

THE DRUGS (FEDERAL INSPECTORS, FEDERAL DRUG LABORATORY AND FEDERAL GOVERNMENT ANALYSTS) RULES, 1976

(Copied from Manual of Drug Law, Pakistan)

S. R. O. 793 (1)176: In exercise of the powers conferred by Sec. 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by subsection (3) of the said section, namely

1 Short title and Commencement : (1) These rules may be called 'the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976.

(2) They shall come into force at once.

2. Definitions: In these rules, unless there is anything repugnant in the subject or context,--

(a) "Act" means the Drugs Act, 1976 (XXX1 of 1976);

(b) "Section" means a section of the Act; and

{c) "form" means a form set forth in the Schedule.

3. Qualification of Federal Inspectors: (1) A Federal Inspector shall be a person who-

(a) has a degree in Pharmacy from a Pakistani University or any other institution recognised for this purpose by the Federal Government; and

(b) has for a period of, or for periods: aggregating, not less than ten years' practical experience in, (i) the manufacture, testing or analysis of drugs, or (ii) in drug administration:

Provided that the condition of experience may be relaxed in exceptionally deserving cases or for persons with higher qualifications or where the candidate; with requisite experience are not readily available:

Provided further that the Federal Government may, by notification in the official Gazette, for the exercise of such powers as may be specified in such notification, appoint as ex officio Inspector any officer of medical or public health department who is a registered medical practitioner or any officer who is working in the drugs administration of a Government who has a degree in Medicine or Science or Pharmacy or any person having similar qualifications working as a teacher in any pharmaceutical or medical educational institution

(2) The Federal Inspector shall be under the control of the licensing authority referred to in Section 18.

Explanation: For the purposes of this sub-rule and rule 4, "licensing authority" means the Director General Health, Government of Pakistan, or an officer authorised by him in this behalf.

4. Duties of Federal Inspectors: (1) Subject to the instructions of the licensing authority, it shall be the duty of an inspector, within the local limits for which he is appointed--

(a) to inspect not less than twice a year, all premises licensed for the manufacture of drugs including the plant and the process of manufacture, the means employed for standardising and testing the drugs,, the methods and places of storage, the location, construction and administration of the establishment likely to affect the potency for purity of the product, records and registers and to satisfy himself that the conditions of the licence and the provisions of the Act and the rules made thereunder, are being observed ;

(b) to inspect from time to time establishment licensed for the import, export or sale of drugs and to satisfy himself that the conditions of the licence are being observed;

(c) to send forthwith to the licensing authority after each inspection a detailed-report indicating the conditions of the licence and provisions of the Act and the rules made thereunder which are being observed and the conditions and provisions, if any, which are not being observed;

(d) to take samples of any drug which he has reason to suspect that it is being manufactured, stocked, sold or exhibited for sale in contravention of the provisions of the Act or the rules made thereunder. and send them for test or analysis;

(e) to investigate any complaint in writing which may be made to him; [.....]

(f) to institute, if necessary, prosecutions in respect of breaches of the Act and the rules made thereunder. and

(g) to give advice to pharmaceutical industry on technical matters pertaining to the manufacture of drugs in accordance with good manufacturing practices with a view to improve the standard of industry and quality control of drugs;

(h) to conduct surveillance of the marketed drugs for ensuring quality control and compliance of the various provisions of the Act and these rules, and

(i) to assist in organizing and conducting the programme for monitoring of the adverse reactions of drugs.

(2) A Federal Inspector shall, for the purpose of clause (i) of sub-section (1) of Section 18 take the approval of, and for the purpose of clause (ii) of sub-section (3) and sub-section (5) of Section 19, send the sample to, or, as the case may be, inform. the Registration Board in the case of registered Drugs and the Central Licensing Board in all other cases.

5. Form of orders not to dispose of stocks: An order in writing by an Inspector under clause (i) of sub section (1) of Section 18 requiring a person not to dispose of any stock in his possession shall Form 1.

6. Form of receipt for seized drug: A receipt by an inspector for the stock of any drug seized under clause (f) of sub-section (.1) of Section 18 shall be in Form 2.

7. Form of Intimation of purpose of taking samples: Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 3 to the person from whom he takes it.

8. Procedure for despatch 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 (3) of Section shall be sent by registered post or by hand in a sealed packet enclosed together with a memorandum in Form 4 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.

9. Confiscation of drugs: When any person has been convicted under the Act for contravening the provisions of clauses (a) to (e), (g) and (h) of Section 23, the stock of the drug or a substance in respect of which the contravention has been made may be confiscated if the Drug Court so directs.

10. Prohibition of disclosure of Information: Except for the purpose of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

11. The Federal Drug Laboratory: This Federal Drug Laboratory shall have the following functions, namely :--

(i) to test and analyse such samples of drugs as may be sent to it under sub-section (5) of Section 22;

(ii) to test or analyses such samples as may be sent to it by the Federal Government:

(iii) to carry out such other functions as may be entrusted to it by the Federal Government or, with the prior approval of the Federal Government, by & Provincial Government.

12. The Regional Drugs Testing Laboratory. The Regional Drugs Testing Laboratories established by the Federal Government shall perform the following functions, namely :--

(i) to test and analyse such samples of drug as may be sent to it under sub-section (2) of Section 33;

(ii) to analyse such samples as may be sent to it by the Registration Board,. the Central Licensing Board or a Federal Inspector;

(iii) to carry out such other functions as may be entrusted to it by the Federal Government or, with the prior approval of the Federal Government, by the Provincial Government.

13. Qualifications of Federal Government Analyst: A Federal Government Analyst shall be a person who has a degree in Pharmacy or Pharmaceutical Chemistry or Medicine of a Pakistani University or of any other institution recognised by the Federal Government for this purpose and has not less than three years post-graduate experience in the test and analysis of drugs or experience of the Drugs Control Administration or Drugs Quality Control Administration or of both for a period aggregating not less than five years.

14. Despatch of samples for test or analysis: (1) Samples for test or analysis shall be sent to the officer for the time being in charge of the Federal Laboratory by registered post in a sealed packet, together with a memorandum in Form 5, in case the sample is being sent under sub-section (5) of Section 22.

(2) The packet, as well as the outer cover shall be marked with a distinguishing number.

(3) In the case of submission of samples under sub-section (5) of Section 22, a copy of the memorandum in Form 5 and a specimen impression of the seal used to seal the packet and a sample of the cloth and thread, if used, shall be sent to the officer for the time being in charge of the Federal Laboratory.

15. Recording of condition of seals: (1) On receipt of the packet, it shall be opened by the officer for the time being in charge of the Laboratory, a Government Analyst or any responsible officer authorised in writing by any of them in this behalf who shall record the conditions of the seals on the packet, on the form accompanying the sample, and on a register maintained for the purpose.

(2) Immediately on receipt of the sample, the officer opening the packet containing the sample shall examine the sample for any contravention of provisions of the Act in respect of labelling.

16. Report of result of test or analysis: (1) After test or analysis the result thereof together with full protocols of the test applied, shall be supplied forthwith to the sender in Form 6.

(2) The Government Analyst shall, for the purpose of sub-section (1) of Section 22, forward a copy of the report to the Registration Board in the case of a registered drug and to the Central Licensing Board in all other cases.

(3) For the purpose of sub-section (2) of Section 22, the further period within which the report should be made available to the Inspector shall be sixty days.

17. Signature on certificate: Certificates issued under these rules by the Laboratory, or a Government Analyst shall be signed by the officer-in-charge of the Laboratory or by an officer authorised by the Federal Government by notification in the official Gazette to sign such certificates or by a Government Analyst, as the case may be.

18. Fees: The fees for test or analysis of any drug shall be those specified in Schedule II.

SCHEDULE 1

FORM 1

(See rule 5)

ORDER UNDER SECTION 18 (1) OF THE DRUGS ACT 1976, REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS POSSESSION.

Whereas I have reason to believe that the stock of drugs in your possession detailed below contravenes the provisions of the Drug. Act, 1976 or rules made thereunder; and whereas I have reported the: facts to tee Board concerned or the authority and have been authorised by it to take action under clause (i) of Section 18 of the said Act;

I hereby require you not to dispose of the said stock for a period ofdays from this date.

Date..... Inspector

Details of stock of drugs

Inspector

FORM 2

(See rule 6)

RECEIPT FOR STOCK OF DRUGS SEIZED UNDER SECTION 8 (f) OF THE DRUGS ACT, 1976

The stock of drugs/materials/articles detailed below has this day been seized by me under the provision of clause (f) of Section 19 of the Drugs Act, 1976, from the premises of..... situated.....

Date Inspector

Details of drugs seized

Inspector.....

FORM 3

(See rule 7)

INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN.

I have this day taken from the premises ofsituated atsamples of the drugs specified below for the purposes of test or analysis.

Inspector Date

Details of sample taken

Inspector

FORM 4

(See rule 8)

MEMORANDUM TO GOVERNMENT ANALYST

Serial No

From

To

The Federal Government Analyst.

The portion of sample/container described below is sent herewith for test and analysis under the provisions of clause (i) of the sub-section (3) of Section 19 of the Drugs Act, 1976.

The portion of sample or container has been marked by me with the following mark :-

Details of portion of sample or container with name of drug which it purports to contain :-

Date..... Inspector

FORM 5

(See rule 14)

MEMORANDUM TO THE FEDERAL LABORATORY

Serial No

From

To the Officer. in-charge, Federal Drugs Laboratory.

I send herewith, under the provisions of sectionof the Drugs Act, 1976, sample (s) of a drug purporting to befor test or analysis and request that a report of the result of the test or analysis may be supplied.

2. The distinguishing number on the packet is

3. Particulars of offence alleged

4. Matter on which opinion is required.....

DateDrug Court.

FORM 6

(See rule 16)

*CERTIFICATE OF TEST OR ANALYSIS BY THE FEDERAL 'DRUGS
LABORATORY/GOVERNMENT ANALYST*

Certified that the samples, bearing number.....purporting to be a sample of.....received onwith memorandum NoDated.....from.....has been tested/analysed and that the result of such test/analysis is as stated below :-

2. The condition of the seals on the packet of receipt was follows

3. In the opinion of the undersigned the sample is not/is .adulterated/ sub standard/misbranded/spurious, as defined in the Drugs Act, 1976 for the reasons given below :-

Details of results of test or analysis: (with protocols of tests applied}.

Director, Federal Drugs Laboratory

or other authorised officer/Government Analyst.

Secretary