

Drug Investigation and Inspection Rules, 2040 (1983)

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Amendment

Drug Investigation and Inspection (First
Amendment) Rules, 2047 (1991)

2047.10.28 (24 Jan. 1991)

In exercise of the powers conferred by Section 40 of the Drugs Act, 2035 (1978), the Government of Nepal has framed the following Rules.

1. **Short title and commencement:** (1) These Rules may be called as the "Drug Investigation and Inspection Rules, 2040 (1983)."

(2) These Rules shall come into force in such area and on such date as the Government of Nepal may appoint, by a Notification in the Nepal Gazette.¹

2. **Definitions:** Unless the subject or the context otherwise requires, in this Rules;-

- (a) "Act" means the Drugs Act, 2035 (1978).
- (b) "Department" means the Department of Drugs Administration.
- (c) "Administrator" means Chief of the Department.
- (d) "Inspector" means the inspector having the qualification as referred to in Section 23 of the Act.

¹ These Rules commence throughout Nepal from 2043.4.1 as per the Notification of Nepal Gazette of 2043.2.12.

(e) “Analyst” means a person appointed by the Department from amongst the person who has the qualification as referred to in Section 23 of the Act and are working with drug analysis in any research center, laboratory, hospital, dispensary or clinic.

3. **Inspection, investigation and search may carryout:** The Inspector may, upon making an inspection, investigation or search of a place where drug is produced, sold or distributed or being transported pursuant to Sub-section (1) of Section 20 of the Act, carry out inspection or investigation of the work, person involved with the work, environment of the place or the commodities or tools and the substances discovered in the place. The Inspector may also search of those places if he/she deems necessary.

4. **Modus operandi or procedure of inspection, investigation and search:** The Inspector is not allowed to carry out inspection or investigation or search of any place under the Rule 3 without permission of the concerned drug keeper or his/her agent.

Provided that, if the Inspector fails to obtain such permission or the permission is not granted, he/she may, if the time so permits, carry out inspection or investigation or search of the place between the period of sunrise and sunset, in general, in witness of a representative of the ²municipality or the village development committee or of an employee of any governmental office nearby.

5. **Drug may be suspended:** (1) Upon the inspection or investigation or search pursuant to Rules 3 and 4, if the Inspector deems it necessary to suspend any drug, he/she may suspend such drug and hand over it to the concerned drug keeper or his/her agent with sealed.

² Amended by First Amendment.

(2) The drug keeper or his/her agent shall collect the drug hold by the Inspector pursuant to Sub-rule (1) and the drug keeper or the agent shall give a copy of the receipt thereof to the Inspector.

6. **Held drug may be seized if not collected:** (1) If the drug keeper or the agent does not agree to collect the drug suspended by the Inspector pursuant to Rule 5, the Inspector may restrain the drug.

(2) The Inspector shall give the receipt of the drug if restrained pursuant to Sub-rule (1).

7. **May be Removed the substance irrelevant with drug:** (1) Upon the inspection, investigation or search carried out in any place, if the Inspector discovers any substance other than drug and if the drug keeper or his/her agent fails to justify satisfactorily the use of the substance; and if there is a possibility of blending the substance with the drug, the Inspector may give order to immediately remove such substance from the place.

(2) If the Inspector gives an order to remove any substance pursuant to Sub-rule (1), the drug keeper or his/her agent shall remove the substance.

8. **Sample of drug:** (1) Upon an inspection or investigation or search pursuant to Rule 3 or upon suspension of any drug pursuant to Rule 5, the Inspector shall take the sample of the drug.

(2) The Inspector shall, upon collecting the sample of the drug pursuant to Sub-rule (1), collect the drug not less than the quantity as specified by the Department for the purpose of examination and analysis of such drug.

(3) The Inspector shall collect the sample of the drug in separate boxes with seal in order to give the sample to the concerned drug keeper or his/her agent, send to the analyst for examination and analysis and to keep in the department as well.

(4) The Inspector shall make payment of the drug as per the prevailing price which was collected in order to be sent to the analyst and the Department.

9. Method of sealing of box: The Inspector shall adopt the following method while sealing the box pursuant to Sub-rule (3) of Rule 8.

- (a) Name and quantity of the drug kept inside the box including the indicative number if any, has to be clearly mentioned outside of the same box.
- (b) Box should be closed and corked properly by which the drug kept inside the box may not leak or seep out.
- (c) The cork and the box should be tightened by the thread and the thread should be sealed.
- (d) The seal should be set in such way that the box may not open without breaking the seal.

10. Setting of clear stamp while sealing: (1) The Inspector and the drug keeper or his/her agent shall, upon sealing the box of the drug, set the stamp of their own name on at least four places of the box in a legible manner.

(2) If the drug keeper or his/her agent refuses to set the seal pursuant to Sub-rule (1), the Inspector shall seal the box and set the stamp of his/her own name legibly on at least four places of the box in witness of the representative of the ³municipality or the village development committee or an employee of a government office.

11. Notice to be given to the Department: If the drug keeper or his/her agent denies setting the seal in the box or refuses to collect the box after

³ Amended by First Amendment.

setting the seal, the Inspector shall give the notice thereof to the Department immediately.

12. Reporting: (1) After carrying out the inspection, investigation or search pursuant to Rules 3 and 4, the Inspector shall submit a written report to the administrator (manager) within Three days from the date of completion of the work.

(2) The Inspector shall mention the following matters, in particular, in the report submitted pursuant to Sub-rule (1).

- (a) The place, and cause of carrying such inspection, investigation or search,
- (b) What kind of drug was discovered in the place and what kind of materials, tools or substance related to the drug were used; and which pharmacist; professional or person is engaged with the production, sale and distribution, transport and storage of the drug.
- (c) Where the drug found has to be withheld or seized, reason for such withholding or seizure of drug,
- (d) Reason for collecting the sample of the drug.
- (e) Upon suspending or collecting the sample of the drug, how many drugs are kept in the box and how it is sealed and why and to whom the box is given.

13. Issuance of identity card while deputing the Inspector: The Department shall give an identity card to the Inspector in a format as referred to in Schedule-1 while deputing him/her.

14. Sealed box to be sent to the analyst: The box sealed with the sample of the drug as per these Rules shall be sent to any analyst after following the procedures by filling the form in a format referred to in Schedule-2. Sample may be forwarded by post or any means of transport.

(a) Box should be packed safely and entwined by thread with seal and stamp at least four places of the thread by making legible of his/her own name or as per the terms of the analyst or the method in accordance with the prevailing law.

(b) Name and quantity including the indicative number of the drug shall be clearly mentioned outside the box packed with seal.

15. Examination or analysis of the sample of the drug: (1) After receipt of the box sent for the examination or analysis of the drug as per this Rules, the analyst shall check whether the seal set on the box and out side of the pack is accurate and shall open the pack and the box upon keeping records thereof.

(2) The analyst of the sample of the drug shall, after opening the box pursuant to Sub-rule (1), examine, analyze and report to the Administrator in a format as referred to in Schedule-3.

16. Sample of the drug may be re-examined or analyzed: (1) If the drug keeper wants to have re-examined or analyzed the sample of the drug concerned with the case pursuant to this Act, he/she may submit an application before the Adjudicating Authority, with the box of the drug kept with him/her.

(2) After submission of report pursuant to Sub-rule (1), the Adjudicating Authority, if he/she deems appropriate to have it re-examined or analyzed, shall send the box, received with the application, to any analyst and shall give notice thereof to the Department.

(3) After receiving the box of the drug sent pursuant to Sub-rule (2), the analyst shall examine and analyze the sample of the drug and send the report to the concerned Adjudicating Authority in a format as referred to in Schedule-3 through the Department.

17. Expenditure of re-examination and analysis to be borne by the drug keeper: The expenditure made upon examination or analysis of any drug under Rule 16 shall be borne by the concerned drug keeper.

18. Recognition of research centre or laboratory: (1) For the purpose of examination or analysis of drug by any analyst pursuant to the Act or the Rules, if the Government of Nepal has to grant recognition to any domestic or international research centre or laboratory, recognition shall be granted on the advice of the Drug Advisory Council.

(2) The Government of Nepal may, if it deems necessary, cancel the recognition of any research centre or laboratory granted pursuant to Sub-rule (1) on the advice of the Drug Advisory Council.

19. Functions, duties and powers of the Administrator: In addition to the functions to be carried out under the Act and these Rules, the Administrator shall perform the following functions, duties and powers:

- (a) To implement, or cause to be implemented, the decisions made by the government of Nepal regarding the complaints against the order of cancellation issued by him/her pursuant to Sub-section (4) of Section 20 of the Act.
- (b) To inspect acts and proceedings of the Inspector if he/she deems necessary.
- (c) Cause to be performed acts and proceedings of the Inspector of an area through the Inspector of another area.

- (d) To give instructions to the Inspector regarding his/her duty, subject to his/her general administration.
- (e) To perform such other functions as specified by the Government of Nepal subject to the Act and these Rules.

20. Release of the withheld or seized drug: If the analyst, upon the examination and analysis of the sample of the drug reaches in a conclusion that the drug withheld or seized is safe for people, effective and of qualitative, the Administrator shall release the withheld or seized drug.

21. Not to cause any obstruction to the Inspector: The drug keeper, his/her agent or any one shall not make any obstruction to the Inspector while he/she is making inspection, investigation or search pursuant to Rule 3.

NEPAL LAW COMMISSION

Schedule-1

(Relating to rule 13)

Government of Nepal

Ministry of Health and Population and Population

Department of Drugs Administration

IDENTITY CARD

No.

Name and surname of Inspector:

Signature:

Date:

Passport size
photograph of
the Inspector

You are deputed to act as an Inspector from the following date and in the area unless otherwise provided by order, subject to the Drugs Act, 2035 (1978) and the Drugs Inspection and Investigation Rules, 2040 (1983).

Area	Date	Deputing Officials'		
		Name of the Office	Name, Surname	Sign and date

Note:

1. This identity card should be kept with the Inspector while carrying out inspection, investigation and search in any place of the area of deputation.
2. This identity card shall not be handed over or given to any person in any circumstance.
3. If the Inspector quits his/her job or he/she is dismissed from his/her job for any reason, he/she shall return this identity card to the Department immediately.

NEPAL LAW COMMISSION

Schedule-2

(Relating to Rule 14)

Form for sending the sample of the drug

Ref No.

To.....

The sample of the drug kept in the sealed box is, hereby, sent mentioning the following details for examination and analysis as per the Drugs Act, 2035(1978) and the Drugs Inspection and Investigation Rules, 2040(1983). I do, hereby, request to send a report to.....of the outcomes of the examination and analysis of the drug and the condition of the box while received

1. Number of the sealed box
2. Name of the drug and quantity
3. Serial number of the sample of the drug mentioned in the record
4. Indicative number mentioned outside the pack
5. Sample of seal set outside the box and the pack.
6. Date and place of collection of the sample of the drug
7. Matters to be examined and analyzed
8. Other necessary matters, if any:

Name of the Office:

Inspector's

Stamp of the Office

Signature

Date:

Name and surname

Schedule-3

(Relating to Sub-rule (2) of Rule 15 and Sub-rule (3) of Rule 16)

Report of the outcomes of the examination and analysis

It is certified that.....number of box kept the sample of drug.....send by Mr./Mrs./Ms.....enclosing the letter of ref no.....dated....., serial number.....and indication no.....for examination and analysis is received. The condition of the box while received and the outcomes of the examination and analysis of the drug are as follows;

1. Condition of the seal set on the outside of the box and the pack:
2. Method adopted for the examination and analysis:
3. Outcomes of the examination and analysis:
4. Own opinion about the outcomes of the examination and analysis

Name of the research center or laboratory:

Stamp of the research center or laboratory:

Address of the research center or laboratory:

Analyst's

Signature

Name and surname

Designation

Date

Note: The words Ministry of Forest in these Rules is, hereby, replaced by the Ministry of Health from the year 2044 (1988) as per the decision of the Government of Nepal.