IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 17.03.2026

Pronounced on : 01.04.2026

CORAM:

THE HONOURABLE MR. JUSTICE G.K.ILANTHIRAIYAN

Crl.O.P.No.9789 of 2023
and
Crl.MP.No.6408 of 2023

1. M/s.RPG Life Sciences Limited
   Rep. by its Chief Manager QA
   Thiru.Yugal Kishor Chothuram Sikri

2. Thiru.Yugal Kishor Choturam Sikri
   Managing Director,
   M/s. RPG Life Sciences Limited

3. Thiru. Hiralal B. Patel
   Authorised Signatory,
   M/s. RPG Life Sciences Limited

All the above at:
3102/A, GIDC Estate,
Ankleshwar – 393002
Dist. Baruch, Gujarat, India. ... Petitioners

vs

State represented by
The Drugs Inspector,
Vadapalani Range,
O/o. The Asst. Director of Drugs Control
Zone – II, No.259-261, DMS Campus,
Chennai – 600 006. … Respondent

Prayer: Criminal Original Petition is filed under Section 482 of Criminal Procedure Code, praying to call for records in C.C.No.3992 of 2022 pending on the file of the IV Metropolitan Magistrate Court, Saidapet, Chennai – 600 015 and quash the same.

For Petitioners : Mr.R.Johnsathyan
Senior Counsel for
Mr.T.D.Selvan Babu

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

O R D E R

This petition has been filed to quash the proceedings in C.C.No.3992 of 2022 pending in the IV Metropolitan Magistrate Court, Saidapet, Chennai.

2. The petitioners are accused 1 to 3 in the complaint lodged by the respondent alleging that on 16.06.2021, a sample of Tricaine MPS Gel has been drawn for analysis by the respondent from the premises of M/s.Rajam Medicals, Ground Floor, 34/15, Kamaraj Salai, Virugambakkam, Chennai – 92, under Form-17 dated 16.06.2021 and sent to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai for analysis under Form-18 dated 17.06.2021. The samples have been declared as Not of Standard Quality by the Laboratory *vide* report dated 27.07.2021 for the reason that the sample does not conform to the

label claim for Tricaine MPS Gel with respect to the content of Oxethazaine (47%).

3. Therefore, the respondent issued a notice to the said M/s.Rajam Medicals from whom the sample was drawn for analysis requesting them to disclose the name and address of the person from whom they acquired the subject drug. In their reply, M/s.Kamalam Medical Corporation, SIDCO Industrial Estate, Chennai, dated 11.08.2021 stated that the said drug was supplied by the petitioners after collection of all invoices and other documents. The show cause notice was issued alleging that the petitioners had contravened Section 18 (a) (i) of Drugs and Cosmetics Act, 1940. Though, the petitioners submitted a reply and explanation, it was not satisfactory and the respondent filed a complaint for contravention of the provisions under Section 18 (a) (i) of the Act for having manufactured for sale and sold the subject drug, which was not of standard quality, punishable under Section 27 (d) of the said Act.

4. The learned Senior Counsel appearing for the petitioners submits that the respondent did not follow the procedures as contemplated under the Act to

prosecute the petitioners. The Government Analyst ought to have asked the petitioners for the standard and method of analysis of Oxethazaine, before analysing the drug and ought not to have used an incorrect method of analysis. Based on the said report, the respondent has now initiated the prosecution. The Government Analyst, by its communication dated 06.01.2022, asked the first petitioner to provide the working standard and method of analysis of Oxethazaine in another sample from a different batch of Tricaine and the same was sent to the first petitioner by another Drug Inspector, Tiruchengode, the first petitioner had sent required particulars to the Government Analyst. The said method was forwarded and the letter dated 27.07.2021 shows that there was no contravention of any of the provisions. Therefore, the analyst report is not in accordance with Explanation 3 of Rule 46 of the Act, 1945, since Tricaine MPS Gel is a "Patent and Proprietary Medicine" as defined under Section 3 (h) (ii) of the Act, 1940, which is not included in Indian Pharmacopeia (IP) or Pharmacopeia of any other country and there is no reference standard and method of analysis available except the method of analysis owned by the first petitioner. Therefore, the respondent ought to have obtained a reference standard and method of analysis for the subject drug before supplying it for testing procedure.

5. He further submitted that the respondent failed to make any request to the Central Drugs Laboratory to analyse the assay content of Oxethazaine by the manufacturer specified method given by the petitioners to the respondent while sending the second portion of sample for reanalysis to the Central Drugs Laboratory. Therefore, the subject drug was not tested by proper method which has resulted in an erroneous failure report. Consequently, the report of the Director of Central Drugs Laboratory is defective, unreliable, not in accordance with the validated method of analysis, which is against the provisions under Section 25 (4) of the Act, since, it is not accompanied by the protocol of test or analysis as per Rule 6 of the Drugs and Cosmetics Act, 1945.

6. He further submitted that even as per the label of the drug, it is made under the standards of the british pharmacopeia. Therefore, the method by which the analyst conducted test is not the proper one. The analyst ought to have requested the standard of the british pharmacopeia or the standard method of analysis from the petitioners. Therefore, the entire initiation of prosecution against the petitioners cannot be sustained and is liable to be set aside.

7. On perusal of the records and the submissions made on either side, it is revealed that the ground raised by the petitioners can be considered only during trial by letting in evidence with regard to the method followed by the analyst and the analysis of the drug sample drawn from the subject drug. As per the analyst's report, the drug sample does not conform to the Label claim for Tricaine MPS Gel with respect to the content of Oxethazaine (47%) and therefore, it was declared as Not of Standard Quality. Though the petitioners denied the report of the Government Analyst and as per their request, the second portion of the sample was sent to the Central Laboratory for reanalysis under Section 27 (3) of the Act, the Central Drugs Laboratory analysed the sample and confirmed the findings of the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai that the sample does not conform to the label claim with respect to Oxethazaine content (53.80%) in its report dated 09.12.2021. Therefore, the Central Drugs Laboratory report shall be final and conclusive evidence of the facts stated therein.

8. The learned Senior Counsel further contended that the respondent failed to conduct a manufacturer-level investigation cannot be accepted for the

reason that the initiation of prosecution is based on the statutory test report issued by the Government Analyst and the same was also confirmed by the Central Drugs Laboratory which itself constitutes sufficient material for launching prosecution under the Act.

9. Further, the method used by the analyst can be decided only before the trial Court by letting in evidence which requires expert opinion to qualify the method followed by the Government Analyst to test the sample drug. Therefore, the complaint lodged by the respondent discloses a *prima facie* offence to prosecute the petitioners.

10. The Hon'ble Supreme Court of India in the judgment reported in ***2019 (4) SCC 351*** in the case of ***Devendra Prasad Singh Vs. State of Bihar & Anr., (Crl.A.No.579 of 2019*** *dated* ***02.04.2019)*** while dealing with the petition to quash the entire criminal proceedings held that the High Courts have no jurisdiction to appreciate the statement of the witnesses and record a finding that there were inconsistencies in their statements and therefore, there was no *prima facie* case made out as against the accused. It could be done only by the trial Court

while deciding the issues on the merits or/and by the Appellate Court while deciding the appeal arising out of the final order that the charge sheet has been laid on the basis of the inconsistency statement under Section 161 of Cr.P.C./180 of the Bharatiya Nagarik Suraksha Sanhita, 2023. (*any one)*

11. *Fruther, the Hon'ble Supreme Court of India in the judgment reported in* ***2019 (10) SCC 686*** *in the case of* ***Central Bureau of Investigation Vs. Arvind Khanna, (Crl.A.No.1572 of 2019*** *dated 17.10.2019) held that the High Courts cannot record the findings on the disputed facts. The defence of the accused is to be tested after appreciation of evidence by the trial Court during the trial. Therfore, this Court has no power to consider the disputed facts under Section 482 of Cr.P.C./528 of the Bharatiya Nagarik Suraksha Sanhita, 2023.(any one).*

12. *The Hon'ble Supreme Court of India in another judgment dated* ***02.12.2019*** *passed in* ***Crl.A.No.1817 of 2019*** *in the case of* ***M.Jayanthi Vs. K.R.Meenakshi & anr,*** *held that while considering the petition for quashment of complaint or charge sheet, the Court should not embark upon an enquiry into the validity of the evidence available. All that the Court should see is as to whether*

there are allegations in the complaint which form the basis for the ingredients that consititue certain offences complained of. Further, the Court can also see whether the preconditions requisite for taking cognizance have been complied with or not and whether the allegations contained in the complaint, even if accepted in entirety, would not consititue the offence alleged. Whether the accused will be able to prove the allegations in a manner known to law would arise only at a later stage i.e., during trial.

13. Further this Court cannot observe at this stage that the initiation of criminal proceeding itself is malicious. Whether the criminal proceeding is malicious or not, is not required to be considered at this state. The same is required to be considered at the conclusion of the trial. Therefore, the ground raised by the petitioners to quash the final report/charge sheet cannot be entertained to quash the entire proceedings.

14. In view of the above discussion, this Court is not inclined to quash the proceedings in C.C.No.3992 of 2022 pending on the file of the IV Metropolitan Magistrate Court, Saidapet, Chennai. The petitioners are at liberty to

raise all the grounds before the trial Court. The personal appearance of the petitioners are dispensed with and they shall be represented by a counsel after filing appropriate application. However, the petitioners shall be present before the Court at the time of furnishing of copies, framing charges, questioning under Section 351 of BNSS and at the time of passing judgment. The trial Court is directed to complete the trial within a period of six months from the date of receipt of a copy of this Order.

15. Accordingly, the Criminal Original Petition stands dismissed. Consequently, connected miscellaneous petition is also closed.

01.04.2026

Speaking order / Non-speaking order
Index : Yes / No
Neutral Citation : Yes / No
dh
To
1. The Metropolitan Magistrate Court – IV,
Saidapet, Chennai – 600 015.

2. The Drugs Inspector,
Vadapalani Range,
O/o. The Asst. Director of Drugs Control
Zone – II, No.259-261, DMS Campus,
Chennai – 600 006.

G.K.ILANTHIRAIYAN, J.

dh

Pre-delivery order made in
Crl.O.P.No.9789 of 2023

01.04.2026