

IN THE MATTER OF DRUGS  
AND COSMETICS ACT, 1940  
& RULES MADE THERE-  
UNDER.

**IN THE COURT OF HON'BLE ADDITIONAL  
CHIEF JUDICIAL MAGISTRATE AT NAGPUR**

R.Cr.Case No. 1832/2012

Date: 16/7/12

State of Maharashtra

At the instance of Smt.Taji Shahnaz Farhat Abdul Khalil,

Drugs Inspector,

Food and Drugs Administration (M.S.)

Nagpur

..... Complainant

~ VERSUS ~

1. Vinod Gupta S/o. Shri Beniprasad Gupta,  
Aged 70 years,  
Partner - M/s. Perennial Medicare, Shamti,  
R/o. Surya Vihar, Rajgarh Road, Solan (H.P.).

.....Accused No.1

2. Mr.Gajendar Kumar Singh,  
Aged 38 years, Manufacturing Chemist  
of M/s. Perennial Medicare,  
Shamti (Solan)

.....Accused No.2

3. M/s. Perennial Medicare  
Situated at Shamti (Solan) 173212 (H.P.).....

.....Accused No.3

**Charges: - CONTRAVENTION UNDER SECTION 18 (A)(i)  
R/W. SECTION 16 PUNISHABLE UNDER SECTION 27(d), &  
18 (B) R/W. SECTION 16 PUNISHABLE UNDER SECTION  
28(A) OF DRUGS & COSMETICS ACT 1940 & RULES  
THEREUNDER.**

**MOST RESPECTFULLY SHEWETH AS UNDER:**

1. That the complainant is an Inspector appointed under Section 21 of Drugs and Cosmetics Act 1940 and Rules there under (hereinafter referred to as the said Act), and is authorized to institute this prosecution under section 32 of Drugs & Cosmetics Act, 1940.

2. That the complainant is Drugs Inspector Joined in Food & Drug Administration Nagpur on 16<sup>th</sup> Jan 2012 and working at same place.

3. That the Complainant received papers from Shri. P. M. Ballal the then Drug Inspector, Nagpur on 13/06/2012 (after his Transfer from Nagpur to Amravati) in respect of Not of Standard Quality Drugs OPTIMOX-CV Powder for Oral Suspension, B.No: PM-3814, Manufacturing Date: 02/2011, Expiry Date: 07/2012, Manufacturing License No: MB/06/453, Manufactured by accused No: 3, i.e. M/s. Perennial Medicare Situated at Shamti (Solani) 173212 (H.P.) along with one part of sealed sample of drug in question.

4. That the Accused No.3 is the firm holding drug manufacturing licenses in Form 25 and 28 bearing No.

MNB/06/452 and MB/06/453. The licenses are issued by Drugs Controlling Cum Licensing Authority, Shimla (H.P.) on 9.1.2007 and valid upto 8.1.2012. under said licenses they have permission to manufacture and sale of Drug including OPTIMOX-CV Powder for Oral Suspension.

5. That the Accused No.1 is the Partner of the company who looks after day to day activities of the Accused no.3 i.e. company M/s. Perennial Medicare, Shamti and he is responsible for manufacturing of NOT OF STANDARD QUALITY Drug OPTIMOX-CV Powder for Oral Suspension, B.No: PM-3814.
6. That the Accused No.2 is the manufacturing chemist of the Accused no.3 i.e. company M/s. Perennial Medicare, Shamti. and he is responsible for manufacturing of NOT OF STANDARD QUALITY Drug OPTIMOX-CV Powder for Oral Suspension, B.No: PM-3814.
7. That from the paper received, it is revealed that on 29.02.2012 Shri. P. M. Ballal the then Drug Inspector, Nagpur visited the premises of M/s. Sainath Medicos



situated at 2<sup>nd</sup> floor Handloom Market Gandhibagh Nagpur for regular sampling. At the time of visit Shri.Manish Lalwani proprietor of the firm was present. The then Drugs Inspector Shri.P.M.Ballal examined the drugs stocked for sale and drawn the sample of drug including OPTIMOX-CV Powder for Oral Suspension 4x2x4.5gm/30ml B.No: PM-3814, Manufacturing Date: 02/2011, Expiry Date: 07/2012, Manufacturing Licence No: MB/06/453, Manufactured by Accused No: 3, i.e. M/s. Perennial Medicare Shamti Solan (H.P). The details of the sample are mentioned in Form.17 dated: 29/02/2012 bearing No: FDA/PMB/FEB-87/12 as per procedure laid down under Drugs and Cosmetics Act, 1940. Shri.P.M.Ballal the then Drug Inspector handed over original copy of Form No.17 dated.29/02/2012 and one sealed part of said drug sample to Shri.Manish Lalwani proprietor of M/s. Sainath Medicos and taken acknowledgment thereof. The Firm issued Bill No. 7479 dated. 29/02/2012 against the said sample and the payment of said bill is issued to the firm by the Office of the Complainant.



8. That on 01/03/2012 Shri.P.M.Ballal the then Drug Inspector prepared Form 18 in triplicate bearing No. NAG/REG/FRM/20927/MH-MUM DT. 01/03/2011 and original copy of Form 18, along with one counterpart of said sample was sent to Government Analyst, Drug Control Laboratory, Mumbai by registered post parcel and one copy of said Form 18 along with specimen impression of seal used to seal said sample was sent separately to Government Analyst.

9. That the office of the complainant on 02/05/2012 received Analytical Report in Form 13 vide Report No. NSQ/MUM/20927/2012 dt. 24.04.2012 from the Govt. Analyst, Drugs Control Laboratory, Mumbai. Government Analyst reported that "the said sample is NOT OF STANDARD QUALITY for the reason "Content of Claclavulanic Acid in the sample (when freshly prepared) is less {1.77% of the labeled amount} Than IP 2010 limit as given in the protocol and "The content of Clavulanic Acid in the sample (when stored) is less {0% of the label amount} than IP 2010 limit as given in the protocol".

10. That the Shri.P.M.Ballal the then Drug Inspector vide letter dt. 05.05.2012 handed over original copy of Analytical Report to Shri.Manish Lalwani proprietor of M/s. Sainath Medicos. Gandhibagh Nagpur and asked the firm to disclose name and address of the firm from whom he acquired the drug in question alongwith documentary proof. The complainant also informed for stopping sale of said drugs.

11. Shri.Manish Lalwani proprietor of M/s. Sainath Medicos. disclosed vide his letter dt. 09.05.2012 that, their firm purchased the said drug from M/s TROIKAA PHARMACEUTICAL LTD. H.No.5063, Ground floor Ward No.1, NR.T Point, Amravati road wadi Nagpur Vide following Invoices:

Sr.No	Invoice No.	Date	quantity
1.	IGN1100121	30/09/2012	200x4.5gm/30ml
2.	IGN1100279	31/01/2012	150x4.5gm/30ml

M/s. Sainath Medicos Submitted purchase Invoice, mode of transport and sale details of said Drug.

12. That vide office letter No. D&C/PMB/784/2012/7 dated. 11/05/2012 Shri.P.M.Ballal the then Drug Inspector sent

letter to M/s Perennial Medicare Pharma, Shamti, Solan - 173212 (H.P.) along with one sealed part of sample alongwith original copy of Form.13 i.e. Govt. Analyst Report to Under the compliance of section 23 (4) (III) and section 25 (2) of the said Act .

13. Accused No. 3 vide his letter dated 13/06/2012 inform that they received the letter No. D&C/PMB/784/2012/7 dated. 11/05/2012 without Govt. Analyst Report. Interestingly the then Drugs Inspector Shri. P.M Ballal vide RPAD letter No. D&C/PMB/784/2012/7 dated. 11/05/2012 send sealed part of sample and original copy of Govt. Analyst report of drug in question to Accused No.3 and in spite of receiving said RPAD to Accused, Accused denying receipt of report. It seems that Accused had a malafied intension and delay tactics as drug in question is expiring on 31/07/2012 and Accused want to free from the clutches of Law. Complainant once again vides E-mail dated 25/06/2012, Fax dated 25/06/2012 and Reg.AD to Accused No.3 sent copy of Form. 13 i.e. Govt. Analyst report No. NSQ/MUM/20927/2012 dt. 24.04.2012. and also aware Accused regarding expiry of drug in question and his right under section 25(4).



14. that The complainant sent letter to Mr. Hemang .A Parikh power of attorney Holder of M/s. TROIKAA PHARMACEUTICAL LTD. H.No.5063, Ground floor Ward No.1, NR.T Point, Amravati road wadi Nagpur on dt. 05.07.2012 alongwith copy of Analytical Report and asked the firm to disclose name and address of the firm from whom they acquired the drug in question along with documentary proof.

15. That on 05/07/2012 the complainant received letter from Mr. Hemang .A Parikh power of attorney Holder of M/s. TROIKAA PHARMACEUTICAL LTD. Wadi Nagpur, along with copy of licenses and Purchase Invoices. As per information submitted by Mr. Hemang .A Parikh power of attorney Holder of M/s. TROIKAA PHARMACEUTICAL Ltd, it is disclosed that the stock of said drugs Transferred by M/s. TROIKAA PHARMACEUTICAL Ltd, Commerce House-1, Satya Marg Bodakdev Ahmadabad-54 vide S.T.N, 1) No. S001100259 dt. 26/04/2011, 2) S001100339 dt.07/05/2011, and 3) No. S001100462 dt. 18/05/2011.

16. That on 05/07/2012 the complainant sent letter through Fax to M/s. TROIKAA PHARMACEUTICAL Ltd, Commerce House-1, Satya Marg Bodakdev Ahmadabad-54

and asked to disclose the source from whom they acquired drug in question along with documentary proof.

17. That on 09/07/2012 through Fax and on 11/07/2012 through post the complainant received letter from Mr. Prakash J.Shah Executive Director of M/s. TROIKAA PHARMACEUTICAL LTD. Commerce House-1, Satya Marg Bodakdev Ahmadabad-54, along with copy of licenses and Purchase Invoices. As per information submitted by Mr. Prakash J.Shah Executive Director of M/s. TROIKAA PHARMACEUTICAL Ltd. Ahmadabad-54, it is disclosed that the firm purchased the said drug from Accused No.3 i.e M/s. Perennial Medicare Situated at Shamti (Solan) 173212 (H.P.) vide Invoice No. 1362, dt. 04/03/2011 Quantity.8984 x 4.5gm/30ml.

18. That the Complainant vide letter dated.07/07/2012 received copy of licenses and constitution of Accused No.3 from Shri.S.K.Nandekar Drugs Inspector Nagpur.

19. That on 10.7.2012, the complainant seized the stock of Not of standard quality drug from Mr.Manish Lawani, Prop. M/s. Sainath Medicoe situated at 2<sup>nd</sup> floor Handloom Market Gandhibagh Nagpur M/s. Nagpur under Panchnama &

Form 16 dated 10/07/2012. Complainant took custody permission vide Misc. Application No.1539/12 from Hon'ble A.C.J.M Court Nagpur.

20. That on 29/05/2012 office of the Shri.P.M.Ballal received prosecution order No. MUM/20927/2012/1068-12/10, dated 08/05/2012 from Joint Commissioner and Controlling Authority, [H. Q.], Food and Drugs Administration [M.S.] (H. Q.), Mumbai to launch prosecution against the manufacturer i. e. Accused No. 3.

**21. The investigation made by complainant revealed as under:-**

- i) Accused No. 3 is firm holding Drug Manufacturing License in Form 28 bearing no. MB/06/453 under which manufacturing of Optimox-cv powder for oral suspension was permitted. Accused no. 1, 2 & 3 manufactured Optimox-cv powder for oral suspension Batch no. PM-3814 around 8984 bottles of said drug distributed to M/s. TROIKAA PHARMACEUTICAL Ltd. Ahmadabad-54, and out of which total 2548 bottles quantity supplied to M/s M/s. TROIKAA




PHARMACEUTICAL Ltd. Nagpur further they sold the said drug to M/s Sainath Medicoe, Nagpur in Quantity 350 bottles from which the then Drugs Inspector drawn samples on 29/02/2012 which is declared NOT OF STANDARD QUALITY.

- ii) That the accused no. 1 is the partner who looks after the day to day activities of the company i.e. M/s Perennial Medicare Shamti, Solan (H.P).
22. That the Optimox-cv Popwder for Oral Suspension is the drug within the meaning of section 3 (b) of the Drugs & Cosmetics Act, 1940.
23. The Section 18 <sup>(a)</sup>~~(A)~~ (i) of Drugs & Cosmetics Act, 1940 read as follows:
- "No person shall himself or by any other person on his behalf manufacture for sale or sell or distribute any drug which is not of standard quality.

**CHARGES:**

That the complainant therefore charges that -

- i) On or before Feb.2011 the accused had manufactured for sale / distribution of 'NOT OF STANDARD QUALITY' drug i.e. OPTIMOX-CV Powder for Oral Suspension 4.5gm/30ml B.No: PM-3814, Manufacturing Date: 02/2011, Expiry Date: 07/2012, and distributed to M/s Sainath Medicose, Nagpur through above mentioned distributors and committed offence under Section 18<sup>(a)</sup>~~(b)~~(i) rendering themselves liable for punishment under Section 27 (d) of Drugs & Cosmetics Act, 1940. 

- ii) Complainant also charges that Accuse No. 1 & 3 failed to produce manufacturing/testing/distribution etc. details of drug in question as required under section 18-B by the complainant and the then Drugs Inspector Shri.P.M.Ballal and Hence committed offence under section 18-B punishable under section 28-A of Drugs & Cosmetics Act 1940.

**PRAYER:-**

The complainant therefore prays that -

- i) All the documents of Misc. Application No. 1539/12, dt.11/07/2012 may be amalgamated with this Case..
- ii) The process may please be issued against the accused and they may be dealt with accordance to law and for this act of kindness the complainant shall be duty bound ever pray.

COMPLAINANT



(Taji Shahnaz F.A.Khalil)  
Drugs Inspector,  
Food & Drug Administration,  
Nagpur (M.S.)

Nagpur,

Date: 16/3/12

**Enclosure :**

- i) List of Witnesses
- ii) List of documents and original documents as per list.
- iii) Set of complaint and documents for accused.



**LIST OF WITNESSES in C.C. No.**

- 1) Shri.P.M.Ballal Drugs Inspector, Food & Drug Administration, Amravati,(M.S).
- 2) Shri. S.K.Nandekar, Drugs Inspector, Food & Drug Administration, Amravati,(M.S).
- 3) Shri.Manish Lalwani proprietor of M/s. Sainath Medicos situated at 2<sup>nd</sup> floor Handloom Market Gandhibagh Nagpur.
- 4) Mr. Hemang .A Parikh power of attorney Holder of M/s. TROIKAA PHARMACEUTICAL LTD. H.No.5063, Ground floor Ward No.1, NR.T Point, Amravati road wadi Nagpur.
- 5) Mr. Prakash J.Shah Executive Director of M/s. TROIKAA PHARMACEUTICAL Ltd. Commerce House-1, Satya Marg Bodakdev Ahmadabad-54.
- 6) Shri. S.M. Saptarshi Govt.Analyst, Drugs Control Laboratory - Mumbai.
- 7) Shri. Satish. D. Kumbalwar, Panch. No:1, Maya Nagar Indora Nagpur
- 8) Shri. Shravan. R. Sabad, panch. No.2 mata chowk near Devichadevda Nagpur.

Any other witness with the kind permission of this Hon'ble Court.



(Taji. Shahnaz F.A. Khalil)  
Drugs Inspector,  
Food & Drug Administration,  
Nagpur (M.S.)