SINDH DRUGS RULES, 1979
AS AMENDED UPTO
27th April, 2010.

CHAPTER 1.

SHORT TITLE AND COMMENCEMNT:

1. (1) These rules may be called the Sindh Drugs Rules, 1979.

(2) They may come into force at once.

DEFINITIONS:

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

(a) "Act" means the Drugs Act, 1976.

(b) "Analyst" means and Analyst appointed by Government under the Act.

(bb) "Authorized agent means a person who is authorized in writing by the manufacturer, importer or indenter to sell and issue warranty on their behalf in respect of drugs distributed or sold.

(c) "Board" means the Quality Control Board for Sindh.

(cc) "Provincial Drug Control Administration" includes Provincial Quality Control Board Sindh, Provincial Drug testing laboratory Sindh, Provincial Inspectors and Provincial Appellate Authority";

(d) "Form" means a form in schedule A.

(e) "Government" means the Government of Sindh.

(f) "Inspector" means Inspector appointed by Government under the Act.

(g) "Narcotics" means drugs specified in schedule B.

(gg) " Pharmacy" means, a shop, a store, premises or a place where a drug a prescription of Registered Medical Practitioner is executed by way of compounding or dispensing under the direct supervision of a Registered Pharmacist ";

(ggg) "Provincial Appellate Authority means" an Authority constituted under the section 9A of the Act"; and

(gggg) " Registered Pharmacist" means a person who is registered in the Register "A" with the Provincial Pharmacy Council as provided in the Pharmacy Act, 1967";

(h) "Registered Medical Practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance, 1962 (xxxii of 1962).

(i) "Retail Sale" means a sale at Maximum Retail Price to the consumer by the licensee, on Form 6, 8 or 9";

(j) "Whole sale" means sale by a manufacturer, importer, indenter or their agent having a drug sale license on Form 7 Or 7-A of the said rules, as the case may be and under written warranty on Form 2A of the Drugs (Licensing, Registering and Advertising Rules 1976).

(k) "Schedule" means a schedule to these rules,

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

(m) "Warranty" means a written statement or a declaration given by the manufacturer, importer, indenter and their authorized agent on Form 2A as prescribed in the Drugs (Licensing, Registering and Advertising Rules 1976).

CHAPTER – 2
PROVINCIAL QUALITY CONTROL BOARD, GOVERNMENT ANALYST AND PROVINCIAL DRUG INSPECTOR.

3. (1) The Board shall consist of the following member,

(a) Special Secretary, Public Health, Health Department,

(b) The Additional Secretary, Public Health, Health Department, shall be the Vice Chairman of the Board.

(c) **An officer of the Provincial Drug Control Administration who shall be Pharmacy graduate registered A with Pharmacy Council of Sindh nominated by the Government to be the Secretary of the Board,**

(d) **One member from Pharmacy profession, who shall be a Pharmacy graduate, registered A with Pharmacy Council of Sindh, nominated by the Government having no financial interest in the pharmaceutical trade or industry,**

(e) **One Professor of Pharmacology, preferably Pharmacy graduate registered A with Pharmacy Council of Sindh nominated by the Government having no financial interest in the pharmaceutical trade or industry,**

(f) **One Professor of Pharmaceutics, preferably Pharmacy graduate registered A with Pharmacy Council of Sindh nominated by the Government having no financial interest in the pharmaceutical trade or industry,**

(g) **One Professor of Pharmacognosy, preferably Pharmacy graduate registered A with Pharmacy Council of Sindh nominated by the Government having no financial interest in the pharmaceutical trade or industry,**

(2) The Special Secretary, Public Health, Health shall be the Chairman of the Board,

(3) The Additional Secretary, Public Health, Health Department, shall be the Vice Chairman of the Board.

(3a) Deputy Secretary of the Board, who shall be the member of the Board and graduate in Pharmacy, Registered in Register A with Pharmacy Council of Sindh and in absence of Secretary of the Board, he shall conduct the meeting and perform all duties and functions of the Secretary of the Board.

(4) The Board may Co-Opt any other qualified expert having formal training and experience in the field concerned.

(5) No act or proceeding of the Board shall be invalid merely by reason of any vacancy, or any defect in the constitution of the Board.

(6) The meetings of the Board shall be shall be presided over by the Chairmen and in his absence by the Vice-Chairmen.

(7) The meetings of the Board shall be held at least once every two months.

(8) The meetings of Board shall be held in such manner and at such time and place as may

be directed by the Chairman.

(9) The meetings shall on the directions of the Chairman be convened and the minutes of such meetings shall be recorded by the Secretary along with the names of members present at such meetings.

(10) All correspondence for and behalf of the Board shall be conducted by the Secretary.

(11) The Secretary shall be responsible for day to day affairs of the Board and shall perform such other functions under rules as may be assigned to him by the Chairman.

QUALIFICATION OF INSPEOTORS AND ANALYSITS:-

4. (1) No person shall be appointed as Inspector unless he possesses a degree in pharmacy from a Pakistani University or any other institution recognized by the Pharmacy council of Pakistan and has at least **one** year experience in the manufacture, sale, testing or analysis of drugs or as worked at least for the same period in the Drug Control Administration or a hospital or Pharmacy.

(2) No person shall be appointed as an analyst unless he possesses a degree in Pharmacy form a Pakistani University or any other institution recognized by the Pharmacy council of Pakistan and has at least **five** year's experience in the manufacture, testing and analysis of drugs or has worked for the same period in the drug control administration.

Provided that if a person of the above qualification is not available, a person possessing a degree in Medicine or Pharmacy with five year's experience in testing of drugs and medicine may be appointed as Inspector or Analyst. Provide further that the person holding the post of Inspector or Analyst immediately before coming into force of these rules shall, not withstanding the above qualification or experience continue to hold such posts.

4-A Qualification of Provincial Inspector of Drugs

(a) No person shall be appointed as a Provincial Inspector or Government Analyst unless he is Pharmacy graduate registered in register A with

Pharmacy Council of Sindh as prescribed under Pharmacy Act, 1967.

(b) The Regional or Divisional Drug Inspector and Inspectors shall perform their functions under the control and supervision of the Chief Inspector of Drugs Sindh.

(c) subject to the general control of the Chief Inspector Sindh, all Inspector within the division or region shall be under the control and supervision of Regional or Divisional Drug Inspector.

(d) The Licensing Authority shall enjoy general superintendent referred in section 18 of the Act

over Chief Inspector of Drugs Sindh, Regional or

Divisional Drug Inspector, Drug Testing laboratory and Inspectors.

Explanation for the purpose rule 4 and 4-A licensing Authority means the Secretary, Health Department Government of Sindh.

4-B. <u>DUTIES OF PROVINCIAL INSPECTOR.</u>

(a) Subject to the instructions of the licensing Authority, it shall be duty of a Provincial Inspector:-

(i). to inspect not less than twice a year all establishments of drugs licensed for sale and all

establishments licensed to manufacture of drugs within the assigned area and to keep record of such inspections;

(ii). to check all the conditions of the license are being observed by the licensee;

(iii). to take and send for test / analysis, if necessary, samples of any drug which he has reason to suspect is being manufactured or sold, stocked or exhibited for sale in contravention of any of the provision of the Act and the rules;

(iv). to investigate any complaint in writing which may be made to him and furnish the report in respect thereof to the licensing Authority;

(v). to institute prosecution in respect of contravention of the Act and the rules;

(vi). to maintain record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and seizure of stocks and submit reports of such record as may be required by the Provincial Quality Control Board or his controlling officers;

(vii). to make such enquiries and inspections as may be necessary to stop manufacture and sale of drugs in contravention of the Act and any rules framed there under and

(viii). to inspect all premises licensed to under the Act and these rules before granting or renewal of such license.

(b) Duties of Regional or Divisional Drug Inspector.

(i). The Regional or Divisional Drug Inspector shall scrutinize the monthly inspection reports and counter check the inspections of sale establishments or manufacturing units done by the inspectors, along with his own monthly working and submit the same to the Chief Inspector of Drugs Sindh with his comments or remarks;

(ii). Further on quarterly basis's he shall evaluate the working performance of the inspectors and submit to the Chief Inspector of Drugs Sindh;

(iii). The Chief Inspector of Drugs up on receipt of monthly report and quarterly performance report shall add his own remarks and submit the same along with the working performance of the Regional or Divisional Drug Inspector to the board;

(iv). Further he shall convey the instructions to the inspectors regarding drug control issued by the Federal or Provincial Government or Board with mode of implementation;

(v). and arrange compact training and refresher programs for Inspectors to improve their performance as and when required with coordination of Board or other agencies.

PROHIBITION OF DISCLOSURE OF INFORMATION.

5. Except for the purpose of official business or when required by a court of law, an inspector or Analyst shall not disclose to any person any information required by him in the course of his official duties.

(5-A) Monthly report: - An Inspector shall submit monthly report in form-1 to the Board in respect of actions taken by him under section 18.

SEIZED DRUGS AND MATRIAL AND SAMPLES.

6. (1) The intimation, under sub-section (2) of section 19, of the purpose for which a sample taken shall be in form-2.

1-A* The prohibitory order under clause (i) of Sub-section (1) of section 18 shall be in Form 2-A.

(2) The receipt of the drug or any other article seize by the Inspectors under section 18 shall be inform-3.

(3) In pursuance of the clause (i) of sub section (3) of section 19, the sample shall be sent to he Analyst through a memorandum in orm-4.

(4) In case the sample is delivered to the Analyst other than by the Inspector personally, a copy of the memorandum, a specimen impression of seal or mark on the

Packet together with the impression of the seal or mark of the person form whom the sample is drawn, shall be sent to the Analyst separately **by registered post or by hand.

PROCEDURE ON RECEIPT OF SAMPLES FROM INSPECTOR.

7. On receipt of a package from an Inspector containing a sample for test and analysis, the analyst shall compare the seals on the packet with the specimen impression received separately and shall note the condition of the seal on the package.

8. An analyst shall also cause to be tested and analyzed such samples of drugs as may be

submitted to him in writing from a Government Department or any other public institutions shall furnish the report of the result of the test and analysis to the Government Department or the public institution concerned in form 4-A.

9. (1) An Analyst shall forward to the Government a Monthly report containing such information as may be required by Government along with a copy of result to the sample tested and analyzed during the period under report.

(2) Government may, if it is of opinion the results of any test or analysis of any drug should be published for the information of the public, forwarded a copy of such result to the Federal Government for publication under section 40 of the Act.

10. FEE FOR TEST AND ANALYSIS OF DRUGS: - The fee for test and analysis of drugs in respect of samples sent by persons other than an inspector or a Government Institution shall be as laid down in Schedule **C.**

CHAPTER - 3
PART III SALE OF DRUGS.

Licensing Authority:

11. (1) The Secretary, Health Department shall be the licensing authority for the purpose of rules.

(2) The licensing Authority may by order by order in writing authorize any person under his control to exercise such powers of the licensing Authority in such area and subject to such conditions as may be specified I the order such area and subject to such conditions as may be specified in the order.

12. Licenses shall be the following types,

(i) License to sale by way of retail sale on Form-6,

(ii) License to sale by way of whole sale shall be issued to manufacturer, importer or indenter shall be on Form 7,

(iii) License to sale by way of whole sale as authorized agent of manufacturer, importer or indenter shall be issued on Form 7-A,

(iv) License for Pharmacy shall be on Form 8.

(v) License to sell Narcotics substances shall be on Form-9.

13. (1) An application for the grant or renewal of license referred to in rule 12 shall be made in form 5 to the licensing authority.

(2) An application under sub-rule (1) shall be accompanied by a fee of five thousands rupees in case new license and three

Thousands rupees in case of each renewal,

(3) An application for issuance of duplicate copy of license or change in the name qualified person shall be accompanied by a fee of two thousands rupees. .

(4) For any change of ownership and or premises, a new license shall be required to be obtained.

(5) The fees so collected shall be deposited under the Head of Account of Provincial Quality Control Board Sindh, for its utilization in the strengthening and up gradation of Drug Control Administration

Forms of Licenses to sell Drugs.

14. (1) A license to sell, stock, exhibit for sale or distribute drugs by way of retail sale shall be in form-6.

(2) A license to sell, stock, exhibit for sale or distribute drugs by way of whole sale by manufacturer, importer or indenter shall be inform-7.

(2a) A license on Form 7-A shall be issued to sell, stock, exhibit for sale or distribute drugs by way of whole sale to a person who is authorized agent of manufacturer, importer or indenter and

(3) A License for Pharmacy shall be in Form-8.

(4) A License on Form-9 shall be issued to sell, stock, exhibit for sale or distribute Narcotics and other controlled drugs.

Sale at more than one place:-

15. If drugs are sold, stocked, exhibited for sale or distributed at more places than one, a separate license shall be required in respect of each such place.

Provided that no license, shall be required for Godown which is used for storage and meets the prescribed storage conditions and is listed with its address in the license.

Duration of Licenses.

16. (1) A license issued under the rules shall, unless sooner suspended or cancelled, remain in force for two years from the date of issue or until the disposal of the application

for renewal of such license whichever is latter.

(2) An application of renewal of a license shall be made within three months of the expiry thereof:

Provided that an application for renewal of a license may be entertained by the licensing Authority if such application is made within three months after the expiry of license and the licensing Authority is satisfied that the application could not be made earlier for reasons beyond the control of licensee.

(3) The licensing authority shall dispose of the application for renewal of license within three months of receipt of such application.

(4) The licensing authority shall submit monthly report to the Board containing the names and addresses of the persons who made applications for grant/renewal of licenses, date of receipt of such applications, the number of applications disposed along with the number of license granted, renewed, suspended or cancelled including the reasons of suspension and cancellation and the number of applications not disposed within three months with reasons of delay.

PRE – CONDITIONS FOR THE ISSUE OF LICENSES: -

17. (1) The licensing Authority shall not issue:-

(a) A license in Form 6 and 8 unless.

(i) The premises shall be not less than 100 square feet area for retail and 200 square feet area for whole sale and Pharmacy, mentioned in the application have proper facilities for stocking and storage of drugs, including their protection from direct sunlight, dust or dirt and refrigeration facilities, where necessary, for preserving the quality of drugs;

(ii) The applicant under takes to keep the premises clean and in hygienic and tidy condition;

(ii-a) the licensee to sell drugs on any form shall give under- taking that he shall not sell, stock, exhibit for sale or distribute any chemical or substances as specified under section 23 (1) (h) of the Drugs Act,

(ii-b) No new license shall be issued within three hundred meters of a shop which is already operating on a license on form 6,8or 9,

(iii) The sale is supervised by a person.

(a) Who is registered as a Pharmacist under the Pharmacy Act, 1967 or

(b) In the case of a Pharmacy the requirements prescribed in Schedule 'D' have been complied with.

Explanation ~~ For the purpose of this sub-rule the term 'PHARMACY' shall mean a store or other place-

(i) where drugs are dispensed, that is, measured or weighed or made up and supplied or

(ii) where prescriptions are compounded or

(iii) where drugs are prepare; or

(iv) which has upon it or displayed within it affixed to or used in connection with it, a sign bearing the word or words "Pharmacy" "Pharmacist" or "Dispensing Chemist"; or

(v) Which by, sign, symbol or indication within it or upon it gives the impression that operations mentioned at (i.)(ii) and (iii), are carried out in the premises, or

(vi) Which is advertised in terms referred to in (iv) above.

(2). the licensing Authority shall not issue a license in Form 7 unless the applicant.

(i). is an indenter, importer or manufacturer; and

(ii). Fulfills the conditions laid down in clause (i) (ii) and (iii) of sub rule (1).

(2A). the licensing Authority shall not issue a license on form-7A, unless the applicant is an authorized agent of a licensed manufacturer, importer or indenter.

18. Conditions of licenses.

A license issued in **Form 6, 7, 7A, 8 or 9** shall be subject to the conditions, mentioned in the license and to the following conditions namely:

(i). The sale of any drug by way of retail sale shall be recorded in a register maintained for the purpose and such register including bills or counterfoils concerning retail sale shall be preserved for a period of three years from the date of the sale;

(ia). The original valid drug sale license along with original registration certificate of qualified person shall be displayed prominently in the part of premises,

(ib). The name of the sale establishment or Pharmacy with complete address of the premises and license number should be visibly painted out side the premises,

(ic). All license holders shall provide their N.I.C and N.T.M. Numbers,

(id). The holder of license on form 6, 8 and 9 shall always issue printed cash memo under their license name carrying complete address of their shop and shall mention : -

- **(i). Name of Patient / purchaser,**
- **(ii). Date of issue,**
- **(iii). Name of the Product with potency and quantity,**
- **(iv). Batch number,**
- **(v). Date of expiry,**
- **(vi). Mane of manufacturer, and**
- **(vii). Price of each drug and total thereof, and place their legible signature at the end of the cash memo,**

(ie). The holder of the license on form 7 shall not sell to anyone, other than to a person who has

valid drug sale license on form 7A and whom they authorized and appointed in writing to be their authorized gent,

Provided that no sale shall be conducted without issuance of proper warranty on form 2A as prescribed under section 23 (1) (i) of the Act.

(if). The holder of license on form 7A shall not sell to any other person holding license on form 7 or form 7A and shall only sell to a retailer having a license on form-6 or Pharmacy having license on form-8or a person having a license on form- 9, for narcotic and controlled substances,

Provided that no sale shall be conducted without issuance of proper warranty on form 2A as prescribed under section 23 (1) (i) of the Act.

(ii) The drugs specified in schedule 'B', 'E' or 'F' and preparations containing such drugs shall not be sold by way of retail except on a prescription of a registered medical practitioner which shall-

(a). be in writing and be signed by the person giving it with his usual signature and be dated by him;

(b). specify the name and address of the person for whose treatment it is given;

(c). indicate the total quality of drugs to be supplied and the doses to be taken.

Provided that prescription shall not be required for sale of drugs to a registered medical practitioner, hospital or dispensary or such other institution approved by the licensing authority.

(iii) the sale of any drug specified in schedule 'B', 'E' or 'F' by way of retail sale shall be recorded in a register

specially maintained for the purpose and the following particulars shall be entered in the register, namely:-

(a) S.No.
(b) Bill / Invoice /Cash memo No.
(c) Date of Sale.
(d) Name of the patient / purchaser with complete address.
(e) Name of the drug.
(f) Batch No.
(g) Name of the manufacturer.
(h) Quantity.
(i) Signature of the person authorized to supervise the sale.
(j) Name of the registered medical practitioner.

(iv) the purchases and sales of drugs by way of whole sale with the following details shall be recorded in a register maintained for the purpose and such register including invoices of purchase and sale shall be preserved for a period of three years from the date of last entry in the register : -

(a) the date of purchase and sale;

(b) the name and address of the purchasing or selling concern;

(c) the names of the drugs, their batch numbers, their date of expiry, where applicable,

(d) the name of the manufacturer.

(v) Cash memo of every drug specified in schedule 'B', 'E' or 'F' sold to any person or institution, shall be issued particularly indicating batch No. date of expiry and name of the manufacturer of the drug sold with the approved retail price;

(vi) Substances specified in schedule 'F' and falling under the list of poisons and substances specified in 'B' shall be stored in a retail shop in a locked almarah, cupboard or drawer reserved for the storage of such drug or in such part of the shop to which unauthorized or un-concerned person dose not have access;

(vii) any change of name of the person authorized to supervise the sale shall be immediately notified to the licensing authority under intimation to the Board and the Inspector concerned;

(viii) an inspection book shall be maintained for recording inspection proceedings and opinion of the visiting member of the Board or Inspector about the working of the licensee and the defects or irregularities noticed by him and the inspection note or proceedings shall be signed by the person who has recorded such note or proceedings, by the licensee and the person supervising the sale and such defects or irregularities shall be rectified by the licensee under intimation to the Board and the inspector concerned;

(ix) all registers and records maintained under these rules and such other

information as may be required shall be made available to the visiting member of the Board or Inspector as the case may be.

Cancellation and Suspension of licenses.

18. **(1) The licensing Authority on the report of an Inspector scrutinized by the Divisional or Regional Inspector of Drugs or on its own motion initiate proceedings under section 41 of the Drugs Act, 1976,**

(2) A licensee whose license has been cancelled or suspended under sub rule (1) may appeal to the Provincial Appellate Authority within thirty days of the date of such order.

20. **PROVINCIAL APPLETE AUTHORITY.**

The Provincial Applet Authority shall consist of:-

(i) Secretary Health Department; *Chairman.*

(ii) One officer no below the rank of *Member/* an officer of (BS-18) *of* the Drug Control *Secretary.* Administration preferably a Pharmacy Graduate Registered A with the Pharmacy Council of Sindh nominated by Government;

(iii) Secretary of the Pharmacy Council *Member.*

Council Sindh;

(iv) One representative of Pakistan *Member.* Pharmacist Association.

(2) The non official members shall hold office at the pleasure of Government for a period of two years and shall be eligible for re - nomination.

(3) Any non official member may at any time resign his office by addressing letter to Government.

(4) No act or proceeding of the appellate authority shall be invalid merely on the Ground of the existence of any vacancy or any defect in its constitution.

(5) The appeal shall be in triplicate and be accompanied by a copy of the impugned order and shall contain all material, statement, arguments, relied upon by the appellant.

(6) The Appellate Authority shall transmit a copy of appeal to the Licensing Authority, against whose decision appeal has been filed for submitting reply.

(7) The Appellate Authority shall meet as and when required to perform its functions.

(8) The meeting shall be held in accordance with the regulations until such regulation are framed, the meeting shall be held in the manner as directed by the Chairman.

(9) The Appellate Board shall exercise such powers, including the powers of an Inspector, as may be prescribed by regulations.

(10) The Appellate Authority may-opt any person as a member for particular purpose.

(11) The Licensing Authority shall on demand produce before the Appellate Authority the record of the case leading to the decision.

(12) The Appellate Authority shall, after giving parties to the appeal an opportunity of being heard, pass such order as it thinks fit and such order shall be final and implemented by the licensing Authority.

(13) The Appellate Authority may appoint experts or committee for scrutiny and report on any specific matter placed before it.

(14) The Appellate Authority shall with the approval of Government and by Notification in the official Gazette make regulations to regulate the conduct of its business.

21. INSTRUTIONS TO THE MANUFATURERS, IMPORTERS AND INDENTERS:

Manufactures, Importers and Indenters bound to disclose their distribution network:-

(a) Every manufacturer, importer or indenter of drugs as defined in clause (g) of section 3 of the Act, operating his business in the Province, based any where in Pakistan shall bind himself to provide the following information to the Provincial Quality Control Board Sind at the beginning of every quarter of the year

(b) Complete list of their products with copy of: -

(i) Registration Certificate & enclosures of form-5,

(ii) Manufacturing License or import License as the case may be.

(c) Complete List with address of their authorized agents for market and institution supplier (if different), along with copy of:-

(i). their valid drug sale license & Telephone number,

(ii). Authority letter, authorizing them to issue warranty on their behalf,

(iii). Name of the person authorized to sign and issue warranty on their behalf,

(iv). Complete details with batch numbers of the sale to each of their authorized agents.

22. ALL BOUND BY LAWS:-

All public and private hospitals, institutions, where drugs are purchased, procured, stored,

stocked, distributed, dispensed or compounded upon specific prescription of a Registered Medical Practitioner for specific individual whether sterile or non sterile shall acquire Drug Sale license as the case may be and shall be bond by all rules and regulations made in accordance with the provisions of the Act.

Schedule (A)

FORM – 1.
(See rule 3 (1))
MONTHLY REPORT FORM INSPECTOR
FOR THE MONTH OF .....

PLACE INSPECTED	NAME OF CONCERNED WITH COMPETE ADDRESS & VALIDITY OF LICENSE.	NAME OF CONCERNED FOUND VIOLATING LAW.
NO. OF SAMPLES DRAWN IF ANY.	DETAILS OF ACTION TAKEN UNDER SECTION 18, IF ANY.	REMARKS

DETAILS OF VIOLATIONS IN RESPECT OF DRUGS.
Reports of samples of drugs not in compliance with law.

Name of drug.	Batch No.	Name of manufacturer
Place of taking of sample.	Date of receipt of test report with nature of result.	Action taken indicating details of seizer / sale restriction.

FORM NO. 2.

Intimation of purpose to person from whom sample is taken.

To,

I have this day taken from the premises of .....

Situated .....

Samples of the drugs specified below for the purpose of test / analysis.

Name of Drug. Name of Manufacture. Regd: No. Batch No.

Quantity. Bill No. Value.

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

FORM - 2A.
(See rule 6 (1-A)
Order under section 18 (1) (i)

Requiring a person not to dispose of stocks in his possession.

Whereas, I have reason to believe that the stocks of drugs in your possession detail below contravene the provision of section . . . . . of Drugs Act 1976,

Now, therefore I hereby direct you not to dispose of the said stocks for a period of ..... Day's from this date.

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

Details of stocks of Drugs.

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

FORM 3
See rule 6 (2)

Receipt for stock of drug and other material / articles seized under section 18 clause (f) of Drugs Act 1976.

and other material and articles

The stock of drugs details below has this day been seized by me under the provisions of clause (f) of section 18 of Drugs Act 1976, from the premises of ----------situated at ----------

---

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

Details of Drugs, other material and articles of drugs seized.

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

FORM-4
MEMORANDUM TO ANALYST.
(See rule 6 (3))

Serial No. of memorandum
.....
From,

To,
The Analyst,

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

The sample is of the drug ....., and Purports to contain .....

The portion of the sample has been marked by me with the following mark.

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

FORM – 4A.
(See rule (8)
CERTIFICATE OF TEST OR ANALYSISBY THE DRUG TESING LABORATORY / GOVERNMENT ANALYST.

Certified that the sample, bearing number .....purporting to be a sample of ..... received on ..... with memorandum NO. ..... dated ..... from ..... has been tested / analyzed and that the result of such test / analysis is as stated below:-

2. The conditions of the seals on the packet on receipt was as 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:-

Government Analyst.

Details of result of test or analysis

Government Analyst.

FORM – 5.

(SEE rule 13 (1)

APPLICATION FOR LICENSE TO SELL, STOCK AND EXHIBIT FOR SALE AND DISTRBUTE DRUGS.

I/We ..... of ..... hereby apply for a license to sell drugs by way of retail / whole sale / Pharmacy on the premises situated at .....

2. The sale of drugs will be under the personal supervision of .....

(NAME) .....(QULIFICATION)
(NAME) ..... (QULIFICATION)

3. I/We /am / are submitting herewith the following documents:-

(i) Attested copies of the Qualifications of persons mentioned above.

(ii) Photo state copy of National Identity Card of the proprietor and the above qualified persons;

(iii) Two attested copies of the photographs of above qualified persons;

(iv) Affidavit binding the proprietor and qualified person to inform the licensing authority and the Inspector as soon as either of the party ceases to have interest in the license issued under these rules;

(v) Attested photo state copy of the registration issued by the C.C.I. and E in case of indenter / importer.

(vi) Manufacturer's authority as agent.

Treasury Challan for Rs.....

Dated. ..... Signature of applicant.

NAME AND PERMANENT HOME ADDRESS.

FORM -6.

See Rule 14 (1)

License to sell stock and exhibit for sale and distribute drugs by way of retail sale.

..... is hereby licensed to sell, stock and exhibit for sale and distribute drugs by way of Retail sale on the premises situated at .....
Subject to the conditions specified below and to the provisions of the Drugs Act, 1976, and these rules.

2. This license will be in force for two years from the dates given below:

   Name (s) of qualified person (s) along with N.I.C number;

   (i)
   (ii)

3. Address of Godown/Godowns where drug shall be stored.

Date Licensing Authority.

CONDITIONS OF LICENSE.

1. This license shall be displayed in a prominent place in the part of the premises open to the public.
2. The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules there under for the time being in force.
3. The licensee shall repot forthwith to the Licensing Authority and change in the qualified staff in charge.
4. No drug requiring special storage condition of temperature and humidity shall be stored or sold unless the precautions for preserving the properties of the contents have been observed throughout the period during which it has been in possession of the licensee.

FORM-7.
(SEE RULE 14 (2))

1. License to sell stock and exhibit for sale, distribute and sell drugs by way of whole sale by manufacturer, importer or indenter.

M/s ..... being manufacture/importer or indenter, is hereby licensed to stock, exhibit for sale, distribute and sale by way of whole sale on the premises situated at ..... subject to the conditions specified and to the provisions of the Drugs Act, 1976, and these rules.

2. This license will be in force for two years from dates given below:

3. Name (s) of proprietor or partner or director along with residential address, N.I.C. and N.T.N number,

4. Name (s) of qualified person (s) along with N.I.C number;

5. Address of Godown (s) where drug will be stored.

Date Licensing Authority.

FORM-7-A.
(SEE RULE 14 (2))

1. License to sell stock and exhibit for sale, distribute and sell drugs by way of appointment as an authorized agent of manufacturer, importer or indenter.

M/s ..... being authorized agent of M/s ..... being authorized agent of M/s ..... is hereby licensed to

stock, exhibit for sale, distribute and sale by way of whole sale on the premises situated at ..... Subject to the conditions specified and to the provisions of the Drugs Act, 1976, and these rules.

2. This license will be in force for two years from dates given below:

3. Names of the Firms/companies with addresses who have appointed them as their authorized agent;

(i)
(ii)
(iii)

4. Name (s) of proprietor or partner or director along with residential address, N.I.C. and N.T.N number,

5. Name (s) of qualified person (s) along with N.I.C number; (i)

(ii)

6. Address of Godown (s) where drug will be stored.

Date **Licensing Authority.**

FORM – 8.
(See rule 14 (3)

License to sell drugs in Pharmacy ..... is hereby licensed to compound or prepare on prescription the drugs and sell, distribute drugs by way of Retail sale on the premises situated at .....
.....

Subject to the conditions specified below and to the provisions of the Drugs Act, 1976, and the rules made there under.

2. This license will be in force for two years from the date given below:

3. Name (s) of qualified person (s) along with N.I.C number;

(1) (2)

4. Address of Godown/Godowns where drug shall be stored.

Date Licensing Authority.

CONDITIONS OF LICENSE.

5. This license shall be displayed in a prominent place in the part of the premises open to the public.

6. The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules there under for the time being in force.

7. The licensee shall repot forthwith to the Licensing Authority and change in the qualified staff in charge.

8. No drug requiring special storage condition of temperature and humidity shall be stored or sold unless the precautions for preserving the

properties of the contents have been observed throughout the period during which it has been in possession of the licensee.

FORM 9.

License to sell stock and exhibit for sale, Narcotic and other controlled drugs / substances.

M/s ..... is hereby licensed to stock, exhibit for sale and sell narcotics and other controlled drugs / substances on the premises situated at ..... Subject to the conditions specified and to the provisions of the Drugs Act, 1976, and these rules.

4. **This license will be in force for two years from dates given below:**

5. **Name (s) of proprietor along with residential address, N.I.C. and N.T.N number,**

6. **Name (s) of qualified person (s) along with N.I.C number;**

   (i)
   (ii)

7. **Address of Godown (s) where drug will be stored.**

Date **Licensing Authority.**