

IN THE COURT OF IV ADDL.JUDL.MAGISTRATE OF I CLASS,  
CHITTOOR

PRESENT: SRI. Ch. Yugandhar,  
IV ADDL.JUDL.MAGISTRATE OF  
I CLASS, CHITTOOR.

*Friday, the 18<sup>th</sup> day of December, 2015.*

**C.C.No.527 of 2010**

Between

The State of Andhra Pradesh,  
Rep., by Drugs Inspector,  
Proddatur.

... Complainant.

And

1. M/s Parennial Medicare, Shamthi Solan, (H.P), represented by his partner, Vinod Gupta, S/o S.H.Beni Prasad Gupta, age 66 years. (A-1)
2. Mr Vinod Gupta,S/o S.H. Beni Prasad Gupta, age 66 years, Partner, M/s Parennial Medicare, Shamthi Solan. (H.P). (A-2)
3. M/s Sudhakar and Company, Amrut House, Rajgarh Road, Shamthi Solan,(H.P), represtned by its Proprietor, Sudhakar Kanna, age 60 years. (A-3)
4. M/s Hall Mark chemicals, D.No.27-III/978, Upstairs, Ram Nagar, Nellore represented by its Partner, P. Vijaya Sarathy, age 32 years. (A-4)
5. P. Vijaya Sarathy, Partner, M/s Hall Mark chemicals, D.No.27-III/978, Upstairs, Ram Nagar, Nellore, age 32 years. (A-5)
6. M/s Anjanadri Medical Agencies, D.No.17/210, Kummara Street, Chittoor, represtned by its Partner, P. Ramesh Reddy, age 25 years. (A-6)
- 7.P.Ramesh Reddy, age 25 years, Partner, M/s Anjanadri Medical Agencies, D.No.17/210, Kummara Street, Chittoor. (A-7)

.. Accused.

This case coming for final hearing before me on 09-12-2015 in the presence of APP for the complainant and of *Sri R.Chandrasekhar*, Advocate for accused and upon hearing the arguments of both sides and on perusal of all relevant records this court delivered the following:-

**J U D G M E N T**

1. The Drugs Inspector, Chittoor filed complaint against accused for violation of Section 18(a)(i) r/w Sec.27(d) of the Drugs and Cosmetics Act, 1940.

2. The case of the complainant in brief are as follows :-

Complainant-Y.V.V. Satyanarayana, (LW1), is the Drugs Inspector appointed U/Sec.21 of the Drugs and Cosmetics Act having powers U/Sec.22 and 23 of the Act and he is having jurisdiction over entire state of

A.P., and empowered to institute prosecution U/Sec.32 of the Act.

On 31-01-2008 Y.V.V. Sathyanarayana (LW1), Drugs Inspector inspected the wholesale Medical shop M/s Anjanadri Medical Agencies(A-6) situated at D.No.17/210 of Kummara Street, Chittoor, at that time found A-7 partner of A-6 agencies, then he picked up four varieties of Drug for analysis out of four, he had picked up for 4 x 5 x 10 of Lincla-kid, Amoxycillin Trihydrate with Clavunate Potassium Dispersible Tablets, Mfg. License No.MB/06/453, B.No.PM-073,Mfg. Date Sep 2007, Exp. Date 2/2009, Mfd., by A-1, M/s Pareniel Medicare, Shamthi, Solan, 173212 (HP) for analysis. The Drugs Inspector, divided the sample in the four portions by inserting 5 x 10 tablets in each of four sample in the four portions by inserting 5 x 10 tablets in each of four polythene cover and each cover was sealed with the seal of Drugs Inspector, Chittoor. A-7 partner of A-6, M/s Anjanadri Medical Agencies, Chittoor affixed their signatures on all sealed portions. The cost of the drug was paid by the Drugs Inspector as per Bill No.C000794,dt.31-01-2008 and the details of samples of drugs taken for analysis are entered in Form No.17 by the Drugs Inspector and a copy of Form 17 and one sealed sample portion of subject drug are handed over by him to A-7 under acknowledgment. On 31-01-2008 one sealed sample portion of Lincla-kid Tables, B.No.PM073, Manufactured by A-1 Firm along with Form 18 were sent to the Government Analyst, Hyderabad by the Drugs Inspector by Registered Parcel. Another copy of Form 18 with covering letter was sent by Regd. Post separately to the Government Analyst, Hyderabad for comparison of Specimen impression of seal. On 04-08-2008, the Drugs Inspector received Analytical report from the Government Analyst, Hyderabad declaring the sample as Not of standard quality for the reason that one of the active ingredient Clavunic Acid was found to contain 2.2 mg out of declared label claim of 28.5 mg per each tablet. On 05-08-2008 a copy of Analytical report along with letter are served to A-7 partner of A-6 agencies and in turn he had disclosed that he purchased the subject drug from A-4, M/s Hall Mark Chemicals, Nellore by submitting attested copies of purchase bills and sale bills. On 06-08-2008 a copy of Analytical report and sealed sample portion of 5 x 10 tablets of subject drug along with covering letter are sent by Regd.

Post to A-4 company requesting to disclose the source of supply of subject drug. On 08-08-2008 a copy of Analytical report along with covering letter are sent to the manufacturer A-1 by Registered Post and was asked to submit the details of manufacturing analysis of the subject drug and postal acknowledgment to this extent is received on 11-09-2008. On 01-09-2008, Drugs Inspector inspected A-4 and obtained a letter from him giving details of purchase and sale of subject drug. LW2, P.Hemasunder Rao, General Manager of A-4 company disclosed that they have purchased the said drug from A-3 company as per invoice No.KCP246, dt.24-09-2007. On 01-11-2008 LW2, P.Hemasunder Rao, General Manager of A-4 company submitted details of recall particulars of subject drug along with copy of purchase and sale bills and details of stocks returned by them. On 29-04-2010, Drugs Inspector inspected A-4 company at Nelloe in the presence of A-5, P. Vijaya Sarathy, Partner of A-4 company who submitted attested copies of drug license, purchase bills, sale details, recall particulars and stocks returned by them. On 02-09-2008 copy of analytical report along with covering letter are sent to A-3 to disclose the source of supply of subject drug and since no reply is received, another letter is sent on 01-05-2010. On 19-05-2010 Sudhakar Khanna, Proprietor of A-3 company sent copy of purchase bill, sale bill and license copies of A-3 and A-1 company. On 20-05-2010 a letter was addressed to R.K.Chowdary (LW3), Assistant Drug Controller and licensing authority, Solan District, Solan to give details of Constitution particulars of the manufacturing firm. On 22-05-2010 another copy of letter was sent to manufacturing firm A-1 to give details of manufacturing and analysis of subject drug. On 14-07-2010 a letter was received from the Assistant Drug Controller, Solan District, giving attested copies of licenses of A-1 and also its partnership deed. On 06-10-2008 a copy of letter was received by the Drugs Inspector and the letter was addressed to the Drug Controller giving details of the case and requesting for constitution particulars of the manufacturing unit. Thus A-1 firm represented by A-2 violated Section 18(1) (i) of Drugs and Cosmetics Act, 1940 punishable U/Sec.27(d) of the Act for manufacturing and selling not of standard quality drug. A-1 represented by A-2 also violated Section 18(B) of Drugs and cosmetics Act by not submitting

the records of manufacturing and analysis of subject drug and punishable U/Sec.28(A) of Drugs and Cosmetics Act, 1940 and Rules. A-3 to A-7 also violated Sec.18 (a) (i) of Drugs and Cosmetics Act, 1940 for having distributed subject drug which is not of standard quality drug and thereby punishable U/Sec.27(d) of the Drugs and Cosmetics Act, 1940. It is also submitted that the subject drug was manufactured by A-1 firm and marketed by A-4.

Therefore, A-1 to A-7 are liable to be punished Under Section 18(a)(i) r/w Sec.27(d) of the Drugs and Cosmetics Act, 1940.

Hence the complaint.

3. This case has been taken on file Section 18(a)(i) r/w Sec..27(d) of the Drugs and Cosmetics Act, 1940 and numbered as CC No.527/2010.

4. On appearance of accused, copies of necessary documents were furnished in compliance with Sec.207 Cr.P.C.

5. A-1 to A-7 were examined U/Sec.251 Cr P C.The substance of accusation punishable U/Sec.18(a)(i) punishable U/Sec..27(d) of Drugs and Cosmetics Act against accused was readover and explained to accused, for which they pleaded not guilty, denied the charge and claimed to be tried.

6. In order to establish the case of complainant, the complainant himself examined as PW1 and proprietor of A-4 Firm examined as PW2 and got marked Ex.P-1 to Ex.P-27 documents.

5. Accused were examined U/Sec.313 Cr P C examination for the incriminating material appearing in the evidence of PW1 and PW2, for which they pleaded not guilty, reported no defence witnesses to be examined on their behalf.

6. Heard the arguments of both sides.

7. The points that falls for determination are :-

Whether prosecution has established the guilt of accused for the offence U/Sec.18(a)(i) punishable U/sec.27(d) of Drugs and Cosmetics Act beyond reasonable doubt?

8. **POINT** :-

It is the case of prosecution that PW1 was appointed under Sec.21 of Drugs and Cosmetics Act, 1940 as per G.O.Ms.No.103 Medical and Health Dt.6-2-1986 under Ex.P1 is gazette notification (Serial No.7). Being so on 31-1-2008, PW1 inspected A-6, M/s.Anjanadri Medical Agencies, Chittoor situating in D.No.17/210, Kummara Street in Chittoor town and during inspection he has taken four varieties of drug for analysis and he entered the details of the drug and prepared Form.17 under Ex.P-2. Out of four the first item of drug Lincla-Kid dispersible tablets, batch No.PM-073, Manufacturing Date Sep.2007. Expiry date Feb 2009, manufactured by A-1, Perennial Medicare Solan, Himachal Pradesh, he has taken 20 x 10 tablets and divided them into four portions, each portion containing 5 x 10 tablets and all the four portions are individually sealed with his seal and affixed with his signatures and one P.Ramesh Reddy i.e.,A7. One sealed sample portion is handed over to A7 under acknowledgment along with copy of Ex.P2, Form.17 and the same was received under Ex.P-3, Acknowledgment of A-7 on rear side of Ex.P2 Form.17. The Cost of drug taken for analysis is paid to A7 vide Cash bill No.C000794 for Rs.2521/- by PW1. Ex.P4 is said Cash bill. On the same day i.e., 31-1-2008 PW1 sent one sealed sample portion along with Form.18 under Ex.P-5, to the Government Analyst, Hyderabad with a covering letter under Ex.P-6 through registered parcel and post. Ex.P7 is postal receipts (2 in numbers). On 04-08-2008 he received report from Government Analyst declaring the sample drug is not of standard quality for the reason one of the ingredient Clavulanic acid was found to contain 2.2 Mg out of label claim of 28.5 Mg. Ex.P-8 Government Analyst report. Ex.P9 is covering letter of the said report. On 05-08-2008 he served copy of Ex.P-8 report to A-7 along with covering letter and obtained acknowledgment. Ex.P10 is covering letter showing service of copy of Ex.P-8. Ex.P-11 is acknowledgment of A-7 showing receipt of copy of Ex.P-8. On the same day i.e., 05-08-2008, A-7 gave reply stating that he has purchased the said drug from A-4, M/s Hall Mark Chemicals, Nellore and he has submitted the copies of purchase bills along with covering letter and copies Drug license for A-6 Firm for which A-7 representing. Ex.P12 is covering letter including purchase bills (5 pages). Ex.P13 is copy of drug license of

A6. On 06-08-2008 he sent copy of analytical report Ex.P8 along with sealed another sample portion to M/s Hall Mark Chemicals, Nellore (A4) through registered post. On 8-8-2008 I have sent another copy of analyst report Ex.P8 along with covering letter to M/s Perrenial Medicare (A1) by registered post and I have received acknowledgment from them. Ex.P14 is covering letter analyst report sent to A1. Ex.P15 is acknowledgment of A1. On 01-09-2008, he inspected A-4, M/s Hall Mark Chemicals, Nellore at that time one Hemasundara Rao who was present, who is General Manager of said Firm and he had submitted a letter stating that the said drug is received by them from A-3, M/s.Sudhakar and Company, Himachal Pradesh and he had submitted purchase bill copies and sales details statement along with covering letter and also drug license copy. Ex.P16 is covering letter along with purchase bills and sale details (4 pages). Ex.P17 is copy of drug license of A-4, M/s Hall Mark Chemicals. On 01-11-2008, he received letter from A-4, M/s Hall Mark Chemicals, Nellore giving details of sales particulars and recall particulars along with the copies of documents. Ex.P18 is details of Sale and recall particulars (21 pages). On 29-04-2010, He inspected A-4, M/s.Hall Mark Chemicals, Nellore in presence of A-5, P.Vijayasaradhi (A5) and obtained statement from him regarding the purchase, sale distribution and recall particulars. Ex.P19 is statement (21 pages) which is corresponding to Ex.P18. On 02-09-2008 he addressed a letter M/s Sudhakar and Company, Himachal Pradesh, along with copy of analytical report Ex.P8. Ex.P20 is said letter. Later he has also issued a reminder on 1-5-2010 under Ex.P-21. On 19-05-2010, he received reply under Ex.P-22 from A-3, M/s Sudhakar and company giving details of purchase of said drug from A1 Firm which is manufacturing firm and he had enclosed purchase bill, sale bill and drug license copy and also drug license copy of A-1.Firm. On 20-05-2010 he addressed a letter to R.K.Chowdary, Asst Drug Controller, Himachal Pradesh requesting for constitution particulars A1.Firm. Ex.P-23 is said letter Dt.20-5-2010. On 22-05-2010 he addressed another letter to A1.Firm asking for details of records of the said drug in question under Ex.P2-4. On 03-06-2010 he addressed a letter to the Drug Inspector, Sirumour district, Himachal Pradesh State, requesting for details of A-3, M/s.Sudhakar and Company

under Ex.P-25. On 14-07-2010 he has received reply from Asst. Drug Controller, Himachal Pradesh, giving details of license of A-1 Firm and also partnership deed of A-1 Firm. On 06-10-2008 he received a copy of letter addressed by Director General, Drug Control Administration, Hyderabad to the Drug Controller, Himachal Pradesh requesting constitutional particulars of A-1 Firm. PW1 filed the charge sheet as per circular Dt.19-9-2008 CIR.RC.No.035/Peshi/97-12. Wherein it is mentioned that no sanction is necessary to launch prosecution by Drug Inspector.

9. During course of trial the complainant the then Drug Inspector, Chittoor examined himself as PW-1 and reiterating the same contents of the complaint by narrating chronological events from lifting sample of drug in question till filing complaint. Besides his oral evidence he also got examined PW2 the Proprietor of A-4, M/s Hall Mark Chemicals, Nellore.

10. PW1, Y.V.V.Sathyanarayana is the then Drug Inspector of Chittoor and who visited the shop of A-6 and lift the samples is examined as PW-1 and deposed that he was appointed U/sec.21 of Drugs and Cosmetics Act, 1940 as per G.O.M.S.No.103 Medical & Health Department, dt.6-2-1986 which is marked as Ex.P-1. He further deposed that on 31-1-2008 he inspected Ms.Anjanadri Medical Agencies (A-6) which is situating in D.No.17/2010, Kummara Street, Chittoor town. During his inspection he found some of varieties of drugs and he lifted four varieties of Drug for analysis. The same were entered in Form-17 which is marked as Ex.P-2. Out of four drugs the 1<sup>st</sup> item of drug Linclakid dispersible tablets batch No.PM-073, Manufacturing date September, 2007 and expiry date February, 2009 the same was manufactured by A-1 firm. Then he has taken 20 X 10 tablets and divided into four portions and sealed individually with his seal and affixed his signature and also obtained the signature of A-7 who is said to be the owner of A-6 shop. One sealed sample portion was handed over to A-7 under acknowledgment along with copy of Ex.P-2 Form-17 the acknowledgment of A-7 is marked as Ex.P-7. He further deposed that cost of drug is paid to A-7 under vide cash bill, Ex.P-4 No.C 000794 for Rs.2,527/-. Then he send one sealed portion of sample along with Form-18 to Government analyst,

Hyderabad with a covering letter through registered parcel and post. Form-18 is marked as Ex.P-5. The covering letter is marked as Ex.P-6. Postal receipts are marked as Ex.P-7. He further deposed that on 04-8-2008 he received analysis report which discloses that the sample drug is not of standard quality for the reason one of the ingredient Clonazepam was found containing 2.2 mg out of label claim of 28.5 mg. The government analyst report is marked as Ex.P-8. The covering letter is marked as Ex.P-9. He further deposed that on 5-8-2008 he served copy of Ex.P-8 analyst to A-7 along with covering letter and obtained acknowledgment. On the same day A-7 gave a reply stating that he has purchased the said drug M/s Hallmark chemicals, Nellore and he has submitted the copies of purchase bills along with covering letters and copies of drug licence of A-6 firm for which A-7 representing. He further deposed that on 6-8-2008 he send copy of analyst report Ex.P-8 along with sealed another sample portion to M/s Hallmark chemicals, Nellore through registered post. On 8-8-2008 he send an another copy of analyst report Ex.P-8 along with covering letter to M/s Perennial Medicare Care (A-1) by registered post and he received acknowledgment for them. He further deposed that on 01-09-2008 he visited M/s Hallmark Chemicals, Nellore at the time one Hemachandra Rao who is General Manager of the said firm and he had submitted a letter stating that the said drug is received by them from M/s Sudhakar and company, Himachal Pradesh and also he submitted purchase bill copies and sales detailed statements and sales dates and also drug license copy. Further he deposed that on 01-11-2008 he received a letter from Hallmark Chemicals, Nellore giving details of sales particulars and recall particulars along with copies of document. Then he inspected M/s Hallmark Chemicals, Nellore on 29-04-2010 in the presence of P.Vijayasarithi and obtained statement from him regarding the purchase sale distribution and recall particulars. He further deposed that on 02-09-2008 he addressed a letter to M/s Sudhakar and company, Himachal Pradesh along with copy of Analytical report. He had also issued a reminder on 1-5-2010. Later on 19-5-2010 he received a reply from M/s Sudhakar and Company (A-3) giving details of purchase of said drug from A-1 firm which was manufacturing the drug. Further the A-1 firm had also enclosed purchase



bills, sale bill and drug license copy and also drug license copy of A-1 firm. He further deposed that on 20-5-2010 he addressed a letter to R.K.Chawdari, Asst. Drug Controller, Himachal Pradesh requesting constitutional particulars of A-1 firm. On 22-05-2010 he addressed another letter to A-1 firm seeking the details of the records of drug in question. He also addressed a letter to Drug Inspector, Sirumour District on 03-06-2010 requesting the details of M/s Sudhakar and Company. On 14-07-2010 he received reply from Asst. Drug Controller, Himachal Pradesh giving details of A-1 firm and also partnership deed of A-1 firm. He has also received a copy of letter addressed by Director General, Drug Control Administration, Hyderabad requesting constitutional particulars of A-1 firm. As there is no necessity of sanction for launching prosecution as per circular in CIR.RC.No.035/Peshi/97-12. The circular is marked as Ex.P-27. One of the subject drug is marked as MO-1.

10. During cross examination it is elicited that Ex.P-1, Gazette Notification is related for entire State of A.P and it is not related to specific area for which it was suggested to him that Ex.P-1 does not confer him over Jurisdiction of Chittoor where the shop of A-6 and A-7 is located for which he denied.

Further it is suggested that he has not filed any documents to show that he had undergone training as specified under Rule 49 of Drugs and Cosmetics Rules and further it is elicited that Ex.P-1 also does not refer about his training. It is true that there is targets fixed by their department to Drugs Inspectors to lift the samples in a month. Atleast the Drug Inspector has to lift 5 samples per month.

It is further elicited that he did not conduct any search or seizure in the shop of A-6 and A-7 but he only inspected the said shop and he has not issued any prohibitory orders to A-6 and A-7.

It is further elicited that the said drug should be stored in a proper storage condition from the date of despatch from the manufacture till the date of analysis.

It is further elicited that if the drug is not properly stored there is every possibility for failure of drug in ASSY Test. It is further elicited that he has not collected any information from the manufacturer pertaining to the

precautions taken by them in respect of maintaining of quality.

It is further elicited that he has not enquired specifically with regard to the precautions taken by the manufacturer under Ex.P-24, Letter dt.22-05-2010 addressed to A-1 firm asking the details of records of the subject drug.

It is further elicited that A-3 purchased the subject drug from A-1 on 22-09-2007 and the same was sold to A-4 by A-3 on 24-09-2007 and A-6 purchased the subject drug from A-4 on 10-10-2007. It is further elicited that he has not filed any documents to show the storage conditions of the subject drug in the premises of A-6.

It is further elicited that portion of subject drug despatched by him on 31-01-2008 to Government Analyst and the same was received by the Government Analyst on 04-02-2008. Further he stated that he cannot say about the storage conditions of the subject drug during the transit period from 31-01-2008 to 04-02-2008. It is further elicited that the analytical report is dt.23-07-2008. So it remains at Government Analyst lab from 04-02-2008 to 23-07-2008 for which he stated that he cannot say the storage conditions of the subject drug during the period of Government Analyst lab.

Further it is elicited that he did not address any letter to Government Analyst to expedite the analysis and report. It is further elicited that he is competent to inspect the premises of A-1 as per the Act but he did not prefer to inspect the premises of A-1.

It is further elicited that the analyst must furnish the protocol applied for the analysis of the drug in his report. It is further elicited that he did not ask A-3 about the storage conditions about the subject drug in his premises.

It is further elicited that after his first inspection P. Hemasundhar (LW2) who is General Manager of A-4 Firm recalled the subject drug from all the purchasers and sent back the subject drug to A-3. To that effect he also made a correspondence with him. It is further elicited that he did not enquire about the storage conditions of the drug in the premises of A-4 and he did not get any documents to that effect. It is further elicited that he did not ask A-6, A-7 about the storage conditions of subject drug in the premises of A-6.

11. One P. Hemasundar Rao is examined as PW2, he deposed that he has been running the Firm in the name and style of M/s Hall Mark Chemicals at Nellore since 2002. The said firm is a Medical distributors. He further deposed that on 24-09-2007 he purchased the subject drug ie., Lincla-Kid tablets from A-3 company. On 06-08-2008 he received a letter from PW1 stating that the subject drug is substandard one and requested to submit their license and purchase particulars of subject drug and distribution particulars of subject drug and also they have instructed to recall the subject drug from the retailers. On that they submitted all the relevant particulars as called for by PW1 and recalled the subject drug from various retailers. On 01-09-2008 PW1 visited their firm and inspected their premises.

During cross examination by the learned counsel for A-1 and A-2, it is elicited that the subject drug was delivered by A-3 company to their firm after one week or 10 days from the date of their invoice, dt. 24-09-2007. He sold the said drug to A-6, A-7 and other retailers on 10-10-2007. It is further elicited that the said drug is to be stored in proper storage condition. The drug was remains in their custody for 4 or 5 days. Later it was distributed. During the stay the subject drug was kept in proper storage conditions. When PW1 inspected their premises on 01-09-2008 he did not enquire about the storage conditions of the subject drug in their premises.

12. At the stage of Sec.313 Cr P C examination, statement of defence filed on behalf of A-1 and A-2 along with copy of drug manufacturing license, copy of purchase bills of Amoxycillin, Copy of Test report of Amoxycillin, copy of purchase bill of Clavulanate Potassium, Copy of Test report of Clavulanate Potassium, batch manufacturing record of product Lincla kid tablets pertaining to Perrinial Medicare.

13. During course of arguments, learned counsel for A-1 and A-2 submitted besides their written arguments interalia that the Drugs Inspector -PW1 does not have no proof or Gazette publication regarding the appointment or jurisdiction for the local area of Chittoor at the relevant time as per Sec.32 of Drugs and Cosmetics Act. No prosecution shall be instituted except by an Inspector defined as per Section 3(d)(ii) of the Act. As per Sectio. 21 (1) of the Act Central Government or State Government may by

notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned them by the Central Government or the State Government as the case may be. As per Sec.22 of the Drugs and Cosmetics Act, subject to the provisions of Section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed (a) Inspect; (b) take samples of any drug or cosmetics etc.” Therefore, the powers of Inspectors are assigned as per Section 22 within the local limits of the area for which he is appointed. Hence it shows that it is imperative upon the Drugs Inspector to prove that he was appointed as a Drugs Inspector for a particular area. In this regard, PW1 failed to furnish any documents except Ex.P-1 which is gazette notification issued for the entire state of A.P which does not specify any local area. Therefore as contemplated U/Sec.21(1) of Drugs and Cosmetics Act, 1940, Drugs Inspector failed to prove that he was appointed to local area of Chittoor to inspect the premises of A-6. Therefore, in the absence of any proof, he has not competent to inspect.

14. Per contra, on behalf of the prosecution written arguments filed by the Drugs Inspector and contended with regard to the competency of PW1 as Drugs Inspector over the local area of Chittoor at the relevant time. It is submitted that the notification of appointment of PW1 under Ex.P-1 which clearly reads “Appointment of Drugs Inspector for the entire state in G.O.Ms.No.103, Medical and Health,dt.06-02-1986”. It shows that for the entire state of A.P, PW1 was appointed as Drugs Inspector and the Chittoor is part and parcel of A.P.State. Hence appointment of PW1 is valid and notification of the appointment as per Section 21 of the Drugs and Cosmetics Act. Thus he got jurisdiction over the entire state of AP and also authorised to launch prosecution U/Sec.32 of the act and referred to a decision of Hon`ble High Court in a case between *Public Prosecutor Vs Hatam Bhai and Others* in their written arguments but the copy of Judgment has not been furnished to this court.

15. In this context it is apt to refer to the decision of Hon'ble High Court of A.P., in case between *M/s Gaba Pharmaceuticals, Rep., by its*

*Proprietor, Mr.Raju Gaba & Other Vs State of A.P., Rep., by Drug Inspector, Hyderabad, wherein His Lordship dealt with the relevant provisions Sec.20 and 21 of Drugs and Cosmetics Act relating Government Analyst and appointment of Drug Inspectors respectively and finally it was held that for the purpose of carryout the objects in the Drugs and Cosmetics Act, the Government has to issue a notification duly notifying the area under which the Inspector can discharge his duties.*

16. The learned defence counsel rightly contended that the Drug Inspector PW-1 has not been appointed for the local area of sample drug which said to have lifted by him. The provisions relating the powers of Inspector dealt U/sec.22 of Drugs and Cosmetics Act.

17. According to Sec.22 State Government has to issue notification allocating local limits of area to Drug Inspector for which area he/she is appointed.

18. Sec.21 deals with appointment of Inspector as per which, the state government may by notification in the official gazette appoint such person as it things fit, having the prescribed qualifications, to be inspectors for such areas as may be assigned to them by the Central Government or the case may be. So, in view of the provisions of Sec.21 and 22 of the Act the drug Inspector is not only required of gazette notification showing his appointment over the entire state and also he has to produce the notification of the order under which the local area ie., Chittoor. But except Ex.P-1 there is no orders or notification produced before this court to show his appointment over the said area, but it does not constitute as notification or orders issued by State Government. So, it can be said that the Drug Inspector PW-1 has failed to show that he was empowered U/sec.22 of the Act to lift the samples. In this regard it is apposite to refer the recent decision of our Hon'ble High Court of Judicature, Telangana and Andhra Pradesh at Hyderabad in case between *Johnson and Johnson Ltd., Himachala Pradesh and another Vs State of Andhra Pradesh and another reported in 2015(2)ALD(Crl) Page No.457 wherein his lordship dealt with same aspect by referring all the relevant provisions U/sec.21, 22 of Drugs and Cosmetics Act.*

19. In view of the observations made in the said decision, it is clear that not only the appointment made U/Sec.21 of the Drugs and Cosmetics Act and also a separate notification is required for the Drugs Inspector that he was appointed within local area limits of the area for which he is appointed for inspection or to take samples of any Drug or Cosmetics etc., as laid down U/Sec.22 of the Drugs and Cosmetics Act, 1948. So the Drugs Inspector-PW1 cannot get any right through Ex.P-1, Gazette notification, unless it is coupled with notification U/Sec.22 of the Act.

20. The another important contention on behalf of the accused is that the subject drug must be stored in proper storage condition, otherwise, it will fail in analysis. In this regard, learned counsel for accused vehemently argued that the subject drug is to be stored in proper storage condition i.e., it shall be kept in cool dark place protect from light, failing which the subject drug will fail in respect of its description. In support of his contention, in this case he placed the documents of managing of manufacturing record of the subject drug and drawn the attention of this court to the package of subject drug Lincla-kid tablets containing the instructions of storage which leads storage in cool, dry place protected from direct light. It is further contended that the subject drug contain ingredient of Clavunate Potassium is highly sensitive to temperature, humidity and light. In this regard, learned counsel for accused also elaborated that the cool means any temperature between 8 C 15 C and dry place denotes a place that does not exceed 40% average relative humidity as per the General notices clauses 10.30.30 and 10.30.100 on Page 12 of the US Pharmacopoeia, National Formulary and the copy has also been furnished to this court, at the time of examination of accused U/Sec.313 Cr PC.

21. It is further submitted that the above said storage conditions are not maintained as per label and that the Clavulanate potassium may have lost its potency. In this regard, learned counsel for the accused referred to information elicited from PW1 where PW1 admitted that the subject drug should be stored in proper storage conditions from the date of despatch from the manufacture till the date of analysis and if the drug is not properly stored as stated above, there is possibility of failure of drug in ASSAY Test.

22. In this regard, it is further submitted that once the drug delivered

or despatched from the premises of the manufacturer, he is not responsible with regard to the storage conditions. If the Drug Inspector proves that at all places where the drug was stored, it was stored in proper storage conditions but the drug was failed in quality/Assay test, then the manufacturer will be liable for the same.

23. It is further submitted that the subject drug was in the custody of A-3 for 2 days and in the custody of A-4 and A-4 for 15 days and in the custody of A-6 and A-7 for a period of 4 months and in the custody of Government Analyst for a period of 4 months 20 days i.e., from 04-02-2008 to 23-07-2008. In this regard, PW1 stated that he is not aware of the stored conditions of all these premises. So if the drug is not stored from 22-09-2007, date of sale by A-1 to A-3 till 23-07-2008 to analyze in proper stored conditions, there is every possibility for failure of the drug, if the drug is not stored in storage conditions.

24. As counter arguments on the aspect of storage conditions of the subject drug it is contended by the drug Inspector that the subject drug is combination of Amoxicillin Trihydrate with Clavulanate Potassium and in the form of Dispersible tablets which are not indicated to be stored under any sort of special storage conditions as per Schedule P of the Act. Clavulanate Potassium or Clavulanic Acid name is not at all found in the list of Schedule P whereas Amoxicillin Trihydrate was included at Sl.No.8,9 and 10 of category of Antibiotics in schedule P however, Sl.No.9 & 10 are concerned with capsules and dry syrup while Sl.No.8 related to plain bulk drug. Hence the law does not prescribe any special storage conditions for the subject drug.

25. Although there may not be mentioned in Schedule P of the Act intimating the subject drug requiring special storage conditions but PW1 being the Assistant Director, Drug Control Department, he himself stated that the subject drug should be stored in proper storage conditions, otherwise there is possibility for failure of drug in ASSAY test. He did not refer about the schedule P at the juncture of cross examination in this regard. When PW1 being the Drug Inspector at the relevant time who lifted the subject drug he himself stating that it must be stored in proper storage conditions certainly it has to be taken in to consideration.

26. As regards to complexity of each accused for the alleged offences, A-1 is the managing firm of the subject drug, A-2 is representative of A-1 firm, A-3 is the Firm who purchased the subject drug from A-1 and A-2. A-5 is the partner and representative of A-4 firm. A-7 is the representative of A-6 Firm. A-3 to A-6 are dealers, distributres and retailers of the subject drug. So as per Sec.19(3) of the Drugs and Cosmetics Act they are protected since they are not being the manufacturer of the drug and they acquired the drug from duly licensed manufacturer A-1 and A-2 and there is no evidence that they could know with reasonable diligence that the subject drug in any way contravened the provisions of the Act. Moreover PW1 himsself categorically asserted that he has not enquired with regard to the storage conditions of the subject drug in their possession and he has not inspected the premises of A-3, A-4 and A-6. Hence it can be deemed that they preserved the subject drug in a proper storage conditions.

27. In view of these circumstances, A-3 to A-7 are protected U/Sec.19(3) of the Act, here it is relevant to note that the subject drug, admittedly remained at the Government lab for a period of 4 months 20 days ie., from 04-02-2008 to 23-07-2008. In this regard, there is no proper explanation offered on behalf of the prosecution why the analyst has taken so much of time for conducting analysis. Moreover, PW1 also pleads ignorance about the storage conditions of the subject drug at the Government Analyst Lab. Hence it cannot be ruled out the plea of the accused that there is every possibility at the Government Analyst lab, the drug cannot be stored in a proper storage conditions, consequently it effects on the analysis.

28. Above all the Drug Inspector- PW1 has failed to prove his competency over the local area of Chittoor to inspect the premises of A-6 firm and lift the samples. Hence culminating all these circumstances, resulting into extending the benefit of doubt to the accused.

29. In view of the above observation it can be said that the complainant has failed to prove the guilt of accused beyond reasonable doubt. Hence the accused A-1 to A-7 are entitled for acquittal.

In the result, A-1 to A-7 are found not guilty for the offences U/Sec.18(a)(i) punishable U/Sec.27(d) of Drugs and Cosmetics Act and they



are acquitted of the same U/Sec.255(1) Cr P C. Bail bond of accused, if any, shall stand cancelled after six months from the date of this Judgment.

MO1 – Sample Portion of Subject Drug Viz., Lincla-Kid, Amoxicillin Trihydrate with Calcium Potassium Dispersible Tablets, Mfg. B.No.PM-073, Mfg. Date Sep. 2007, Exp. Date 2/09, is ordered to be destroyed after expiry of appeal time.

Dictated to the Personal-Assistant, after his transcription, corrected pronounced by me in Open Court on this the **18<sup>th</sup> day of December, 2015.**

Sd/- Ch. Yugandhar,  
IV ADDL.JUDL.MAGISTRATE OF I CLASS,  
CHITTOOR.

**APPENDIX OF EVIDENCE**  
**WITNESS EXAMINED FOR**

**COMPLAINANT**

**DEFENCE**

PW1 :	Y.V.V. Sathyanarayana.	NIL
PW2 :	P. Hemasundara Rao.	

**EXHIBITS MARKED ON BEHALF OF**

**COMPLAINANT :**

- Ex.P-1 : Copy of Gazette notification showing the appointment of PW1 as a Drug Inspector over the entire state of Andhra Pradesh.
- Ex.P-2 : Form No.17.
- Ex.P-3 : Acknowledgment of Ex.P-2.
- Ex.P-4 : Cash Bill vide No.C000794 for Rs.2521/-.
- Ex.P-5 : Form No.18.
- Ex.P-6 : Covering Letter.
- Ex.P-7: Postal acknowledgment receipts (2 in numbers)
- Ex.P-8 : Government Analyst Report.
- Ex.P-9: Covering letter of Ex.P-8.
- Ex.P-10: Covering letter showing service of copy of Ex.P-8.
- Ex.P-11: Acknowledgment of A-7 showing receipt of copy of Ex.P-8.
- Ex.P-12: Covering letter including purchase bills (5 pages).
- Ex.P-13: Copy of Drug license of A-6.
- Ex.P-14: Covering letter of Analyst report sent to A-1.
- Ex.P-15: Acknowledgment of A-1.
- Ex.P-16: Covering letter along with purchase bills and sale details (4 pages).
- Ex.P-17: Copy of Drug license of M/s Hall Mark Chemicals.
- Ex.P-18: Details of Sale and recall particulars (21 pages)
- Ex.P-19: Statement (21 pages) corresponding to Ex.P-18.
- Ex.P-20: Letter,dt.02-09-2008 addressed to M/s Sudhakar and company, Himachal Pradesh along with copy of Analytical report-Ex.P-8.

- Ex.P-21: Reminder,dt.01-05-2010.  
Ex.P-22: Reply,dt.19-05-2010 given b y M/s Sudhakar and company  
(7 pages)  
Ex.P-23: Letter,dt.20-05-2010 addressed to R.K.Chowdary, Assistant  
Drug Controller,Himachal Pradesh requesting for constitution  
particulars.  
Ex.P-24: Letter,dt.22-05-2010 addressed to A-1 Firm.  
Ex.P-25: Letter,dt.03-06-2010 addressed to Drug Inspector, Sirumour  
District, Himachal Pradesh State.  
Ex.P-26: Reply,dt.14-07-2010 from Assistant Drug Controller, Himachal  
Pradesh giving details of A-1 firm (5 pages).  
Ex.P-27: Circular,dt.19-09-2008, CIR.RC.No.035/Peshi/97-12.

**DEFENCE :**

NIL

Material Objects marked

Sd/- Ch. Yugandhar,  
IV AJFCM CHITTOOR.

// true copy //

IV Addl. Judl. Magistrate of I Class,  
Chittoor.

IN THE COURT OF THE IV ADDL. JUDL. MAGISTRATE OF I CLASS, CHITTOOR  
CALENDER IN C.C.No. 527/2010

Date of offence	: Prior to 31-01-2008		
Date of complaint	: 30-07-2010		
Date of apprehension of accused	: 01-11-2012		
Date of taken on file	: 22-12-2010		
Date of commencement of trial	: 26-02-2015		
Date of close of trial	: 09-12-2015		
Date of Sentence or Order	: 18-12-2015		
Complainant	: The Drugs Inspector, Chittoor.		
Name of the accused	Father's Name	Age	
A-1, M/s Perennial Medicare,	-	-	
A-2 Vinod Gupta,	S/o S.H. Beni Prasad Gupta,	66 years	
A-3, M/s Sudhakar and Company, Amrut House, Rajgarh Road, Shamthi Solan (H.P), represented by its Proprietor, Sudhakar Kanna, 60 years	-	-	
A-4, M/s Hall Mark Chemicals, D.No.27-III/078, Upstairs, Ram Nagar, Nellore, represented by its Partner P. Vijaya Sarathy, age 32 years	-	-	
A-5, P.Vijaya Sarathy, age 32 years, Partner D.No.27-III/078, Upstairs, Ram Nagar, Nellore,	-	32 years	
A-6, M/s Anjanadri Medical agencies, D.No.17/210, Kummara Street, Chittoor represented by its Partner, P. Ramesh Reddy, age 25 years	-	-	
A-7, P. Ramesh Reddy	-	25 years	
Village	Mandal	Religion	Calling
A-1, Shamthi Solan, (H.P) represented by his partner Vinod Gupta, S/o S.H. Beni Prasad Gupta, age 66 years	-	-	Firm
A-2 representing M/s Perennial Medicare,	Shamthi Solan, (H.P)	-	Partner
A-3, Amrut House, Rajgarh Road, Shamthi Solan (H.P),	-	-	Firm

A-4, D.No.27-III/078, Upstairs, Ram Nagar, Nellore, represented by its Partner P. Vijaya Sarathy, age 32 years	-	-	Firm
A-5, D.No.27-III/078, Upstairs, Ram Nagar, Nellore,	-	-	Partner
A-6, D.No.17/210, Kummara Street, Chittoor	-	-	Firm
A-7, D.No.17/210, Kummara Street, Chittoor	-	-	Partner
Section of law	U/Sec.18(a)(i) punishable U/Sec.27(d) of Drugs and Cosmetics Act		
Nature of offence	Manufacturing, selling/distribution of not of standard quality subject drug		
Finding of the Court	Found not guilty		
Sentence or order	<p>In the result, A-1 to A-7 are found not guilty for the offences U/Sec.18(a)(i) punishable U/Sec.27(d) of Drugs and Cosmetics Act and they are acquitted of the same U/Sec.255(1) Cr P C. Bail bond of accused, if any, shall stands cancelled after six months from the date of this Judgment.</p> <p>MO1 – Sample Portion of Subject Drug Viz., Lincla-Kid, Amoxycillin Trihydrate with Calvunate Potassium Dispersible Tablets, Mfg. B.No.PM-073, Mfg. Date Sep. 2007, Exp. Date 2/09, is ordered to be destroyed after expiry of appeal time.</p>		

IV ADDL.JUDL.MAGISTRATE OF I CLASS, CHITTOOR.