IN THE COURT OF THE JUDICIAL FIRST CLASS MAGISTRATE-I, KAYAMKULAM

Present:- Smt. Aiswaryarani, Judicial First Class Magistrate - I

Dated this the 16th day of December 2024

CC 1174/2016

Complainant	:	State represented by the Drugs Inspector, Alappuzha. (By A.P.P. Sr. Grade)
Accused	:	1. M/s. Kausikh Therapeutics (P) Ltd. , Plot No. 6 & 7, Paraniputhur Village, Gerugambakkam, Chennai – 602101 2. V Neelakandan, (Managing Director), No.12, Durairaj Street, Palavanthaagal, Chennai, 6001114. 3. V Anantharamkrishnan (Sleeping Director) No.12, Durairaj Street, Palavanthaagal, Chennai, 6001114. (Case quashed) 4. V. Ramasubrahmanian, (Sleeping Director) No.12, Durairaj Street, Palavanthaagal, Chennai, 6001114. (Case quashed) (By Adv. George Varghese)
Charge	:	U/s. 18(a)(i) and 27(d) of Drugs and Cosmetics Act, 1940.
Plea	:	Not Guilty
Finding	:	Not Guilty
Sentence or order	:	Accused are acquitted under Section 248(1)of the Code of Criminal Procedure, 1973 for the offences punishable under Section 18(a)(i) and 27(d)of the Drugs and Cosmetics Act, 1940.

DESCRIPTION OF THE ACCUSED

Sl. No.	Name	Father's Name	Occupation	Residence	Age
1	M/s. Kausikh Theraputics (P) Ltd. ,			A company at Chennai	
2	V Neelakandan, (Managing Director),			Chennai	

3	V Anantharamakrishnan (Sleeping Director)			Chennai	
4	Ramasubrahmanian, (Sleeping Director)			Chennai	

DATE OF

Offence	Complaint	Period of detention undergone during investigation, inquiry or trial for the purpose of section 428 Cr.P.C	Release on bail	Commencement of trial	Close of Trial	Sentence or order
20.07.12	05.08.16	-	-	27.05.19	11.12.24	16.12.24

The case having been finally heard on 11.12.24 the court on 16.12.2024 delivered the following:-

J U D G M E N T

This is a case instituted on the basis of the complaint filed under Section 32 of Drugs and Cosmetics Act, 1940 by the Drugs Inspector, Alappuzha alleging commission of the offence punishable under Sections 18(a)(i) and 27(d) 27(d) of Drugs and Cosmetics Act.

2. The prosecution case, in brief, is as follows:- The accused manufactured Enzole-20, Omeprazole tablets that were found to be not of standard quantity. Thus, the accused persons committed the aforesaid offences.

3. On filing the Complaint, the case was taken on file and process was issued to the accused pursuant to which they appeared before the Court. They were enlarged on bail. Copies of the prosecution records were furnished to them. After hearing, charge under Section 18(a)(i) and 27(d) 27(d) of Drugs and Cosmetics Act was read over and explained to

them in Malayalam. They pleaded not guilty and claimed to be tried.

4. From the side of the prosecution, PW1 to PW5 were examined and Exhibit P1 to P28 and MO1 were identified and marked. Meanwhile, through the order of the Hon'ble High Court in Crl. MC NO. 4395/2017 the case against 3rd and 4th accused was quashed.

5. After prosecution evidence was closed, all the incriminating circumstances found against the accused persons were put to the 1st accused through the 2nd accused, since the 1st accused is a company, in the examination under Section 313(1)(b) of the Code of Criminal Procedure, 1973 and they denied them all. From the side of the defence no evidence was adduced.

6. Heard both sides.

7. The following points arise for consideration:-

1. *Whether the accused manufactured Enzole-20, Omeprazole tablets that are not of standard quality?*
2. *What is the order or sentence if found guilty and convicted?*

8. **Point No. 1:**- As part of their duties on 20.07.2012, PW2 conducted an inspection at SG Labs, Kayamkulam and sampled a batch of Enzole-20 tablets of Omeprazole, Batch No. K11 11051, manufactured in November 2011, with expiry date October 2013. PW2 collected 20 strips of the medicine, each containing 10 tablets, and divided them into four equal portions. Each portion contained 50 tablets, which were then sealed with metallic seals and wax. The samples were marked with 5/7/2012 and each portion was signed by the person in charge. PW2 also documented the process in Ext. P10, Form 17, noting the details and sealing the samples accordingly. One portion of the samples was handed over to the person in charge for their records and MO1 was produced before the court. Subsequently, PW2 prepared Ext. P11, Form 18, which was sent to the Government Analyst's Drug Testing Laboratory in

Thiruvananthapuram for analysis. The results confirmed that the drug was of substandard quality, with the Omeprazole content being only 11.95%, far below the required 99-101% according to the Indian Pharmacopoeia. This result was documented in Ext. P13, Form 13 and the laboratory protocol.

9. PW2 deposed that further investigations revealed that Enzole-20 tablets were purchased from the 1st accused as evidenced by a letter from SG Labs and subsequent correspondence marked as Ext.P13 and Ext.P14. The purchase details and sales information were collected and submitted as evidence and marked as Ext.P15 and Ext.P15(a). PW2 also sent the third portion of the sample to the accused via registered post, with the acknowledgment cards from the company confirming receipt marked as Ext.P19 and Ext.P19(a). However, the company did not challenge the Government Analyst's report. Based on these findings, the 1st accused was identified as the manufacturer of the substandard drug, and further proceedings were initiated against them.

10. PW2 then contacted the company for additional documents, including the Articles of Association, Memorandum of Association, Certificate of Incorporation, and other corporate details, which were obtained through the cooperation of the Tamil Nadu Drug Controller. These documents were collected and submitted and marked as Ext.P22 through Ext.P27. Further, PW2 confirmed that Enzole-20 was licensed for manufacture, but the batch failed to meet the required standards due to the significantly lower Omeprazole content.

11. PW2 was questioned about whether anyone had complained about the drug. PW2 clarified that the drug was used as a supporting medicine, and no complaints had been received regarding adverse effects. The defence also questioned the storage conditions, with PW2 explaining that the drugs were stored in a wooden rack at room temperature, as per the

requirements outlined in Ext. P10, Form 17. However, it was noted that there was no specific mention of temperature conditions being recorded in Ext. P10, Form 17. PW2 further clarified that the drugs were stored below 30°C, but did not have the means to measure the temperature accurately. The defense argued that SG Labs was responsible for proper storage and climate control, and questioned the validity of the storage conditions during the investigation. PW2 acknowledged that the Ext.P12 Government Analyst's report was conclusive, and there were no challenges made to the findings. However, the defense claimed that the case was initiated inappropriately and raised concerns about how the samples were handled and whether they were stored correctly before being sent for testing. The defense also questioned whether PW2 had followed the proper procedures for sampling, particularly in regard to the temperature conditions and storage of the samples during transit. PW2 denied these allegations and confirmed that the samples were handled in accordance with the law.

12. PW1, collected additional documents, including the Ext.P1 Mahazar reports and Ext.P2 Form 16, which were submitted to the court. Based on these findings, PW1 submitted a complaint identifying the 1st accused as the manufacturer of the substandard drugs. Consequently, complaint was filed against the accused persons.

13. During cross-examination, PW1 clarified that he had not directly observed the purchase or storage of the drugs from the wholesaler. While the drugs were stored in wooden racks inside the premises, PW1 could not confirm whether the storage conditions violated legal standards. However, PW1 explained that the drugs were stored at room temperature, which was not explicitly recorded as a violation. The defence further questioned the storage conditions and raised doubts about whether the drugs had been properly stored at the required temperature. Despite these concerns, PW1 maintained that the drugs were stored in compliance with the regulations

outlined in Ext. P10 Form 17, which did not mention storage violations. However, PW1 has no means of deposing as to the collection of sample and their proper storage therein as the sample was collected and sent for analysis by PW2. Hence, the deposition of PW1 to the extend of the itergrity of the collection and storage of the sample cannot be relied on.

14. PW3 works at SG Labs, Kayamkulam and identified their signature on Ext.P10. PW3 recalled that the samples were properly sealed, but could not clearly remember the impression of the seal. Although PW3 did not write the details in Form 17, they acknowledged that their signature was present. PW3 clarified that the samples were stored on a wooden shelf, which had a door, and that the storage was in accordance with the drug rules. PW4 works as a Medical Representative at SG Labs, Kayamkulam. PW4 identified their signature in the Ext. P1 Mahazar.

15. One of the primary requirements for a prosecution under the Drugs and Cosmetics Act, 1940 is ensuring that drug samples are stored in the appropriate conditions. However, the prosecution has not provided sufficient evidence to establish that the Enzole-20 tablets were stored in the requisite temperature and conditions as per the established guidelines. The deposition of PW2, the Drug Inspector, indicated that the samples were stored on a wooden shelf at room temperature. While Form 17 mentioned the storage conditions, there was no definitive proof that the samples were stored at the prescribed temperature of 30°C or below, nor was there any evidence of temperature monitoring during the storage period. PW3 and PW4, who were involved in handling the samples, also failed to provide any specific details confirming the temperature conditions at the time of storage. The lack of proper documentation and temperature records raises serious doubts about whether the samples were stored in compliance with the statutory requirements. In the absence of such evidence, it is not possible to conclusively determine that the drugs were stored properly,

which is a critical factor in ensuring the integrity of the samples.

16. Another critical deficiency in the prosecution's case is the failure to produce the specimen seal. The specimen seal is an essential element in establishing the chain of custody of the samples. The absence of the seal creates a significant gap in the evidence, as there is no way to confirm that the samples tested by the Government Analyst were indeed the same as those initially collected. Although the samples were purportedly sealed in the presence of relevant witnesses, as indicated in the depositions of PW3 and PW4, the prosecution did not produce any physical evidence of the seal or offer an explanation as to why it was not available. This failure to produce the specimen seal undermines the credibility of the prosecution's claim that the samples were handled and tested in accordance with the law.

17. The prosecution also failed to provide details regarding the protocol used by the Government Analyst in testing the samples. The deposition of the Government Analyst was not presented, and the prosecution did not specify the methodology followed during the analysis of the samples. Without this crucial information, the court cannot be certain that the tests were conducted in accordance with established procedures, or that the results accurately reflect the quality of the drug. The absence of a clear protocol further weakens the prosecution's case, as it raises questions about the reliability and validity of the testing process.

18. Lastly, there is an inordinate delay in initiating the prosecution. The incident in question occurred on 20.07.2012, Ext. P11 is dated 05.08.2013 and the prosecution was not initiated until much later on 05.08.2016, significantly undermining the integrity of the case. The delay in bringing the case to trial has compromised the ability to establish a clear and continuous chain of events. The delay in prosecution is particularly troubling in cases

involving drug quality testing, where the integrity of the evidence is paramount. The prolonged period between the alleged incident and the filing of charges has contributed to the uncertainty surrounding the case and raises doubts about the authenticity and relevance of the evidence presented.

19. Considering the above factors—namely, the failure to prove proper storage conditions, the absence of the specimen seal, the lack of details about the testing protocol, and the substantial delay in initiating the prosecution—the prosecution has not met the burden of proof required to convict the accused. The case against the accused lacks the necessary corroborative evidence, and the gaps in the evidence cast serious doubts on the reliability and credibility of the allegations.

20. **Point No. 2:-** In the result, accused are acquitted of the offences punishable under Section 18(a)(i) and 27(d) of the Drugs and Cosmetics Act. 1940 under Section 248(1) of the Code of Criminal Procedure, 1973. Their bail bonds stands cancelled.

(Typed by me on my personal laptop, corrected by me and pronounced by me in the open court on this the 16th day of December, 2024).

Judicial First Class Magistrate-I

APPENDIX

Witness for the Petitioner

PW1: Sarath Kumar
PW2: Saina
PW3: Gangadharan
PW4: Binu Mohan
PW5: Abdul Kalam

Exhibits for the Petitioner:

P1/PW1 : Mahazar dtd. 06.05.16
P2/PW1 : Form 16 dtd. 06.05.16
P3/PW1 : Purchase Invoice dtd.12.11.2011
P4/PW1 : Complaint dtd 05.08.2016
P5/PW1 : Copy Gazette Notification No. 14312/F1/2000/H&FWD dtd

19.11.01
P6/PW1 : Travancore Cochin Gazette Notification(copy) dtd. 19.11.1953
P7/PW1 : Travancore Cochin Gazette Notification (copy) dtd. 14.06.1954
P8/PW1 : Proceedings of the Drugs Controller Kerala State, Thiruvananthapuram dtd. 23.06.2012
P9/PW1 : Proceedings of the Drugs Controller Kerala State, Thiruvananthapuram dtd. 05.12.15
P10/PW2 : Form 17 dtd. 20.07.12
P11/PW2 : Form 18 dtd. 21.07.12
P12/PW2 : Form 13 dtd. 05.08.13
P12(a)/PW2 : Laboratory Protocol dtd. 05.08.13
P13/PW2 : Letter No. A2-2017/2012/AL dtd. 21.08.2013 of the Drugs Insepctor (Zone III)
P14/PW2 : Letter from SG Labs (Pharmaceutical Distributors) dtd. 21.08.13
P15/PW2 : Purchase details (SG Labs) dtd. 20.08.13
P15(a)/PW2 : Sale details (SG Labs) dtd. 20.08.13
P16/PW2 : Delivery Challan dtd. 01.02.2013
P17/PW2 : Letter No. A2-2017/2012/AL of the drugs inspector dtd. 23.08.13
P18/PW2 : Letter No. A2-2017/2012AL of the drugs inspector dtd. 23.08.13
P19/PW2 : AD card dtd. 03.09.13
P19(a)/PW2 : AD card dtd. 03.09.13
P20/PW2: Letter No. 10759/13/DC dtd. 30.08.13 of the Drugs Inspector, Thiruvananathpuram
P21/PW2 : Letter No. A2-2017/2012/AL dtd.16.12.13 of the Drugs Inspector, Alappuzha.
P22/PW.. :Articles of Association dtd Nil.
P23/PW2 : Memorandum of Association dtd. Nil
P24/PW2 : Certificate of Incorporation dtd Nil
P25/PW2 : List of Directors of the company(Kausikh) during November 2011 dtd Nil
P26/PW2 : Manufacturing license dtd. 21.02.2002
P27/PW2 : Certificate of renewal of license dtd. 29.05.12.
P28/PW2 : List of products dtd. 29.05.2012

Witness for the Respondent:
Exhibits for the Respondent:
MATERIAL OBJECTS :-
MO1 – Sealed packet.

Judicial First Class Magistrate-I