

Press Release

Drugs Control Administration, Telangana busted illegal manufacturing of an anti-cancer drug ‘Cyclophosphamide Injection’ at **Indian Genomix Pvt. Ltd., Cherlapally, Hyderabad**. The company is manufacturing cytotoxic anti-cancer drugs together with antibiotic injections, thereby posing a serious risk to public health.

Cytotoxic drugs damages or destroys living cells.

Cytotoxic Anti-cancer drug ‘Cyclophosphamide Injection’ damages the genetic material (DNA and RNA) of the cells thereby stopping growth and multiplication of cancer cells. It is used in chemotherapy in cancer patients and causes severe side effects.

Cytotoxic Anti-cancer drugs shall be manufactured in “separate dedicated and self-contained production facilities”, as per Good Manufacturing Practices (GMPs) guidelines, in order to ensure a clear-cut separation of these cytotoxic substances from other general drugs; as ‘**cross-contamination**’ of general drugs with ‘cytotoxic anti-cancer drugs’, if manufactured in the same facility, leads to serious health consequences in the patients.

Dedicated facilities are crucial for handling cytotoxic drugs. **Indian Genomix Pvt. Ltd. located at IDA Cherlapally** illegally manufactured the anti-cancer drug, without a drug licence, in an antibiotic injection manufacturing line which poses a risk of a serious medical hazard.

DCA Telangana officials raided Indian Genomix Pvt. Ltd. located at IDA Cherlapally on 6th & 7th February and seized the stocks.

The details are as follows:

On credible information, Drugs Control Administration, Telangana officials raided Indian Genomix Pvt. Ltd., located at Plot No. 135/1, 135/2, Phase-II, IDA Cherlapally, Medchal-Malkajgiri District, on 6th and 7th February, and detected illegal manufacturing of a **cytotoxic anti-cancer drug** 'Cyclophosphamide Injection'.

Cyclophosphamide is a cancer '**chemotherapy**' drug used to treat various types of cancers viz. blood cancer, breast cancer, ovarian cancer, lymphoma etc.

Indian Genomix Pvt. Ltd. does not hold licence to manufacture 'anti-cancer drugs' at its manufacturing facility and also **does not have separate, dedicated facility to manufacture cytotoxic anti-cancer drugs.** The firm holds licences **only** to manufacture antibiotic injections and other general drugs.

Cytotoxic Anti-cancer drugs cannot be manufactured together with general drugs. Dedicated facilities are mandatory for handling cytotoxic drugs. Cytotoxic drugs destroy living cells and shall be manufactured in "separate dedicated and self-contained production facilities", as per Good Manufacturing Practices (GMPs) of Drugs and Cosmetics Act, 1940, as **cross-contamination of general medicines with cytotoxic anticancer drugs leads to serious health issues in patients.**

Patients who take 'antibiotic injections' **contaminated** with cytotoxic anti-cancer drugs may experience **serious side effects** such as blood in urine, bone marrow suppression, heart damage, anemia, decrease of White Blood Cell (WBC) counts leading to infections due to suppression of immune system, oral mucositis, hair loss, bleeding, bruising, vomiting, diarrhea, nausea, infertility etc., due to destruction of normal and healthy cells.

During the raid, DCA officials detected manufacturing of a cytotoxic anticancer drug 'Cyclophosphamide Injection', without a drug licence, together with antibiotic injections, contravening the provisions of Good Manufacturing Practices (GMP), thus placing the patient's health at grave risk.

DCA officials detected three Aluminium Canisters of anticancer drug Cyclophosphamide API (Active Pharmaceutical Ingredient) in the production area of the antibiotic injectable facility. The said API canisters were labelled as manufactured by: BO-Chem Private Limited, K-66, Tarapur- MIDC, Boisar, District-Palghar, Maharashtra.

During the raid, the director of the company Indian Genomix Pvt. Ltd., M. Anil Kumar revealed that the said anticancer API canisters was procured from SP Accure Labs Pvt. Ltd. (SPAL Private Limited), located at Plot No. 20, Biotech Park, Phase-II, Lalgadi-Malakpet, Shameerpet.

M. Anil Kumar, director of the company, also revealed that they utilized the anticancer drug Cyclophosphamide API, received from SP Accure Labs Pvt. Ltd., to manufacture the formulation 'Cyclophosphamide Injection' in their antibiotic injectable facility and sold the formulation again to SP Accure Labs Pvt. Ltd. (SPAL Private Limited), located at Plot No. 20, Biotech Park, Phase-II, Lalgadi-Malakpet, Shameerpet. M. Anil Kumar submitted delivery challans and

invoices regarding the transactions with SP Accure Labs Pvt. Ltd. regarding the said anti-cancer drug.

DCA officials seized the stocks of anti-cancer drug Cyclophosphamide along with delivery challans and invoices during the raid 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.

Assistant Director M. Vijay Gopal, Assistant Director P. Ramu and Drugs Inspectors T. Shiva Teja, M. Varaprasad, Ch. Karthik Siva Chaitanya, E. Thirupathi, A. Rashmi are among the DCA officers who carried out the raid.

Drugs Control Administration, Telangana intensified surveillance on the manufacturing units in the State to detect illegal activities which pose a serious threat to public health.

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 manufacturing facilities in the State to verify adherence of the manufacturers to Good Manufacturing Practices (GMP) and to detect unlicensed activities. Stringent action shall be taken as per the law against violators.

07-02-2024

V.B. KAMALASAN REDDY, IPS

DIRECTOR GENERAL

Photographs

