

## Press Note

Drugs Control Administration, Telangana, in a **joint operation** with the Prohibition & Excise Department, busted a godown storing illegally manufactured and stocked **Bulk Drugs** (Active Pharmaceutical Ingredients) at Door No. 3-21, First Floor, Potharam Y-Junction, Muduchintalpally Village, Medchal-Malkajgiri District. The godown belongs to **Aspen Biopharma**.

Kadari Sateesh Reddy of Aspen Biopharma, a habitual offender in several cases with the DCA, was operating the godown where the illegal stocks were detected.

Stocks of drugs, including anticancer, antiviral, antifungal, anticoagulants, antidepressants, etc., worth **Rs. 96 lakhs** were seized during the raid.

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The details are as follows:

Based on credible information, a joint operation was carried out by the Drugs Control Administration officials of the Shameerpet Zone and the Prohibition and Excise Department officials, leading to the busting of an illegal godown stocking large quantities of bulk drugs.

A godown located at Door No. 3-21, First Floor, Potharam Y-Junction, Muduchintalpally Village, Medchal-Malkajgiri District, was raided by the teams on 23rd July 2024.

During the raid, large stocks of bulk drugs (Active Pharmaceutical Ingredients) of various categories, including anticancer, antiviral, antifungal,

anticoagulants, antidepressants, etc., which were illegally manufactured, were found stocked at the godown belonging to **Aspen Biopharma Pvt. Ltd.**

The details of the stocks of Bulk Drugs (APIs) detected:

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<b>1. Sertraline Hydrochloride (Qty: 350.0 Kg)</b>
<b>2. Misoprostol (Qty: 352.5 Kg)</b>
<b>3. Darifenacin (Qty: 1.5 Kg)</b>
<b>4. Heparin sodium (Qty: 1.3 Kg)</b>
<b>5. Amisulpride (Qty: 9.0 Kg)</b>
<b>6. Pazopanib (Qty: 2.5 Kg)</b>
<b>7. Palbociclib (Qty: 1.5 Kg)</b>
<b>8. Nilotinib (Qty: 3.2 Kg)</b>
<b>9. Losartan (Qty: 2.0 Kg)</b>
<b>10. Terazosin (Qty: 6.5 Kg)</b>
<b>11. Sertaconazole (Qty: 4.5 Kg)</b>
<b>12. Posoconazole (Qty: 1.4 Kg)</b>
<b>13. Darunavir (Qty: 0.5 Kg)</b>
<b>14. Ropinirole (Qty: 0.6 Kg)</b>
<b>15. Daptomycin (Qty: 0.8 Kg)</b>
<b>16. Ibrutinib (Qty: 0.6 Kg)</b>
<b>17. Tenofovir (Qty: 1.5 Kg)</b>
<b>18. Abiraterone (Qty: 8.0 Kg)</b>
<b>19. Docetaxel (Qty: 0.9 Kg)</b>
<b>20. Gemcitabine (Qty: 0.9 Kg)</b>
<b>21. Levetiracetam (Qty: 6.0 Kg)</b>
<b>22. Ritonavir (Qty: 0.7 Kg)</b>
<b>23. Rivastigmine Tartrate (Qty: 8.92 Kg)</b>

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The godown, operating illegally without any drug license, belongs to Kadari Sateesh Reddy of Aspen Biopharma, who is the prime accused in the spurious anti-cancer drugs case detected at Machabollaram in December 2023. He is also the key conspirator in the illicit manufacturing of APIs at Annarugudem Village, Tallada Mandal, Khammam District, which was detected in the same month.

The stocks of Bulk Drugs/APIs present in the godown are in LDPE bags and only bear the name of the bulk drug. Certain stocks bear only code names of the APIs. The batch details and the details of the manufacturer are not indicated on the API stocks found, **indicating unlicensed manufacturing of the APIs.**

**Drugs manufactured by unlicensed entities pose a severe threat to public health.** They do not adhere to any 'Good Manufacturing Practices' (GMP). According to the Drugs and Cosmetics Act, drugs must be manufactured in ISO-8 Clean Rooms while adhering to GMP. GMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug. GMP ensures 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 includes a review of the manufacturer's compliance with GMPs.

Unlicensed entities do not follow GMPs and lack formal system of controls which prevent instances of contamination, mix-ups, deviations, failures, and errors. **Hence drugs manufactured and sold by unlicensed**

**entities may not meet quality standards and such drugs may have serious implications on patient's health.**

During the raids, drugs worth **Rs. 96 lakhs** were seized.

Officers from **Drugs Control Administration** viz. Smt. Anjum Abida, Assistant Director, Shameerpet, Sri B. Praveen, Drugs Inspector, Shameerpet, Dr. B. Lakshmi Narayana, Drugs Inspector, Uppal, and Sri. P. Ambedkar, Drugs Inspector, Medipally &

Officers from **Prohibition and Excise Department** viz. Sri. Bharat Bhushan, Excise Inspector and Sri. Srinivas Reddy, Excise Sub-Inspector and their staff are among the officers who carried out the raid.

Further investigation will be conducted, and appropriate action will be taken as per the law against all the offenders.

**Illegal manufacturing and stocking of drugs without a drug license is punishable under the Drugs and Cosmetics Act, with imprisonment for up to five years.**

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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: 24-07-2024

V.B. KAMALASAN REDDY, IPS

DIRECTOR GENERAL

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