

**“METHOD OF INVESTIGATION OF  
NSQ AND SPURIOUS DRUGS”**

**AT NIHFV, DELHI**

**16<sup>TH</sup> FEB 2023**

**K. R. Chawla**

**Controlling Authority/Deputy Drugs Controller/  
Head of the Office**

**Drugs Control Department**

**Govt. of N.C.T. of Delhi**

**91-9811262327**

# SCHEME OF PRESENTATION

- Definitions
- Method of Investigation
- Case Laws
- Case Studies
  - Involving original manufacturer
  - Involving others



# Drug

Under section 3 (b) of “**Drugs and Cosmetics Act, 1940** ” drugs are defined as -

- all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
- such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;



# Drug

- (iii) all substances intended for use as components of a drug including **empty gelatin capsules**;
- (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.



# Cosmetic

Under **section 3 (aaa) of “Drugs and Cosmetic Act, 1940 ”** Cosmetics are defined as -

“cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic



**WHY IT IS IMPORTANT TO KNOW  
SCOPE OF ABOVE DEFINITIONS**



# DEFINITIONS

- **Misbranded drugs ----- Sec 9 & 17**
- **Adulterated drugs ----- Sec 9A & 17A**
- **Spurious drugs ----- Sec 9B & 17B**
- **Standards of quality ----- Sec 8 (1)(a) & 16 (1)(a)**
- **Misbranded Cosmetics ----- Sec 9C & 17C**
- **Adulterated Cosmetics ----- 17E**
- **Spurious Cosmetics ----- Sec 9D & 17D**
- **Standards of quality ----- Sec 8 (1)(b) & 16 (1)(b)**



# Not of Standard Quality (NSQ) Drugs/Cosmetics

Drugs not complying the requirements of **Section 8 of Chapter III & Section 16 of Chapter IV of Drugs & Cosmetics Act, 1940** are referred as **Not of Standard Quality (NSQ) Drugs/Cosmetics**.

- Manufactured under different name
- Imitation of other drug
- Lack of identity
- Fictitious manufacturer
- Substituted by another drug or substance

- Coloured, coated, powdered or polished to conceal damage
- Not properly labelled
- False claim

Misbranded

Not of Standards Quality

Spurious

Adulterated

- Contains filthy, putrid or decomposed substance
- Insanitary conditions
- Contents injurious to health
- Colour other than prescribed
- Mixed with substance to reduce quality or strength



# Misbranded Drugs

As per Section 17 of Drugs and Cosmetics Act, 1940, a drug shall be deemed to be misbranded:

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

*\*17 (b) – Drugs which does not comply the Labeling requirements given in Drug Rules, 1945 (Rule 96 to Rule 104)*

*\*17 (c) - Drugs which does not comply the Rule 106 of Drug Rules, 1945.*



# Adulterated Drugs

As per Section 17 A of Drugs and Cosmetics Act, 1940, a drug shall be deemed to be adulterated:

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for the purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

# Spurious drugs

As per Section **17B of Drugs and Cosmetics Act, 1940**, a drug shall be deemed to be spurious,—

- (a) if it is manufactured under a name which belongs to another drug; or
- (b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or
- (c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug , which individual or company is fictitious or does not exist; or
- (d) if it has been substituted wholly or in part by another drug or substance; or
- (e) if it purports to be the product of a manufacturer of whom it is not truly a product.



# POINTS OF INVESTIGATION

- Whether any complaint ?
- Check the elements of complaint.
- Decide about the points to be investigated.
- Contravention likely to be observed.
- Documents to be collected to prove the contraventions .
- Statement of the accused to be taken voluntarily.



## DOCUMENTS TO BE COLLECTED WHERE THE INVESTIGATION IS LIKELY TO RESULT IN PROSECUTION

- Person in charge and responsible for the conduct of business.(Section 34)
- ID proof.
- Proof of ownership / possession (house tax receipt, electricity bill, water charges bill, property papers etc)
- If rented , rent receipt , rent agreement etc.
- Constitution of the firm.
- Statement of the accused / person involved.
- Statement of landlord.
- Spot Memo duly signed by accused and witness.



# ELEMENTS OF SPOT MEMO

- Time of beginning, Time of completion
- Purpose of visit
- Layout plan of site/ site map indicating landmarks.
- Personal Search offer
- Public witness.
- Item wise Details of drugs/cosmetics/documents seized if any.



## ELEMENTS OF SPOT MEMO-CONT

- Reference of sampled drugs.
- Reference of specimen samples taken.
- Details of proceedings
- Reference to any disclosure sought u/s 18A/18B/22CCA etc.
- Contravention made out.
- Signature of IO, witnesses and accused.
- Acknowledgement of spot memo by the accused.



## FURTHER INVESTIGATIONS

- a) On receipt of report of govt analyst.
- b) Disposal of sample and test reports as per prescribed procedure.

### CASE Laws

- ❑ Amery Pharmaceuticals v/s State of Rajasthan, SC (2001)
- ❑ Medicament Biotech v/s Rubina bose; SC (2008)
- ❑ Laborate Pharmaceuticals India Ltd v/s State of Tamilnadu; SC (2017)
- ❑ Varun Kapoor and Others v/s DI, Amritsar Punjab and Haryana High Court (2023)





# CASE STUDY

## CASE- I , III & IV

When the Drug under reference is not manufactured by its original manufacturer.

## CASE- II

When the Drug is manufactured by original manufacturer.



# CASE STUDY- I



## Chymoral Forte Tablets

(Trypsin-Chymotrypsin Tablets)

Manufactured by

M/s Elder Pharmaceuticals, Navi Mumbai.



# SEQUENCE OF EVENTS



- Complaint received from the Delhi office of manufacturer M/s Elder Pharmaceuticals Ltd., Navi Mumbai
- Some Chemist shops were named in the complaint who were allegedly dealing in spurious Chymoral forte tabs.....  
Also enclosed bill of chemist.
- Chymoral forte tablet is an enzymatic product containing Trypsin- Chymotrypsin.



# SEQUENCE OF EVENTS

CONTD. ....

- Premises of chemist/ retailer raided alongwith company's representatives  
(Team of two DI's deputed)
- Despite best efforts drugs could not be recovered initially
- Reported to office about no recovery.
- Took sample of other drugs stocked in the premises.



# SEQUENCE OF EVENTS

CONTD. ....

- Suddenly one black pouch was detected in a drawer which on opening was found containing:
  - ✓ 3x1x20 tablets of Chymoral Forte.  
(Total 60 Tabs.)
  - ✓ 4x1x10 tablets – drawn as Sample u/s S-23  
(Total 40 Tablets)
  - ✓ 1x20 Tablets – Specimen sample U/s 22(1)(d)
- Spot memo prepared, witness and accused signed.



# SPECIMAN SAMPLE



# SEQUENCE OF EVENTS

CONTD. ....

- Statement taken
- Specimen sample sealed and signed.
- No Purchase bill was produced on demand
- Memo U/s 18A & Rule 65(6) issued
- Sample forwarded to GA, CIPL, Ghaziabad.



# SEQUENCE OF EVENTS

CONTD. ....

**Declared NSQ  
&  
Spurious by  
the Government Analyst**





# SEQUENCE OF EVENTS

CONTD. ....

- Enquiry made from the Delhi office of Manufacturer
- Preliminary study pointed out the drug to be spurious.
- Directed to make final enquiry at Manufacturer's level at Navi Mumbai.
- Spot memo after confronting the spurious sample
- Statement



## ENQUIRY AT MANUFACTURER LEVEL

- Joined local DI from FDA Maharashtra.
- On enquiry with Mfr., QA manager: Ms. Usha T Narker was deputed.
- Confronted the spurious sample collected for drug verification.....
- Took out 3 tablets.... Physical Comparison  
Chemical Comparison  
(Manner of taking tablets out of strip is important)



# SPECIMAN SAMPLE



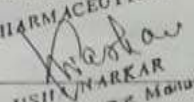
ANNEXURE

OBSERVATIONS

DATE : 03-04-2000

A. Differences in Packaging Material :

MATERIAL	CONTROL SAMPLE B.NO.82407	SAMPLE SHOWN BY DRUG INSPECTOR MR.K.R.CHAWLA B.NO.82407 (SPURIOUS)
1. <u>Outer Carton</u>		
a) Overprinting (Coding of batch No.)	Full stop after batch No.	Full stop after batch No. is missing.
b) Printing quality	Letter print is sharp	Not sharp but blurred.
2. <u>Strip</u>		
a) Overprinting		
i) Coding of batch No.	Full stop after batch No.	Full stop after batch No. is missing.
ii) Stereo size of batch No.	23 mm L x 2 mm H (upto full stop)	17 mm L x 1.5 mm H
iii) Composite stereo size.	25 mm L x 21 mm H	28 mm L x 23 mm H
3. <u>Test for PVDC</u>		
Outer surface of clear foil is tested with a drop of Pyridine and Methanolic KOH solution.	Gives positive test for PVDC (dark brown colouration is produced).	Does not give dark brown colouration. Hence clear foil is not PVDC.

For ELDER PHARMACEUTICALS LTD.  
  
 VISHAL MARKAR  
 Quality Assurance Manager



02


B. Differences in Tablets

TESTS	INHOUSE SPECIFICATION	CONTROL SAMPLE BATCH NO.82407	SAMPLE SHOWN BY DRUGS INSPECTOR MR. K.R. CHAWLA BATCH NO.82407 (SPURIOUS)
1. Shape	Deep biconvex	Deep biconvex	biconvex
2. Diameter	7.8 - 8.1 mm	7.93 mm	8.73 mm
3. Average Weight	290 - 310 mg	296 mg	334 mg
4. <u>Broken Tablets :</u>			
i) Colour of Core	-	Slightly yellowish	White
ii) Texture	-	Sticky	Non-sticky
iii) Smell/Odour	-	Characteristic Enzymatic smell	None
5. <u>Assay:</u>	NLT 90% of Labelled Amt.	97.67%	NIL

EMER PHARMACEUTICALS LTD.  
USHA MURKAR  
(Quality Assurance Manager)



## ENQUIRY AT MANUFACTURER LEVEL

- Letter/Statement collected.
  - Testing in front of Investigating team
  - Reported as spurious
  - Letter from manufacturer giving the points of differences.
  - Spot Memo prepared.
  - Collected back the unconsumed portion of the spurious sample
- 

# FILED COMPLAINT



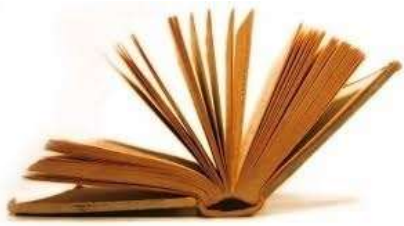


# COURT PROCEEDINGS

- Cognizance of offence
- Summoming of the accused
- Apperance of the accused/acceptence of Bail Bond
- Handing over the copies of the complaint
- Precharge evidence
  - Chief
  - Cross
- Two witnesses examined.....







# COURT PROCEEDINGS

CONTD.....

- Specimen Sample exhibited with details of investigation, documents and GA Reports.
- Framing of charges.
- Pleaded Guilty.
- Young age.
- Probation with one year community service.





## CASE STUDY - II

- ETHICON DIVISION (JOHNSON & JOHNSON)  
AURANGABAD
- SAMPLE OF A SUTURE (“**VICRYL’ Absorbable Surgical Suture U.S.P**”) COLLECTED FROM UNLICENSED PREMISES REPORTED AS NSQ BY GOVT. ANALYST
- THE ACCUSED COULD NOT PRODUCE PURCHASE BILL
- SPECIMEN SAMPLE ALSO TAKEN
- ON RECEIPT OF REPORT OF GA (**SAMPLE FAILED IN RESPECT OF DIAMETER**), MATTER REFERRED TO STATE DRUGS CONTROLLER
- REPORT OF GA CHALLENGED BY MANUFACTURER.



# CASE STUDY

CONTD.....

- CDL, KOLKATA ALSO DECLARED IT AS NSQ
- SPECIMEN SAMPLE SENT FOR VERIFICATION TO ORIGINAL MFR.
- MFR. CONFIRMED ITS GENUINNESS
- PROSECUTION LAUNCHED AGAINST THE ACCUSED NO. 1 (WITHOUT LICENSE/NSQ/18 A)
- PROSECUTION LAUNCHED AGAINST THE MFR. (NSQ)



# **CASE STUDY - III**

## **PAN D**

(Pantoprazole Enteric Coated 40 mg and Domperidone Sustained Release 30 mg Capsules)

**Labelled as Manufactured By –**

M/s ALKEM LABORATORIES LTD., Central Pendam Block, Dugailaka, Kumrek, Rangpo, East Sikkim-737132



## CONTD.


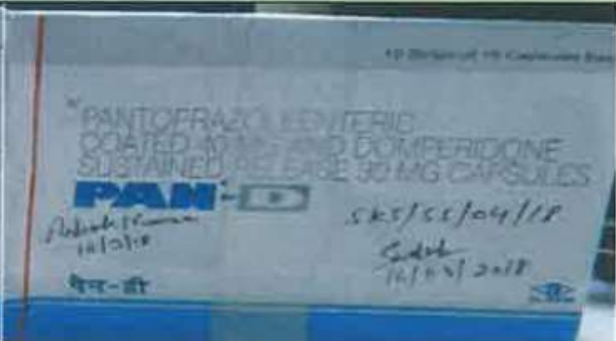
- On 16/03/2018, specimen sample were taken/ collected from accused from the unlicensed manufacturing premises situated Village Kirari, Delhi
- Further, to verify genuineness of the drugs from original manufacturing firm, M/s ALKEM LABORATORIES LTD. East Sikkim
- Portion of specimen sample handed over after resealing it
- Physical & Chemical comparison were carried out by QA Deptt.
- The remaining untested specimen sample resealed
- Other necessary documents collected, spot memo prepared



# PHYSICAL ANALYSIS REPORT

Sr. No.	Physical/ Chemical Test Evaluation	Observation		Remark
	Individual checked Parameter	Control Sample (Retain Sample)	Suspected Sample	
		B. No.- 7131914	B. No.- 7131914 (SKS/SS/04/18)	

## A. COMPARISON OF CARTON (SHOW BOX):

1.	Carton	<div style="display: flex; justify-content: space-around;">   </div>		Suspected Sample Does not Comply with Control Sample
2.	Stereo	7131914 JUN. 2017 MAY 2019 In <u>Control (Retained) sample</u> , <ul style="list-style-type: none"> <li>The <b>Exp.</b> is mentioned as <b>MAY 2019</b>.</li> <li>The mentioned stereo is printed in <b><u>DOTED</u></b> form.</li> </ul>	7131914 JUN. 2017 MAR. 2019 In <u>Market Complaint sample</u> , <ul style="list-style-type: none"> <li>The <b>Exp.</b> is mentioned as <b>MAR. 2019</b>.</li> <li>The mentioned stereo is <b><u>NOT</u></b> printed in DOTED.</li> </ul>	Suspected Sample Does not Comply with Control Sample

**CERTIFIED COPY**  
 UNCONTROLLED

3.

Label Claim

Each hard gelatin capsule contains:  
 Pantoprazole Sodium IP  
 equivalent to Pantoprazole.....40  
 mg  
 (As enteric-coated pellets)

Domperidone IP .....30  
 mg  
 (As sustained release pellets)  
 Excipients .....q.s.

Colour Indigo carmine, Sunset  
 Yellow FCF & Titanium dioxide IP  
 used in pellets

- **Used in pellets** - is mentioned in control sample.
- It is mentioned as Colour, in Control sample.
- Colon is NOT present after Colour.

Each hard gelatin capsule contains:  
 Pantoprazole Sodium IP  
 equivalent to Pantoprazole... 40 mg  
 (As enteric-coated pellets)  
 Domperidone IP..... 30 mg  
 (As sustained release pellets)  
 Excipients.....q.s.  
 Colour Indigo carmine, Sunset  
 yellow FCF & Titanium dioxide IP  
 used in pellets.

Each hard gelatin capsule contains:  
 Pantoprazole Sodium IP  
 equivalent to Pantoprazole.....40 mg  
 (as enteric coated pellets)

Domperidone IP .....30 mg  
 (as sustained release pellets)  
 Excipients .....q.s.







Colours: Indigo carmine, Sunset Yellow  
 & Titanium dioxide IP.

- **Used in pellets** - is NOT mentioned in market complaint sample.
- It is mentioned as colourS in market complaint sample, which is not matched with control sample.
- Colon is present after ColourS.

Each hard gelatin capsule contains:  
 Pantoprazole Sodium IP  
 equivalent to Pantoprazole ... 40 mg  
 (as enteric-coated pellets)  
 Domperidone IP ..... 30 mg  
 (as sustained release pellets)  
 Excipients.....q.s.  
 Colours: Indigo carmine, Sunset yellow  
 & Titanium dioxide IP.

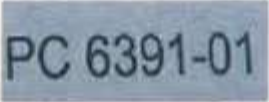

Suspected  
 Sample  
 Does not  
 Comply  
 with  
 Control  
 Sample



4.	Brand Name	<p>Hindi brand name of retained sample is <b>LIGHT</b> in color.</p> 	<p>Hindi brand name of suspected sample is <b>DARK</b> in color.</p> 	<p>Suspected Sample Does not Comply with Control Sample</p>
5.	Alkem Logo	<p>Alkem logo is in retained sample is-</p> <ul style="list-style-type: none"> <li>• Less Bold</li> </ul> 	<p>Alkem logo is in suspected sample is-</p> <ul style="list-style-type: none"> <li>• More Bold</li> </ul> 	<p>Suspected Sample Does not Comply with Control Sample</p>
6.	Generic Name	<p><b>PANTOPRAZOLE ENTERIC</b> COATED 40 MG AND DOMPERIDONE SUSTAINED RELEASE 30 MG CAPSULES</p> <p><b>CERTIFIED COPY</b></p> <ul style="list-style-type: none"> <li>• In retained Sample, there is space between PANTOPRAZOLE &amp; ENTERIC</li> </ul> 	<p><b>PANTOPRAZOLEENTERIC</b> COATED 40 MG AND DOMPERIDONE SUSTAINED RELEASE 30 MG CAPSULES</p> <p><b>UNCONTROLLED COPY</b></p> <ul style="list-style-type: none"> <li>• In suspected sample, there is <b>NO</b> space between PANTOPRAZOLE &amp; ENTERIC.</li> </ul> 	<p>Suspected Sample Does not Comply with Control Sample</p>









7.	Item Code	PC 6391-01 In retained Sample, the revision number of carton item code is <b>01</b>  	PC 6391 In suspected sample, the revision number of carton item code is <b>NOT PRESENT.</b>  	Suspected Sample Does not Comply with Control Sample
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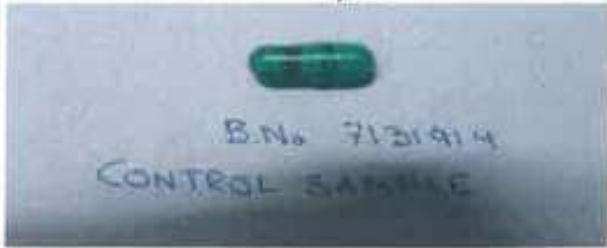

### B. COMPARISON OF STRIPS:

8.	Comparison of Stereo Impression on strip including batch number, mfg, exp, mrg and font size etc.	7131914 JUN. 2017 MAY 2019 170.00 <ul style="list-style-type: none"> <li>• There is NO DOT present after MAY</li> <li>• Font type</li> <li>• Ink Color</li> </ul> 	7131914 JUN. 2017 MAY.2019 170.00 <ul style="list-style-type: none"> <li>• There is DOT present after MAY</li> <li>• Font type doesn't match with retained sample.</li> <li>• Ink color is different from retained sample.</li> </ul> 	Suspected Sample Does not Comply with Control Sample
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9.	Mfg. Lic. No.	<p>M/450/07</p> <p>In retained Sample, <b>there is no gap</b> between DOT (.) and COLON (:)</p> <p>(:)</p> 	<p>M/450/07</p> <p>In suspected sample, <b>there is gap</b> between the DOT (.) and COLON (:)</p> 	Suspected Sample Does not Comply with Control Sample
10.	Item code of foil	<p>PF 6022-03</p> <p>In retained Sample, the revision number of foil's item code is <b>03</b></p> 	<p>PF 6022-02</p> <p>In suspected sample, the revision number of foil's item code is <b>02</b></p> 	Suspected Sample Does not Comply with Control Sample



## CHEMICAL ANALYSIS REPORT

S. No.	Test Description	Control Sample (Retain Sample)	Suspected Sample	Remark
		B. No.- 7131914	B. No.- 7131914 (SKS/SS/04/18)	
I.	Description of Capsule Shell	<p>In Retained Sample,</p> <ul style="list-style-type: none"> <li>Brand name PAN D is in <b><u>Brown</u></b> color printed on Capsule Shell.</li> <li><b><u>Color of Capsule</u></b> shell is light Green (Cap &amp; Body both) in Retained Sample.</li> </ul> 	<p>In suspected sample,</p> <ul style="list-style-type: none"> <li>Brand name PAN D is in <b><u>Bluish</u></b> color printed on Capsule Shell.</li> <li><b><u>Color of Capsule</u></b> shell is light Green (Cap &amp; Body both)</li> </ul> 	Suspected Sample Does not Comply with Control Sample in respect of colour for brand name.



<p>2.</p>	<p>Description of pellets</p>	<p>In Retained (Control) Sample, inside the capsule shell-</p> <ul style="list-style-type: none"> <li>• Pellets present are of <b><u>BLUE &amp; ORANGE</u></b> Color.</li> </ul>  <p>CONTROL SAMPLE PAN D B.N. 7131914</p>	<p>Among of three strips of Pan – D of batch number 7131914, out of them, <b>two strips having dark blue &amp; light orange</b> coloured pellets in capsule shell.</p>  <p>MARKET COMPLAINT SAMPLE</p> <p>Other one strip containing only <b>white</b> pellets in capsule shell.</p>  <p>Market Complaint</p>	<p>Suspected Sample Does not Comply with Control Sample</p>
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<p><b>Assay (% Label Claim)</b> ;</p> <p>Pantoprazole sodium IP equivalent to Pantoprazole: 40 mg/Capsule.  (as enteric-coated pellets)</p> <p>Domperidone IP : 30 mg/Capsule  (as sustained release pellets )</p>	<p>Not less than 36.0 mg/capsule and not more than 44.0 mg/capsule of Pantoprazole (C<sub>16</sub>H<sub>15</sub>F<sub>2</sub>N<sub>3</sub>O<sub>4</sub>S).</p> <p>Not less than 90.0 % and not more than 110.0 % of labeled amount of Pantoprazole (C<sub>16</sub>H<sub>15</sub>F<sub>2</sub>N<sub>3</sub>O<sub>4</sub>S).</p> <p>Not less than 27.0 mg/capsule and not more than 33.0 mg/capsule of Domperidone (C<sub>22</sub>H<sub>24</sub>ClN<sub>5</sub>O<sub>2</sub>).</p> <p>Not less than 90.0 % and not more than 110.0% of labeled amount of Domperidone (C<sub>22</sub>H<sub>24</sub>ClN<sub>5</sub>O<sub>2</sub>).</p>	<p>39.16 mg/capsule</p> <p>97.9 %</p> <p>29.82 mg/capsule</p> <p>99.4 %</p>	<p>22.08 mg/capsule <b>(DOES NOT COMPLY)</b></p> <p>55.2 % <b>(DOES NOT COMPLY)</b></p> <p>14.4 mg/capsule <b>(DOES NOT COMPLY)</b></p> <p>48.0 % <b>(DOES NOT COMPLY)</b></p>
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## Conclusion

After complete analysis it is concluded and confirmed that sample handed over by Drugs Inspector [REDACTED] does not belong to our company i.e. not manufactured by Alkem Laboratories Limited (Central Pendam Block, Kumrek, Rangpo, East Sikkim-737132) and thus the suspected drug is Spurious.



SPURIOUS



ORIGINAL





# **CASE STUDY- IV**



**Pantoprazole tablets IP  
(Pantocid Tablets)**

**&**

**Enteric coated Pantoprazole Sodium  
and sustained Release Domperidone  
Capsules  
(Pantocid DSR capsules)**

**Labelled as Manufactured By –**

M/s Sun Pharma Laboratories Ltd. Plot No. 107-108,  
Namli Block. P.O. Ranipool, East Sikkim - 737135.



# SEQUENCE OF EVENTS



- ❑ That on 06.07.2017, the Premises of chemist/ Wholesaler raided During Special Inspection Programme.
- ❑ The Firm was found stocking for sale and distribution of various drugs. On demand, firm failed to produce the purchase records of the few drugs found stocked in his premises on the spot at the time of inspection.
- ❑ Legal & Specimen samples of 03 drugs were taken to verify its genuineness from their original manufacturer.

# SEQUENCE OF EVENTS

CONTD. ....

- ❑ Statement taken
- ❑ Legal & Specimen sample sealed and signed.
- ❑ No Purchase bill on demand was produced
- ❑ Memo U/s 18A & Rule 65(6) issued
- ❑ Sample forwarded to GA, RDTL, Chandigarh



# SEQUENCE OF EVENTS

CONTD. ....

**Declared Spurious by  
Original Manufacturer under  
Section 17B (e)**



## ENQUIRY AT MANUFACTURER LEVEL

- ❑ **Joined local DI from FDA, Govt of Sikkim.**
- ❑ **On enquiry with Mfr., QA manager: Sh. Prakash Singh, Deputy General Manager was deputed.**
- ❑ **Confronted the spurious sample collected for drug verification.....**
- ❑ **Took out 06 Capsules & 05 tablets....**

**Physical Comparison**

**Chemical Comparison**

**(Manner of taking Capsules/tablets out of strip is important)**



**Product Details**

Name of Product : Pantocid  
 Batch No : EMR1051  
 Mfg. Date : 09/2016  
 Exp. Date : 08/2019  
 MRP : Rs.125.00 per 15 Tablets

Sr. No.	Test	Suspected Sample	Retain Sample	Specification	Remark
		Batch No.	Batch No.		
		EMR1051	EMR1051		
1	Description	A light Yellow coloured circular biconvex double radius <b>seems to be film-coated tablet</b> having plain on both sides ( <b>No brightness in surface of coated layer</b> )	A Yellow coloured circular biconvex double radius enteric coated tablet having plain on both sides (Brightness is observed in surface of coated layer)	A yellow coloured circular biconvex double radius enteric coated tablet having plain on both sides.	<b>Does not comply</b>
2	Average Weight (mg)	256.15	223.02	222.0 mg ± 7.5% (205.4 mg to 238.7 mg)	<b>Does not comply</b>
3	Assay of Pantoprazole (By HPLC)	28.6% mg/units=11.44	97.7 % mg/units= 39.08	NLT 90.0% and NMT 110.0% of labelled amount of Pantoprazole	<b>Does not comply</b>

**Conclusion:** Test for Description, Average weight & Assay has been carried out for the suspected sample and does not comply with the our specification limits.

Prepared by	Checked by	Approved by
 23/Aug/2017 (Sign/Date)	 23/Aug/2017 (Sign/Date)	 23/Aug/2017 (Sign/Date)



Suspected Sample  
(DELHI)



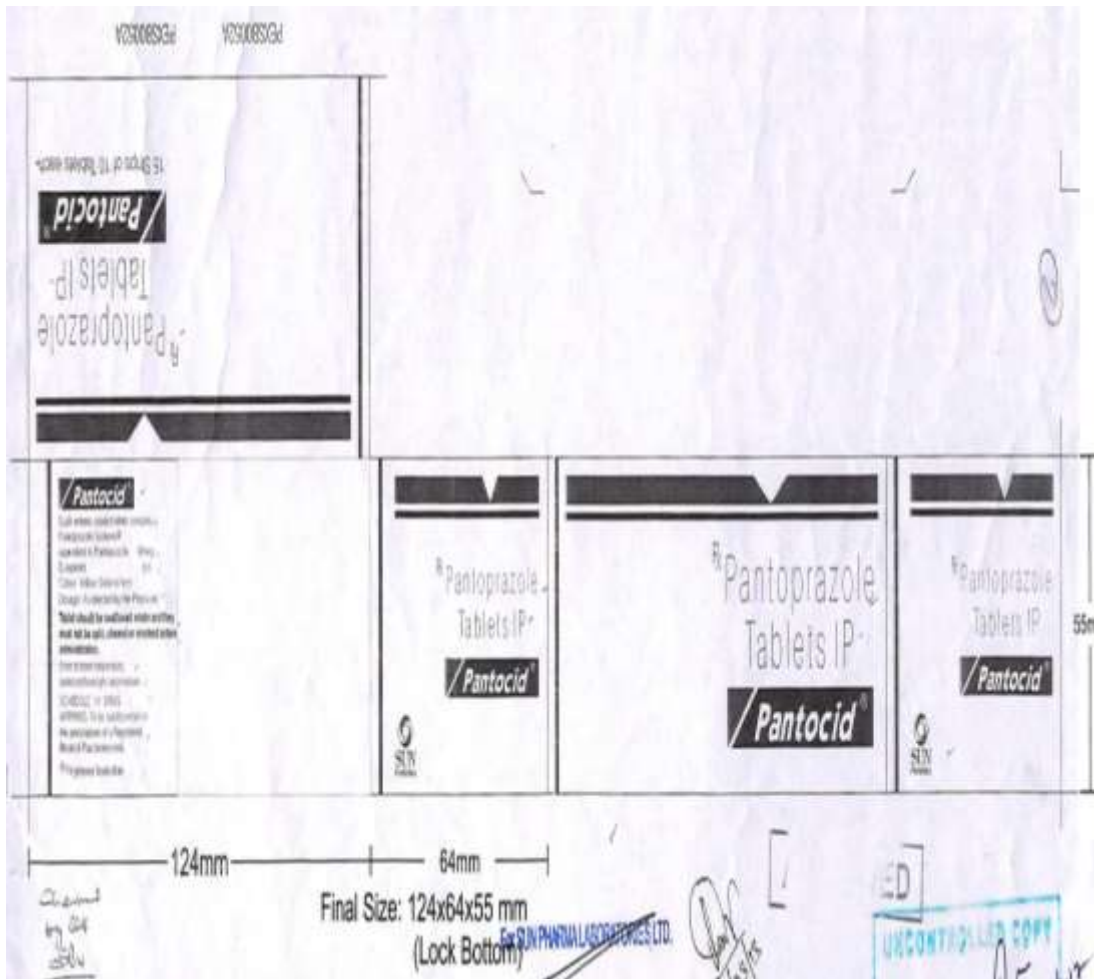
Original.  
SUN PHARMA.



Physical Parameters Checked		Observations		Remark
		Suspected Samples	Retain Sample	
Sr. No.	Batch No.	EMR1051	EMR1051	
1.	Item Code of printed foil	PEMPF0249	PEMPF0249	Item code is same.
2.	Generic Name	Pantoprazole tablets IP	Pantoprazole tablets IP	Generic name is same.
3.	Brand Name	Pantocid®	Pantocid®	Brand name is same.
4.	Label claim on blisters	Each enteric coated tablet contains: Pantoprazole Sodium IP equivalent to Pantoprazole 40 mg Excipients q.s. Colours: Ferric oxide (Yellow) USP-NF, Titanium Dioxide IP	Each enteric coated tablet contains: Pantoprazole Sodium IP equivalent to Pantoprazole 40 mg Excipients q.s. Colours: Ferric oxide (Yellow) USP-NF, Titanium Dioxide IP	Label claim is same.
5.	Colour of Printed matter on blisters	Blue	Blue	Colour of printed matter on blister is same.
6.	Overprinting dimensions on blisters	34 X 8 mm	33.5 X 7.5 mm	Overprinting dimensions are not same.
7.	Red Line width	1.0 mm	1.0 mm	Red Line width is matching with retain sample.
8.	Units per blister	15	15	Same units per blister.

Physical Parameters Checked		Observations		Remark
		Suspected Samples	Retain Sample	
Sr. No.	Batch No.	EMR1051	EMR1051	
1.	Item Code of printed foil	PEMPF0249	PEMPF0249	Item code is same.
9.	Blister Size (Length)	100mm	99 mm	Blister Length is not same.
10.	Blister Size (Width)	60 mm	60 mm	Blister width is same.
11.	Pocket Size (Diameter)	15 mm	16 mm	Pocket size is not same.
12.	Sealing	Sealing found satisfactory.	Sealing found satisfactory.	Sealing is satisfactory.
13.	Pre-printed text Matter	Colour of the text matter is darker	Colour of the text matter is lighter	Text matter mismatches
		'®' symbol is smaller	'®' symbol is larger	
		All text matter are in dark colour.	All text matter are in light colour.	





Back side over coding with M.L No. , company name & address as per below (M.L No. , company name & address as per location)

M.L:  
S.No: MPPR  
MFG: PER 10 TABLETS  
EXP: INCL. OF ALL TAXES



Sr. No.	Test	Suspected Sample	Retain Sample	Specification	Remark
		Batch No.	Batch No.		
		EMR1528	EMR1528		
1	Description	Hard gelatin capsule size 2 with bluish light green cap and bluish light green body filled with mixture of dark blue and dark orange coloured spherical pellets.	Hard gelatin capsule size 1 with bluish light green cap and bluish light green body filled with mixture of blue and orange coloured spherical pellets.	Hard gelatin capsule size 1 with bluish light green cap and bluish light green body filled with mixture of blue and orange coloured spherical pellets.	Does not comply
2	Identification	The retention time of the pantoprazole and domperidone peaks in the chromatogram of the test preparation corresponds to that of the respective peaks with standard preparation as obtained in the assay	The retention time of the pantoprazole and domperidone peaks in the chromatogram of the test preparation corresponds to that of the respective peaks with standard preparation as obtained in the assay	The retention time of the pantoprazole and domperidone peaks in the chromatogram of the test preparation corresponds to that of the respective peaks with standard preparation as obtained in the assay	Complies
3	Average Fill Weight(mg)	255.49	309.23	Standard Fill weight 313.40 mg $\pm$ 7.5% (289.89 to 336.90)	Does not comply



Suspected Sample  
(DELHI)


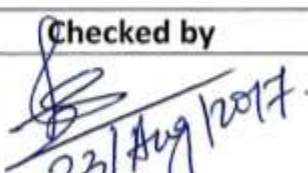
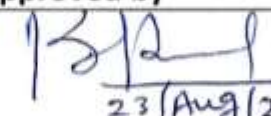


Original.  
SUN PHARMA.



Sr. No.	Test	Suspected Sample	Retain Sample	Specification	Remark
		Batch No.	Batch No.		
		EMR1528	EMR1528		
4	Assay of Pantoprazole	69.1 %	93.5 %	NLT 90.0% and NMT 110.0% of labelled amount of Pantoprazole	Does not comply
5	Assay of Domperidone	70.7%	99.1 %	NLT 90.0% and NMT 110.0% of labelled amount of Domperidone	Does not comply

**Conclusion:** Tests for Description, Average Fill Weight, Identification & Assay have been carried out for the suspected samples. Description, Average Fill Weight and Assay of Pantoprazole & domperidone in suspected sample does not comply with our specification limit.

Prepared by	Checked by	Approved by
 22/Aug/2017 (Sign/Date)	 23/Aug/2017 (Sign/Date)	 23/Aug/2017 (Sign/Date)

Physical Parameters Checked		Observations		Remark
		Suspected Sample	Retain Sample	
Sr. No.	Batch No.	EMR1528	EMR1528	
1.	Item Code of printed foil	PEXPF0055 Font size of item code is smaller than retain sample.	PEXPF0055 Font size of item code is bigger than the suspected sample.	Foil item code is same but font size of item code of the suspected sample is smaller than the retain sample.
2.	Generic Name	"Enteric Coated Pantoprazole Sodium and Sustained Release Domperidone Capsules" here font is normal.	"Enteric Coated Pantoprazole Sodium and Sustained Release Domperidone Capsules" here font is darker.	Generic name is same but font of retain sample is darker as compared to suspected sample.
3.	Brand Name	Pantocid® DSR	Pantocid® DSR	Brand name is same.
4.	Label claim on strips	Each capsule contains: Pantoprazole sodium IP equivalent to pantoprazole 40 mg (as enteric coated pellets) domperidone IP 30 mg (as sustained release pellets) Excipients q.s.	Each capsule contains: Pantoprazole sodium IP equivalent to pantoprazole 40 mg (as enteric coated pellets) domperidone IP 30 mg (as sustained release pellets) Excipients q.s.	Label claim is same..

Physical Parameters Checked		Observations		Remark
		Suspected Sample	Retain Sample	
Sr. No.	Batch No.	EMR1528	EMR1528	
5.	Colour of Printed matter on strips	Blue & black	Blue & black	Colour of printed matter on strip is same.
6.	Overprinting dimensions on Strips	31 X 22 mm	31 X 20 mm	Overprinting dimensions are not same.
7.	Red Line width	1.0 mm	1.0 mm	Red Line width is matching with retain sample.
8.	Units per Strip	10	10	Same units per strip
9.	Strip Size(Length)	142mm	145 mm	Strip Length is not same.
10.	Strip Size (Width)	82 mm	84 mm	Strip width is not same.
11.	Pocket Size (Length)	35 mm	35 mm	Pocket length is same.
12.	Pocket Size (Width)	22 mm	22 mm	Pocket width is same.
13.	Sealing	Sealing found satisfactory.	Sealing found satisfactory.	Sealing is satisfactory.
14.	Pre-printed text Matter	"capsules should be swallowed whole and not chewed." Text matters are bold.	"capsules should be swallowed whole and not chewed." Text matters are Bold and darker than suspected sample colour.	Text matter mismatches
		'R' is normal in '@' symbol	'R' is bold in '@' symbol	
		Nothing is pre-printed over the sealing area of the strip.	"GFL" is pre-printed over the sealing area on one side of strip.	

Over coding area: 70x63mm  
 To be over print as per below in over coding area  
 (M.L. No., company name & address as per location)  
 M.L.  
 S. No.: MFP Rn  
 MFG.: PER 10 CAPSULES  
 EXP.: INCL. OF ALL TAXES

Mfg. Co. of Product: Pantocid DSR Capsules		AMS TYPE	Country	Language	Location
		Generic	INDIA	ENGLISH	SRM
Product Code	PER00001	Vendor Code No. P0000010	IS No. P00-001-		
Product Name	10x10x10mm	Reason: Common Anmark	SRM/MS		
Unauthorized Area	SRM/MS	No. of Colors: 3			
Composition: Subsequent	10x10x10mm	Color codes:	<input checked="" type="checkbox"/> Pantocid 200 C <input checked="" type="checkbox"/> Pantocid 200 C <input checked="" type="checkbox"/> Pantocid 400 C		
Specification / Type of Salt	SRM/MS	Anmark Prepared by: Sun Pharmaceutical Industries Limited Packaging Development Department (PDD) SPL - Vadodra			
SAC Name	SRM/MS				
QSP No.	SRM/MS				
Location	SRM/MS	Prepared by	Checked by	Approved by	
Six	SRM/MS	SRM/MS	SRM/MS	SRM/MS	
Approved	YES	SRM/MS	SRM/MS	SRM/MS	

Serial Print Head (SRM/MS)	MFG. No.		Date		Status	
	ML	WB	DD	MM	YY	SRM/MS
Serial No.	SRM/MS		SRM/MS		SRM/MS	
Product Code	SRM/MS		SRM/MS		SRM/MS	
Product Name	SRM/MS		SRM/MS		SRM/MS	
Product Code	SRM/MS		SRM/MS		SRM/MS	
Product Name	SRM/MS		SRM/MS		SRM/MS	
Product Code	SRM/MS		SRM/MS		SRM/MS	
Product Name	SRM/MS		SRM/MS		SRM/MS	
Product Code	SRM/MS		SRM/MS		SRM/MS	
Product Name	SRM/MS		SRM/MS		SRM/MS	

Insert Printer Logo as shown



Checked by SRM/MS

For SUN PHARMACEUTICALS LTD

Final Size: 150x63x30 mm (Lock Bottom)

SRM/MS

APPROVED  
UNCONTROLLED CO




Back side over coding with M.L. No., company name & address as per below (M.L. No., company name & address as per location)

M.L.  
 S. No.: MFP Rn  
 MFG.: PER 10 CAPSULES  
 EXP.: INCL. OF ALL TAXES





## ENQUIRY AT MANUFACTURER LEVEL

- ❑ Letter/Statement collected.
  - ❑ Testing in front of Investigating team
  - ❑ Reported as spurious
  - ❑ Letter from manufacturer giving the points of differences.
  - ❑ Spot Memo prepared.
  - ❑ Collected back the unconsumed portion of the spurious sample
- 

# SEQUENCE OF EVENTS

CONTD. ....

**Declared NSQ by  
Government  
Analyst**



FORM 13  
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER  
SECTION 25 (1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received : Swapnil Ganjidhar Patil, Drugs Inspector, Govt. of N.C.T. of Delhi, F-17, Karkardooma, Delhi-110032.
2. Serial No. and date of Inspector's Memorandum : 19(138)/2017/GADC/151 dated :- 07/07/17
3. Number of Sample : SP/09/17
4. Date of receipt : 18/07/17
5. Name of drugs purporting to be contained in the sample : Pantoprazole Tablets IP ( PANTOCID TABLETS )
6. Condition of seals on the [packet or on portion of sample or container] : Seals were Intact & Identical to the specimen impression of the seal received from the Drug Inspector
7. Result of test or analysis with protocols or test or analysis applied : Please see below
- | Reg. No              | B.No    | D/Mfg.    | D/Exp.    | Mfd. By   |
|----------------------|---------|-----------|-----------|---|
| LSD/RD/TL/0639/17-18 | EMR1051 | Sep./2016 | Aug./2019 | SUN PHARMA LABORATORIES LTD,<br>PLOT NO. 107/108,<br>NAMLI BLOCK, P.O. RANIPPOO,<br>EAST-SIKKIM-737135. |

COMPOSITION

: Each enteric coated tablet is purported to contains:  
Pantoprazole sodium IP  
equivalent to Pantoprazole 40 mg

Result & Protocols

: As per I.P. 2014

Description

: Yellow round biconvex enteric coated tablet, Packed in alu alu blister pack

Identification

: (A) Complies with IP  
: (B) Complies with IP

Average weight

: 253.78mg

Uniformity of weight

: Complies with IP

Dissolution

(Pantoprazole Sodium  
calculated as Pantoprazole)

: Does not comply with IP

ASSAY

: Each enteric coated tablet on an average contains :-

Content of

Content of	Obtained	Claim	Obtained	Limits	Protocol
(Pantoprazole Sodium calculated as Pantoprazole)	11.04mg	40.00mg	27.60%	90% to 110%	I.P. 2014

(Pantoprazole Sodium  
calculated as Pantoprazole)

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below :-

The sample does not conform to claim as per I.P. 2014 in respect to the Dissolution (Pantoprazole Sodium calculated as Pantoprazole) and the Assay of (Pantoprazole Sodium calculated as Pantoprazole).

Dated :- 08/09/17

End Of Report  
Page 1 of 1

GOVERNMENT ANALYST



**FORM 13**  
(See rule 46)

**CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER  
SECTION 25 (1) OF THE DRUGS AND COSMETICS ACT, 1940**

1 Name of Inspector from whom received : Swapnil Ganjidhar Patil, Drugs Inspector, Govt. of N.C.T. of Delhi, F-17, Karkardooma, Delhi-110032.

2 Serial No. and date of Inspector's Memorandum : 19(139)/2017/GADC/152 dated :- 07/07/17

3 Number of Sample : SP/10/17

4 Date of receipt : 18/07/17

5 Name of drugs purporting to be contained in the sample : Enteric-Coated Pantoprazole Sodium and Sustained Release Domperidone Capsules ( PANTOCID DSR CAPSULES )

6 Condition of seals on the [packet or on portion of sample or container] : Seals were Intact & Identical to the specimen impression of the seal received from the Drug Inspector

7 Result of test or analysis with protocols or test or analysis applied : Please see below

Reg. No. B.No. D/Mfg. D/Exp. Mfd. By  
 1-SU/RDTL/0640/17-18 EMR1528 Oct./2016 Jul./2018 SUN PHARMA LABORATORIES LTD.  
 PLOT NO.107/108, NAMLI BLOCK, P.O. RANIPOOL, EAST SIKKIM-737135.

**COMPOSITION** : Each capsule is purported to contains:  
 Pantoprazole Sodium IP  
 equivalent to Pantoprazole 40 mg.  
 (as enteric coated pellets).  
 Domperidone IP 30 mg.  
 (as sustained release pellets.)

**Result & Protocols** : **As per P & P (RDTL/MS/222)**

Description : Green cap and green body hard gelatin capsule, filled with orange and green pellets .  
 packed in strip pack .

Identification : Positive for Pantoprazole sodium and Domperidone

Average weight : 330.07mg

Average Fill : 267.67mg

Uniformity of filled weight : Complies

**Dissolution** : **Does not Comply**  
*(Pantoprazole sodium calculated as Pantoprazole in acidic medium)*  
 : **Does not comply**  
*(Pantoprazole sodium calculated as Pantoprazole in buffer medium)*  
 (Domperidone 1 st hour ) : Complies  
 (Domperidone 4 th hour ) : Complies  
 (Domperidone 8 th hour ) : Complies

**ASSAY** : **Each capsule on an average contains:**

Content of	Obtained	Claim	Obtained	Limits	Protocol
<i>Pantoprazole Sodium calculated as Pantoprazole (as enteric coated pellets)</i>	31.54mg	40.00mg	78.85%	90% to 110%	RDTL/MS/222
Domperidone	28.04mg	30.00mg	93.47%	90% to 110%	RDTL/MS/222

In the opinion of the undersigned the sample referred to above is **not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below :-

The sample does not conforms to claim as per Patent & Proprietary in respect to the Dissolution (Pantoprazole sodium calculated as Pantoprazole in acidic medium), (Pantoprazole sodium calculated as Pantoprazole in buffer medium) and the Assay of Pantoprazole Sodium calculated as Pantoprazole (as enteric coated pellets).

Remarks : Dissolution result in Acid Medium is 20.51% (Limit NMT 10%)

# FILED COMPLAINT



## IN SHORT

### INVESTIGATION AT MANUFACTURER LEVEL

- Confront with the specimen samples/ legal samples.
- Collect GPA/Authorization in favor of person representing the manufacturer.
- Take his ID.
- Check BPR/BMR and the supporting documents.
- Constitution of the firm as on the date of offence.
- Liability / personnel responsible for commission of offence.
- Spot memo
- Statement - Physical & Chemical Comparison
- Collect remaining portion of the specimen sample left over of the testing after sealing it properly to be exhibited in the court at appropriate stage.



**QUESTIONS ?**



# THANKS

K. R. Chawla  
Controlling Authority /Deputy Drugs Controller/  
Head of the Office  
Drugs Control Department  
Govt. of N.C.T. of Delhi  
91-9811262327

