

IN THE MATTER OF  
DRUGS AND COSMETICS  
ACT, 1940 AND RULES  
THEREUNDER

IN THE COURT OF CHIEF JUDICIAL MAGISTRATE,

NAGPUR, DIST. Nagpur

C. C. No. 2389, Filed on 24/8/12

State of Maharashtra at the instance of

**Shri. N . V. Lohakare,**

Drugs Inspector, Nagpur

O/o The Joint Commissioner,

Food & Drugs Administration [M.S.], Nagpur.

.....Complainant

Vs.

1] Dr. Pramod Kumar Srivastav, Age - 59 Years. Director of M/s. Medisys Biotech Private Limited, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh). R/o 6305, High Land Knolls Drive, Baker fields, California 93306 USA  
.....Accused No 1

2] Dr. Rahul Sharma, Age - 38 Years. Director of M/s. M/s. Medisys Biotech Private Limited, Village Moginand, Kala - Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh).R/o 11503, Clarion River, Baker fields, California 93311, USA  
.....Accused No. 2

3] Shri Ashok Kumar Srivastava, Age - 54 Years, Director of M/s. Medisys Biotech Private Limited, Village Moginand, Kala - Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh).; R/o. "Sai Dham" 297/1, Near Karamali Railway Station, Carambolim, Tiswadi - 403 110, GOA  
.....Accused No. 3

4] Shri. Ashok Rampal, Age - 49 Years, Director of Medisys Biotech Private Limited, Village Moginand, Kala -

Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh).  
R/o. C - 943 Sushant Lok 1, Gurgaon, Haryana

.....Accused No. 4

5] Mr. Shri. Joel Kurian, Director of Medisys Biotech Private Limited, Village Moginand, Kala - Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh).R/o DD 36, Ground Floor, kalkaji, New Delhi.

.....Accused No. 5

6] Shri K Rajeswar, Director of Medisys Biotech Private Limited, Village Moginand, Kala - Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh). R/o 1-3-5, Poulomi Enclave, Street No.8, Habsiguda, Hyderabad-500 007

.....Accused No. 6

7] Medisys Biotech Private Limited, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh).

..Accused No. 7

CHARGES:- Under section 18 (a) (i) r/w Section 16 Punishable under Section 27(d) of Drugs and Cosmetics Act, 1940 and Rules Thereunder.

MOST RESPECTFULLY SHEWETH

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 presently working in the Office of Joint Commissioner, Food and Drug Administration, Nagpur
2. That the complainant is authorized to institute this prosecution under Section 32 of Drugs and Cosmetics Act, 1940.
3. That the complainant received the Papers of Investigation from Shri. C K Dange the then Drugs Inspector, Nagpur on dated 19/06/2012 ( after his transfer from Nagpur to

Akola) in respect of Not of Standard Quality Drugs NEUROPAT-NV, Batch No.-11T06NV0195, Mfg. Date-06/2011, Exp. Date - 05/2013, Mfg. By- Medisys Biotech Private Limited, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour--(Himachal Pradesh); Mfg. Lic. No. in form 25 MNB/07/574 in and Form No.28 bearing No. MB/07/575 which are granted on 08/06/2007 and valid up to 07/06/2012 as per the procedure laid down under the Drugs and Cosmetics Act, 1940.

4. That, the accused No. 7 is Partnership Firm M/s. **Medisys Biotech Private Limited**, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour--(Himachal Pradesh); bearing Mfg. Lic. No. in form 25 MNB/07/574 in and Form No.28 bearing No. MB/07/575 which are granted on 08/06/2007 and valid up to 07/06/2012. The License is issued in to manufacture for sale and distribution drug including NEUROPAT-NV Tablets
5. That, the accused No. 1 to 6 is Directors of Firm M/s. **Medisys Biotech Private Limited**, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour--(Himachal Pradesh).
6. That from the paper received, it is revealed that on 03/02/2012 Shri C K Dange, the then Drug Inspector, Nagpur visited premises of M/s. Mehadia & Jaiswal Associates, Katol By Pass Road, Plot No.154, Ground floor, Adarsh Nagar, Nagpur, for regular sampling and then drawn sample of drug NEUROPAT-NV Tablets, Batch No.-11T06NV0195, Mfg. Date - Jun -2011, Exp. Date - MAY-2013, Mfg. By-Medisys Biotech Private Limited, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour--(Himachal Pradesh).; Shri C K Dange handed

over original Form 17, dated 03/02/2012 bearing sample No. DI/CKD/NGP/83/2012 along with one sealed part of the said sample to Smt. Hemlata Ramesh Agrawal Partner of M/s. Mehadia & Jaiswal Associates, Katol By Pass Road, Plot No 154, Ground floor, Adarsh Nagar, Nagpur, and obtained acknowledgement from him, Bill No. AMT/190, Dt. 03/02/2012.

7. That, on 06/02/2012 Shri. C K Dange prepared Form 18 in triplicate and original copy of Form 18 along with one sealed counter part of said sample was sent to Govt. Analyst, Drug Control Laboratory, Mumbai by Regd. Post Parcel and one copy of said Form 18 along with specimen impression of the seal used to seal the said sample was sent in a envelop separately to Govt. Analyst, Drug Control Laboratory, Mumbai by Regd. Post.
8. That, on 20/04/2012 office of Shri C K Dange received analytical Report in Form 13, Report No. NSQ/MUM/20149/2012, dated 19/04/2012 from the Govt. Analyst, Drug Control Laboratory, Mumbai. Govt. Analyst, Mumbai reported the said sample to be "Not of Standard Quality" for the reason given below.

**"Content of Vitamin B1 in the sample is less than the permissible limit (i.e. 18%) of the labeled amount.)"**

9. That, on dated 27/04/2012, Shri C K Dange sent a Regd. Post letter with a original copy of Certificate of Analysis NSQ/MUM/20149/2012, dated 19/04/2012 from the Govt. Analyst, Drug Control Laboratory, Mumbai to Smt. Hemlata Ramesh Agrawal Partner of M/s. Mehadia & Jaiswal Associates, Katol By Pass Road, Plot No 154, Ground floor, Adarsh Nagar, Nagpur and asked him to

disclose the name and address of the firm from whom he acquired the drug in question along with documentary proof.

10. That, on 18/05/2012, Smt. Hemlata Ramesh Agrawal, Partner of M/s. Mehadia & Jaiswal Associates, Katol By Pass Road, Plot No 154, Ground floor, Adarsh Nagar, Nagpur of the firm vide letter dated 09/05/2012 disclosed that she purchased the said drug from M/s. Taramani Enterprises Adarsh Nagar, Wadi, Nagpur-23, Bill No. YSH/14, dated 23/11/2011 and Bill No. YSH/16, dated 10/01/2012 and also produced copy of purchase invoice and other related certified documents.
11. That, on 10/05/2012 Shri C K Dange sent Regd. Post letter to M/s. Taramani Enterprises Adarsh Nagar, Wadi, Nagpur-23, and asked the firm to disclose name and address of the firm from whom they has acquired drug in question along with documentary proof.
12. That, Shri. Amit R. Agrawal M/s. Taramani Enterprises Adarsh Nagar, Wadi, Nagpur-23, vide letter dated 10/05/2012 received on 18/05/2012 disclosed that, they had purchased the said drug from M/s. Yash Pharma Murtijapur Road, Akola vide Bill No. YPM/035, dated 23/11/2011 Quantity Purchased=117 strips of 10 x 10 tablets and YPM/042 Dated; 10/01/2012 quantity purchased = 100 strips of 10 x 10 tablets, total quantity purchased 217 strips of 10 x 10 tablets and also produced copies of purchase Invoice along with related documents and the firm accepted that, they sold 217 strips of 10 x 10 tablets to M/s. Mehadia & Jaiswal Associates, Katol By Pass Road, Plot No 154, Ground floor, Adarsh Nagar, Nagpur vide Bill No. YPM/035, dated 23/11/2011 Quantity

Purchased=117 strips of 10 x 10 tablets and YPM/042  
Dated; 10/01/2012 quantity purchased = 100 strips of 10  
x 10 tablets, total quantity purchased 217 strips of 10 x 10  
tablets.

13. That, on 20/06/2012 Shri Neeraj V Lohakare sent e-mail  
scanned copy of letter. no. D&C/NSQ/1143/2012/07.  
Dated; 20/06/12 to M/s. Yash Pharma Murtijapur Road,  
Akola, as the complainant received the Papers of  
Investigation from Shri. C K Dange the then Drugs  
Inspector, Nagpur on dated 19/06/2012 ( after his  
transfer from Nagpur to Akola) and asked the firm to  
disclose name and address of the firm from whom they has  
acquired drug in question along with documentary proof.

14. That, on 12/07/2012, Shri. Santosh R Daga Proprietor of  
Yash Pharma, Akola in their vide letter dated 12/07/2012  
disclosed that he purchased the said drug from M/s.  
Medisys Biotech Private Limited, Village Moginand,  
Kala-Amb, Tehsil Nahan, District Sirmour--(Himachal  
Pradesh), Bill No. 0001027, dated 11/11/2011 and also  
produced copy of purchase invoice and other related  
certified documents and the firm accepted that, they sold  
the said drug to Taramani Enterprises Adarsh Nagar,  
Wadi, Nagpur-23.

Yash Pharma, Akola informed telephonically in the month  
of May to Shri C K Dange they have purchased said drug  
from M/s. Medisys Biotech Private Limited, Village  
Moginand, Kala-Amb, Tehsil Nahan, District Sirmour--  
(Himachal Pradesh), Bill No. 0001027, dated 11/11/2011

15. That, on 19/05/2012 Shri C K Dange visited to accuse  
No. 7 (the firm) with one sealed part of the sample of the  
drug in question (4 strips of 10 x 10 Tablets) along with

original copy of analytical report in Form 13 No. NSQ/MUM/20531/2012, dated 16/04/2012 as per Section 23 (4) (iii) and 25 (2) of Drugs and Cosmetics Act, 1940 and asked the accused No. 5 (the firm) to furnish the information regarding drug manufacturing license, Constitution of the firm, Manufacturing record, Testing record, Analytical record, Purchase detail of raw material, sale details regarding drug in questions.

The complainant also asked accused whether they agree or not with the report of Govt. Analyst, Drug Control Laboratory Mumbai. Then they may challenge the said report and said sample of drug may be re-analyzed from Central Drug Laboratory, Kolkata.

16. That, the accused No. 6 **Shri K Rajeswar** Director of **Medisys Biotech Private Limited**, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour-(Himachal Pradesh). R/o 1-3-5, Poulomi Enclave, Street No.8, Habsiguda, Hyderabad-500 007 vide letter dated 23/05/2012 on behalf of accused No. 5 submitted Names and address of Directors, Certificate of Analysis, Copy of licenses in Form 25 No. MNB/07/574 and Form 28 No. MB/07/575, renewed up to 07/06/2012, Approved product list, Memorandum and Article of Association, Names of Approved Manufacturing & Quality Control Chemist and they did not want to challenge the report of Govt. Analyst, Maharashtra and did not want to send the sample at Central Drug Laboratory, Kolkata for re-analysis. and also accepted that the said drug was sold to M/s. **Yash Pharma** Murtijapur Road, Akola, vide Bill No. 0001027, dated 11/11/2011.

17. The investigation made by **Shri C K Dange** revealed that

the accused No. 1 to 6 are Directors and looking after day to day activities of the firm and holding drug manufacturing licenses in Form 25 No. MNB/07/574 and Form 28 No. MB/07/575 granted on 08/06/20067 and renewed up to 07/06/2012 and renewed up to 05/07/2016 under which the manufacturing of NEUROPAT-NV Tablets was permitted. The accused manufactured about 1 Lakh Tablets and distributed as follows

**Medisys Biotech Private Limited, Sirmour**

Invoice No. 0001027,	Pack-10 x 10
Dated 11/11/2011	Quantity-100
Invoice No. 0001245,	Pack-10 x 10
Dated 28/10/2011	Quantity-100

M/s. Yash Pharma Murtijapur Road, Akola,  
Nagar, Nr. New A P M C, Amravati - 444 605

Invoice No. YPM 035,	Pack-10 x 10
Dated 27/10/2011	Quantity-100 + 17 free
Invoice No. YPM 042,	Pack-10 x 10
Dated 10/01/2012	Quantity-100 + 20 free

**M/s. Taramani Enterprises Adarsh Nagar, Wadi, Nagpur-**

Invoice No. YSH 16	
Dated 10/01/2012	Quantity-1000 + 200 free
Invoice No. YSH 14,	
Dated 23/11/2011	Quantity-1000 + 170 free

M/s. Mehadia & Jaiswal Associates, Katol By Pass Road, Plot  
No 154, Ground floor, Adarsh Nagar, Nagpur,

1) Form the above stock the sample was drawn by the  
Shri C K Dange on 03/02/2012 which is declared as  
"Not of Standard Quality"

II] That the accused manufactured "Not of Standard Quality" drug and distributed the same to M/s.

Mehadia & Jaiswal Associates, Katol By Pass Road,  
Plot No 154, Ground floor, Adarsh Nagar, Nagpur

18. That, the NEUROPAT-NV Tablets, Batch No.- 11T06NV0195, Mfg. Date-06 /2011, Exp. Date - 05/2013, Mfg. By- Medisys Biotech Private Limited, Village Moginand, Kala-Amb, Tehsil Nahan, District Sirmour--(Himachal Pradesh); manufactured by accused is a drug within the meaning of Section 3(b) of Drugs and Cosmetic Act, 1940.
19. That as per Section 16 of the said Act the expression "Standard quality" means -
- (a) In relation to a drug, that the drug complies with standard set out in second schedules.
20. That, as per the provision of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 read follows : "No person shall himself or by any other person on his behalf manufacture for sale or sell or stock or exhibit for sale or distribute any drug which is not of standard quality"
23. That on 29/05/2012 office of the Shri C K Dange received prosecution order No. खटला/MUM/20149/2012/07/-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 manufacturers.
21. CHARGES:
- That the complainant therefore charges that, the accused did manufactured for sale/ distribution not of

standard quality drug i. e. NEUROPAT-NV Tablets,  
Batch No.-11T06NV0195, Mfg. Date-06 /2011, Exp.  
Date - 05/2013,, and distributed to M/s. Yash  
Pharma Murtijapur Road, Akola and to M/s.  
Taramani Enterprises Adarsh Nagar, Wadi, Nagpur  
and to M/s. Mehadia & Jaiswal Associates, Katol By  
Pass Road, Plot No 154, Ground floor, Adarsh Nagar,  
Nagpur, and thereby committed offence under Section  
18(a)(i) r/w Section 16 and 34 and rendered themselves  
liable for punishment under Section 27(d) of Drugs and  
Cosmetics Act, 1940.

PRAYER :-

That, the complainant therefore prays that the  
process may kindly be issued against the accused and  
they may be dealt with accordance to the law.

And for this act of kindness, the complainant  
shall be duly bound ever pray.

Place: Nagpur

Date: 24/8/12



(Neeraj V Lohakare)

Complainant

Drugs Inspector

Food & Drug Administration [M.S.]

NAGPUR