

From

M.Saranya  
Drugs Inspector  
Tiruvannamalai II Range,  
Vellore zone.

To

The Assistant Director of Drugs Control  
Vellore zone.

Ref.No. 92/DI/TVM II/15 dt.20.03.15

Sir,

**Sub:** Drugs-Drugs and Cosmetics Act 1940 and Rules made thereunder – M/s.Res Sancta, Solan-  
Contravention of the Act-Sanction Prosecution accorded-Complaint filed in the Hon'ble  
Court-report Submitted-Reg.


- 8  
2003/15
- Ref:** 1) R.Dis.No. 20881/IW2/2014 (364) dated 03.02.14 of the O/o.The Director of Drugs  
Control, Chennai-6.  
2) Ref. 1528/M3/2014 dt. 15.12.14 of the Assistant Director of Drugs Control,  
Vellore zone, Vellore-9.

\*\*\*\*\*

With reference to the above, I am submitting that the complaint in respect of M/s. Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Distt. Solan -174 101 (H.P) represented by Thiru.Ganesh Dutt working partner of the firm and Thiru.Ganesh Dutt, Thiru.Rajeev Chauhan, Thiru.Samar Singh Chandel & Thiru.Bhagwan Saini working partners of M/s. Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Distt. Solan -174 101 (H.P) was filed in the Hon'ble Judicial Magistrate Court-1 Tiruvannamalai on 18.03.15. The copy of charge sheet is enclosed herewith.

This is for your kind information.

Yours faithfully,

  
20/3/15

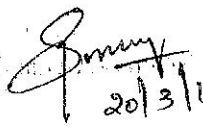
**Drugs Inspector  
Tiruvannamalai II Range**

-2-

## ANNEXURE

1. Range : Tiruvannamalai II Range
2. Sanction Order No & Date : R.Dis.No. 20881/IW2/2014 (364) dated 03.02.14
3. Details of the Accused : M/s. Res Sancta, Solan represented by Thiru.Ganesh Dutt working partner of the firm and Thiru.Ganesh Dutt, Thiru.Rajeev Chauhan, Thiru.Samar Singh Chandel & Thiru.Bhagwan Saini working partners of M/s. Res Sancta, Solan,
4. Contravention Details : Section 18(a)(i) of the Drugs and Cosmetics Act 1940
5. Date on which complaint filed : 18.03.15
6. Name of the Court : JM-1 Court, Tiruvannamalai
7. CC.No/STC No. : not allotted
8. Whether Complaint copy enclosed : yes
9. Remarks :-

Yours faithfully,

  
20/3/15  
**Drugs Inspector**  
**Tiruvannamalai II Range**

-3-

**IN THE HONOURABLE JUDICIAL MAGISTRATE COURT No.1**

**TIRUVANNAMALAI-I**

**STC/CC.No.**

**/2014**

State represented by

**M.SARANYA**

Drugs Inspector

Tiruvannamalai II Range

O/o. The Drugs Inspector,

No.1, 6<sup>th</sup> Street, Gandhi Nagar

**Thiruvannamalai .**

Complainant

Vs

**1. M/s. Res Sancta**

**Represented by Thiru Ganesh Dutt**

Village Beli Deor,

Po-Khera, Tehsil, Nalagarh,

Distt.Solan, H.P.174 101

**2. Thiru.Ganesh Dutt**

Working partner of M/s.Res Sancta

Village Beli Deor,

Po-Khera, Tehsil, Nalagarh,

Distt.Solan, H.P.174 101

**3. Thiru.Rajeev Chauhan**

Working partner of M/s.Res Sancta

Village Beli Deor,

Po-Khera, Tehsil, Nalagarh,

Distt.Solan, H.P.174 101

**4. Thiru.Samar Singh Chandel**

Working partner of M/s.Res Sancta

Village Beli Deor,

Po-Khera, Tehsil, Nalagarh,

Distt.Solan, H.P.174 101

**5. Thiru.Bhagwan Saini**

Working partner of M/s.Res Sancta

Village Beli Deor,

Po-Khera, Tehsil, Nalagarh,

Distt.Solan, H.P.174 101

Accused

-4-

**COMPLAINT FILED UNDER SECTION 32 OF THE DRUGS AND COSMETICS ACT 1940 FOR THE CONTRAVENTION OF SECTION 18(a)(i) OF THE SAID ACT AND IS PUNISHABLE UNDER SECTION 27(d) OF THE SAID ACT.**

The Complainant is the Drugs Inspector having jurisdiction of part of Thiruvannamalai district including Chengam taluk, Thandarampet taluk and part of Thiruvannamalai town and has been duly notified as Drugs Inspector under section 21 of the Drugs and Cosmetics Act 1940 in the state of Tamilnadu vide TamilNadu Government Gazette Extra Ordinary no 200 dated 12.07.2013. Further the complainant is empowered under section 32 of the said Act to file this complaint.

It is further submitted that the complainant being a public servant as defined under section 21 of Indian Penal code and is the officer of the Government whose duty is, as such officer, to prevent offences, to give information of offences, to bring offenders to justice or to protect the public health, safety or convenience.

The complainant being a public servant may be exempted from examination, his evidence may be dispensed with as provided under section 200 of Criminal Procedure Code by invoking the provisions of section 200 (a) of Criminal Procedure Code. The examination of the complainant may be dispensed with and the Honourable Court may take cognizance of the offences.

The Accused A1 M/s. Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Distt. Solan -174 101 (H.P) is a Partnership firm and is represented by Thiru.Ganesh Dutt working partner of the firm, A2, A3, A4 and A5 namely Thiru.Ganesh Dutt, Thiru.Rajeev Chauhan, Thiru.Samar Singh Chandel & Thiru.Bhagwan Saini are the working partners of the accused firm A1 as per the Partnership deed.

A Sample of Dolocold Suspension 60ml, Batch No. ML12117, Mfd dt.11/12, Exp Dt.10/14, Mfd By M/s.Res Sancta, Village Beli Deor, PO Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P), Marketed by M/s.Micro Labs Ltd, No.76, Sri Vagdevi Mansion, Old Tharugupet, Bangalore 560053, India was drawn for analysis on 16.8.13 at M/s.Tirumalai Agencies, No.121, Thamarai Nagar, Tiruvannamalai under Form 17 No. 042756 dated 16.08.13. The same was sent for analysis under Form 18 memorandum No: 06/MSA/14/TVM II dated 16.8.2013 to the Government Analyst, Drugs Testing Laboratory, Tamilnadu, Chennai.

The Government Analyst, Drug Testing Laboratory, Chennai had declared the sample as **NOT OF STANDARD QUALITY** in her report no. 02507- D/2013-14 dated 20.03.14 for the reason that the sample does not conform to Label claim with respect to the content of Phenylephrine Hydrochloride (27.82%). This is in contravention of section

18(a)(i) of Drugs and Cosmetics Act 1940. The Analytical Report was received by the complainant on 27.3.14.

M/s. Tirumalai Agencies, No.121, Thamarai Nagar, Tiruvannamalai, was inspected by the complainant on 28.03.14 and the matter was investigated. There was no stocks of the sampled drug was found. It was found that the sampled drug was supplied by M/s. M.S. Distributors, Dugar Tower, 2A, Mettukuppam road, Maduravoyal, Chennai-95 under Invoice No.SM000989 dated 03.08.13. The total quantity purchased was 320 suspensions.

A Showcause memo dated 28.3.14 along with a copy of Form 13 was issued in person to M/s. Tirumalai Agencies, No.121, Thamarai Nagar, Tiruvannamalai under acknowledgement to offer their explanation for having contravened Section 18(a)(i) of the Drugs and Cosmetics Act 1940 by having sold the Not of Standard Quality drug and to disclose the name, address and other particulars of the person from whom the sampled drug was acquired by them under Section 18-A of the said Act and other required particulars.

M/s. Tirumalai Agencies, No.121, Thamarai Nagar, Tiruvannamalai, had submitted a reply dated 28.3.14, stating that the sampled drug was acquired from M/s. M.S.Distributors, Dugar Tower, 2A, Mettukuppam road, Maduravoyal, Chennai-95 under Invoice No.SM000989 dated 03.08.13, quantity 320 suspensions.

A Showcause memo dated 28.3.14, along with the copy of report in Form 13 was sent to M/s.M.S.Distributors, Dugar Tower, 2A, Mettukuppam road, Maduravoyal, Chennai-95 by registered post with acknowledgement, to offer their explanation for having contravened Section 18(a)(i) of the Drugs and Cosmetics Act 1940 and to disclose the name, address and other particulars of the person from whom they had acquired the sampled drug under Section 18-A of the said Act and other required particulars. The Third portion of the sample was sent, separately by registered parcel, as required under Section 23(4)(iii) of the said Act.

M/s. M.S.Distributors, Dugar Tower, 2A, Mettukuppam road, Maduravoyal, Chennai-95, in their reply dated 2.4.14 had disclosed the purchase particulars and stated to have acquired the sampled drug from M/s. Micro generics, No.709/826, 810/942, Ground & First Floor, Prabhat Godown area, Zirakpur, under Invoice No.000378 & 000406 dated 05.06.13 & 18.06.13 respectively. Total quantity purchased 1600 suspensions.

A showcause memo dated 04.4.14, along with a Photo copy of Form 13 was sent to M/s. Micro generics, No.709/826, 810/942, Ground & First Floor, Prabhat Godown area, Zirakpur by registered post with acknowledgement, to offer their explanation for

having contravened Section 18(a)(i) of the Drugs and Cosmetics Act 1940 and to disclose the name & address of the person from whom they had acquired the sampled drug under Section 18-A of the said Act and other particulars.

But the showcase memo returned with a remark "No such addressee"

As the complainant came to know that the concern M/s. Micro Generics was shifted to a new premises, a showcase memo dated 11.4.14 along with a photo copy of Form 13 was sent again to M/s. Micro Generics, No.114/125, 754/881, 755/882, 837/97, Ground & First Floor, Prabhat Godown area, Zirakpur to the known address by registered post with acknowledgement, to offer their explanation for having contravened Section 18(a)(i) of the Drugs and Cosmetics Act 1940 and to disclose the name, address and other particulars of the person from whom they had acquired the sampled drug under Section 18-A of the said Act and other required particulars.

A letter dated 11.4.14 of M/s. M.S.Distributors, Dugar Tower, 2A, Mettukuppam road, Maduravoyal, Chennai-95 was also received, stating the fact of change of premises of M/s. Micro Generics, No.114/125, 754/881, 755/882, 837/97, Prabhat Godown area, Ground & First Floor, Zirakpur

M/s. Micro generics, No.114/125, 754/881, 755/882, 837/97, Prabhat Godown area, Ground & First Floor, Zirakpur had disclosed in their reply dated 18.4.14 that the sampled drug was acquired from M/s. Micro Labs Ltd., Basement, No.114/125, 754/881, 755/882, 837/971, Prabhat Godown area, Mohali District, Zirakpur under stock transfer note No. 968500363 dated 03.01.2013, quantity 49343 suspensions and produced only part of the documents namely, Certified copy of Licence in Form 20B & 21B, Details of partners, Distribution particulars of the Sampled drug.

A letter dated 28.4.14 was sent to M/s. Micro Generics, No.114/125, 754/881, 755/882, 837/97, Prabhat Godown area, Ground & First Floor, Zirakpur by registered post with acknowledgement to produce the remaining document

M/s. Micro generics, No.114/125, 754/881, 755/882, 837/97, Prabhat Godown area, Ground & First Floor, Zirakpur, in their reply dated 5.5.14, produced the remaining document.

A showcase memo dated 13.5.14 along with a photo copy of Form 13 was sent to M/s. Micro Labs Ltd., Basement, No.114/125, 754/881, 755/882, 837/971, Prabhat Godown area, Mohali District, Zirakpur by registered post with acknowledgement to offer their explanation for having contravened Section 18(a)(i) of the Drugs and Cosmetics Act

-7-

1940 and to disclose the name, address and other particulars of the person from whom they had acquired the Sampled drug under Section 18-A of the said Act and other required particulars.

M/s. Micro Labs Ltd., Basement, No.114/125, 754/881, 755/882, 837/971, Prabhat Godown area, Mohali District, Zirakpur had disclosed in their reply dated 21.5.14 that the sampled drug was acquired from M/s. Res Sancta, Solan, under Invoice no.1285 dated 21.12.2012, quantity 49353 Suspensions and produced only the part of the documents namely, Certified copy of Original Licence in Form 20B & 21B, Details of the Manager and the Competent person, Purchase and distribution particulars of the sampled drug.

A showcase memo dated 28.5.14 along with a Photo copy of Form 13 was addressed to M/s. Res Sancta, Village Beli Deor, PO Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P) by registered post with acknowledgement, to offer their explanation for having contravened Section 18(a)(i) of the Drugs and Cosmetics Act 1940 and to produce particulars under Section 18-B of the said Act.

A reminder dated 23.6.14 was sent to M/s. Res Sancta, Village Beli Deor, PO Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P) by registered post with acknowledgement, since no reply was received from them.

M/s. Res Sancta, Village Beli Deor, PO Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P), in their reply dated 16.6.14 which was received on 4.7.14 had adduced the Government analyst report and produced only the part of the documents namely, Certified copy of Licence in Form 25 & Form 28 and Renewal Certificate, Certified copy of Product endorsement certificate, Copy of Distribution Particulars, Certified copy of Batch Manufacturing Record, Certified copy of Certificate of Analysis (Finished Product).

A letter dated 8.7.14 was also sent to M/s. Micro generics, No.114/125, 754/881, 755/882, 837/97, Prabhat Godown area, Ground & First Floor, Zirakpur, by registered post with acknowledgement, to produce the required particulars.

A letter dated 8.7.14 was also sent to M/s. Micro Labs Ltd. Basement, No.114/125, 754/881, 755/882, 837/971, Prabhat Godown area, Mohali District, Zirakpur, by registered post with acknowledgement, to produce the remaining documents and other required particulars.



8

A letter dated 8.7.14 was also sent to M/s. Res Sancta, Village Beli Deor, PO-Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P) by registered post with acknowledgement, to produce the remaining documents and other required particulars.

M/s.Micro generics, No.114/125, 754/881, 755/882, 837/97, Prabhat Godown area, Ground & First Floor, Zirakpur in their reply dated 17.7.14 had produced the particulars called for except the certified copy of partnership deed.

M/s. Micro Labs Ltd., Basement, No.114/125, 754/881, 755/882, 837/971, Prabhat Godown area, Mohali District, Zirakpur in their letter dated 17.7.14 had produced the remaining documents except the details of Directors at the time of transaction of the sampled drug

M/s.Res Sancta, Village Beli Deor, PO-Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P) in their reply dated 23.7.14 had produced the remaining documents except the Certified copy of raw material stock register of the sampled drug.

A letter dated 23.7.14 was sent to M/s. Micro Labs Ltd, Basement, No.114/125, 754/881, 755/882, 837/971, Prabhat Godown area, Mohali District, Zirakpur by registered post with acknowledgement to produce the remaining document.

A petition was filed and the second sample portion was produced in this Honorable Court by the complainant on 8.9.14 under Section 23(4)(ii) of Drugs and Cosmetics Act 1940 and requested this Honorable Court to send the sample portion to Central Drugs Laboratory, Kolkata under Section 25(4) of the said Act to analyze the sample. The petition was taken by this Honorable court and the CP No.allotted was 376/14.

A reminder dated 15.9.14 was sent to M/s.Res Sancta, Village Beli Deor, PO-Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P) by registered post with acknowledgement to produce the certified copy of raw material stock register for the sampled drug and the same was furnished by them along with their letter dated 29.09.14

It was found that,

M/s.Res Sancta Village Beli Deor, PO-Khera, Tehsil Nalagarh, Distt.Solan-174 101 (H.P) is a Partnership firm having valid Drug licence in Form 25 bearing No.MNB/07/608 and in Form 28 bearing No. MB/07/609, both dated 01.08.2007 and renewed up to 31.07.2017 and there are four working partners namely, Thiru.Ganesh Dutt,



Thiru.Rajeev Chauhan, Thiru.Samar Singh Chandel & Thiru.Bhagwan Saini and the sampled drug is endorsed in their licence.

The Manufacturer stated that the control sample was examined and tested by their Quality Control department and found it complies with all quality standards, but no documentary evidence in proof thereof was furnished by them.

They had stated that it was necessary for the Government Analyst to test the sample as per the procedure provided by the manufacturer as per Rule 46 of the Drugs and Cosmetics Act 1940. They also stated that the procedure was never asked from them. But as per Sub-clause 3 of Rule 46 of Drugs and Cosmetics Rules 1945, for patent and proprietary medicines containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied, a description of the actual tests or, as the case may be, analysis or methods of assays so applied is given in the report and in compliance thereof, the Government Analyst had given the method/procedure applied in carrying out the analysis. Hence the manufacturer statements made in their reply is not correct.

Further the manufacturer had stated that the procedure for analysis of the said product was not asked from them by the Government Analyst, since there is no such procedure prescribed in the Drugs and Cosmetics Act 1940.

The Manufacturer stated that the alleged drug specifically in relation to the content of Phenylephrine hydrochloride was manufactured and analysed under the testing procedure laid down in Indian Pharmacopoeia. But, there is no method prescribed in Indian Pharmacopoeia for analysis of Phenylephrine hydrochloride in formulation containing more active pharmaceutical ingredient. Further, the Indian Pharmacopoeia prescribed the method of analysis for Phenylephrine hydrochloride and Phenylephrine hydrochloride injections only by potentiometric method and not as stated by the manufacturer by measuring the absorbance at 500nm.

It is proved that the Accused had contravened, Section 18(a)(i) of the Drugs and Cosmetics Act 1940 by having manufactured for sale and sold a **"Not of standard Quality Drug"** namely Dolocold Suspension 60ml, Batch No. ML12117, Mfd dt.11/12, Exp Dt.10/14 and is punishable under Section 27(d) of the said Act.

-10-

Necessary Sanction was accorded to the complainant for prosecuting the accused for the above said contravention.


Hence, it is submitted that 1) M/s.Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Nalagarh, Solan represented by Thiru.Ganesh Dutt, 2) Thiru.Ganesh Dutt ,working partner of M/s.Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Nalagarh, Solan 3)Thiru.Rajeev Chauhan, working partner of M/s.Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Nalagarh, Solan, 4) Thiru.Samar Singh Chandel, working partner of M/s.Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Nalagarh, Solan, 5) Thiru.Bhagwan Saini working partner of M/s.Res Sancta, Village Beli Deor, Po-Khera, Tehsil, Nalagarh, Solan had contravened Section 18(a)(i) of the Drugs and Cosmetics Act 1940 by having manufactured for sale and sold a **"Not of Standard Quality Drug"** namely Dolocold Suspension 60ml, Batch No. ML12117, Mfd dt.11/12, Exp Dt.10/14, and is punishable under Section 27(d) of the Drugs and Cosmetics Act 1940.

Hence it is prayed that the Honorable Court may be pleased to take this complaint on file and be disposed off in accordance with law.

Further it is humbly submitted that the Honorable Court may also be pleased to permit the prosecution to include any more additional witnesses during the time of trial, if necessary.

It is also humbly prayed that the Honorable Court may pleased to pass order under Section 35 of Drugs and Cosmetics Act 1940 to publish the details of the accused and conviction, if convicted, in newspapers as the Honorable court decides.

Enclosed 266 sheets

  
18/3/15  
Complainant / Drugs Inspector,  
Tiruvannamalai II Range,  
Vellore Zone, Vellore.

**Documents relied upon and originals are enclosed:**

01. Form 17 No. 042756 dated 16.08.13.
02. Form 18 dated 16.08.13.
03. Form 13 No 02507- D/2013-14 dt 20.03.14 of the Government Analyst, Drug Testing Laboratory, Chennai-06.
04. Showcause Memo dated 28.3.14 issued to M/s.Thirumalai Agencies, Tiruvannamalai.
05. Reply dated 28.3.14 of M/s.Thirumalai Agencies, Tiruvannamalai.
06. Show cause memo dated.28.3.14 sent to M/s.M.S.Distributors, Maduravoyal, Chennai-95.
07. Reply dated 2.4.14 of M/s.M.S.Distributors, Maduravoyal, Chennai-95.
08. Showcause memo dated 4.4.14 sent to M/s.Micro Generics, Zirakpur.
09. Showcause memo returned dated.10.4.14 of M/s.Micro Generics, Zirakpur.
10. Showcause memo dated 11.4.14 sent to M/s.Micro Generics, Zirakpur.
11. Letter dated 10.4.14 of M/s.M.S.Distributors, Maduravoyal, Chennai-95.
12. Reply dated 18.4.14 of M/s.Micro Generics, Zirakpur.
13. Letter dated 28.4.14 sent to M/s.Micro Generics, Zirakpur.
14. Reply dated 5.5.14 of M/s.Micro Generics, Zirakpur.
15. Showcause memo dated 13.5.14 sent to M/s.Micro Labs, Zirakpur.
16. Reply dated 21.5.14 of M/s.Micro Labs, Zirakpur.
17. Showcause memo dated 28.5.14 sent to M/s.Res Sancta, Solan.
18. Reminder dated 23.6.14 sent to M/s.Res Sancta, Solan.
19. Reply dated 16.6.14 of M/s.Res Sancta, Solan.
20. Letter dated 8.7.14 sent to M/s.Micro Generics, Zirakpur
21. Letter dated.8.7.14 sent to M/s.Micro Labs Ltd., Zirakpur
22. Letter dated 8.7.14 sent to M/s.Res Sancta, Solan
23. Reply dated 17.7.14 of M/s.Micro Generics, Zirakpur
24. Reply dated 17.7.14 of M/s.Micro Labs Ltd., Zirakpur.
25. Reply dated 23.7.14 of M/s.Res Sancta, Solan
26. Letter dated 23.7.14 sent to M/s.Micro Labs Ltd.,Zirakpur.
27. Petition dated 8.9.14 filed in Honourable Judicial Magistrate Court No.1, Tiruvannamalai.
28. Reminder dated 15.9.14 sent to M/s.Res Sancta, Solan.
29. Reply dated 29.9.14 of M/s.Res Sancta, Solan.
30. Sanction order R.Dis.No. 20881/IW2/2014 (364) dated 03.02.14 of the Director of Drugs Control, TamilNadu, Chennai

-12-

**List of Witnesses:**

1. Ms.M.Saranya  
Drugs Inspector  
Tiruvannamalai II Range  
O/o The Drugs Inspector,  
1, Sixth Street, Gandhi Nagar  
Tiruvannamalai .

To speak about investigation  
and filing of complaint.

2. Thiru.D. Balamurugan  
Proprietor of M/s.Tirumalai Agencies  
No.121, Thamarai Nagar  
Tiruvannamalai.

To speak about sampling

3. Tmt.Thilagam  
Government Analyst  
Drug Testing Laboratory  
Teynampet, Chennai-6.

To speak about analysis