

AZAD GOVERNMENT OF THE STATE OF JAMMU AND KASHMIR
HEALTH SECRETARIAT

'Muzaffarabad'
Dated: 16-11-2021

Notification

No. SH(54) 2 /2021. In exercise of the powers conferred by sub-section (1) of Section 44 of the Drugs Act, 1976 (XXXI of 1976) as adopted in Azad Jammu and Kashmir vide the Drugs (Adaptation) Act, 1986, the Azad Government of the State of Jammu and Kashmir is pleased to make the following rules, namely:-

CHAPTER I PRELIMINARY

1. **Short title and commencement:**-(1) These rules may be called the Azad Jammu and Kashmir Drugs (Sales) Rules, 2021.
(2) They shall come into force at once.
2. **Definitions:-** (1) In these rules, unless there is anything repugnant in the subject or context:
 - (a) "Act" means the Drugs Act, 1976 (XXXI of 1976), adopted in Azad Jammu and Kashmir vide Drug Adaptation Act 1986;
 - (b) "Board" means the Azad Jammu and Kashmir Quality Control Board constituted under rule 3;
 - (c) "Committee" means a committee of the Board;
 - (d) "Form" means a form mentioned in the Schedule A;
 - (e) "Government" means the Azad Government of the State of Jammu and Kashmir;
 - (f) "Inspector" means Inspector appointed under section 17 of the Act and includes Deputy Drug Controller;
 - (g) "Licensing authority" means the Secretary Health Department, Azad Government of State of Jammu and Kashmir or an Government officer duly authorized by the Secretary Health;
 - (h) "Medical store" means a premises where drugs are stored, sold or offered for sale and bear a licence on Form 9;
 - (i) "Manufacturer" means a manufacturer of a drugs having valid drug manufacturing Licence;
 - (j) "Narcotic, psychotropic or controlled drug" mean a drug specified in the Schedule B or the Schedule D;
 - (k) "Pharmacy" means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription;
 - (l) "Registered medical practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance 1962 (XXXII of 1962);
 - (m) "Retail Sale" means a direct sale to consumer;
 - (n) "Schedule" means a Schedule to these rules;

- (o) "Section" means section of the Act;
- (p) "Seller" means the seller of a drugs having valid drug sale licence; and
- (q) "Wholesale or distributor" means a person who buys drug for the purpose of selling the same to retailer(s) and includes only authorized agent of a manufacturer, importer or indenter entitled to issue warranty in accordance with sub-Section (1) of Section 23 of the Act.
- (2) All the terms used in these regulations but not defined herein shall have same meaning as assigned to them in the Act.

CHAPTER II

BOARD, GOVERNMENT ANALYST AND INSPECTOR

3. **Board:-**(1) There shall be Azad Jammu and Kashmir Quality Control Board consisting of the following ex-officio Chairman and Members:

(a)	Secretary Health	Chairman
(b)	Drug Controller / Chief Drug Inspector	Vice Chairman/ Member
(c)	Director Health Services (Procurement) DGH office	Member
(d)	Head of Pharmacology Department from AJK Medical College, Muzaffarabad	Member
(e)	Secretary Quality Control Board / Drug Controller DGH office	Member/Secretary

- (2) The Vice Chairman shall act as Chairman in his absence.
- (3) The minimum quorum for a meeting of the Board shall be three members including the Chairman.
- (3) No act or proceeding of the Board shall be invalid merely on the ground of the existence of any vacancy or any defect in the constitution of the Board.
- (4) The Board may co-opt any other qualified expert having formal training and experience in the pharmaceutical field as member.

Function of the Board:-(1) An Inspector and a Government Analyst shall submit monthly reports on Form 1 and Form 2 respectively to the Board and a summary of the overall situation of quality control in his area of jurisdiction. The Board shall maintain the information in order to monitor the quality of all the drugs sold and to review the performance of the manufacturers and the sellers.

- (2) The Board may meet at least once in a month to review the situation of the quality control of drugs on the whole including consideration of any specific point arising during the period on the working of various firms, drug testing laboratories and Inspectors.

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(3) The Board shall examine a case referred to it by an Inspector and shall, if any action is proposed to be taken against a person under the Act or the rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the Licensing Authority.

(4) Before referring a case to a Drug Court, the Board shall ascertain the name of the director, partner and employee of the company, corporation, firm or institution who is prima facie responsible for the commission of the offence under the Act or the rules and may allow an Inspector to institute prosecution against such person.

(5) The Board may, in case of a minor contravention, direct the manufacturer or the seller to bring improvement, issue a warning to him, order the de-sealing and take any other action including recall of batches.

(6) The Board may forbid a person, for a period not exceeding three months, from removing or disposing of a Drug, article or other thing likely to be used as evidence in an offence under the Act or the rules.

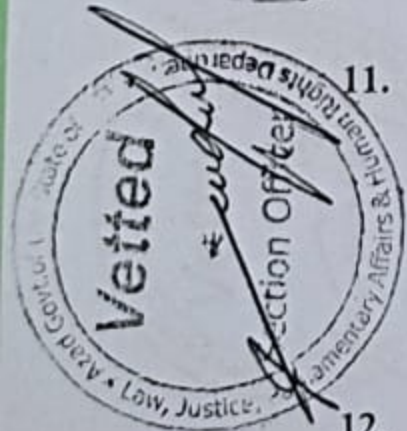
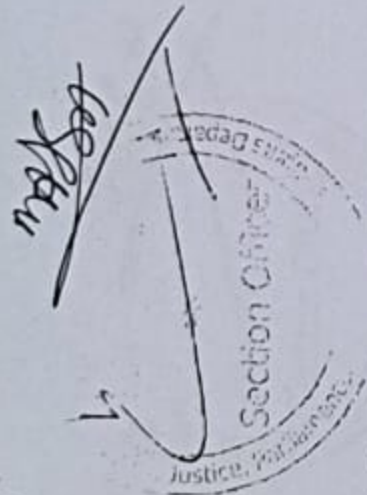
5. **Qualifications of Inspectors/ Government Analyst etc:-** No person shall be appointed as an Inspector, Government Analyst or shall be authorized to perform any function under these rules unless he holds a minimum qualification prescribed for such post.

6. **Duties of Inspectors:-** Subject to the instructions of the Licensing Authority, an Inspector shall,-

- (a) Inspect a Medical Store, a Pharmacy and a drug manufacturing premises atleast once in three months and maintain record of the inspections;
- (b) Satisfy him-self that the conditions of the licence are being observed;
- (c) If he has reasons to believe that a drug is being manufactured, sold, stocked or exhibited for sale in contravention of a provision of the Act or the rules, he may take samples of the drug and may send it for test or analysis and may seize the drug or any equipment;
- (d) Investigate any complaint made to him in writing against a person and submit a report of his investigation to the Board;
- (e) Initiate prosecution on the direction of the Board and to pursue cases in the Drug court;
- (f) Maintain record of actions taken by him in the performance of his duties, including the taking of samples and seizure of Drugs or equipment, and submit reports of such record to the Board;
- (g) Stop manufacturing or sale of Drugs being carried in contravention of the Act and these rules; and
- (h) Inspect a place licensed under the Act or the rules before renewal of the licence.



7. **Prohibition of disclosure of information:-** Except for the purpose of official business or when required by a Drug court, an Inspector or a Government Analyst shall not disclose to any unauthorized person any information acquired by him in the course of his official duties.
8. **Form of order not to dispose of stock:-** An Inspector, requiring a person not to dispose of a drug or other material, shall make the order under Section 18 of the Act in Form 3.
9. **Form of intimation for purpose of taking samples:-**(1) An Inspector who takes sample of a Drug for the purposes of test or analysis, shall intimate the purpose of taking the sample to the person from whom he takes the sample in Form 4 and if he seizes a drug or other material, shall issue receipt of the seizure in Form 5.
- (2) The Inspector shall send a portion of the sample or the container to the Government Analyst for test and analysis through a memorandum in Form 6.
- (3) The Inspector shall send a specimen impression of his seal to the Government Analyst.
10. **Duties of Government Analyst:-**(1) A Government Analyst shall conduct test and analysis of the sample of a drug sent to him under the Act or the rules and shall furnish report, the result of test and analysis in Form 7.
- (2) A Government Analyst shall conduct test and analysis of the sample of a Drug sent to him in writing by an Inspector, a Government Department or any other public institution and shall furnish the report of the result of test and analysis to the Inspector, the Government Department or the public institution.
- (3) A Government Analyst shall forward to the Government monthly report containing results of samples tested and analyzed during the month for publication at the discretion of the Government and furnish such other information as may be required by the Government.
11. **Procedure on receipt of samples from Inspectors:-** On receipt of a sample of a drug from an Inspector, the Government Analyst shall compare the seals on the packet with the specimen impression received and shall note the condition of the seal on the package and after the test and analysis has been completed, he shall forthwith supply to the Inspector and the Board, a report of the result of the test and analysis.
12. **Fee for test and analysis of drugs:-** The fee for test and analysis of drugs in respect of samples sent by a person other than an Inspector or a Government Institution shall be determined by the Government Analyst or the person incharge of the Government laboratory or any other laboratory of Pakistan, authorized by the Government in accordance with the fees specified in Schedule "C".



CHAPTER III
SALE OF DRUGS

13. **Licensing Authority:-**(1) The Secretary Health Department shall be the Licensing Authority for the purpose of these rules
- (2) The Licensing authority may authorize any person under his authority, through notification in the official gazette to sign the licence and to exercise such other powers and in respect of such other areas, as may be specified in the notification.
14. **Type of Licences to sell Drugs:-** Following are the types of the licences, namely:-
- Licence for drugs by way of retail sale;
 - Licence for drugs by way of whole sale;
 - Licence for narcotics and other controlled drugs; and
 - Licence for drug in a Pharmacy.
15. **Application and fee for licence:-**(1) A person may apply to the Licensing Authority for the grant or renewal of a licence referred to in clauses (i) to (iv) of rule 14 in Form 8.
- (2) The applicant shall deposit the fee for issuance or renewal of a licence in the Head of Account No. 101-Health-Other Receipt, at the following rates:
- Three thousand rupees for grant of a licence to sell drugs by way of retail sale and one thousand and five hundred rupees for its renewal.
 - Three thousand rupees for grant of a licence to sell drugs by way of whole sale and one thousand and five hundred rupees for its renewal.
 - Three thousand rupees for grant of a licence for narcotics and other controlled drugs and one thousand and five hundred rupees for its renewal.
 - Three thousand rupees for the licence of a Pharmacy and one thousand and five hundred rupees for its renewal.
- (3) The Licensing Authority shall issue or renew a licence subject to the conditions prescribed in the Act and the rules.
- (4) The applicant shall pay one thousand rupees fee for change of the qualified person or the duplicate copy of the licence.
16. **Forms of licenses to sell drugs:-** (1) A licence to sell, store, exhibit for sale or distribute drugs by way of retail sale shall be issued in Form-9.
- (2) A licence to sell, store, exhibit for sale or distribute drugs by way of whole sale shall be issued in Form-10.
- (3) A licence to sell, store, exhibit for sale or distribute narcotics and other controlled drugs shall be issued in Form-11.
- (4) A licence to sell drugs in a Pharmacy shall be in Form-12.

17. **Sale at more than one place:-** (1) If a person desires to sell, store, exhibit for sale or distribute drugs at more than one place, he shall apply for a separate licence in respect of each place.

(2) Provision of sub-rule (1) shall not apply in case the drugs are properly stored in a godown, used only for storage of drugs and which meets the storage conditions and is enlisted along with its complete address on the licence.

18. **Duration of licenses:-** (1) A licence issued or renewed under these rules shall unless suspended or cancelled earlier, remain in force for a period of two years from the date of issue.

(2) If a person fails to apply for the renewal of a licence within thirty days after the expiry of the licence, his licence shall stand cancelled.

(3) If a person applies for the renewal of a licence within thirty days after the expiry of the licence, his licence shall remain enforce until an order on the application is passed by the licensing authority.

(4) The Licensing Authority shall issue a receipt of an application of a licence or renewal of a licence.

(5) The Licensing Authority shall dispose of an application for a licence or renewal of a licence within 45 days of the receipt of the application.

(6) If the Licensing Authority fails to dispose of the application within the specified time, it shall record reasons for its failure.

(7) If in the opinion of the Licensing Authority, it is not expedient in public interest to grant a license, it may refuse the application by assigning reasons in writing.

(8) The Licensing Authority shall not renew a licence without an inspection report of the Inspector concern on Form 13.

19. **Conditions for issuance of licences:-** (1) The Licensing Authority shall not issue,-

a) A licence in Form 9 (Retail Sale) and Form 12 (Pharmacy) unless,-

i) the Premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility; where necessary for preserving the properties of drugs to which the licence applies.

ii) the Premises is clean, hygienic and in tidy condition;

b) Licence in Form 10 unless the applicant is an indenter, importer, manufacturers or distributors of drugs and fulfill the condition lay down in sub - clause (a); and

c) Licence in Form 11 unless:-

i. the applicant possess a licence in Form 9, Form 10; and

ii. the applicant has never been convicted of any offence under the Act.

(2) The sale of drugs shall be supervised in following manners:-

a) the sale of drugs on Form-9 shall be supervised by:-

i. any person who is a qualified Pharmacist and holds a degree in Pharmacy from a University or an Institution recognized by the Pharmacy Council of Pakistan.

ii. any person having diploma of Pharmacy Assistant category "B" or category "C" from any recognized Provincial Pharmacy Council of Pakistan with at least one year practical experience.

iii. any person having certified Dispenser certificate / diploma from recognized faculty of provincial Government of Pakistan or Government of Azad Jammu & Kashmir with at least six months practical experience in relevant field.

iv. for veterinary drugs only; a person having Stock Assistant course from any recognized institute of AJK or Pakistan with the recommendations of AJ&K Live Stock Department.

b) the sale of drugs on Form-10, Form-11 and Form-12 shall be supervised only by a qualified Pharmacist who holds a degree in Pharmacy from a University or an Institution recognized by the Pharmacy Council of Pakistan and has agreed to personally supervise the sale of drugs for licence.

c) The existing licence holders on Form-9 supervisors including Pharmacy Assistant / Dispenser / Stock Assistant from the date of implementation of these rules will be given grace period of two years to upgrade their supervisors to Pharmacist. To safeguard public health and quality assurance, Form-10 and Form-11 however, will not be renewed except for the qualification of Pharmacist from any recognized University.

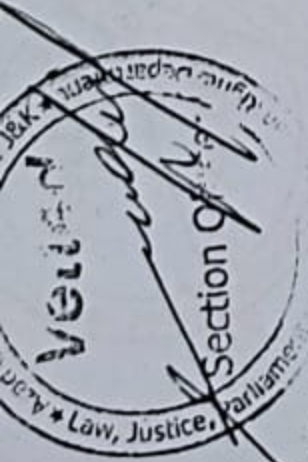
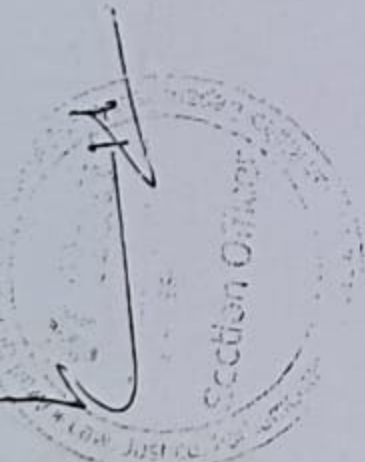
(3) In the case of a licence of a pharmacy (Form 12) in which preparation or compounding of a drug is undertaken, the premises has fulfilled the requirements contained in the Schedule F;

(4) In the case of renewal of already licenced premises, the licence shall not be renewed unless they employ on whole time basis a qualified person as mentioned in sub-rule (2).

20. **Conditions of licenses:-** (1) The Licensing Authority shall issue a licence in Forms 9,10,11 and 12 subject to the conditions stated in the licence and to the following, general conditions:

a) In the case of Pharmacy, the person shall display the word "Pharmacy" outside wall of pharmacy in white writing on a green coloured signboard having minimum length of 5 feet and width of

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2.5 feet and in the case of Retail Sale or Whole Sale the person shall display the word "Medical Store" or "Distributor" in white writing on a blue coloured signboard with the same minimum dimensions as required for a pharmacy.

- b) A person who is a qualified Pharmacist shall personally supervise the sale of drugs under licence in Form 10 (Wholesale), Form 11 (Narcotics) and Form 12 (Pharmacy), a person who is a Pharmacy Technician or Dispenser shall supervise Sale of drugs under licence in Form 9 (Medical Store) and a person who is Stock Assistant shall supervise only sale of veterinary drugs under licence in Form 9 (Veterinary Medical Store).
- c) the supply of a drug shall be recorded suitably and the records, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale;
- d) a drug specified in the Schedules B and D and a preparation containing such drug shall not be sold by retail sale except on and in accordance with the prescription of a registered medical practitioner with Pakistan Medical and Dental Council. A prescription shall be dispense only once, unless or otherwise specifically directed by the Prescriber to repeat it provided that no such prescription shall be required for sale of these drug to a registered medical practitioner, a hospital dispensary or any other institution approved by a order of Licensing Authority for such sale.
- e) a licence of a medical store shall not sell or store a drug mentioned in Schedule G.
- f) the sale of a drug specified in the Schedules B and D by way of retail sale shall be recorded at the time of supply in a register specially maintained for the purpose and the serial number of the entry in the register shall be entered in the prescription, and the following particulars shall be entered in the register, namely;
- | | | | |
|-----|-----------------------------------|------|-----------------------------------|
| i | Serial No. | vi | Name of the manufacturer |
| ii | Date of Sale | vii | Quantity sold |
| iii | Name of the prescriber | viii | Batch No |
| iv | Name of the patient or Purchaser. | ix | Quantity purchased and balance. |
| v | Name of the drug | X | Signature of the qualified person |

Explanation: If the drug specified in Schedule "D" are sold on a prescription on which the drug has been sold on a previous occasion, it shall be sufficient if the entry of the register include Serial No, the date of sale, the quantity sold and sufficient reference to an entry in the register recording the dispensing of the drug on a pervious occlusion.

- (2) For the purpose of this rule, a prescription shall-
- i. be in writing and be signed by the person giving it with his usual signature and be dated by him;
 - ii. specify the name and address of the person for whose treatment it is given; and
 - iii. indicate the total quantity of the Drug to be supplied and dose to be taken.

(3) All invoices and bills for the purchase of drugs shall be preserved for a period of at least three years.

(4) In case of sale of drug by way of whole sale by manufacturer or their authorized dealer, they must invariably ensure the purchaser holds a valid drug sale licence, and shall issue an invoice and warranty at the time of sale of the drug.

(5) A registered medical practitioner or a doctor of veterinary medicine is exempted from the requirement of a drug sale licence, if:

- i. The drug is for his patients; and
- ii. The record of a drug specified in the Schedule B and D is maintained as prescribed under this rule:

Provided that no pharmacy or medical store shall be allowed except and in accordance with the provisions of these rules.

(6) The invoice and warranty shall bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and shall be dated.

(7) The manufacturer, importer or seller of a drug shall maintain record of purchase or sale of a drug and shall preserve the record for a at least three years containing the following particulars:

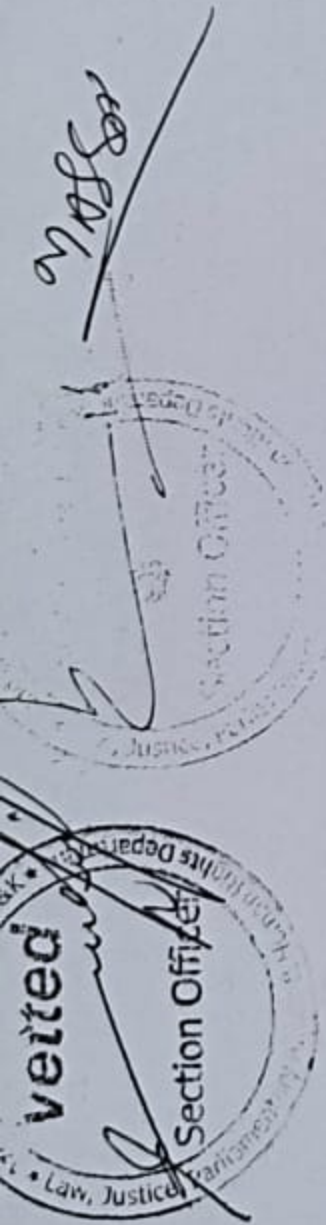
- i. the date of purchase or sale;
- ii. the name and address of the concern from which the drug is purchased or the concern to whom the drug is sold;
- iii. the name of the drug, its batch number, the date of its expiry and the quantity of the drug;
- iv. the name of the manufacturer.

(8) Except as otherwise provided in these rules, a record required to be maintained under these rules shall be preserved for a period of not less than three years from the date of the last entry.

(9) The licensee shall produce for inspection by an Inspector on demand a register or record maintained under these rules, and shall supply to the Inspector such information as the Inspector may require.

(10) A substance specified in the Schedule E and that fall under the list of poisons and the drug specified in the Schedule B shall be stored in:

- i. in a part of the premises to which customers do not have access; or



ii. in a locked almirah, cupboard or drawer, reserved solely for the storage of the substance or the drug.

(11) A substance that falls under the list of poisons in the Schedule E shall be stored in a container, impervious to the poison, and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.

(12) A substance that fall in the list of poisons under the Schedule E when compounded and dispensed shall be labeled with the word "Poison".

(13) For distribution of drugs a vehicle with adequate capacity and air condition facility is required, this will be applicable as per rule 1(3) of these rules and also name of distributor and monogram () in writing in red.

21. **Cancellation or suspension of licence:-** The Licensing Authority may, on the report of an Inspector or the Board, after giving the licensee an opportunity to show cause and by an order in writing stating the reasons, therefor, cancel a licence issued under these rules or suspend it for such period as it deems fit, if in its opinion the licensee has failed to comply with any of the conditions of the licence or with any of the provisions of the Act or these rules.

22. **AJ&K Appellate Authority:-** (1) A person aggrieved by an order of the Licensing Authority may prefer an appeal to the AJ&K Appellate Authority within thirty days of the date of the order.

(2) Board shall be the Appellate Authority for the purpose of hearing appeals against an order of the licensing authority.

(3) The AJ&K Appellate Authority (AJ&KQCB) shall, after giving the appellant an opportunity of hearing, pass such order as it deems fit and the order of the Authority shall be final and cannot be called in question before any forum.

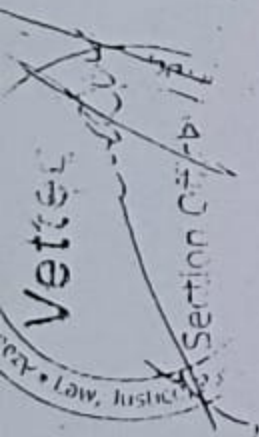
23. **Good Storage and Distribution Practices:-** A licensee under these rules, a public sector institution or a private organization dealing in distribution and storage of drugs shall comply with the good storage and distribution practices contained in Schedule H.

24. **Repeal:-** The Azad Jammu and Kashmir Drugs (Sales) Rules, 1979 are hereby repealed

M Ashfaq Abbasi
16/11/2021
(Muhammad Ashfaq Abbasi)
Section Officer

Copy to the:

1. The Secretary to the President of Azad Jammu & Kashmir.
2. The Secretary to the Prime Minister, Azad Govt. of State of Jammu & Kashmir.
3. PS to the Minister Health, GoAJ&K.
4. The Chief Secretary, GoAJ&K.
5. The Secretary, Health, GoAJ&K/ Chairman, AJ&K Quality control Board.



6. The Secretary Law, Justice, Parliamentary Affairs and Human Rights Department, GoAJ&K. with reference to their letter No. LD/vetting/414-15/2021 dated 14.09.2021.
7. The Secretary, Population Welfare, GoAJ&K.
8. The Accountant General, Azad Jammu & Kashmir, Muzaffarabad.
9. The Director General Health, GoAJ&K.
10. The Executive Director, AIMS, GoAJ&K.
11. The Director, Health Services (Procurement), Directorate General Health, GoAJ&K.
12. The Drug Controller/ Chief Drug Inspector, Department of Health, GoAJ&K/ Vice Chairman Quality Control Board.
13. Chief Executive Officer, Drugs Regulatory Authority, MONHSR&C, Govt. of Pakistan, Islamabad.
14. Head of Pharmacology Department, AJK Medical College, Muzaffarabad/ Member Quality Control Board.
15. The Secretary, Quality Control Board/ Drug Controller, Directorate General Health, GoAJ&K.
16. All Districts Health Officer, all Districts of AJ&K through Directorate General Health.
17. All Medical Superintendent DHQ/ THO Hospital in AJ&K through Directorate General Health.
18. The Controller, Printing & Stationery Department, GoAJ&K, for issuance in Extra Ordinary Gazette.
19. Master File.

M. A. S. S. O. J.
16/11/21
Section Officer