From

Mrs.S.L.Dheivanai,
Drugs Inspector,
Gudiyattam Range,
Vellore Zone, Vellore-9.

To

The Asst. Director of Drugs Control
Vellore zone, Vellore-9.

Ref.No:4372/DI/GYM/13 dated: 09.12.14.

Sir,

Sub: Drugs-Drugs and Cosmetics Act 1940 and Rules made thereunder-DI Sample - Glipizide Tablets IP.5mg, Batch No GPT 88, Mfd Dt Feb/13, Exp Dt Jan/15 Mfd By M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamilnadu - Deemed to be Spurious Drug -Sanction Prosecution accorded - Complaint filed in the Hon'ble Court –Report submitted – Reg.

Ref: 1. 4372/DI/GYM/13 dt 10.07.2014 of the Drugs Inspector, Gudiyattam Range.
2. Ref.No.17390/IW3/NSQ-103/2013-14 dt.17.12.13 O/O The Director of Drugs Control, Chennai-6.
3. R.Dis.No. 15741/IW2/2014 (240). dated 07.10.2014 of the Director of Drugs Control, Chennai-6, Tamilnadu.

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In continuation of the letter reference 3rd cited, I am hereby submitting that the complaint in respect of M/s Alfred Berg & Co (1) Pvt Ltd, Mr.C.Dheeraj Jain Director of of M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamilnadu, Mr.R.Chantrakant Jain, Director of M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamilnadu, Mr.P.S.Sajeethar Technical Staff of M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamilnadu and S.Sankar Technicals Staff for testing M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamilnadu was filed in the Hon'ble Judicial Magistrate Court-I, Gudiyattam on 08.12.2014. The copy of Complaint is enclosed herewith.

Yours faithfully,

9/12/14

மருந்துகள் ஆய்வாளர்
குடியாத்தம் சரகம்

Annexure I

Details of the prosecution launched :

1.Sanction order R.Dis.No. and date : . 15741/IW2/2014 (240) dated 07.10.2014 of the Director of Drugs Control, Tamilnadu, Chennai -6.

2.Name and address of the accused (in case of individuals Name, age, fathers name and status proprietor/partner/ Managing director etc,) :

1. M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamilnadu represented by Thiru. C. Dheeraj Jain, Director,
2. Thiru. C. Dheeraj Jain, Director of M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamilnadu
3. R.Chandrakant Jain Director of M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamilnadu.
4. Ms.Sajeethar the competent technical staff for Manufacturing M/s Alfred Berg &Co(1)PvtLtd,C-25,SIDCOPharmaceuticalComplex,Alathur, 603110,Tamilnadu.
5. Mr.S.Sankar the competent technical staff for testing M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamilnadu.

3. Contraventions (Section, Rule, Act to be detailed) :

1. Section 18(a)(i) of Drugs and Cosmetics Act 1940 read with section 17.B(d) of said Act for having manufactured for sale and sold a "Spurious Drug" and punishable under Section 27(c) of the said Act.
2. Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(c) of Drugs and Cosmetics rules 1945 for having failed to completely test the finished product of the said batch of subject drug which is punishable under Section 27(d) of the said Act and
3. Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(d) of Drugs and Cosmetics rules 1945 for having failed to maintain the required records and registers as per schedule U of Drugs and Cosmetics Act 1940 which is punishable under Section 27(d) of the said Act.

4. Date of filing : 08.12.2014

5. Court at which filed : Judicial Magistrate Court, Gudiyattam.

6. CC No. /STC No. allotted. : Not Allotted.

7. Copy of charge sheet filed : Yes, enclosed.

Dr. நடேசன்
Deputy Director

IN THE HONOURABLE COURT OF JUDICIAL MAGISTRATE,GUDIYATTAM

C.C.NO / STC NO : /2014

STATE REPRESENTED BY :
The Drugs Inspector,
Gudiyattam,
Office of the Assistant Director of Drugs Control,
No.3, EkambaramStreet,Pulavar Nagar,
Rangapuram,Sathuvacheri,
Vellore. .....**Complainant**

---VS –

M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,
Tamil Nadu. .....**Accused(A1)**

Thiru. C. Dheeraj Jain, Director
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,
Tamil Nadu. ..... **Accused (A2)**

R.ChandrakantJain, Director
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,
Tamil Nadu. .....**Accused (A3)**

P.S.Sajeedhar
Technical Staff for Manufacturing
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,
Tamil Nadu. .....**Accused (A4)**

S.Sankar
Technical Staff for Testing
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,
Tamil Nadu.

.....**Accused(A5)**

COMPLAINT FILED UNDER SECTION 36AB OF THE DRUGS AND COSMETICS ACT 1940 FOR THE CONTRAVENTIONS OF SECTION 18(a)(i) OF DRUGS AND COSMETICS ACT 1940 READ WITH SECTION 17.B(d) OF SAID ACT AND PUNISHABLE UNDER SECTION 27(c) OF THE SAID ACT, SECTION 18(c) OF DRUGS AND COSMETICS ACT 1940 READ WITH RULE 74(c) OF DRUGS AND COSMETICS RULES 1945 AND PUNISHABLE UNDER SECTION 27(d) OF THE SAID ACT, SECTION 18(c) OF DRUGS AND COSMETICS ACT 1940 READ WITH RULE 74(d) OF DRUGS AND COSMETICS RULES 1945 AND PUNISHABLE UNDER SECTION 27(d) OF THE SAID ACT READ WITH 200 CRPC.

The Complainant is the Drugs Inspector having jurisdiction of part of Vellore district including Gudiyattamtaluk and Amburtaluk and has been duly notified as Drugs Inspector under section 21 of Drugs and Cosmetics Act 1940 in the state of Tamil Nadu vide Tamil Nadu 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) is the Manufacturing concern namely, M/s Alfred Berg & Co (1) Pvt Ltd situated at C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Accused (A2) Thiru. C. Dheeraj Jain, is the Director of the Manufacturing concern namely M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Accused (A3) Thiru. R.Chandrakantjain is the Director of the Manufacturing concern namely M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Accused (A4) Thiru.P.S.Shajeethar is working as the competent staff for manufacturing at the manufacturing concern namely M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Accused (A5) Thiru. S.Sankar is the endorsed competent staff for testing at the manufacturing concern namely M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Drugs Inspector P.Mahalakshmi, Thiruppatur Range and Gudiyattam Range In-charge had inspected the premises of Government Hospital, Gudiyattam, Vellore District and drew a sample of Glipizide tablets I.P.5 mg, Batch No GPT88, Mfd dt2/13,ExpDt 1/15, Mfd By M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamil Nadu for analysis on 22.08.2013 under

Form 17No.042606 dated 22.8.2013. The same was sent for analysis under Form 18 Memorandum No: 04/PML/DI/13 dated 22.08.2013 to the Govt. Analyst, Drugs Testing Laboratory, Tamil Nadu, Chennai - 06.

The Government Analyst, Drugs Testing Laboratory, Chennai had declared the sample as **NOT OF STANDARD QUALITY** for the reason that the sample does not conform to IP specification for Glipizide Tablets with respect to the content of Glipizide (Nil content). The sample is also deemed to be **SPURIOUS** since it has been substituted by another drug Glibenclamide. This is in contravention of Section 18(a)(i) of Drugs and Cosmetics Act 1940 read with Section 17-B (d) of Drugs and Cosmetics Act 1940.

The Government Hospital, Gudiyattam, Vellore District was inspected by the Drugs Inspector Thirupathur Range and then in-charge of Gudiyattam Range on 18.12.2013 and found nil stock of subject drug.

A Letter dated 18.12.2013 along with a copy of Form 13 was issued to the Chief Pharmacist, Thiru. R.Chandrarajan under acknowledgement requesting to disclose the name, address and other particulars of the person from whom the subject drug was acquired as per section 18A of the Drugs and Cosmetics Act 1940.

Thiru. R.Chandrarajan, the Chief Pharmacist had submitted a letter dated 18.12.2013 stating that the subject sampled drug was supplied by the District drug Warehouse, Tamil Nadu Medicals Services Corporation Ltd, Adukkambarai, Vellore under OGR No N018277 dated 22.06.2013. Total Quantity of tablets received is 20,000 and the stock available is nil. A copy of the OGR was enclosed with the reply.

The Drugs Inspector Thirupathur Range and then in-charge of Gudiyattam Range had inspected the District Drug Warehouse, Tamil Nadu Medical Services Corporation Limited, Adukkambarai, Vellore on 19.12.2013 and found nil stock of the subject drug. A letter dated 19.12.2013 along with a copy of Form 13 was issued in person under acknowledgement to the warehouse in-charge and called for particulars of the name, address and other particulars of the person from whom they had acquired the subject drug as per Section 18A of Drugs and Cosmetics Act 1940.

A letter dated 19.12.2013 was received in person from the warehouse in-charge District Drug warehouse, Tamil Nadu Medical Services Corporation Limited, Adukkambarai, Vellore in which it was stated that the District Drug Warehouse had supplied the subject drug to Government Hospital, Gudiyattam under the OGR No N018277.

The warehouse In-charge, District Drug Warehouse, Tamil Nadu Medicals Services Corporation ltd, Adukkambarai, Vellore had also disclosed under Section 18A of the Drugs and Cosmetics Act 1940 that the above said sampled drug was acquired by them from the manufacturer M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu under Invoices No 196 and 232 both dated 01.06.2013.

Hence the Drug Inspector, Thirupathur Range and then in-charge of Gudiyattam Range had sent a Show cause memo dated 06.01.2014 by registered post with acknowledgement to M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu to offer their explanation for the contravention of Section 18(a)(i) of Drugs and Cosmetics Act 1940 read with Section 17.B(d) of Drugs and Cosmetics Act 1940 for having manufactured for sale and sold a drug which is deemed to be "**SPURIOUS**" namely Glipizide Tablets IP.5mg, Batch No GPT 88, MfdDt Feb/13, ExpDt Jan/15. They were also requested to submit the other particulars like Copy of their drug license with constitutional details, endorsement copy, Batch Manufacturing Record, Analytical report of raw materials, Purchase details, analytical report of the

finished product, Raw Material register, Packing Material Register, Purchase details of Raw Material etc., under Section 18-B of the said Act.

Permission to cause investigation at the manufacturer's level was requested on 07.01.14 and necessary permission was accorded by the Director of Drugs Control, Tamil Nadu, Chennai -06 in his letter dated 08.01.14 to cause investigation at M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Premises of M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamil Nadu was jointly inspected by the Drugs Inspector Thirupathur Range and then in-charge of Gudiyattam Range along with Mr.R.Kannan Senior Drugs Inspector in-charge of Kanchipuram Zone on 08.01.14 and the matter was investigated. The findings of the investigation were as follows.

i. The firm had not produced the Drug Licences copy and endorsement of the subject drug for joint inspection and stated that they are not available with them at the factory site but may be available at their head office situated at Choolai.

ii. The firm had not produced Records/Registers for joint inspection except Batch Manufacturing Records. Hence the required Records/Registers were called for under Section 18B of the Drugs and Cosmetics Act 1940 in writing along with show cause memo which is delivered in person.

iii. The third portion of the sealed sample along with Copy of Analytical report of government Analyst, Drugs Testing Laboratory, Chennai in Form 13, were also handed over to Mr.C.Dheeraj Jain Director.

iv. The Director of the firm had stated that they are not maintaining the raw material register and packing material register either as computer hard copy or hand written register but only maintaining soft copy and showed a CD. The CD submitted by the Director could not be read since the computer did not open the file. He stated that the firm has changed the operative programme recently that may the reason for failure. The director assured that the records and registers will be produced at a later date and requested three days time.

v. The firm had not maintained any Quality Control Records for the sampled drug at their firm and on enquiry, Mr.Sankar, Quality Control in-chatge stated that as and when the records were completed, the same will be sent to their head office and no copies are maintained by them at factory level.

vi. The firm had not maintained separate Quality Assurance Department but Mr.Sankar who is in-charge is also looking after the Quality Assurance Part. He stated that no records are also available for Quality Assurance aspects of the sampled drug.

On perusal of the Batch Manufacturing Records produced by M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu at the time of joint inspection, the following errors/discrepancies were noticed by the Drugs Inspector Thirupathur Range and then Gudiyattam Range in-charge

i) In the indent slip the tare weight and Gross weight column are not filled up which leads to doubt in proper weighing by the Raw Material issuing person.

ii) The compression record shows that the compression took place on 25.02.2013 between 9.00 A.M to 5.30P.M but the weight variation record

shows that weight variation was carried out on 3 days (25.02.13 at 10.00 A.M to 27.02.2013 at 10.00 A.M) but the record is without any authorization that too the weight of 20 tablets is shown in milligram as 2.69 mg.

iii) The average weight of 20 tablets shown on page no.7 and page no 8 of 20 did not tally each other even though the time of test is same. In page no 9 of 20 tablets weight variation record individual tablets weight are entered. But once again the total weight of 20 tablets mentioned in this page did not tally with the total weight of 20 tablets mentioned in previous pages. This record also did not bear any authorization.

iv) The Batch Manufacturing Records shows that the Raw Materials were issued on 12.2.2013 and Granulation was done on 13.02.2013 but the compression was made only on 25.2.2013. The long gap between the granulation and compression might have been the reason for mix up.

v) It is also observed that the record did not contain in-process particulars such as Hardness test, Thickness test, Friability test and Disintegration Test.

vi) The firm has analysed only the finished tablet which is final stage of in-process but they have not analysed the finished product. Since the compression started on 25.02.2013 and the compressed tablet taken for sample on 25th itself and the result of the Quality Control Report was on 28.02.2013 but strip packing started on 28th. So the final product was not tested by the company and even in the first report it is mentioned only for 100 tablets and the quantity shown are not in strip. So it may construed as in process control report but not as finished product report.

vii) In the distribution details of the sampled drug given by the firm, the invoice no is given as 1507 dated 08.05.2013 instead of 196 in their reply at the time of joint inspection. It is also observed that the firm had supplied 1,57,000 tablets of subject drug to District Drug House, TNMSC Ltd, Adukkambarai, Vellore under invoice No.196 dated 08.05.2013 and 1,50,000 tablets of subject drug under invoice no.232 dated18.05.2013 and about 2,60,000 tablets of subject drug to Kanchipuram TNMSC under invoice No.200.

viii) On General inspection of the firm it is observed by the then Drugs Inspector, Thiruppathur Range that they are not following Good Manufacturing Practices in general and the whole premises is congested with ready for compression granules, compressed tablets,packing materials and raw material without any proper labelling and strips of final packing of Glibenclamide four batches were kept together without any demarcation.

ix) The firm had not maintaining the required records and registers as per schedule U of Drugs and Cosmetics Act 1940. The impression is that simply manufacturing the drug first and creating records thereafter. This is in contravention of 18(c) of Drugs and Cosmetics Act 1940 read with rule 74(d) of Drugs and Cosmetics Rules 1945.

x) They also requested one week time for the submission of their explanation towards the show cause memo dated 21.06.2013.

The observation is that they simply manufacturing the drugs first and then creating records thereafter. The joint inspection team opined that the manufacturer did not produce the proper and genuine records to investigate and inspection to cover their

mistakes. It is also found that the cost of Glipizide is around Rs.9000/kg while that of Glibenclamide is 1900/kg. So the accused had substituted Glibenclamide instead of Glipizide for the profit purpose. An investigation report was prepared by the joint inspection team on the same day. This was submitted by the Drugs inspector, Thirupathur Range and then in-charge of Gudiyattam Range to the Director of Drugs Control, Tamil Nadu, Chennai -06.

The file was handed over to the complainant after her return from maternity leave on 20.01.2014. The Letter dated 11.01.2013 was received by the complainant from M/S Alfred Berg & Co (1) Pvt Ltd, C-25 SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu on 20.01.2014.

On perusal of the reply, it was found that,

The firm is having valid Drug license in Form 25 bearing no. 515 and Form 28 bearing No. 290 both dated 02.02.1987 and renewed up to 31.12.2012 and applied for renewal for the period 1.1.2013-31.12.2017 as per Letter L.dis.No. 2039/D1/1/13 dated 04.03.13 of the Director of Drugs Control, Tamil Nadu, Chennai. Thriu. P.S.Sajeether. Thiru. N.Sourirajan were the competent staffs for manufacturing, and Thiru. R.Sekar was the competent staffs for testing as per the renewal certificate.

i) The firm had produced the copy of endorsement for the subject drug dated 26.04.2012 approved by the Department of Drugs Control,Tamil Nadu.

ii) The Directors are Thiru. C. Dheeraj Jain and R.Chandrakant Jain as per their statement and Thriu. P.S Sajeether who is the competent staff for manufacturing is present and Thiru. R.Sekar was the competent staffs for testing had resigned his job approximately one year back and Mr.S.Sankar was the competent staffs for testing as per their statement.

iii) It is observed in the firm's analytical report of the subject drug(report no: ABC/FP/ X2501 /12 dated 28.02.2013) that the test for the Friability was not carried out. Hence, they did not test the said batch of the subject drug completely which is in contravention of section 18(c) of Drugs and Cosmetics Act 1940 read with rule 74(c) of Drugs and Cosmetics Rules 1945.

iv) The other competent staff for testing, Mr.S.Sankar is also responsible for the contravention.

v) The firm had produced 5,75,400 tablets and released 5,67,000 tablets for sale. The Director stated that there is no stock in hand at the time of joint inspection. There is no any details for the remaining 8,400 tablets.

vi) The firm had not maintained stock register for the year 2012-2013 properly. Simply they maintain the purchased quantity of Raw material only.

vii) In their Reply, M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu had not produced some documents such as Raw material Register, Packing material register, Analytical report for raw material etc. Hence the complainant sent a reminder dated 29.01.2014 to M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

In the meanwhile, a letter dated 25.02.2014 requesting permission to cause further investigation at the manufacturer's level at M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu was sent to the Director of Drugs control, Tamil Nadu, Chennai -06 by the complainant since the manufacturer did not furnish all the details called for, and necessary permission was received from the Director of Drugs Control, Tamil Nadu, Chennai -06 to cause

investigation at the manufacturer's level at M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu vide letter dated 24.03.2014.

A reply was received from M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu on 15.04.2014.

On perusal of the reply, it was found that

i. The firm had not conducted the stability test of the sample drug.
ii. The firm had not maintained the raw material register, batch packaging record and packing material register.

The Premises of M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu is jointly inspected by the complainant along with Mr.R.Kannan Senior Drugs Inspector in-charge of Kanchipuram Zone on 21.04.14 and the matter was investigated further. During the course of investigation, ThiruC.Dheeraj Jain said to be a Director of the company was present. Mr.Sankar Quality control in-charge and the manufacturing chemist Mr.P.Shajeethar were also present. A letter dated 21.04.2014 for producing the raw material stock register for the year 2013-2014, Bank payment details of purchase of raw materials, Distribution details of Glibenclamide tablets Batch No. GBT 125, GBT 126, GBT 127 etc was given in person to Dheerajjain, Director of M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu.

The Director of the firm Mr.C.Dheerajjain had stated that the requested particulars are not readily available in the company since the documents are pertaining to the year 2012-2013 and it was in their head office situated at No.1 hunters road, choolai and they also requested three days time for the submission of their explanation towards the letter dated 21.04.2014.

An investigation report was prepared by the joint inspection team on the same day. This was submitted by the Drugs inspector, Gudiyattam Range to the Director of Drugs Control, Tamil Nadu, Chennai -06.

A Reply was received on 05. 05.2014 from M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110, Tamil Nadu. In that, they had stated that they are not maintained the stock register for the year 2012-2013 and packing material register.

On perusal of the reply, it was found that

i. The firm had not maintained the Records of Raw Materials properly.
ii. The firm had not maintained the packing material register, Batch packaging record separately.
iii. The firm had produced 5,75,400 tablets and released 5,67,000 tablets for sale. The Director stated that there is no physical stock in hand in their reply at the time of joint inspection dated 08.01.2014 and 21.04.2014 and in their reply dated 05.05.2014 they stated that the balance 8400 tablets were lying with their factory.
iv. Glibenclamide 5mg Tablet, Batch No GBT-125 the batch size mentioned in their reply at the time of joint inspection was 1500000 and Batch distributed is 1310200(In their reply dated 05.05.2014) and GBT-127 batch size was 150000 and Batch Distributed is 1038000(In their reply dated 05.05.2014).

After perusal of the records and facts available, it was observed that M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamil Nadu had contravened Section 18(c) of Drugs and Cosmetics Act 1940 read with Section 17.B(d) of the said Act for having manufactured for sale and sold a **"NOT OF STANDARD QUALITY DRUG"** which is deemed to be **"SPURIOUS"** for the reason that the active drug Glipizide has been substituted by another drug Glibenclamide, in the sampled drug namely Glipizide Tablets IP.5mg, Batch No GPT 88, Mfddt Feb/13, ExpDt Jan/15. This is in contravention of Section 18(a)(i) of Drugs and Cosmetics Act 1940 read with Section 17.B(d) of the said Act .

Also, they had not tested the subject drug completely which is, in contravention of Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(c) of Drugs and Cosmetics Rules 1945. However, the subject batch of the drug had been released for sale and supplied before the finished product was completely analysed in accordance with the label claim.

The firm had not maintained the required records and registers (Records of Raw Materials, Packaging Records,Batch Packaging Records) as per schedule U of Drugs and Cosmetics Act 1940. This is in contravention of Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(d) of Drugs and Cosmetics Rules 1945.

Hence, it is established that,

M/s Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, 603110,Tamil Nadu had contravened,

1. Section 18(a)(i) of Drugs and Cosmetics Act 1940 read with section 17.B(d) of said Act for having manufactured for sale and sold a "Spurious Drug" and punishable under Section 27(c) of the said Act.
2. Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(c) of Drugs and Cosmetics rules 1945 for having failed to completely test the finished product of the said batch of subject drug which is punishable under Section 27(d) of the said Act and
3. Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(d) of Drugs and Cosmetics rules 1945 for having failed to maintain the required records and registers as per schedule U of Drugs and Cosmetics Act 1940 which is punishable under Section 27(d) of the said Act.

Thiru. C.Dheeraj Jain and Thiru.R.Chandrakanthjain are the Directors of the companyas per the Memorandum of Association. They are also responsible for the contraventions.

Thiru.P.S.Sajeethar is one of the Endorsed Competent staff for manufacturing as per the Drug License. He is also the person in-charge for manufacturing at the time of manufacture of the sampled drug and hence, he is also responsible for the contraventions.

Mr.S.sankar is the endorsed competent technical staff for testing and hence, he is also responsible for the contravention.

Sanction was accorded by the Director of Drugs control, Tamil Nadu, Chennai-06 to prosecute the above said accused persons under R.Dis.no: 15741/IW2/2014 (240) dt 07.10.2014 of the Director of Drugs Control, Tamil Nadu, Chennai -06.

Hence it is submitted that,

M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110, *Tamil Nadu*

Thiru. C. Dheeraj Jain, Director
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110, *Tamil Nadu*

R.ChandrakantJainDirector
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,*Tamil Nadu*

P.S.Shajeedhar
Technical Staff for Manufacturing
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 603110,*Tamil Nadu*

S.Sankar
Technical Staff for Testing
M/s Alfred Berg & Co (1) Pvt Ltd,
C-25, SIDCO Pharmaceutical Complex,
Alathur, 60311*Tamil Nadu*

Had contravened

1. **Section 18(a)(i) of Drugs and Cosmetics Act 1940 read with Section 17-B(d) of the said Act for having manufactured for sale and sold a "Spurious Drug" and is punishable under Section 27(c) of the said Act.**
2. **Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(c) of Drugs and Cosmetics Rules 1945 for having failed to completely test the finished product of the said batch of subject drug which is punishable under Section 27(d) of the said Act and**
3. **Section 18(c) of Drugs and Cosmetics Act 1940 read with Rule 74(d) of Drugs and Cosmetics Rules 1945 for having failed to maintain the required records and registers as per schedule 'U' of Drugs and Cosmetics Act 1940 which is punishable under Section 27(d) of the said Act.**

Hence, it is humbly prayed that the Honourable Court may be pleased to take this complaint on file and issue summons to the accused persons noted in the complaint accordance with law and render justice.

Further, it is prayed that this Honourable Court may be pleased to permit and allow to examine any additional witnesses, if any, and to allow the prosecution to file the relevant original documents during trial.

It is also prayed that this Honourable Court may be pleased to pass orders under Section 35 of the Drugs and Cosmetics Act 1940 in case of conviction of the Accused and to have the particulars of conviction published in the newspaper as of when the case is finalised, and thus Justice may be rendered.

Dated at Gudiyattam on this 8 th day December 2014

COMPLAINANT/
DRUGS INSPECTOR.

LIST OF DOCUMENTS RELIED ON BY THE PRESECUTIONS AND COPIES ENCLOSED HERE WITH:

1. Form 17 No.042606 dated 22.8.2013
2. Form 18 No.PML/06/TPT/2013 dated 22.8.2013
3. Analytical Report No 02500-D/2013-14 dt 10.12.13 0f Govt. Analyst, Chennai in Form 13.
4. Ref No. 17390/IW3/NSQ-103/2013-14dt 17.12.2013 of the Director of Drugs Control
5. Letter dated 18.12.2013 sent in person to the Chief Pharmacist, Government Hospital, Gudiyattam.
6. Reply dated 18.12.2013 from the Chief Pharmacist, Govt Hospital, Gudiyattam.
7. Requisition Letter dated 18.12.2013 to Assistant Director of Drugs Control, Vellore Zone.
8. Letter dated 19.12.2013 sent in person to the Warehouse Incharge, District Drug Warehouse, Adukkambarai, Vellore.
9. Reply dated 19.12.13 received from the Warehouse In-charge, District Drug Warehouse, Adukkambarai, Vellore.
10. Letter dated 27.12.2013 sent in person to the Chief Pharmacist, Government Hospital, Gudiyattam.
11. Letter dated 06.01.2014 sent to the M/S Alfred Berg & Co (1) Pvt Ltd,C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.
12. Requisition letter dated 07.01.2014 sent to the Director of Drugs Control, Chennai.
13. Letter dated 08.01.2014 received from the Director of Drugs Control, Chennai.
14. Joint investigation on 08.01.2014 at M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu and report submitted on 10.1.2014.

15. Letter dated 08.01.2014 given in person to the M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur,Tamil Nadu.
16. Letter dated 08.01.2014 received in person from the M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.
17. Letter dated 08.01.2014 given in person to the M/S Alfred Berg & Co(1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.
18. Letter dated 11.01.2014 received on 17.01 2014 of M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur,Tamil Nadu.
19. Reminder dated 29.01.2014 sent to the M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.
20. Requisition letter dated 25.02.2014 sent to the Director of Drugs Control, Chennai.
21. Letter dated 24.03.2014 received from the Director of Drugs Control,Chennai.
22. Reply Received on 15.04.2014 from M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.
23.Joint investigation on 21.04.2014 at M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.and report on22.4.2014.
24.Reply Received on 15.05.2014 from M/S Alfred Berg & Co (1) Pvt Ltd, C-25, SIDCO Pharmaceutical Complex, Alathur, Tamil Nadu.
25. Sanction order No: R.Dis.no: 15741/IW2/2014 (240) dt 07.10.2014 of the Director of Drugs Control, Tamil Nadu, Chennai -06.

LISTOF PROSECUTION WITNESSES:

1. S.L.Dheivanai
Complainant
Drugs Inspector,
Gudiyattam Range,
Vellore Zone.

2. P.Mahalakshmi
Drugs Inspector,
Thiruppatur Range,
Vellore Zone.

3.A.Thilagam
Government Analyst
Drugs Testing Laboratory,
Teynampet,Chennai-06

4.R.Chandrarajan
Chief Pharmacist,
Government Hospital,
Gudiyattam.

5. N.Karunakaran
The Warehouse Incharge,
District Drug warehouse,
Vellore.

6. R.Kannan
Senior Drugs Inspector in-charge,
Kanchipuram Zone.