2026:BHC-NAG:945

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
NAGPUR BENCH, NAGPUR.

CRIMINAL WRIT PETITION NO. 967 OF 2024

1. Mr. Ashwani s/o Ram Pyara Lamba, a/a 66 years, Occ-Director of M/s Oscar Remedies Pvt. Ltd. Oscar House, Badi Majra, Yamunanagar, Haryana.

2. Mr. Navdeep Kumar s/o Jagan Nath Dhingra, a/a 63 years, Occ-Director of M/s Oscar Remedies Pvt. Ltd. Oscar House, Badi Majra, Yamunanagar, Haryana.

3. Smt. Asha w/oNavdeep Dhingra, a/a 60 years, Occ-Director of M/s Oscar Remedies Pvt. Ltd. Oscar House, Badi Majra, Yamunanagar, Haryana.

4. Mr. Ashwani Kumar s/o Ramdut Kumar, a/a 34 years, Occ-Director of M/s Oscar Remedies Pvt. Ltd. Oscar House, Badi Majra, Yamunanagar, Haryana.

5. M/s Oscar Remedies Pvt. Ltd. Oscar House, Badi Majra, Yamunanagar, Haryana.

... PETITIONERS

VERSUS

State of Maharashtra at the instance of Nalanda B. Urkude, working as a Drugs Inspector, at the office of the Assistant Commissioner, Food & Drugs Administration M.S. Barrack No. 2, Unit No. 2 Complex, Gadchiroli.

... RESPONDENT

Shri V.R. Borkar, Advocate for the petitioner.
Shri A.R. Chutke, APP for the State.

CORAM: M.M. NERLIKAR, J.
DATE : 17.01.2026.

ORAL JUDGMENT :

1. **RULE**. Rule made returnable forthwith.

2. Heard the learned Counsel for petitioners and learned APP appearing for the State. In the present petition, following prayer is made :

> *"II. Further be pleased to quash the criminal prosecution bearing S.C.C. No.637/2023 "State of Maharashtra Vs. Mr. Ashwani Lamba and other" pending on the file of learned C.J.M. Gadchiroli, Dist.- Gadchiroli against the petitioners in the interest of justice."*

3. The only question, which was raised in the present petition is the non-compliance of Rule 45 of the Drugs and Cosmetics Rules, 1945 (for short 'the Rule, 1945'). Rule 45 reads as under :

> *"45. Duties of Government Analysts.- (1) The Government Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him*

> *by Inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these Rules within a period of 60 days of the receipt of the sample.*
>
> *Provided that where it is not possible to test or analyse the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving specific reasons for delay in such testing or analysis.*
>
> *(2) A Government Analyst shall from time to time forward to the Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government."*

4. Learned Counsel appearing for the petitioners submits that there was no compliance of Rule 45 of the Rules, 1945. The Drug Inspector visited the City Medical shop on 12.07.2022, samples were drawn of RTZOL-DSR (Rabeprazole Sodium (EC) and Domperidone (SR) as Capsules Batch No.C-2111250, having manufacturing date as November 2021, and Expiry date as October 2023.

5. It is submitted that Rule 45 of the Rules, 1945 provides that Government Analysts to send the report within 60 days however in the present case the stipulated time of 60 days have not been complied and even extension which was sought by the Government Analysts was after expiry of 60 days and there was no compliance of Rule 45, therefore,

the entire proceedings is vitiated and hence, the complaint deserves to be quashed and set aside. In support of his submission, he has relied upon the judgment of this Court in the case of ***Swapnil s/o Liladhar Mane and ors. vs. State of Maharashtra 2024(4) Mh.L.J. (Cri.) 673***.

6. On the other hand, the learned APP vehemently opposes the present petition on the ground that, it is the petitioners, who was not able to send the samples to the Central Drug Laboratory, though the notice was issued on 12.04.2023 to the petitioner and it was served on 19.04.2023 along with the Chemical Analysts ('CA') report dated 10.01.2023, which was received on 18.01.2023, and therefore, as there was no reply nor the samples were sent to the Central Drugs Laboratory, therefore, there is no substance in the contentions of the petitioners. He further submits that admittedly the samples were sent to the Government Analyst on 14.07.2022 whereas extension was sought on 01.11.2022 and the Government Analyst's report i.e. CA report was received on 18.01.2023 stating that the drug is not of standard quality. Therefore, he submits that ultimately if the drug is not of standard quality, it would affect the public at large and from that angle the matter is required to be viewed.

7. He further submits that after receiving the sanction to

prosecute the petitioner, complaint was filed on 23.08.2023 i.e. before the expiry of shelf life of the drug. He further submits that mere non-compliance of Rule 45, that by itself is not sufficient to quash the complaint, when the petitioners have failed to exercise their right under Section 25(3) and 25(4) of the Drugs and Cosmetic Act, 1940. Lastly, he submits that there is no merit in the petition and same deserves to be dismissed.

8. Upon careful perusal of the record and after giving thoughtful consideration to the arguments advanced by the learned Counsel and the learned APP, there are some undisputed facts, that the Drug Inspector went to the M/s. City Medical Shop on 12.07.2022. Thereafter samples were drawn, samples were sent to the Government Analyst on 14.07.2022 and further it appears that extension was sought on 01.11.2022. However, CA report i.e. report of Government Analyst was received on 18.01.2023. admittedly, the extension was sought beyond 60 days. This Court in the case of *Swapnil s/o Liladhar Mane and ors. vs. State of Maharashtra (supra)*, particularly in paragraph 14, observed as under :

> "*14. The third and most important ground pressed into service by the petitioners is the non-compliance of Rule 45 of the Drugs Rules, 1940. As stated above, the sample was drawn on 27.09.2019. The*

> *sample was forwarded to the Analyst on 27. 09.2019. The report of the Analyst is dated 18.11.2020. The date of analysis is 18.11.2020. The report was generated on the same date. It is therefore apparent on the face of the record that the sample was analyzed after one year. In my view, the analysis of the sample within a period of sixty days is necessary to ensure the standard of quality for the purpose of the analysis and an accurate report. On this count also, the prosecution against the accused Nos. 6, 7 and 8 cannot be sustained. The complaint lacks the reasons for the delayed analysis of the sample. The delayed analysis of the sample in such a case violates the vital right of the accused to get the sample rechecked. In my view, therefore, on all these counts, the complaint and the order of issuance of bailable warrant against the accused Nos. 6, 7 and 8 cannot be sustained. Learned Judge has mechanically passed the order of issuance of bailable warrant. Learned Judge was required to pass reasoned order for the issuance of process against the accused. Even while issuing a bailable warrant no reasons have been recorded. In my view, therefore, the prosecution against the petitioner/ accused Nos. 6, 7 and 8 cannot be sustained. As such, the writ petition is allowed."*

9. Therefore, apart from the judgment of this Court, there are other catena of judgments in which the law has been laid down that if there is no compliance of Rule 45, the entire proceedings would not sustain. So far as the testing is concerned, time is of the essence for the reason that the quality of the drug should be maintained. By not adhering to the time limited provided under Rule 45, it would vitiate the entire proceedings. It would be important to note that Rule 45 of the Rules, 1945 mandates that it is the duty of the Government Analyst

to analyse or test the samples of the Drug within a period of 60 days from the receipt of the samples. However, further proviso is provided wherein the Government Analysts is at liberty to seek extension of time from the Government by giving specific reasons for delay in testing the drug or analyzing the drug, when it is not possible to test or analyse the samples as provided under the Rule 45 of the Rules 1945. Though in the present case extension was sought on 01.11.2022, however same was sought after the expiry of 60 days and not before that. Even after seeking the extension by the Government Analyst, whether the Government has granted the same or not is not clear from the reply of the Government. Therefore, in the absence of grant of extension and further the extension being sought beyond the stipulated time period, in my opinion, the proceedings initiated by the Drug Inspector cannot be continued and are required to be quashed. Further, it is to be highlighted that the Drug Inspector who was entrusted with the matter, has not taken any efforts at least to send the reminder to the Government Analyst in view of purport of Rule 45 of the Rules, 1945.

10. It is further to be noted that even after the receipt of CA report on 18.01.2023, the notice was delivered to the Manufacturer on 19.04.2023 i.e. almost after four months. I am surprised by the leniency shown by the authorities while dealing with the strict time limit

provided under the Rule, 1945 thereby jeopardizing the lives of public at large. When the Act or Rules provides to do a particular thing in a particular manner and if the Authorities are sitting idle, under such circumstances, it is necessary to hold the concerned officer responsible.

11. It is necessary to mention at this juncture that the manufacturers, who are manufacturing the sub-standard drugs are required to be dealt sternly for the reason that the effect of such drug on the public at large is huge. However, there are 'n' number of cases wherein the lapses on the part of the department of the Drugs and their officers have come on record. As could be seen that the lapses on the part of the Drug department would be beneficial to the manufacturers who are manufacturing the sub-standard drugs. As was observed earlier that these drugs are adversely affecting the human beings on large scale, it is necessary to issue directions to the department of drugs so that in future they should maintain the time line provided under the Drugs and Cosmetics Act, 1940 and Rules of 1945.

12. Before giving the directions, it is necessary to consider the aims and objectives of the Drugs and Cosmetics Act,1940. The act was enacted with four fold objectives :

(i) ensuring safety, efficacy and quality of drugs and cosmetics sold in India;

(ii) preventing sub-standard products (adulterated and mis-branded drugs or cosmetics) from reaching consumers;

(iii) establishing legal standards and guidelines for the manufacture, import, sale and distribution of drugs and cosmetics;

(iv) Protecting public health by ensuring that harmful or ineffective substances do not enter the market;

Due to the conduct of the concerned officers, the objectives with which the Act was enacted is getting frustrated.

13. Considering the above facts and circumstances of the present case, the prosecution cannot sustain and the Writ Petition is allowed in terms of prayer clause(II).

14. As observed earlier, it is necessary to issue directions considering the sensitivity of the matter, hence the following directions :

(a) The Commissioner, Food and Drugs Administration, Drug Department, State of Maharashtra, Mumbai shall ensure the report of samples shall be received by the concerned officer within time as provided under Rule 45 of the Drugs and Cosmetics Rules, 1945.

(b) In case of failure by any of the concern Officer to comply with

the provisions of the Drugs and Cosmetics Act, 1940, so also Rules, 1945, strict action should be taken against them.

(c) In case, the samples are not tested due to heavy work load at the Government Laboratory, then the Commissioner shall request the Government to create more laboratories in order to tackle the situation.

(d) The Government Analysts shall also ensure that they should send the report timely as provided under Rule 45 of the Rules, 1945 and in case, it is not possible to comply the prescribed time limit, benefit should be taken of proviso provided to Rule 45 and seek extension immediately by giving reasons in writing to the Government.

(e) The Government should act promptly on the communication of the Government Analyst seeking extension and shall ensure timely communication and co-ordination between Government and Government Analysts.

(f) The Commissioner of Food and Drugs Administration, Drug Department is also directed to ensure that an efficient online system be created, whereby the drug samples which are sent for test/analysis are expeditiously tested and analyzed by the

Government Analyst within 60 days, and the reports sent by them are available online on a real-time basis. This creation of an effective mechanism is to ensure that the entire process is monitored, and unnecessary delay is not caused in the conduct of the test/analysis of the drugs sample sent for test to the Government Analysts would ensure that the ill-effects of a drug of doubtful quality is prevented.

(g) The Commissioner of Food and Drugs Administration, Drug Department, State of Maharashtra shall preferably ensure that this entire process be web-hosted so that all the concerned are aware of the process of testing and its outcome;

So far as the aforesaid directions (f) and (g) are concerned, High Court of Karnataka at Bengaluru in Criminal Petition No.8341 of 2018 on 30.08.2024 has already issued directions to the Drugs Controller General (India), however, I am issuing these directions to the Commissioner of Food and Drugs Administration, Drug Department, State of Maharashtra.

Above directions shall be complied within three

months from the date of receipt of the order by the Commissioner of Food and Drugs Administration, Drug Department, State of Maharashtra.

15. The compliance to be reported to this Court within three months from the date of receipt of the order. Learned APP shall ensure the communication of this order to the Commissioner of Food and Drugs Administration, Drug Department, State of Maharashtra.

16. With the above observations and directions, the petition stands disposed of accordingly.

17. List the matter for noting the compliance on 04.05.2026.

(M.M. NERLIKAR, J.)

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