SHAMBHUNATH INSTITUTE OF PHARMACY

First Sessional Examination 2019-20

B.Pharm 3rd Year 5th Semester

PHARMACEUTICAL JURISPRUDENCE

Time: - 1.30 hrs. **Total Marks: – 30**

Paper Code: -BP-505T **Roll No: -**

Section A

Attempt all questions. **(5X2=10)**

a). ―cosmetic‖ means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

b). *patent means*-in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted medicine under Drugs and Cosmetics Act, 1940.

c). "registered pharmacist" means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy.

d). The objectives of *Pharmacy Act,* 1948 are A) to provide uniform training and education to the persons willing to enter the profession of pharmacy. B) Maintaining control over persons entering the profession of pharmacy by providing for their registration in every state and union territory. ?

e) *Misbranded* drugs- if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is.

Section B

Attempt any two parts. **(2X5=10)**

1. The *composition and function* of Pharmacy council of India

The Central Government shall, as soon as may be, constitute a Central Council consisting of the following members, namely:— (a) six members, among whom there shall be at least one teacher of each of the subjects, pharmaceutical chemistry, pharmacy, pharmacology and pharmacognosy elected by the [University Grants Commission] from among persons on the teaching staff of an Indian University or a College affiliated thereto which grants a degree or diploma in pharmacy; (b) six members, of whom at least 4 [four] shall be person possessing a degree or diploma in, and practising pharmacy or pharmaceutical chemistry, nominated by the Central Government; (c) one member elected from amongst themselves by the members of the Medical Council of India; (d) the Director General, Health Services, ex officio or if he is unable to attend any meeting, a person authorised by him in writing to do so; (d) the Drugs Controller, India, ex officio or if he is unable to attend any meeting, a person authorised by him in writing to do so; (e) the Director of the Central Drugs Laboratory, ex officio; (f) a representative of the University Grants Commission and a representative of the All India Council for Technical Education;]. (g) one member to represent each State elected [from amongst themselves] by the members of each State Council, who shall be a registered pharmacist; (h) one member to represent each State nominated by the State Government, who shall be a registered pharmacist.

Function of PCI: a) to prescribe the minimum standard of education required for qualification as pharmacist. B) to regulate the minimum educational standard by inspecting the institutions. C) To compile and maintain a central register for pharmacists containing name of all registered persons. D) any other function required for the furtherance of objectives of the act.

2. Write a note on *retail sale* of drugs.

!! Retail Sale !!

For retail sale two types of licences are issued, (*i*) General, and (*ii*) Restricted. **General licences** are granted to persons who have premises for the business and who engage the services of a *Qualified Person* to supervise the sale of drugs and do the compounding and dispensing.

Licences for retail sale of drugs 'other than those specified in Sch. C, C1 and X' are issued in **Form 20**, for drugs specified in 'Sch. C, C1 excluding those specified in Sch. X' in **Form 21** and for Sch. X drugs in **Form 20F**.

Conditions:

1. Licence should be displayed in a prominent place in a part of the premises open to public.
2. Licensee should comply with provisions of Drugs and Cosmetics Act and Rules in force.
3. Any change in the qualified staff in charge should be reported by licensee to licensing authority within 1 month.
4. Drugs should be purchased only from a duly licensed dealer or manufacturer.
5. Any change in constitution of licensed firm should be informed to licensing authority within 3 months and in the meantime a fresh licence should be obtained in the name of the firm with changed constitution.
6. Precautions prescribed by licensing authority for storage of 'Sch. C, and C1 drugs; should be observed.
7. For sale of additional categories of drugs listed in 'Sch. C and C1 excluding X', the licensee must take prior permission of licensing authority.

Restricted Licences Licences for restricted sale of drugs 'other than those specified in Sch. C, C1 and X' and those specified in 'Sch. C, and C1 but not in Sch. X' are issued in the **Form 20A** and **21A**, respectively.

Conditions for Restricted Licence

1. Licensee must have adequate premises equipped with facilities for proper storage of drugs to which licence applies provided that this condition does not apply to vendors.
2. Licence should be displayed in a prominent place in a part of the premises open to public or should be kept on the person of vendor who shall produce the same on demand by an Inspector or other officer authorized by State Government in this behalf.
3. Licensee should comply with provisions of Drugs and Cosmetics Act and Rules in force.
4. Drugs should be purchased only from a duly licensed dealer or manufacturer.
5. Licensee can deal only in such drugs as can be sold without the supervision of a registered pharmacist.
6. If licensee is a vendor having no fixed place of business, he should buy drugs from dealers specified in his licence.
7. Drugs should be sold in their original containers.

3. Enlist the conditions required for the manufacture of Drugs specified in *Schedules C&C1*.

Manufacture of Drugs specified in Schedule C and C1

(i) The licensed premise must conform to the requirements of Good Manufacturing Practices specified in Schedule M (Schedule M III for devices) and the licensee must provide adequate space, plant and equipment for manufacture of drugs. For the culture and manipulation of the spore bearing pathogenic microorganisms separate laboratories and utensils must be provided and these should not be used for any other purpose;

(ii) The licensee must provide adequate arrangements for testing the strength and quality of drugs in the licensed premises and the testing unit should be separate from the manufacturing unit with an independent head, who should possess a degree in Medicine or Science or Pharmaceutical Chemistry, and should have experience in testing of drugs considered adequate by the licensing authority. In case the tests require sophisticated instruments or biological techniques the same may be permitted by the Licensing Authority to be carried out at an approved institution.

(iii) The manufacture of drugs must be carried out by or under the active direction and personal supervision of technical staff, one of whom should be either (a) graduate in pharmacy or pharmaceutical chemistry with at least 18 months' experience in the manufacture of drugs (six months training is allowed during the course of graduation) to which this licence applies, or (b) a graduate in medicine with at least 3 years' experience in the manufacture and pharmacological testing of drugs to which the licence applies, or (c) graduate in science with chemistry or

microbiology as the principal subject or graduate in chemical engineering with at least 3 years' experience in the manufacture and testing of the drugs to which the licence applies or (d) hold any foreign qualifications which are comparable to those prescribed under (a), (b) and (c). Further any person who was approved by the licensing authority as an expert responsible for the manufacture of drugs immediately before June 29, 1957 shall also be deemed to be technical staff.

The manufacture of Schedule C and C1 drugs meant for animal treatment should be carried out by or under the supervision of graduates in veterinary science or general science or medicine or pharmacy with at least 3 years' experience in the manufacture and testing of veterinary biological products. The manufacture of devices specified in Sch. C should be carried out under the supervision of a graduate in pharmacy or science with physics or chemistry or microbiology as one of the subjects or degree/ diploma holder in mechanical, chemical or plastic engineering.

(iv) The licensee must have adequate facilities for the storage of the drugs manufactured by him, so that their properties would be preserved.

(v) Records of the details relating to the manufacture and testing of each batch of drugs should be maintained. The records for those drugs which have date of expiry should be preserved for a period of at least 2 years from the date of their expiry and for other drugs for a period of 5 years from the date of their manufacture.

(vi) Licensee must allow an inspector appointed under the Act to inspect the premises, processes of manufacture and testing of drugs, records required to be maintained under the Act and the Rules, and to take samples of any drug manufactured by him.

(vii) The licensee must report to the licensing authority any changes in the expert staff employed for the manufacture of drugs and also any material changes in the plant or premise used for the manufacture since the date of last inspection.

(viii) The licensee must on request, furnish to the licensing authority samples of drugs from each batch or such batches as the licensing authority may direct, together with full details of the test applied by him, if any. Further, if the licensing authority so directs, the licensee must not sell or offer for sale any batch in respect of which a sample has been furnished to the licensing

Section C

Attempt any one part. **(1X10=10)**

1.The duties and powers of *drug inspectors*. The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or State Government, as the case may be. (2) The powers which may be exercised by an Inspector and the duties which may be performed by him,

the drugs or 9 [classes of drugs or cosmetics or classes of cosmetics] in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

Powers of Inspectors.—(1) Subject to the provisions made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed, inspect,— (i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic; (ii) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed; (b) take samples of any drug or cosmetic,— (i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed; (ii) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee; (c) at all reasonable times, with such assistance, if any, as he considers necessary,-- (i) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or (ii) enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or (iii) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed.

2. Write a note on *Labelling and Packing* of Drugs.

LABELLING AND PACKING OF DRUGS

A. Labelling

Significant legal requirements of labelling drugs are as follows:

1. Identity of drug and its manufacturer, through its official name, trade name, if any, manufacturer's name and address and licence number and batch number. For Schedule W drugs only official names can be used.
2. Potency, standard, grade, dose etc. expressed as millilitres, grains, units etc.
3. Net contents by volume/weight/number.
4. Manufacturing and expiry dates (schedule P and C drugs only).
5. Precautions for handling, storage, sale/usage etc.
6. Special requirements for specified drugs like physicians' samples, veterinary drugs, drugs containing specific materials like spirit, color etc.
7. Special Provisions for dispensed drugs/drugs for export.

Some illustrative aspects of the above are summarised below:

I. Drugs Needing Cautionary Labelling.

Drugs	*Particulars*
Schedule G drugs	"*Caution*: It is dangerous to take this preparation except under medical supervision."
Schedule H drugs	(i) "Schedule H drug. *Warning*: To be sold on the prescription of a Registered Medical Practitioner only."
	(ii) Symbol R_x prominently on left hand top corner of the label.
	(iii) Symbol NR_x prominently on left hand top corner if drug is covered under Narcotic Drugs and Psychotropic Substances Act.
Schedule X drugs	(i) "Schedule X drug. *Warning*: To be sold on prescription of RMPs only.
	(ii) Symbol XR_x in red on left hand top corner.
Schedule C drugs	(i) Where a test for maximum toxicity is prescribed a statement that it has passed that test.
	(ii) Nature and percentage of antiseptic, if any.
Veterinary drugs	(i) 'Not for human use. For animal treatment only,
	(ii) Head of any domestic animal
Opthalmic solutions/ suspensions/ointments	(i) Use within one month of opening. Not for injection.
	(ii) Name and concentration of preservative.