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Duration : Y M D

IN THE COURT OF CHIEF JUDICIAL MAGISTRATE, PUNE
AT : PUNE
(Presided over by Dr. Yeshwant G. Chaware)

R. C. C. NO. 2730 OF 2006
EXH.

State of Maharashtra at the instance of Shri S.V. Pratapwar, Drug Inspector Food & Drug Administration, M.S. Pune. ...Complainant.

V/S.

1. Mr. S. Sriniwasan, 1, Tejas Apartment, 53, Haribhakti Colony, Near Race Course Circle Baroda-390015.

2. Mr. T. Shrikrishan M/s. Low Cost Standard Therapeutics, Plot No. 85, G. I. D.C, Por Ramangamdi N. H. 8, Dist Baroda 391243(Gujarat)

3. Mr. Pradeep C. Patel. M/s. Low Cost Standard Therapeutics, Plot No. 85, G. I. D.C, Por Ramangamdi N. H. 8, Dist Baroda 391243(Gujarat)

4. M/s. Low Cost Standard Therapeutics, Plot No. 85, G. I. D.C, Por Ramangamdi N. H. 8, Dist Baroda 391243(Gujarat)

... Accused.

CHARGES : Contravention of section 18(a)(i) punishable under section 27 of the Drug and Cosmetics Act.

APPEARANCE :-
Shri. P. B. Gaikwad, Lrd., A. P. P. for the State.
Shri S. A. Tamhane, Advocate for the accused nos.1 to 4.

J U D G M E N T
[Delivered on 31-03-2009]

1. The accused are prosecuted for contravention of section 18(a)(i) of the Drugs and Cosmetics Act, 1940, punishable under section 27 of the Drugs and Cosmetics Act, 1940. (In short hereinafter called D & C Act).

2. Fact of the prosecution case in brief are as under :-

The complainant is a notified Drug Inspector. The accused no. 1 is Managing Trustee of the firm accused no. 4 and looking after the day-to-day business of the firm. The accused no. 2 is a competent technical person responsible for manufacturing of tablets and accused no. 3 is a competent technical person responsible for testing of drugs in the firm accused no. 4.

3. The complainant has stated that on 23/1/2006 he visited the premises of Dr. Samee Narayan Mone, Lokayat Medical Center, Law College Road, Pune and drawn the samples of 4x3x10 tablets Enalapril Maleate Tablets I. P. B. No. 2370 mfg by M/s. Low Cost Standard Therpeutics, Plot No. 85, G. I. D. C., Por Ramangamdi, N. H. No. 8, District Baroda 391243 Gujarat from the stock of drugs meant for distribution. He issued Form No. 17 and one sealed part (1x3 Tab) of the sample of the said drug to the Dr. Mone and obtained acknowledgment from Dr. Mone. Dr. Mone refused to accept the fair price of the sample therefore, complainant issued Form No. 17-A. On 24/1/2006 the complainant sent one sealed part of the sample to the Government Analyst, Aurangabad along with copy of Form No. 18 with specimen seal impressions used to seal the samples. He received Government Analyst

report on 27/4/2006 wherein the Government analyst has declared that the sample Enalapril Maleate Tablets I. P. B. No. 2370 mfg by M/s. Low Cost Standard Therpeutics, Plot No. 85, G. I. D. C., Por Ramangamdi, N. H. No. 8, District Baroda 391243 Gujarat to be not of standard quality for the reason- The content of Enalapril Maleate in the sample is less (45.8% of the stated amount) than the permissible limit. (Permissible limit : Not less than 90.00 % and not more than 110.00 % of the stated amount). On receipt of this report the complainant immediately sent copy of analysis report with protocol of tests supplied to Dr. Mone, Lokayat Medical Center,Law College Road, Pune and asked to produce purchase details under section 18-A of the Act. Dr. Mone acknowledged the analysis report and protocol of tests. He has also submitted copies of purchase bill of the drug from accused no. 4 along with other relevant documents.

4. The complainant has sent copies of analysis report and protocol of tests applied along with sealed part of the sample to M/s. Low Cost Standard Therapeutics and asked to produce the manufacturing and testing details along with other documents. The accused no. 1 acknowledged the receipt of the analysis report along with protocol of tests applied and he submitted the copies of the relevant documents including manufacturing license, approved list of products, Batch manufacturing record, sales record, analytical report, list of trustees etc. The batch manufacturing records reveals that the drug in question was manufactured under supervision of accused no. 2 and was released for sale after certified by the accused no.3.

5. The Enalapril tablets I. P. B. No. 2370 mfg by M/s. Low Cost Standard Therapeutics, Plot No. 85, G. I. D. C., Por Ramangamdi, N. H. No. 8, District Baroda 391243 Gujarat is drug within the meaning of

section 3(b) of said D & C Act, 1940. There is a bar to manufacture for sale or for distribution, sell, stock, exhibit or offer for sale any drug which is not of standard quality, or is misbranded, adulterated or spurious. Therefore, the accused have contravened the said provisions of Drugs and Cosmetics Act hence present complaint filed.

6. The process was issued. The accused have appeared in response to the summonses. This case is other than police report. Therefore, the case was fixed for evidence before charge. Prosecution has examined P. W. No. 1 in order to produce prima facie evidence. Considering prima facie evidence of P. W. No. 1 and documentary evidence on record, the Charge was framed against the accused. The contents of the charge were read over and explained to the accused and it has been asked to the accused whether do you plead guilty? The accused have denied to plead guilty and claimed for trial.

7. The defence of the accused is of total denial and they submitted that they are falsely implicated in this case.

8. On the above facts and the evidence placed before me, the following points arises for my determination and my findings with reasons are as under :-

POINTS	**FINDINGS**
1. Whether the prosecution has proved that the accused nos. 1 to 4 on 23.01.2006 and before that they manufactured the drug Enalapril tablets I. P. B. No. 2370 mfg by M/s. Low Cost Standard Therapeutics, for sale distribution and sold the said drug which is not of standard quality ?	..In affirmative.
2. What order ?	.As per final order.

R E A S O N S

AS TO POINT NO. 1 :-

9. In order to prove the guilt against the accused, prosecution has examined P. W. No. 1- Mr. Shamsundar Pratapwar. His evidence speaks that he has joined as Drug Inspector in Food & Drug Administration on 5/1/1994. He has submitted gazette notification about his appointment at Exh. 28. He joined as Drug Inspector at Pune on 15/4/2005. He has filed notifications empowering him to file prosecution which are at Exh 29 to 30. The evidence of P. W. No. Further speaks that on 23/1/2006 he visited the premises of Dr. Sameer Narayan Mone, Lokayat Medical Center, Brahme Bungalow, Law College Road, Pune. He carried inspection. He drawn sample of Enalapril maleat tablets IBP 5 mg batch No. 2370 manufacturing date 7/2005 expiry dated 6/2007 manufactured by M/s. Low Cost Standard Therapeutic, GIDC por Ramangandi, District Baroda. The sample was drawn and sealed as 4x3x10 tablets. Out of these one 1x3x10 tablets sealed sample part was handed over to Dr. Sameer Mone along with intimation in form No. 17 on 23/1/2006. This copy of Form No.17 is at exh. 31 which bears signature of Dr. Mone and also bears signature of this witness and Dr. Mone acknowledged the same. P. W. No. 1 further stated that he offered to pay Rs.170/- towards cost of sample including other samples. Dr. Mone refused to accept the price. Therefore, Form No. 17A was issued to him. The copy thereof is at Exh. 32 which bears signature of this witness and signature of Dr. Mone. Exh. 32 speaks that the copy of Form No. 17is received by Dr. Mone. On 24/1/2006 the P. W. No. 1 has sent one sealed part of the sample 1x3x10 tablets of the above said drugs to Government Analyst, Drug Control Laboratory. Aurangabad along with Form 18, specimen seal impression separately. Third copy of Form 18 is on record which is at Exh. 33 its acknowledgment is at exh. 34.

10. The evidence of P. W. No. 1 speaks that he received Government analyst report on 27/4/2006 in Form 13 vide No. M/213/2006 dated 25/4/2006. The Government analyst Aurangabad has opined that the above said sample is not of standard quality for the reason that the content of Enalapril maleat in the sample is 45.8 % of labeled amount.

11. Further this witness has stated that on 29/4/2006 he sent copy of analytical report along with his covering letter dated 29/4/2006 to Dr. Mone and asked him to disclose the source of purchase of the said drug. The letter is at Exh. 38. On 29/4/2006 Dr. Mone submitted information about purchase of drug and his qualification along with his letter. The letter dated 29/4/2006 is at Exh. 39 and xerox copy of registration is at Exh. 40 and xerox copy of purchase bill is at Exh. 41. As per Exh. 41 Dr. Mone has purchased 200x10 tablets of above said drugs from manufacturer i.e. accused no.4. The payment receipt of the drug purchased by Dr. Mone is at Exh. 42. Exh. 42 speaks that receipt is issued by Low Cost Standard Therapeutic and said Low Cost Standard has received Rs.10,000/- from Dr. Mone, Lokayat Medical Center.

12. The evidence further speaks that on 2/8/2006 the P. W. No. 1 has sent a copy of analytical report and sealed sample part to accused no. 4 along with his letter. The letter is at Exh. 43. The accused no. 4 has submitted the information and the documents pertaining to manufacture and sell of said drugs. The letter bears signature of accused no. 1. The said letter is at Exh. 44. The xerox copy of manufacturing licenses, approved list of product, batch manufacturing record and testing record and sale bill are also submitted along with said letter collectively at Exh. 45. The accused have admitted that they have manufactured and sold the drug to Dr. Mone. Accused no. 1 by his letter dated 28/8/2006 admitted

that he himself and accused no. 2 are responsible for day-to-day business of the firm and for manufacturing. The said letter is at exh. 46. The accused no. 1 has admitted by his letter that the sample was tested by them. The report speaks that 36.4 % of active ingredient. The accused also admitted that the formulation was unstable and they are in the process of preparing a stable formulation.

13. The evidence of this witness speaks that the Jt. Commissioner, HQ, FDA, Mumbai has ordered him to launch the prosecution against accused. The order dated 5/6/2006 is at Exh. 47. Therefore, he filed present complaint. The witness has submitted one sealed part of sample with his application Exh. 25.

14. This witness was cross examined in detail. The witness has stated in his cross examination that above said medicines were in box and those box were kept in a rack. The sample was stored in well closed restraint container. A suggestion was given to the witness that Dr. Mone has not stored the medicines as directed. The witness has denied the said suggestion. Further suggestion was given to the witness that medicines were stored in proper condition by Dr. Mone and the witness has admitted the same. He has also admitted that drug was not adulterated.

15. The witness has further stated in his cross examination that after receipt of analysis report he called manufacturing and testing report from the accused. From the record provided by the accused it appears that manufacturing including packing was completed on 29/10/2005. The accused himself has stated in his letter Exh. 44 that we found the content of Enalapril maleate to have reduced to 36.40 % as per the report of M/s. Choksi Analytical Laboratory. Witness has shown his inability to state the substance in the medicines which can be diminished. The

Enalapril maleate substance if it is stable it can be diminished. The accused informed vide Exh. 44 that "we found the content of Enalapril maleate to have reduced as peer report. The Government analyst report and the report of Choksi Laboratory was referred by the accused. In his letter it appears that the product is not stable. The drug inquestion is being used for hypertension. The witness has not carried investigation to ascertain the fact that whether any person sustained grievous hurt by the use of substandard medicines in question.

16. The witness has stated that as per invoice the drug in question was sent to Dr. Mone on 30/10/2005 by the accused. The complainant has not paid any visit to manufacturer unit and he is unable to state about the manufacturing process, packing process, storing process etc.. This witness has informed the accused to withdraw the medicines supplied for sale. A question was asked to the witness that if product is not stable then its percentage can be reduced. The witness has answered that if product is not stable the contents can be reduced over period of time. The witness has further stated that the word stable means the contents of active ingredients in the medicines should be within the specified limit till its shelf life mentioned on the label. The accused has not denied the fact that the Drug Enalapril maleate is not a standard quality as the contents of the Enalapril maleate in the sample is less than the permissible limit. (45.8%). Exh. 37 speaks permissible limit : not less than 90.00% and not more than 110.00% of the stated amount. The accused has not denied the condition of permissible limit mentioned in Exh. 37.

17. The witness was recalled as per order below Exh. 54 and he was cross examined. During the course of cross examination the witness has shown his inability to state that Lubricate separate magnesium, talcum, aerosil, starchi, geletin is used for formation of tablets namely

Enalapril maleate. The Drug and Cosmetics Act provides the schedule of reference of book of the standard of the Drug.

18. The learned APP for the state has argued that the fact of visit of complainant to Lokayat Medical Center, the fact of issuing of Form No. 17, 17A, sending of sample to Government analyst, Aurangabad, the fact of manufacturing of the drug in question by the accused, the fact that the accused nos. 1 to 3 are the responsible person of the accused no. 4, the fact that the drug in question was purchased by Dr. Mone, Lokayat Medical Center, bill under invoice were issued by accused no. 4, the fact of making payment by Dr. Mone, purchase of drug in question are not disputed. The accused have also not disputed the report of Government analyst and the report of Choksi Laboratory. The accused have also not disputed the label of the medicines, manufacturing number, batch number, expiry date etc. The accused have also not disputed the standards of Enalapril maleate mentioned in the Government analyst report. The drug in question was not of standard for the reason that the contents of Enalapril maleate is less than the permissible limit i.e.. 45.8%. These particular fact is also not denied by the accused. A simple suggestion was given to the witness that the witness is deposing false that the drug in question is not of standard quality. The said suggestion was denied by the accused.

19. The learned prosecutor for the State has argued that the contents in the drug should be stable till the date of expiry i.e.. shelf life of the drug in question. The date of manufacture of the drug in question is 7/05, date of expiry of the drug is 6/07. The sample was drawn on 23/1/2006 i.e.. after six months from the manufacture of the drug and within six months the said drug was not stable and therefore, it is not of standard quality. The accused has supplied the information to

complainant vide Exh. 44 and it has been specifically mentioned in Exh. 44 that "we sent a sample of Enalapril Maleate (B. No. 2370) as per our routine retain sample testing procedure to M/s. Choksi Analytical, Baroda on 7-5-2006. We found the content of Enalapril Maleate to have reduced to 36.40% as per the report of M/s. Choksi Analytical Laboratory vide their report No. 02589/06-07 dated 12.05.2006.

20. The learned prosecutor further argued that the evidence on record oral as well as documentary established the guilt against the accused therefore, prayed to convict the accused according to law.

21. The learned counsel for the accused has argued that the accused no. 4 is trust which is manufacturing the medicines and distributing to Low Cost Standard Therapeutics. The complainant has not collected any evidence to show that by using the drug in question not of standard quality any one has sustained harm. The complainant has not furnished India Pharmacopia. Therefore, it cannot be stated that the standards mentioned in Government analyst report are standards as per law. The P. W. No. 1 has specifically stated in his cross examination that he has not produced book of India Pharmacopia. However he has stated that he will produce the same. Inspite of such contentions he has not produced the said book therefore, the report cannot be considered that the drug in question is not of standard quality.

22. The learned counsel for the accused has argued that no evidence is on record, to indicate that, what testing was applied to reveal the alleged contents of Enalapril Maleate in the sample is less than the permissible limit and relied on authority reported in **1979(1) PFA Cases Page No. 146, State of Maharashtra V/s. Jawaharlal Shamlal Ujawana**. AND **1988(I) PFA Cases Page No.98, The State of**

Maharashtra V/s. Shri Hasmukhrai Fulchand Shab and lastly prayed to acquit the accused.

23. The accused has not disputed about the permissible limit of the standard mentioned in the Government analyst report. The accused himself have produced their own report of analysis i.. report of Choksi Laboratory which also speaks that the contents of Enalapril Maleate is less than the permissible limit.

24. The documentary evidence placed on record is that the accused has manufactured the drug in question distributed the same for sale and the drug in question is not of standard. The said drug was purchased by Lokayat Medical. The sample was taken from him and it is declared by the Government analyst after analysis as not of standard quality and as it is not disputed and own report of the accused of Choksi Laboratory also speaks the similar report of not of standard quality. Therefore, I hold that the prosecution has proved that the accused has manufactured the said drug in question and distributed for sale which is not of standard quality therefore, the accused have contravened section 18(a)(i) and committed offence punishable under section 27 of the Act. Accordingly, I have recorded my findings of point No. 1 in affirmative.

25. As the offence is proved it is necessary to hear the accused on the point of sentence. I heard the accused on the point of sentence.

26. The Ld. counsel for the accused submitted that this is first offence of the accused. The accused are manufacturing the medicines on low cost as social service with a view that the poor people should get medicines on lower cost. Further the Learned counsel argued that the accused are only earning members of their family. Family members are

dependent. The poviso is provided in section 27 and by the authority of the said proviso the sentence for a term of less than one year can be passed by this Court by recording adequate and special reasons. Considering the special reason advanced before this Court punishment may be passed less than one year.

27. Further Learned counsel for the accused argued that accused may be punished Till rising Court and relied on authority report in **1948-1997 Sri Krishan Gopal Sharma V/s. Government of N. C. T. of Delhi, Supreme Court on Food Adulteration Cases, Page 1075**. The Hon'ble Supreme Court observed in this case that " for adequate and special reasons, may bring down the minimum sentence. The constitution Bench has also observed that all violations of provisions of the Act and Rules need not be treated alike because "there are violations and violations". In the special facts and these cases, it appears to us that a deterrent punishment of imprisonment is not called for and imposition of fine will meet the ends of justice". The learned counsel submitted that considering this accused may be released on probation and sentence till rising of court and fine may be awarded and lastly prayed for lenient view while sentencing the accused.

28. The accused have submitted that as the accused no. 4 is trust the medicines will not be supplied to the medical stores and the accused no. 4 manufacturer used to supply the medicines to the social institution only for discharging medical services.

29. The Learned APP for the state has submitted that offence is proved against the accused. The drug in question is not of standard quality therefore object of the Law is to provide the drugs of the standard quality to the patients. The accused have contravened provisions of Act and accused may be punished as per law.

30. Considering argument advanced by both sides it is an admitted position that the accused no. 4 is a trust and the medicine is supplied only to the institutions. As the accused no. 4 is a trust, manufacturing medicines and distributing the same. The accused no. 4 should have its own research unit. Its own testing laboratory so that every possible care should be applied before sending the medicines for use to the patients. The accused have committed offence. Considering above aspects, I am of the opinion that no severe punishment is required and accused should be punished simple imprisonment till rising of court and sentenced to fine as provided under the law. With this I proceed to pass the following order :-

O R D E R

1. The accused Nos. 1 to 4 are hereby convicted under section 248(2) of Criminal Procedure Code for contravention of section 18(a)(i) of the Drugs and Cosmetics Act, 1940, punishable under section 27 of the said Act and sentenced to pay fine of Rs. 10,000/-(Rs. Ten Thousand) each accused and suffer simple imprisonment Till Rising of the Court, in default of payment of fine, the accused shall undergo R. I. for six months.

(Dictated and delivered in open Court)

Pune
Date :- 31-03-2009

(Dr. Yeshwant G. Chaware)
Chief Judicial Magistrate,
Pune.

I affirm that the contents of this P. D. F. file Judgment are same word for word as per original Judgment.

Name of Steno	:	Patil Shivaji N.
Court Name	:	Chief Judicial Magistrate, Pune.
Date	:	04/05/2009