UNIVERSITY OF THE PUNJAB

Final Prof. A/2015
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All questions carry equal marks.

Q. No		Question	Marks
1		Give brief answers	
		i. Define Drug as per DRAP 2012.	06
		ii. Conditions of drug sale license related to schedule G drugs	02
		iii. Pharmacy Services	02
		iv. Misbranded Drug	05
		v. Alternate medicine	02
		vi. Manufacturing Cost	03
2	a	What are the requirements of Plant and Equipment (Schedule B-I for manufacturing of tablets?	08
	b	Explain provision of the Drugs Act 1976 related to the advertisement of drugs? What type of drugs can be advertised under this Act?	08
	c	What are the labelling requirements for suspensions?	04
3	a	What is the formula for fixation of Maximum Retail Price of a drug to be manufactured locally?	05
	b	Describe procedure of renewal of registration of a veterinary drug.	08
	c	What are the conditions of drug manufacturing license (by way of formulation) under Drugs Act 1976?	07
4	a	Discuss following under Pharmacy Act 1967 (a) Preparation and maintenance of registers (b) Procedure for registration (c) certificate of registration (e) Election of Vice-President (f) Furnishing of information	04 each
5		Discuss the following under Factory Act:	
		i. Seasonal factory	05
		ii. Restriction on the working hours of a child	05
	b	Explain the procedure of sampling by an Inspector?	10
6	a	What are the functions of Provincial Quality Control Board (PQCB) and District Quality Control Board (DQCB)?	07
	b	What are the conditions of drug sale license?	10
	c	What is Provincial Appellate Authority and its function?	03
7		Describe the following under Drug Act 1976	
		i. Cognizance of offences	05
		ii. Pleas	07
		iii. Offences and Penalties	08

UNIVERSITY OF THE PUNJAB

Final Prof. A/2016
Examination: Doctor of Pharmacy
(Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All questions carry equal marks.

Q.No		Question	Marks
1		Give brief answers of the following i. Define adulterated drug ii. Qualification of Govt. Analyst iii. Seasonal factory iv. Landed cost v. Validation	4 each
2	a)	Discuss Good Manufacturing Practices (GMP) related to design of building and services for License to manufacture by way of formulation (Schedule B-II)	10
	b)	Is the advertisement of every drug legal? Provide a list of drug/categories that can be advertised.	10
3	a)	Define the following terms as per DRAP Act 2012. i) Pharmacy services ii) Biologicals iii) Alternative medicine	5+3+2
	b)	Describe the power and functions of Drug Regularity Authority of Pakistan (DRAP).	10
4	a)	Describe the following under Drug (labeling and packing) Rules 1986 i) Exemption ii) Labelling of drugs for export	5+5
	b)	Describe prohibitions and penalties related to owning premises, possession of assets, aiding/abetment in narcotic offences given under Control of Narcotic Substances Act 1997.	10
5	a)	What types of health and safety measures should be provided to workers under Factory Act?	10
	b)	What is the composition and functions of Central Pharmacy Council?	10
6	a)	How many types of drug sale license are? How you will apply for the new license of your pharmacy?	10
	b)	What are conditions of drug sale license related with i) Schedule B & D drugs ii) schedule E drug	5+5
7		Describe the following as under Drug Act 1976 i. Composition of Drug Registration Board. ii. Offences and Penalties.	10 10

UNIVERSITY OF THE PUNJAB

Final Prof. 2nd A/2016
Examination: Doctor of Pharmacy
(Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All questions carry equal marks.

Q.No		Question	Marks
1		Give brief answers of the following under the Drugs Act 1976 i. Spurious drug ii. Types of drug manufacturing licenses iii. Qualification of Federal Inspector iv. IMS data v. Quarantine	4 each
2	a)	Discuss Good Manufacturing Practices (GMP) related to location and surrounding and size of building for License to manufacture by way of formulation (Schedule B-II)	10
	b)	Is the advertisement of every drug legal? Provide a list of drug categories that cannot be advertised.	10
3	a)	Define the following terms as per DRAP Act 2012. i) Drug ii) Medical devices iii) Therapeutic goods	5+3+2
	b)	What is the composition of Drug Regularity Authority of Pakistan (DRAP)?	10
4	a)	Describe the following under Drug (labeling and packing) Rules 1986 i) Labelling of medical devices. ii) Labelling of drugs for Government supply.	5+5
	b)	Describe prohibitions and penalties related to possession, import/export and trafficking of narcotic drugs given under Control of Narcotic Substances Act 1997.	10
5	a)	Discuss the following under Factory Act: i) Inspecting staff and their powers. ii) Safety of workers.	5+5
	b)	Discuss following under Pharmacy Act 1967 (i) Preparation and maintenance of registers under section 24 (ii) Procedure for registration under section 26	5+5
6	a)	Enlist various types of drug sale license. How you will apply for the new license of your pharmacy?	10
	b)	What are conditions of drug sale license related with i) Registered Medical Practitioner (RMP) ii) Schedule E drugs	5+5
7		Describe the following under Drug Act 1976 i) Conditions under which a drug is registered. ii) Reports of Govt. Analyst	10 10

UNIVERSITY OF THE PUNJAB

Final Prof: Annual - 2017
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All questions carry equal marks.

Q 1		Give brief answers of following terms. i. Counterfeit drugs ii. Form 6 & 7 for alternative drugs iii. Name the cognizable offences iv. Controlled delivery under Narcotic Act. v. Formula of price fixation for imported drugs.	4 Marks each
Q 2	a)	Describe the requirements of plant and equipment for sterile dosage forms as given in Schedule B-I under Drugs Act 1976.	10 marks
	b)	Give labeling requirements for external preparations under drugs labelling and packaging rules 1986.	10 Marks
Q 3	a)	What type of drugs can be advertised under Drugs Act 1976 and rules framed thereunder? Describe the conditions to be fulfilled for advertisement of drugs.	10 marks
	b)	Write down the Powers of Inspector under Drugs Act 1976.	10 Marks
Q 4	a)	Give procedure of registration of a drug for local manufacturing.	10 Marks
	b)	Give types of drug manufacturing Licenses. Briefly describe the condition of drug manufacturing License.	10 Marks
Q 5	a)	Describe the procedure of PQCB in a case of over pricing of drugs referred by provincial inspector of drugs.	10 Marks
	b)	Mr."X" wants to start a business of sale of drugs. Discuss the conditions according to Punjab Drugs Rules 2007 which are required to be fulfilled to get the License.	10 Marks
Q 6	a)	Discuss the following under Factory Act 1934: i) Certificate of fitness (Section 52) ii) Restriction on the working hours of a child worker (Section 54)	5 marks each
	b)	Discuss the prohibition of practice without registration under section 31 in Pharmacy Act 1967?	10 Marks
Q 7	a)	Define the following terms as per DRAP Act 2012. i) Health and OTC products ii) Medical devices iii) Qualification of chief executive officer (CEO)	(4+4+2) Marks
	b)	Describe the procedure for change of qualified person of a Pharmacy.	10 Marks

UNIVERSITY OF THE PUNJAB

Final Prof: 2nd Annual - 2017
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All questions carry equal marks.

Q 1		Give brief answers of following terms i. Adulterated drug ii. Health and OTC products iii. Opium under Narcotic Act iv. Formula of price fixation for local drugs v. Quality audit	4 Marks each
Q 2	a)	Describe the requirements of Premises as given in Schedule B under Drugs Act 1976.	10 Marks
	b)	Name the types of drugs/remedies that cannot be advertised under Drugs Act 1976. Describe the conditions to be fulfilled for advertisement of drugs.	10 Marks
Q 3		Describe the followings under Drugs Act 1976. i) Offences and penalties ii) Drug courts	10 marks each
Q 4	a)	Give composition of Central Licensing Board (CLB).	10 Marks
	b)	Enlist various types of application of registration of drugs. How renewal of registration can be obtained for biological drugs.	10 Marks
Q 5	a)	Describe the procedure of PQCB in a case of expired drugs referred by provincial inspector of drugs.	10 Marks
	b)	Describe Prohibitions and Penalties under Control of Narcotic Substances Act 1997.	10 Marks
Q 6	a)	Describe the following under Factory Act 1934 i) Precautionary measures taken in case of fire ii) Facilities provided to workers	5 Marks each
	b)	Describe the following under Pharmacy Act 1967. i) Election of Vice-President under Section 11 ii) Furnishing of information under Section 20	5 Marks each
Q 7	a)	Write a list of instructions for a Pharmacist working in Pharmacy with reference to controlled drugs.	10 marks
	b)	What is the composition of Drug Regularity Authority of Pakistan (DRAP)?	10 Marks

UNIVERSITY OF THE PUNJAB

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Roll No. .....

Final Prof: Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Subject: Forensic Pharmacy
PAPER: 4 Part – I (Compulsory)

TIME ALLOWED: 30 min.
MAX. MARKS: 20

Attempt this Paper on this Question Sheet only.

Please encircle the correct statement. Each MCQ carries 1 Mark. This Paper will be collected back after expiry of time limit mentioned above.

Q.1 Select and mark the most appropriate answer of each of following questions.

1. Adulterated drugs means a drug that contains
   A. Decomposed substance
   B. Contaminated with dirt.
   C. Deleterious substance
   D. All of the given options are correct

2. Imitation product means a product that is
   A. Homeopathic
   B. Allopathic
   C. Contaminated with dust
   D. Resembles with some drug in its outer packing.

3. In case of inconsistency between DRAP Act 2012 and Drugs Act 1976. provision of which Act will prevail
   A. Drugs Act 1976
   B. DRAP Act 2012
   C. Factory Act 1934
   D. All of above

4. On which Form; Federal Inspector of Drugs requiring a person not to dispose of the stocks in his possession.
   A. Form 1
   B. Form 2
   C. Form 4
   D. Form 5

5. Under Clause f of sub-section 1 of section 18 under Drugs Act 1976 Inspector of Drugs can
   A. Seal the medical store.
   B. Take samples
   C. Seize the drug
   D. Call for personal appearance.

6. A medical store can sell, store, exhibit for sale, & distribute drugs other than those specified in
   A. Schedule B
   B. Schedule F
   C. Schedule D
   D. Schedule G

7. Daily working hrs for adult worker in non-seasonal factory shall be nine hrs and in seasonal factory he may work for
   A. 11hrs
   B. 10 hrs
   C. 13 hrs
   D. 12 hrs

8. Notice of an examination for registration as pharmacist under Pharmacy Act 1967 shall be published for a continuous period of not less than
   A. One year
   B. Two weeks
   C. One month
   D. One week

PTO

9. The certificate of fitness for employment in a factory by authorized practitioner shall be valid for a period of
   A. One month
   B. Two month
   C. Three month
   D. Four month
10. Drug Regulatory Authority of Pakistan (DRAP) is a
   A. Provincial Organization
   B. District Organization
   C. Federal Organization
   D. All of above
11. Enlistment certificate for herbal drug issued on
   A. Form 4
   B. Form 5
   C. Form 6
   D. Form 7
12. Which one is **NOT** a cognizable offence?
   A. sale of expired drug
   B. Sale of spurious drug
   C. Sale of un-registered drug
   D. manufacturing of drugs without License.

13. A person sentenced by the Drug Court may prefer an appeal to a bench of
   A. Supreme Court
   B. High Court
   C. Session Court
   D. Civil Court

14. Which statement is correct?
   A. Constitution is framed under Act
   B. Rules are framed under Act
   C. Act is framed under Rules.
   D. None of above.

15. Application of drug registration for imported drug is given on
   A. Form 5-A
   B. Form 5-B
   C. Form 5-D
   D. Form 5-E.

16. Federal Drug Inspector can forward cases of contravention of Drugs Act to
   A. Registration Board
   B. Central Licensing Board.
   C. Any other authority specified for the purpose.
   D. All of above.

17. Duration of validity of registration certificate of drug is
   A. one year
   B. Three years
   C. Five years
   D. Ten years.
18. Minimum age limit for appointment as CEO of DRAP is
   A. 40 years
   B. 45 years.
   C. 50 years
   D. 55 years.
19. Prices of drugs fixed under which section of Drugs Act 1976
   A. section 8
   B. Section 10
   C. Section 12
   D. Section 14
20. Drug Appellate Board listen the appeals against decisions of
   A. Provincial Quality control Board
   B. Registration and Licensing Board.
   C. Pharmacy Council
   D. All of above.

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UNIVERSITY OF THE PUNJAB

Final Prof: Annual – 2018
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4 (Part – II)

TIME ALLOWED: 2 Hrs. & 30 min.
MAX. MARKS: 80

Attempt this Paper on Separate Answer Sheet provided.

Attempt any 4 questions. Each question carry equal marks.

Q 2 Give brief answers of following terms. 5 Marks each

i. Spurious drug as per Drugs Act 1976.
ii. Controlled delivery under Control of Narcotic Act 1997.
iii. Landed cost as per Pricing Policy.
iv. Pharmacy Services under DRAP Act 2012.

Q 3 a) Describe the requirements of storage area as given in Schedule B under Drugs Act 1976. 10

b) Enlist various categories of drugs/remedies that can be advertised without permission from Government. 10

Q 4 a) Describe Prohibitions as given under section 23 of Drugs Act 1976. 10

b) Give procedure of sampling by an Inspector as described under section 19 of Drugs Act 1976. . 10

Q 5 a) Write note on Drug discounts and price adjustment Rules 2006. 10

b) Describe the procedure of registration of drugs for local manufacturing. 10

Q 6 a) Mr."X" want to start a business of sale of drugs including compounding and dispensing. Discuss the extra conditions according to Punjab Drugs Rules 2007 which he has to fulfill to get permission for such service. 10

b) Describe the functions of Drug Regularity Authority of Pakistan (DRAP). 10

Q 7 a) Discuss the inspecting staff and their powers under Factory Act 1934. 10

b) Describe the following under Pharmacy Act 1967. 5 Marks each

i) Prohibition of practice without registration

ii) Bye laws made by central and provincial council.

UNIVERSITY OF THE PUNJAB

Final Prof: 2nd Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Forensic Pharmacy
PAPER: 4 (Part – II)

MAX. TIME: 2 Hrs. 30 Min.
MAX. MARKS: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Attempt any *FOUR* questions. Each questions carry equal marks.

Q 2		Give brief answers of the following i. Define Adulterated drug under Drugs Act 1976 ii. Qualification of Govt. Analyst under Drugs Act 1976 iii. Define Opium under Narcotic Substances Act 1997 iv. Manufacturing cost as per Pricing Policy.	5 Marks each
Q 3	a)	Describe the requirements of plant and equipment for tablet dosage forms as given in Schedule B-I under Drugs Act 1976.	10
	b)	Give Qualification and duties of provincial inspector under Drugs Act 1976.	10
Q 4	a)	What type of drugs/remedies cannot be advertised under Drugs Act 1976 and rules framed thereunder?	10
	b)	Give labeling requirements for external preparations under drugs labelling and packaging rules 1986.	10
Q 5	a)	Give procedure of registration of a drug intended to be imported.	10
	b)	Give types of drug manufacturing Licenses. Briefly describe the condition of drug manufacturing License.	10
Q 6	a)	Describe the procedure of PQCB in a case of spurious drugs or un-registered drugs referred by provincial inspector of drugs.	10
	b)	Describe the Drug Discount and Price adjustment Rules 2006.	10
Q 7	a)	What types of precautionary measures should be taken in case of fire under Factory Act 1934?	10
	b)	What is the composition and functions of central pharmacy council under Pharmacy Act 1967?	10

UNIVERSITY OF THE PUNJAB

Final Prof: 2nd Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. in Fig. .....

Roll No. in Words. .....

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Signature of Supdt.:

Subject: Forensic Pharmacy
PAPER: 4 Part – I (Compulsory)

MAX. TIME: 30 Min.
MAX. MARKS: 20

Attempt this Paper on this Question Sheet only.
Please encircle the correct option. Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the right answer cutting and overwriting is not allowed. (1x20=20)

1. Spurious drugs means a drug that contains
   - A. Decomposed substance
   - B. Contaminated things
   - C. No active ingredient
   - D. Putrid substance

2. Under Drugs Act 1976 "prescribed" means
   - A. Prescribed by physicians
   - B. Prescribed by Parliament
   - C. Prescribed by Rules
   - D. Prescribed by Pharmacy council

3. To conduct examinations for the purpose of registration as pharmacists is the function of
   - A. Central Pharmacy council
   - B. Provincial Pharmacy council
   - C. Federal Government
   - D. Provincial Government

4. As per Factory Act 1934 child means who has not completed his
   - A. 18th years
   - B. 15th years
   - C. 16th years
   - D. 20th years.

5. Which one is NOT a cognizable offense under Drugs Act 1976.
   - A. Sale of expired drugs
   - B. Sale of spurious drugs
   - C. Manufacturing of un-registered drug
   - D. Manufacturing of drugs without License

6. Which statement is correct?
   - A. Constitution is framed under the Act
   - B. Act is framed under the Rules.
   - C. Rules are framed under the Act
   - D. All of above

7. Maximum age limit for appointment of CEO of DRAP is
   - A. 53 years
   - B. 56 years
   - C. 58 years
   - D. 65 years.

8. Price of drugs are fixed by
   - A. Provincial Government
   - B. Federal Government
   - C. Both of above
   - D. None of above

9. Enlistment certificate for manufactures of alternative drugs is issued on
   - A. Form 5
   - B. Form 6
   - C. Form 7
   - D. Form 8

P.T.O.

10. Federal Inspector of Drugs take how many portions of a sample of drugs for its analysis under DRAP Act 2012

A. Three
B. Four
C. Five
D. Six

11. Which is NOT the function of Provincial Quality Control Board.

A. Training programs for Govt. Analyst
B. Annual validation of instruments at Drug Testing Laboratories.
C. To advise the Provincial Government on Quality control of drugs.
D. To enlist the alternative medicines.

12. Cross contamination means contamination of

A. starting materials
B. Intermediate product
C. Finished product
D. All of above

13. Regulation of which of following function is primarily dealt by Provincial Government under Drugs Act 1976.

A. Registration of drugs
B. Export of drugs
C. Sale of drugs
D. Manufacturing of drugs.

14. Minimum area requirement for basic installation for filling of hard gelatin capsule under schedule B-I under Drugs Act 1976 is

A. 100 square feet
B. 200 square feet
C. 300 square feet
D. 400 square feet

15. Under drug discounts and price adjustment Rules 2006; sum of all discounts given by firm cannot exceed

A. 15% of printed MRP
B. 25% of printed MRP
C. 40% of printed MRP
D.50% of printed MRP

16. As per pricing policy CPI means

A. Commercial product information
B. Consumer price index
C. Conventional price impact
D. Consumer price impact

17. Drug Inspectors exercise powers under which section of Drugs Act 1976

A. Section 18
B. Section 21
C. Section 23
D. Section 39

18. Drug Appellate Board listen the appeals against decisions of

A. Provincial Quality control Board
B. Registration and Licensing Board.
C. Pharmacy Council
D. All of above.

19. Which is NOT function of central pharmacy council under Pharmacy Act 1967

A. To approve courses of study in pharmacy
B. To recognize degree in pharmacy
C. Inspection of pharmacy institutions
D. To maintain registers of pharmacists.

20. In case of inconsistency between DRAP Act 2012 and Drugs Act 1976, provision of which Act will prevail

A. Drugs Act 1976
B. DRAP Act 2012
C. Pharmacy Act 1967
D. All of above

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2019

Roll No. in Fig. .....

Roll No. in Words. .....

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Signature of Supdt.:

Subject: Pharmacy Practice – VII (Forensic Pharmacy)
Paper: 4 Part – I (Compulsory) (New Course) **Time: 30 Min. Marks: 20**

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.
Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the correct option. **(20x1=20)**

i. Spurious drugs means a drug that is contains
a) Decomposed substance b) Contaminated things
c) No active ingredient d) Putrid substance

ii. Misbranded drug means that is
a) Labelled conspicuously b) Have resemblance of label
c) Not labelled as prescribed d) Manufactured by false manufacturer

iii. Dispensing the wrong medication, compounding errors, failure to detect interactions, failure to contact prescribers about excessive dosages, and failure to warn patients about side effects are the examples of:
a) Pharmacy crimes b) Medication error
c) Prescription errors d) Pharmacist malpractices

iv. Which is NOT the function of central pharmacy council?
a) Approval of examinations in pharmacy
b) To conduct examinations for registration of pharmacists
c) To recognize diploma in Pharmacy for registration as pharmacist
d) To Lay down standard of teaching in pharmacy

v. Who can launch prosecution in Drugs Court Located in Punjab for offense of Expired drug under Drugs Act 1976
a) Registrar Supreme Court b) Provincial Drugs Inspector
c) Federal Inspector of Drugs d) Both B and C

vi. Under Factory Act 1934 is an adult is a person who has completed his:
a) Fifteenth year b) Sixteenth year
c) Seventeenth year d) Eighteenth year

vii. The factory premises for the manufacture of drugs shall comply with the conditions specified in which schedule:
a) Schedule C b) Schedule B
c) Schedule E d) Schedule F

viii. A person can be registered as an apprentice in pharmacy who has obtained certification from which organization to be a qualified compounder and dispenser?
a) Federal Hospital b) Government Hospital
c) Central Council d) Government Institution

ix. Certificate of drug registration is issued on:
a) Form 4 b) Form 5
c) Form 6 d) Form 7

P.T.O.

x. Process of CTD format for registration dossier submission has been initiated by DRAP; and CTD stands for:

a) Correct testing document
b) Cumulative tracking document
c) Comprehensive tabulated document
d) Common technical document

xi. Duration of validity of registration certificate of drug is:

a) One Year
b) Three Years
c) Five Years
d) Ten Years

xii. Under Drugs Act 1976; Provincial Drug Inspector can inspect:

a) Warehouse of Veterinary medicine
b) Store of imported medicines
c) Pharmaceutical manufacturer
d) All of above

xiii. Enlistment certificate to manufacture alternative drugs is issued on:

a) Form 5
b) Form 6
c) Form 7
d) Form 9

xiv. According to national health vision of Pakistan; Health Technology Assessment (HTA) will be created at:

a) Federal level
b) District level
c) Both A and B
d) International level

xv. Obtaining controlled substances for misuse is termed as:

a) Quackery
b) Health care Fraud
c) Scientific Fraud
d) Drug Diversion

xvi. Forensic Pharmacist engage in professional work relating to:

a) Litigation
b) Criminal Justice System
c) Regulatory process
d) All of above

xvii. On which Form; Federal Inspector of Drugs requiring a person not to dispose of the stocks in his possession.

a) Form 1
b) Form 2
c) Form 4
d) Form 5

xviii. Under Clause 'e' of sub-section 1 of section 18 under Drugs Act 1976 Inspector of Drugs can:

a) Seal the medical store
b) Take samples
c) Seize the drug
d) Call for personal appearance

xix. Application of drug registration to manufacture a patented drug is given on:

a) Form 5-B
b) Form 5-C
c) Form 5-D
d) Form 5-E

xx. Subject to nature of the case; Federal Drug Inspector can forward cases of contravention of Drugs Act to:

a) Registration Board
b) Central Licensing Board
c) Any other authority specified for the purpose
d) All of above

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2019

Roll No. .....

Subject: Pharmacy Practice – VII (Forensic Pharmacy) (New Course)
Paper: 4 Part – II

Time: 2 Hrs. 30 Min. Marks: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any *FOUR* questions. Each question carries equal marks.

Q 2 Give brief answers of following — 5 Marks each

i. Define misbranded drug as per Drugs Act 1976.
ii. Give key objectives of national drug policy.
iii. Define Drug under DRAP Act 2012.
iv. What type of drugs/remedies cannot be advertised under Drugs Act 1976 and rules framed thereunder?

Q 3 a) Describe the requirements of plant and equipment for the production of tablets as described in Schedule B-I of drugs Licensing, Registration and Advertising rules 1976. — 10

b) What are essential drugs? Describe the measures adopted in National drug policy to promote the rationale use of drugs? — 10

Q 4 a) Write down the duties of Federal Inspector of Drugs under the rules framed under Drugs Act 1976. — 10

b) How Inspector will distribute the portions of a sample taken from a Pharmacy under Drugs Act 1976? What procedure an Inspector will adopt under Drugs Act 1976 upon receipt of report of a sample; declared sub-standard by Drug Testing Laboratory? — 10

Q 5 a) Give composition of Drug Registration Board. — 10

b) Define Forensic Pharmacy, what is the role of forensic pharmacist in criminal cases? — 10

Q 6 a) Write down the list of minimum requirements to establish a Pharmacy under Punjab Drugs Rules 2007. — 10

b) Write down the composition of Drug Regulatory Authority of Pakistan (DRAP). — 10

Q 7 a) What is the composition and functions of Provincial Pharmacy Council under Pharmacy Act 1967 ? — 10

b) Describe the following under Factory Act 1934. — 5 Marks each

i) Precautions against dangerous fumes

ii) Restrictions on working hours of a child.

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2019

Roll No. in Fig. .....

Roll No. in Words. .....

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Signature of Supdt.:

Subject: Forensic Pharmacy (Old Course)
Paper: 4 Part – I (Compulsory) **Time: 30 Min. Marks: 20**

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.
Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the correct option. **(20x1=20)**

i. Under Drugs Act 1976, prescribed means
a) Prescribed by physicians b) Prescribed by Rules
c) Prescribed by constitution d) All of the given options are correct

ii. Imitation product means a product that is
a) Homeopathic b) Allopathic
c) Contaminated d) Resembles with some drug

iii. Who can launch prosecution in Drug Courts located in Punjab?
a) Federal Inspector of Drugs b) Provincial Inspector of Drugs
c) Both A and B d) None of A, B and C

iv. Under Drugs Act 1976, how many portions of a drug sample is collected by Federal inspector of Drugs from manufacturing unit:
a) Two b) Three
c) Four d) Five

v. Prices of Drugs are fixed by:
a) Provisional quality control board b) Provincial Government
c) Central license board d) Federal Government

vi. A Pharmacy has to fulfill the requirements given if following schedule if have to dispense the compounded prescriptions.
a) Schedule B b) Schedule F
c) Schedule D d) Schedule G

vii. Daily working hours for adult worker in a seasonal factory are:
a) 11 hrs b) 10 hrs
c) 13 hrs d) 12 hrs

viii. Notice of an examination for registration as pharmacist under Pharmacy Act 1967 shall be published for a continuous period of not less than:
a) One year b) Two weeks
c) One month d) One week

ix. The certificate of fitness for employment in a factory by authorized practitioner shall be valid for a period of:
a) One month b) Two months
c) Three months d) Four months

x. How much minimum area is required for basic installation to manufacture hard gelatin capsules?
a) 100 square feet b) 200 square feet
c) 300 square feet d) 500 square feet

P.T.O.

xi. If penalty of an offense is inconsistent in Drugs Act 1976 and DRAP Act 2012, than penalty mentioned in which Act will prevail?

a) Pharmacy Act 1967 b) Drugs Act 1976
c) DRAP Act 2012 d) All of above

xii. Under Drugs Act 1976; Provincial Drug Inspector can inspect:

a) Warehouse of Veterinary medicine
b) Store of imported medicines
c) Pharmaceutical manufacturer
d) All of above

xiii. Drugs Courts are established under which section of Drugs Act 1976.

a) Section 22 b) Section 25
c) Section 28 d) Section 31

xiv. A person sentenced by the Drug Court may prefer an appeal to a bench of:

a) Supreme Court b) High Court
c) Session Court d) Civil Court

xv. Which statement is correct?

a) Constitution is framed under Act b) Rules are framed under Act
c) Act is framed under Rules d) None of above

xvi. Drug Appellate Board listen the appeals against decisions of:

a) Provincial Quality Control Board b) Registration and Licensing Board
c) Pharmacy d) All of above

xvii. Which is NOT the function of Provincial Quality Control Board?

a) Training programs for Govt. Analyst
b) Annual validation of instruments at Drug Testing Laboratories
c) To advise the Provincial Government on Quality control of drugs
d) To enlist the alternative medicines

xviii. Enlistment certificate for herbal drug issued on:

a) Form 4 b) Form 5
c) Form 6 d) Form 7

xix. Which one is **NOT** a cognizable offence?

a) Sale of expired drug b) Sale of spurious drug
c) Sale of un-registered drug d) Manufacturing of drugs without License

xx. Under Clause f of sub-section 1 of section 18 under Dugs Act 1976 Inspector of Drugs can:

a) Seal the medical store b) Take samples
c) Seize the drug d) Call for personal appearance

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2019

Roll No. .....

Subject: Forensic Pharmacy (Old Course)
Paper: 4 Part – II

Time: 2 Hrs. 30 Min. Marks: 80

Note: Attempt any *FOUR* questions. Each question carries equal marks.

2		Give brief answers	
	i.	Define Drug as per DRAP 2012.	06
	ii.	Conditions of drug sale license related to schedule G drugs	02
	iii.	Health and OTC Products	02
	iv.	Misbranded Drug	05
	v.	Form 6 for Alternative medicine	02
	vi.	Landed Cost	03
3	a	What are the requirements of Plant and Equipment (Schedule B-I for manufacturing of tablets?	08
	b	Explain provision of the Drugs Act 1976 related to the advertisement of drugs? What type of drugs can be advertised under this Act?	08
	c	What are the labelling requirements for suspensions?	04
4	a	Discuss following under Pharmacy Act 1967 (a) Preparation and maintenance of registers (b) Procedure for registration (c) certificate of registration (d) Election of Vice-President under section (e) Furnishing of information	04 each
5	a	Discuss the following under Factory Act:	
	i.	Seasonal factory	05
	ii.	Restriction on the working hours of a child	05
	b	Explain the procedure of sampling by an Inspector? What procedure an Inspector will adopt under Drugs Act 1976 upon receipt of report of a sample; declared spurious by Drug Testing Laboratory?	10
6	a	What are the functions of Provincial Quality Control Board (PQCB) and District Quality Control Board (DQCB)?	07
	b	What are the conditions of drug sale license?	10
	c	What is Provincial Appellate Authority and its function?	03
7		Describe the following under Drug Act 1976	
	i.	Drug Courts	05
	ii.	Pleas	07
	iii.	Offences and Penalties	08

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2021

Roll No. in Fig. .....

Roll No. in Words. .....

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Signature of Supdt.:

Subject: Forensic Pharmacy (Old Course)
Paper: 4 Part – I (Compulsory) **Time: 30 Min. Marks: 20**

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.
Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the correct option. (20x1=20)

1. Under Section 27 of Factory Act 1934 lubrication of moving machine can be done by specially trained
   a. Adult male and female workers only
   b. Adult male worker only
   c. Adolescent and any adult worker
   d. Female worker only
2. The Government Analyst have to submit the report of sample of drug received by him within
   a. 45 days
   b. 60 days
   c. 75 days
   d. 90 days
3. Under Section 56 of Factory Act 1934 who is responsible to maintain register of child worker
   a. CEO of the firm
   b. Shift In-charge of the factory
   c. Federal Government
   d. Manger of the factory
4. On which Form, Provincial Inspector of Drugs requiring a person not to dispose of the stocks in his possession?
   a. Form 1
   b. Form 2
   c. Form 3
   d. Form 5
5. Section 12 of Drugs Act 1976 is related to
   a. Prices of drugs
   b. Registration of drugs
   c. Central Licensing Board
   d. Drug Registration board
6. A medical store can sell all drugs EXCEPT those mentioned in.
   a. Schedule B
   b. Schedule E
   c. Schedule D
   d. Schedule G
7. Appellate Board is constituted under which section of the Drugs Act 1976
   a. Section 5
   b. Section 9
   c. Section 14
   d. Section 21
8. Which drug is NOT included in Schedule G under Punjab Drug Sale Rules 2007
   a. Folinic acid
   b. Cefixime
   c. Imipramine
   d. Ribavirin
9. Drug Inspector can seal medical store under which section of Drugs Act 1976
   a. Section 14
   b. Section 17
   c. Section 18
   d. Section 21
10. Minimum area required for basic installation of inhaler and vitrallae manufacturing section under Drugs (L.R.&A) Rules, 1976 is
    a. 100 square feet
    b. 200 square feet
    c. 300 square feet
    d. 400 square feet

P.T.O.

11. Which set of following drugs can be individually manufactured in same manufacturing section
    a. Cephradine and Amoxicillin
    b. Penicillin and Diclofenac Sodium
    c. Dexamethasone and Cephalosporin
    d. Fantanil and Pentazocine
12. Application of drug registration for imported drug is given on
    A. Form 5-A
    B. Form 5-B
    C. Form 5-D
    D. Form 5-E.
13. Federal Drug Inspector can forward cases of contravention of Drugs Act to
    A. Registration Board
    B. Central Licensing Board.
    C. Any other authority specified for the purpose.
    D. All of above.

14. Duration of validity of registration certificate of drug is
    A. one year
    B. Three years
    C. Five years
    D. Ten years.
15. Drug Regulatory Authority of Pakistan (DRAP) Act was implemented in
    a. 1976
    b. 1967
    c. 2012
    d. 2007
16. Which Board can issue the permission of prosecution to Drug Inspector for any offence under Drugs Act 1976
    a. Policy Board of DRAP
    b. Provincial Quality Control Board
    c. Prosecution Board
    d. All of above are correct options
17. After having the prescribed qualification; minimum experience required for appointment as Federal Inspector of Drugs is
    a. 01 year
    b. 05 Years
    c. 10 Years
    d. No experience is required
18. A person can be registered as an apprentice in pharmacy who is certified by a _____, to be a qualified compounder and dispenser
    a. Federal Hospital
    b. Govt. Hospital
    c. Central Council
    d. Govt. institution
19. According to DRAP Act, the _____ is the secretary of policy board.
    a. Secretary of Ministry of National Health
    b. CEO of the Authority
    c. Representative of Ministry of Law & Justice
    d. Secretory of Health Department Punjab
20. The Drug Regulatory Authority of Pakistan consists of a full time Chief Executive Officer (CEO) and _____ Directors.
    a. Eleven
    b. Twelve
    c. Thirteen
    d. Fourteen

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Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2021

Roll No. .....

Subject: Forensic Pharmacy (Old Course)
Paper: 4 Part – II

Time: 2 Hrs. 30 Min. Marks: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any *FOUR* questions. Each question carries equal marks.

Q 2 Give brief answers of following — 5 Marks each

i. Define misbranded drug as per Drugs Act 1976.
ii. Define Supurious drug as per Drugs Act 1976.
iii. Define Drug under DRAP Act 2012.
iv. What type of drugs/remedies cannot be advertised under Drugs Act 1976 and rules framed thereunder?

Q 3 a) Describe the requirements of plant and equipment for the production of tablets as described in Schedule B-I of drugs Licensing, Registration and Advertising rules 1976. — 10

b) Write composition of central Licensing Board. — 10

Q 4 a) Write down the duties of Federal Inspector of Drugs under the rules framed under Drugs Act 1976. — 10

b) What are the powers of Inspector under section 18 of Drugs Act 1976. — 10

Q 5 a) Write note on Drug discounts and price adjustment Rules 2006. — 10

b) Describe the procedure of registration of imported drugs. — 10

Q 6 a) Mr."X" want to start a business of sale of drugs including compounding and dispensing. Discuss the extra conditions according to Punjab Drugs Rules 2007 which he has to fulfill to get permission for such service. — 10

b) Describe the functions of Drug Regulatory Authority of Pakistan (DRAP). — 10

Q 7 a) Discuss the inspecting staff and their powers under Factory Act 1934. — 10

b) Describe the following under Pharmacy Act 1967. — 5 Marks each

i) Prohibition of practice without registration

ii) Bye laws made by central and provincial council.

UNIVERSITY OF THE PUNJAB

Roll No. in Fig. .....

Roll No. in Words. .....

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Signature of Supdt.:

Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2021

Subject: Pharmacy Practice – VII (Forensic Pharmacy)

Paper: 4 Part – I (Compulsory) (New Course) Time: 30 Min. Marks: 20

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.

Division of marks is given in front of each question.

This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the correct option. (20x1=20)

1. A forensic work that a pharmacist at drug information Centre usually do is
   A. Prevents drug diversion
   B. Prevents prescription forgery
   C. Asks patients about urine drug testing
   D. Monitor patients for substance abuse
2. Drug Courts established under which section of Drugs Act 1976.
   A. Section 11
   B. Section 28
   C. Section 31
   D. Section 44
3. Regulation of sale is primarily the function of _____under Drugs Act 1976.
   A. Provincial Government
   B. Federal Government
   C. Provincial Council
   D. Federal Council
4. Schedule II of DRAP Act 2012 is related to
   A. Powers of Inspectors
   B. Prohibitions
   C. Biological Drugs
   D. Cognizance of offences
5. As per pricing policy retailer discounts is
   A. 15% on printed MRP
   B. 25% on printed MRP
   C. 40% on printed MRP
   D. 50% on printed MRP
6. Who is the Provincial Appellate Authority?
   A. Chief Secretary
   B. Additional Chief Secretary
   C. Chief drug Controller
   D. Additional Chief drug Controller
7. Minimum area requirement for grant of drug sale license of a Medical Store under Punjab Sale Rules 2007 is
   A. 96 square feet
   B. 100 square feet
   C. 140 square feet
   D. 200 square feet
8. Reports of Provincial Government Analyst is issue on which Form?
   A. Form 4
   B. Form 5
   C. Form 6
   D. Form 7
9. Which of the following drug is NOT included in Schedule G under Punjab Drug Rules 2007
   A. Streptokinase
   B. Dexamethasone
   C. Acyclovir
   D. Cephradine
10. Under section 20 of Factory Act 1934, no drinking water point shall be within _____ feet from washing place unless approved in writing by Chief Inspector.
    A. Ten feet
    B. Fifteen feet
    C. Twenty feet
    D. Fifty feet

P.T.O.

11. Section 26 of Factory Act 1934 is related to
    A. Lighting
    B. Spittoons
    C. Holidays
    D. Fencing of Machinery
12. Under Drugs (L.R. & A) Rules 1976, how much minimum area is required for basic packing operations in re-packing section?
    A. 200 square feet
    B. 300 square feet
    C. 450 square feet
    D. 900 square feet
13. section 8 of Drugs Act 1976 is related to
    A. Pakistan National Formulary
    B. Provincial Quality Control Board
    C. Regulation of manufacture of drugs
    D. Reports of Government Analyst
14. A person aggrieved by the decision of Central Licensing Board may prefer an appeal to
    A. Supreme Court
    B. Drug court
    C. High Court
    D. Appellate board
15. Certificate of drug registration issued on
    A. Form 3
    B. Form 4
    C. Form 5
    D. Form 6
16. Price of drugs are fixed by
    A. Provincial Government
    B. Federal Government
    C. District Government
    D. Central Pharmacy Council
17. Who nominate the provincial nominee for Central Pharmacy Council?
    A. Provincial Pharmacy Council
    B. Provincial Government in consultation with Federal Government
    C. Federal Government in consultation with Provincial Government
    D. Central Pharmacy Council
18. If a formulation is registered and labeled as Paracetamol 500 mg per tablet however on analysis it is revealed that it contains zero percent paracetamol said formulation shall be considered as
    A. Substandard drug
    B. Spurious drug
    C. Out of specification drug
    D. Adulterated drug
19. According to DRAP Act, the maximum age limit to appoint a person as Chief Executive officer of the Authority is
    A. Not more than 40 Years
    B. Not more than 45 Years
    C. Not more than 50 Years
    D. Not more than 56 Years
20. The general direction, administration and monitoring of the DRAP shall vest in the Policy Board for which the chairperson would be_____
    A. Secretary of the concerned Division (Federal Secretary BS-22)
    B. CEO
    C. Representative of Ministry of Law and Justice not below BPS-20
    D. Secretary of the concerned Department,

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Doctor of Pharmacy (Pharm.D.) Final Prof: Annual–2021

Roll No. .....

Subject: Pharmacy Practice – VII (Forensic Pharmacy) (New Course)
Paper: 4 **Part – II**

Time: 2 Hrs. 30 Min. Marks: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any *FOUR* questions. Each question carries equal marks.

Q 2		Give brief answers of following terms. i. Define spurious drug under Drugs Act 1976 ii. Qualification of Federal inspector iii. Cognizance of offences iv. Additional labeling requirements for medical devices under labelling Rules.	5 Marks each
Q 3	a)	Give composition of Central Licensing Board (CLB).	10
	b)	Describe undercover and controlled delivery operations as described under Control of Narcotic Substances Act 1997.	10
Q 4	a)	Discuss "Measures to promote rational drug use" under National drug policy.	10
	b)	Describe the Powers of inspector as given under Section 18 of Drugs Act 1976.	10
Q 5	a)	Write a short brief on the Modules of Common Technical Document (CTD) for drug registration application? What is procedure for registration of a drug to be manufactured locally?	10
	b)	Give conditions of license under Punjab Drug Rules 2007 for schedule B and D drugs.	10
Q 6	a)	Write a note on the composition and functions of Policy Board under DRAP Act 2012.	10
	b)	Describe the following under Pharmacy Act 1967 I) Functions of inspectors under section 21 II) Withdrawal of approval under section 22	5 Marks each
Q 7	a)	Discuss the inspecting staff and their powers under Factory Act 1934.	10
	b)	What is the composition and functions of Provincial Pharmacy Council under Pharmacy Act 1967?	10