

Photograph of the Product Seized for Price Violation





The public may report any suspected manufacturing activity related to drugs, including narcotic drugs and psychotropic substances, in residential, commercial, or industrial areas, as well as any other complaints regarding illegal

activities concerning medicines, through the Drugs Control Administration, Telangana Toll-Free Number 1800-599-6969, which is operational from 10:30 am to 5:00 pm on all working days.

Date: 23-08-2024 V.B. KAMALASAN REDDY, IPS

DIRECTOR GENERAL

Photograph of Seizure carried out at Karimnagar - Drugs falsely manufactured and sold under the guise of 'food products/nutraceuticals'



Photograph of Seizures carried out for Price Violation in Khammam