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FOPE 's Webinar on Power & Procedures of Inspectors

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Power and Procedures of Inspectors

Under Drugs and Cosmetics Act 1940

- Every Inspector should be very clear on Legal Tools provided to him for Inspection, Investigation Sampling and Seizures etc.
- Every licensee/ Manufacturer should be more clear on Powers and Procedures of Inspectors. Licensee should know the limitations of power Section 22 of Drug Act.
- Procedures to be adopted by the Inspectors Section 23
- Duties of Inspectors Rule 51 & 52
- Procedure of dispatch of sample Rule 57
- Duties of Govt. Analyst Rule 45
- Procedure of Govt. Analyst on receipt of sample Rule 46

Duties of Inspectors of Premises licensed for Sale – Rule 51 (Refer Rule 49 Qualification of Inspectors)

- Subject to Instructions of Controlling Authority (Rule 50 Controlling Authority and Rule 51 Qualification of a controlling authority) duties of inspectors
- (1) Inspect – not less then once a year
- (2) Ensure compliances of Conditions of license Rule 65 for sale license on Form 20, 20A, 20B, 20F, 20G 21 and 21B
- (3) Sampling for Test and Analysis
- (4) Investigate Complaints
- (5) Institute Prosecutions
- (6) Record of Inspection, Sampling Seizure etc and submit to Controlling Authority
- (7) Enquiries and Inspections

Duties of Inspectors specially authorised to inspect manufacture of Drugs Rule 52 also refer Rule 49 Qualification of Inspectors

- Subject to instructions of Controlling Authority duty of Inspector authorized to inspect manufacture of Drugs is as under:-
- (1) Inspect not less then once a year
- (2) Inspect plant process of manufacture means employed for standardizing and testing of Drugs, method and place of storage, technical qualification of staff employed details of location, construction and administration of establishment likely to of potency and purity of product.
- (3) Send inspection to controlling authority forthwith with lists of non compliances
- (4) Collect Samples
- (5) Institute Prosecutions

Duties , Power & Procedure of Inspectors

- Duties as given in Rule 51 & 52 are required to be performed using Power given in Section 22 as per procedure of Section 23

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22. Powers of Inspectors.—(1) 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,—
(i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic;

(b) (ii) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

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(b) take samples of any drug or cosmetic, —
(i) which is being manufactured or being sold or is stocked or exhibited or offered for sale,
or is being distributed;
(ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;

(c) at all reasonable times, with such assistance, if any, as he considers necessary,—
(i) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or
(ii) enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or

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(iii) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed,

and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means o f which the offence has been, or is being, committed or which may be employed for the commission of such offence;

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(cc) examine any record, register, document or any other material object found [with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c),

and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;

(cca) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;

(d) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

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(2) The provisions of [the Code of Criminal Procedure, 1973 (2 of 1974)] shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under [section 94] of the said Code.

[(2A) Every record, register or other document seized under clause (cc) or produced under clause (cca) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.

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(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter [or refuses to produce any record, register or other document when so required under clause (cca) of sub-section (1),] he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

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23. Procedure of Inspectors.—(1) Where an Inspector takes any sample of a drug [or cosmetic] under this Chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug [or cosmetic] under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

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Provided that where the sample is taken from premises whereon the drug [or cosmetic] is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them

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(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:—

(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(ii) the second, he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug [or cosmetic]; and

(iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

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(5) Where an Inspector takes any action under clause (c) of section 22,—

(a) he shall use all dispatch in ascertaining whether or not the drug [or cosmetic]; contravenes any of the provisions of section 18 and, if it is ascertained that the drug [or cosmetic]; does not so contravene, forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(b) if he seizes the stock of the drug [or cosmetic]; he shall as soon as may be inform [a Judicial Magistrate] and take his orders as to the custody thereof;

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(c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug [or cosmetic]; he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform [a Judicial Magistrate] and take his orders as to the custody thereof.

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A. **Krishna Mohan Prasad Vs The State Of Jharkhand and Anr on 22 December 2014.**

   Proceedings quashed as compliance of Section 25(4) not made.

B. **Jackson Laboratories Private Vs The State Of Jharkhand on 20 July 2022.**

   Latest on Right is valuable Right Section25(4).

C. **M/S Meri Odin Ifescience VS State on 8 march 2022**

   Proceedings quashed Compliance of Section 23(4)(iii) not made and Sample potion not sent to manufacturer.

D. **Arvind Mittal Vs State Of Rajasthan**

   Court held that the Right under Section 25(3&4)of the Act 1940 is valuable Right and if such right is Lost, Prejudice will be caused.

Power and Procedures of Inspectors

- Section 25. Reports of Government Analysts.—(1) The Government Analyst to whom a sample of any drug ’[or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.
- (2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken 60[and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.

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- Section (3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken [or the person whose name, address and other particulars have been disclosed under section 18A] has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

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- Section 25(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug] [or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.
- (5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

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- Section 37. Protection of action taken in good faith.—
- No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.]

Sampling Procedure

- Rule57. Procedure for dispatch of sample to Government Analyst.—(1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (4) of section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18, in an outer cover addressed to the Government Analyst.
- (2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

Sampling Procedure

- Rule 45. Duties of Government Analysts.—
- (1) The Government Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him by Inspector or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these rules within a period of sixty days of the receipt of the sample:
- Provided that where it is not possible to test or analyze the sample within the specified period, the Government Analyst shall seek extension of time from the Government giving specific reasons for delay in such testing or analysis.

Sampling Procedures

- Rule 46. Procedure on receipt of sample.—
- On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet or on portion of sample or container with the specimen impression received separately and shall note the condition of the seals on the packet or on portion of sample or container. After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of the test or analysis, together with full protocols of the tests or analysis applied.

Sampling Procedures

- Protocols of the tests or analysis applied
- (1) for pharmacopoeial drug, where the tests or methods of analysis prescribed in the official pharmacopoeia are followed,
- (2) for patent or proprietary medicines for which the tests and methods prescribed in any of the official pharmacopoeias are applicable and are followed
- (3) for patent or proprietary medicines containing pharmacopoeial drugs for which the official tests or analysis or methods of assays are modified and applied.
- (4) for patent or proprietary medicines for which no pharmacopoeial tests or methods of analysis are available or can be applied but for which tests or methods of analysis given in standard books or journals are followed
- (5) for those drugs for which methods of test are not available and have been evolved by the Government Analyst, a description of tests applied is given in the report.

Sampling Procedures (DCGI Guidelines)

Following timelines are to be followed-

a. The Drugs Inspector shall plan the sampling in such a way that samples are forwarded to laboratory on the same day of sampling.

b. If delay happens due to transit from rural location or distant location to office, then sample shall be forwarded to laboratory by next day and not later than that.

c. The disclosure under section 18A of Drugs & Cosmetics Act & Rules there under for Name, Address, copy of purchase invoice and other particulars of the person from whom he acquired the drug or cosmetic shall be obtained during sampling to rule out the possibility of Spurious drug. Further distribution chain establishment up to manufacturer level under section 18A of Drugs and Cosmetics Act is to be completed for all samples. This will be helpful to ensure the availability of true product in the market and also to initiate quick actions for NSQ product declared by the Government Analyst.

Central Medical Device Testing Laboratory (CMDTL) for testing of Medical Devices under MDR 2017

S.No	Name of Laboratory	Category of medical device
1	The National Institute of Biologicals, Noida	In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent
2	The Central Drugs Testing laboratory, Chennai	Condoms
3	The Central Drugs Laboratory, Kolkata	Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant
4	The Regional Drugs Testing Laboratory (RDTL), Guwahati	Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae
5	The Central Drugs Testing Laboratory, Mumbai	Intra Uterine Devices (IUD) and Falope Rings
6	The Regional Drugs Testing Laboratory, Chandigarh	Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Sets, Catheters, I.V. Cannulae, Scalp Vein Set, Ligatures, Sutures, Staplers, Surgical Dressing, Umbilical

Sampling Procedures

Annexure-1

Quantity of Drugs Sample Required for Complete Analysis

S.No.	Name of Drug Sample	Form-18Samples	Survey Samples
1.	Tablets	100 Tablets	20 Tablets
2.	Capsules	100 Capsules	20 Capsules
3.	Syrups / Oral Liquids/Suspensions	12 Bottles	2 Bottles
4.	Injection (Ampoule) (1-10 ml)	40 Ampoules	10 Ampoules
	Injection (Ampoule) (10-100ml)	25 Ampoules	10 Ampoules
5.	Large Volume Parentrals (morethan 100 ml)	10 Bottles	2 Bottles
6.	Powder for injection (Sterile)	40 Vials	5 Vials
7.	Dry Powder for Oral/ Liquid Suspension	25 Bottles	5 Bottles
8.	Oral Rehydration Salt Sachets	30 Pcs	5 Pcs
9.	API Drug	2 x 10 gm	5 gm
10.	Ointment / Creams / Paste / Gel(Non Sterile)	12 Pcs	2Pcs
	Ointment / Creams / Paste / Gel (Sterile)	20pcs	5pcs
11.	Eye / Ear Drops	40 Vials/ pcs	5 Vials/ pcs
12.	Nasal Preparation	20 Vials	5 Vials
13.	Inhalers/ Spray	40 Pcs	5 Pcs
14.	Pessaries / Lozenges	60 Pcs	20 Pcs
15.	Empty Gelatine Capsules	500 Capsules	100 Capsules

Sampling Procedure

- Rule 56. Form of intimation of purpose of taking samples.—
- When an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.
- Rule 56A. Form of receipt for samples of drugs where fair price tendered is refused.—
- Where the fair price, for the samples of drugs taken for the purpose of test or analysis, tendered under sub-section (1) of section 23 has been refused, the Inspector shall tender a receipt therefor to the person from whom the said samples have been taken as specified in Form 17A.

Sampling Procedures

[785][FORM 17

(See rules 56 and 145A)

INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN

To

.....

I have this day taken from the premises of ..... situated at.....samples of the drugs / [786][***] specified below for the purpose of test or analysis.

Date..... Inspector.....

Details of sample taken

Date..... Inspector.....

[787]

Form 17 A

RECEIPT FOR SAMPLES OF DRUGS [788][***] TAKEN WHERE FAIR PRICE TENDERED THEREOF UNDER SUB-SECTION (1) OF SECTION 23 OF THE DRUGS AND COSMETICS ACT, 1940 IS REFUSED

To

.....

Whereas I, this.....day of.....[789][20]....., have taken from the premises of situated at..... samples of drugs/cosmetics as specified below:—

Details of samples.....

And whereas I had offered to pay you rupees.....as the fair price of the samples of drugs/cosmetics taken:

And whereas, you have refused to accept the fair price tendered thereof;

Now, therefore, I give you this receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date.....Inspector.....]

FORM 18

(*See* rule 57)

MEMORANDUM TO GOVERNMENT ANALYST

Sampling Procedures

Date.....Inspector.....]

FORM 18

(See rule 57)

MEMORANDUM TO GOVERNMENT ANALYST

Serial No. of Memorandum.....
From
To

The Government Analyst

The portion of sample/container described below is sent herewith for test or analysis under the provisions of clause (i) of sub-section (4) of section 23 of the Drugs and Cosmetics Act, 1940.

The portion of sample/container has been marked by me with the following mark. Details of portion of sample or container with name of [790][drug/[786][***]] which it purports to contain—

Date..... Inspector.....

Form 13

- 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 .....
- 2. Serial No. and date of Inspector's memorandum .....
- 3. Number of sample .....
- 4. Date of receipt.....
- 5. Names of drugs purporting to be contained in the sample.....
- 6. Condition of seals on the 777[packet or on portion of sample or container].....
- 7. Result of test or analysis with protocols or test or analysis applied.....
  In the opinion of the undersigned the sample referred to above (is of standard/is not of standard) quality as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:—
- Dated..... Government Analyst.....

THANKS