



WEB COPY



Crl.O.P.No.20058 of 2021

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 01.12.2023

CORAM:

THE HONOURABLE MR.JUSTICE G.K.ILANTHIRAIYAN

Crl.O.P.No.20058 of 2021

and

Crl.M.P.No.10913 of 2021

1.M/s.Unicure India Limited,
Represented by its Managing Director,
Mr.Abdul Mateen

2.Abdul Mateen

... Petitioners

Vs.

State represented by
Drugs Inspector,
Tirupur Range,
O/o Assistant Director of Drugs Control,
219, Race Course Road,
Coimbatore – 18.

... Respondent

PRAYER: Criminal Original Petition filed under Section 482 of Cr.P.C. praying to call for the entire records in C.C.No.154 of 2021 on the file of the Chief Judicial Magistrate, Tirupur and quash all further proceeding against the Accused.

For Petitioners : Mr.P.Ramesh Kumar

For Respondent : Mr.A.Gopinath
Government Advocate (Crl. Side)



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ORDER

WEB COPY This Criminal Original Petition has been filed to quash the proceedings in C.C.No.154 of 2021 on the file of the Chief Judicial Magistrate, Tirupur.

2. Heard the learned counsel for the petitioners and the learned Government Advocate (Crl.Side) for the respondent and perused the materials available on record.

3. The respondent filed a complaint for contravention of the provision of Section 18(a)(i) and Section 18 B of the Drugs and Cosmetics Act, 1940 punishable under Sections 27(d) and 28A of the Drugs and Cosmetics Act, 1940. The first petitioner is M/s Unicare India Limited and the second accused is its Managing Director. The sample of Enalapril Maleate Tablets I.P. 2.5 mg, manufactured by the petitioners were drawn for analysis on 31.03.2020 as a routine statutory sample. It was sent to the Government Analyst, Drugs Testing Laboratory, Chennai on 31.03.2020. It was declared as not of standard quality by the Government Analyst, Drugs Testing Laboratory, Chennai, vide its report dated 29.06.2020 for the reason that the sample does not conform to IP specification for Enalapril Maleate Tablets with respect to the content of Enalapril Maleate (76.8%) and dissolution. The distribution is prohibited under



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Section 18(a)(i) of the Drugs and Cosmetics Act, 1940. Therefore, the person who is in charge, viz., the Medical Officer of Government Primary Health Centre, Mangalam, Tirupur was requested to disclose the details of purchase, stock on hand, distribution details of the said drug, etc. The copy of the analytical report in original is handed over to the Medical Officer as contemplated under Section 25(2) of the Drugs and Cosmetics Act, 1940. They had replied on 22.07.2020 stating that the subject drug was acquired from Government Primary Health Centre, Mudalipalayam, Tirupur and received 20,000 tablets. It was subsequently found that the subject drug was acquired from District Drug Warehouse, Tamil Nadu Medical Services Corporation Limited, Kullampalayam, Tirupur. Therefore, a show cause notice dated 23.07.2020 was sent to the petitioners for contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 for having manufactured and sold a drug which is not of standard quality drug. No reply was received from the petitioners and as such a remainder letter dated 26.08.2020 was sent to the petitioners. However, no reply was received from the petitioners. Hence, the complaint.

4. The petitioner raised grounds that the respondent is not an authorized



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person to lodge a complaint and the respondent is not authorized to take any samples for analysis. Further, there was delay in sending the analysis report.

The sample was drawn on 31.03.2020 and the same was sent for analysis on the same day under Form 18. The Government Analyst, by its report dated 29.06.2020, opined that the subject drug was not of standard quality. It was further averred that as per the report of the Government Analyst, the content of the Enalapril Maleate was 76.8% and as per the guidelines issued by the Government of India under Section 33 of the Drugs and Cosmetics Act, the Drugs Inspector is advised not to initiate any prosecution if the drug has failed the dissolution test and the content of the active ingredient is more than 70%. When the content of the active ingredient is 76.8%, the prosecution initiated by the respondent is against the guidelines issued by the Government of India.

5. A perusal of the counter filed by the respondent revealed that the sample was subjected for analysis and found that the subject drug does not conform to IP specification for Enalapril Maleate tablets with respect to the content of Enalapril Maleate (76.8%) and dissolution, which is in contravention of Section 18(a)(i) of Drugs and Cosmetics Act, 1940. Thereafter, it was found that the petitioners are manufacturer of the subject drug and supply to the Government Primary Health Centre, Mangalam, Tirupur. A show cause notice



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dated 23.07.2020 was sent to the petitioners for the contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 for having manufactured and sold a drug which is not of standard quality drug and directed to disclose certain particulars under Section 18B of the Drugs and Cosmetics Act, 1940. Further, the third portion sealed sample drawn for test or analysis was also sent on 23.07.2020 to the petitioners. However, there was no reply from the petitioners.

6. The learned Government Advocate (Crl.Side) appearing for the respondent also pointed out that as per the Government Gazettee dated 12.07.2013, the respondent is duly appointed as Inspectors for the purpose of the said Act for the entire State of Tamil Nadu. Therefore, the respondent is authorized to draw sample. Further, the Analyst who analyzed the drug is also authorized by the notification to test the subject drug. The subject drug is coming under Category B. The Drugs Control General of India issued guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008. Accordingly, the not standard quality is serious in nature to affect the quality of the drug. Such defects may arise out of gross negligence or non-conformance to GMPs during manufacture. The Active ingredient contents below 70% for thermo labile products and below 5% of the



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permitted limits for thermo stable products. Further the tablets/capsules failing in dissolution test and active contents found less than 70% for thermo labile products and below 5% of the prescribed limits for thermo stable products. As far as the subject drug is concerned, as per the report of the Government Analyst, the content of the Enalapril Maleate was 76.8% and also does not conform to IP specification for Enalapril Maleate tablets with respect to dissolution. It is a thermostable drug and if it is below 5% of the prescribed limit, the drug will come under Category B of the guidelines. It is a life saving drug used in the treatment of hypertension and helps to prevent heart attacks, strokes and kidney problems. Therefore, only to meet the ends of justice, the respondent had rightly initiated the proceedings. That apart, the petitioners were issued with a show cause notice dated 23.07.2020 along with a copy of the original analysis report in Form 13 as contemplated under Section 25(2) of the Drugs and Cosmetics Act, 1940. Since there was no reply, a reminder letter dated 26.08.2020 was sent to the petitioners. Even after receipt of the said reminder letter, the petitioners did not reply so far. Therefore, the respondent had rightly initiated proceedings as against the petitioners and the grounds raised by the petitioners can be considered only before the Trial Court during trial by letting in evidence, since it is a mixed question of facts.



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7. In view of the above, this Court is not inclined to quash the proceedings in C.C.No.154 of 2021 on the file of the Chief Judicial Magistrate, Tirupur. The Trial Court is directed to complete the trial in C.C.No.154 of 2021, within a period of six months from the date of receipt of a copy of this order.

8. Accordingly, this Criminal Original Petition is dismissed. Consequently, connected Miscellaneous petition is closed.

01.12.2023

Internet : Yes / No

Index : Yes / No

Speaking / Non Speaking order

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G.K.ILANTHIRAIYAN, J.
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To

- 1.The Chief Judicial Magistrate,
Tirupur.
- 2.The Drugs Inspector,
Tirupur Range,
Office of the Assistant Director of Drugs Control,
219, Race Course Road,
Coimbatore – 18.
- 3.The Public Prosecutor
Madras High Court.

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