WINTER– 16 EXAMINATION
Model Answer Subject Code: 0814

Important Instructions to examiners:

1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any EIGHT of the following:**	**16 M**
	a)	**Define 'Ethics'& 'Law' (1 mark for each definition)** **Ethics -** Rules by which a profession regulates actions & sets standards for all its members. **Law-** Rules of human conduct binding on all persons in a state or nation.	**2M**
	b)	**Give object of Poisons Act, 1919.** i) To regulate & control import, possession & sale of poisons. ii) According to the provision of Poison Act,1919 Central Govt. has been authorized to regulate the import of poisons in India & State Govt. has been authorized to make rules to regulate possession & sale of poison within their respective areas.	**2M**
	c)	**What do Schedule G and Schedule X to D & C Act ,1940 prescribe? (1 mark for each schedule)** **Schedule G**:-List of substances required to be taken only under the supervision of a Registered Medical Practitioner.	**2M**

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		Schedule X:-List of habit forming, psychotropic and other such drugs.	
	d)	**What is the provision for 'Sale of Split Quantity' of drug as per DPCO?** No dealer shall sell loose quantity of any formulation drawn from a pack of such formulation at a price which exceeds the pro-rate (retail) price of formulation plus 5 % thereof, provided such formulations shall not be compounded at the premises of the dealer.	**2M**
	e)	**Write ex-officio members of Pharmacy Council of India.** i) The Director General of Health Services. ii) The Drugs Controller of India iii) The Director of the Central Drugs Laboratory	**2M**
	f)	**Define 'Dutiable goods' under Medicinal & Toilet preparations (E.D.) Act,1955** It includes the medicinal and toilet preparations specified in the schedule as being subject to the duties of excise levied under this Act.	**2M**
	g)	**Differentiate between 'Drug Store' & 'Chemist and Druggist'.** **Drug Store:(1M)** Licensed premises for the sale of drugs, which do not require the services of a qualified person. **Chemist and Druggist:(1M)** Licensed premises for the sale of drugs which require the services of a "Qualified Person" but where the drugs are not compounded against the prescriptions.	**2M**
	h)	**Give two important recommendations of D. E. C. (2 marks for any 2 points)** Following are some important recommendations of DEC- i) Formation of Central Pharmacy Council & State Pharmacy Council which would look	**2M**

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		after the education & training of professionals.These councils would maintain the register containing the names and addresses of the Registered Pharmacists. ii) Creation of Drug Control Department at the Centre with the branches in all the states iii) Establishment of well-equipped Central Drug Laboratory (CDL) with expert staff. It was also suggested that the small laboratories would work under the guidance of Central Drug Laboratory. iv) Appointment of an advisory board to advise the Govt. in making rules. v) The drugs industry in India should be developed. vi) Setting of the test laboratories in all states to control the quality of the production of drugs & pharmaceuticals. vii) Setting of courses for training in pharmacy viii) Prescribing minimum qualification for registration as pharmacist.	
	i)	**Give schedule for the following drugs (each ½ mark)** i) Chlorpheniramine -Schedule G ii) Sewbarbital- Schedule X iii) Insulin- Schedule C iv) Diazepam- Schedule H	**2M**
	j)	**Define "Lunatic and Guardian'' under Medical Termination of Pregnancy Act, 1971. (1 mark for each definition)** **(i) Lunatic :-** Has the meaning assigned to it in Section 3 of the Indian Lunacy Act, 1912. **(ii) Guardian**:- A person having the care of a minor or a lunatic. OR person having the care of the 'person of minor' or a 'mentally ill person'	**2M**
	k)	**Write the objective of Pharmacy Act, 1948.** The main objective of Pharmacy Act is to regulate the profession and practice of pharmacy and to raise the status of profession of pharmacy in India.	**2M**

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	l)	**What penalties are prescribed for :** **i) Using report of Government analyst for advertisement.(1M)** Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug [or cosmetic], shall be punishable with fine which may extend to five thousand rupees. Whoever, having been convicted of an offence under sec.29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to 2 years, or with fine which shall not be less than 10,000/ rupees or with both. **ii) Non-disclosure of name of manufacturer(1M)** Punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than 20,000/ rupees or with both	**2M**
2		**Answer any FOUR of the following:**	**12M**
	a)	**Give the scope and objectives of pharmaceutical legislation.** **Scope of pharmaceutical legislation of India (any 3 points, 1½ marks)** 1) It is related with legal system which regulates the conduct of pharmacy business & practice of profession of pharmacy. 2) A thorough understanding of all laws pertaining to pharmacy is essential & all legal aspects must be satisfied by those who wish to practice the pharmacy business. 3) It helps the pharmacist to understand their legal & ethical responsibilities & their by avoid the danger of unnecessary legal proceedings. 4) The patient should get the drugs of good quality which are tested & evaluated for safety purpose. 5) It also covers the legal aspect relating to manufacture of drugs in Pharmaceutical industries, their storage, sale, distribution. 6) The Pharmaceutical Legislation safeguards the health of the people by making right medication by controlling pharmacy business & profession.	**3M**

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Q. No.	Sub Q. N.	Answer	Marking Scheme
		Objectives- (any 3 points, 1½ marks) 1) To promote health care by regulating the manufacture, supply & distribution of good quality drugs. 2) To make these drugs available to the public at reasonable prices & through qualified person. 3) To safeguard the people from misleading & false advertisements relating to drugs & remedies 4) To regulate the profession of pharmacy. 5) To promote the Indigenous research technology	
	b)	**State the object of Narcotic Drugs and Psychotropic Substances Act, 1985 and define 'Psychotropic Substances' under N.D.P.S. Act, 1985.** **The main object of this Act is- (2 marks)** i) To consolidate & amend law relating to Narcotic Drugs ii) To make strict provision to prohibit, control & regulate the operations relating to Narcotic Drugs & Psychotropic Substances iii) To provide for matters connected therewith. **Definition of Psychotropic Substances' under N.D.P.S. Act, 1985 (1mark)** It means any substance natural or synthetic or any salt or preparation of such substance or material, which is included in the list of psychotropic substances specified in the schedule.	**3M**
	c)	**Mention the classes of advertisements which are prohibited under Drugs and Magic Remedies Act, 1954 (any three)** **Classes of prohibited advertisements under Drugs & Magic Remedies Act and Rules: (any 3 classes, 3 marks)** **I)** Advertisement of drugs which may lead to its/their use for the treatment of certain diseases and disorders; i) For procurement of miscarriage or prevention of conception in women; or ii) For the correction of menstrual disorders in women; or	**3M**

Q. No.	Sub Q. N.	Answer	Marking Scheme
		iii) For the maintenance or improvement of the power of human beings for sexual pleasure or iv) For diagnosis, cure, alleviation, treatment or prevention of any disease or disorder or condition specified in the schedule or in rules made under the act. **II)** Advertisement of Magic Remedies for treatment of certain diseases or disorders which may claim to be efficacious for any of the purposes specified in I as above. **III**) Misleading advertisements in relation to drugs, which: i) Directly or indirectly gives false impression regarding true character of drug or drugs; or ii) Make any false claims for such drug or drugs iii) Is otherwise false or misleading in any material particularly. iv) Ayurvedic remedies to cure liver disorders & memory enhancement. **IV)** Prohibition of advertisements of Magic Remedies for the treatment of certain diseases- Publication of any advertisement related to any Magic Remedy which directly or indirectly claim to be effective for any of the purposes is prohibited.	
	d)	**Describe Schedule N in brief as per Drugs and Cosmetics Act, 1940** Schedule N- List of Minimum equipment's for efficient running of pharmacy: 1) **Entrance:** The front of Pharmacy shall bear an inscription, "Pharmacy". 2) **Premises:** The premises of Pharmacy shall be separate from rooms for private use. The premises shall be well built, dry, well- lit and ventilated and of sufficient dimensions to allow the goods in stock, especially medicaments and poisons to be kept in clearly visible and appropriate manner. The area of the section to be used as dispensing department shall not be less than 6 sq. meters for one pharmacist working there in with additional 2 square meters for each additional pharmacist. The height of the premises shall be at least 2.5 meters.	**3M**

Q. No.	Sub Q. N.	Answer	Marking Scheme
		The floor of pharmacy shall be smooth & washable. The walls shall be plastered or tiled or oil painted so as to maintain smooth, durable & washable surface devoid of holes, cracks, crevices. A pharmacy shall be provided with supply of good quality water. There shall be separate dispensing department to prevent the admission of the public. **3) Furniture**: A pharmacy shall contain furniture of required size & suitable apparatus. Drugs, chemicals & medicaments shall be kept in a suitable room and suitable containers so as to prevent any deterioration of the contents or of contents of container kept near them. Drawers, glasses and other containers used for keeping medicaments shall be of suitable size and capable of being closed tightly to prevent the entry of dust. Every container shall bear a label of appropriate size easily readable with names of medicaments as given in Pharmacopoeias. A pharmacy shall be provided with dispensing bench having impervious and washable top. A pharmacy shall be provided with a cupboard with lock and key for storage of poison & shall be clearly marked with "POISON" in red letters on a white background. Containers of all the concentrated solution shall bear the special labels or marking with the words "To be diluted". **4) Apparatus and Equipment:** A pharmacy shall be provided with following minimum apparatus: Balance-dispensing, sensitivity30 mg Balance-counter, capacity 3 kg, sensitivity 1 kg Beakers, lipped assorted sizes Corks assorted sizes and toppers Cork extractor Evaporating dishes Funnel –glass	

Q. No.	Sub Q. N.	Answer	Marking Scheme
		Litmus paper-blue and red Measuring glass cylinder 10, 25, 50, 100 & 500 ml Mortar & pestle Ointment slab, porcelain Pipettes, graduated, 2ml, 5ml,& 10 ml Scissors Spatula, glass rods, thermometer, tripod stand, watch glasses, water distillation still, water bath, weights, wire gauze, pill machine, pill boxes, suppository mould. **5) Books:** The pharmacopoeia (current edition) National formulary of India (current edition) The Drugs and Cosmetics Act, 1940 and Rules, 1945 The Pharmacy Act, 1948 Narcotic Drugs & Psychotropic Substances Act, 1985. **6) General Provisions:** A pharmacy shall be conducted under the continuous personal supervision of a Registered Pharmacist whose name shall be displayed conspicuously in the premises. The pharmacist shall always put on clean, white overalls. The premises and pharmacy shall be properly kept and everything must be in good order & clean. All records and registers shall be maintained in accordance with the laws in force. Any container taken from the poison should be replaced therein immediately after use & cupboard is to be locked. The keys of cupboard shall be kept in personal custody of a responsible person. Medicament when supplied shall have labels conforming to the provisions of the laws in force.	

Q. No.	Sub Q. N.	Answer	Marking Scheme
	e)	**Mention the duties of drug inspector in relation to sale of drugs and cosmetics.** **Duties of Drug Inspectors in relation to sale of drugs and cosmetics-(any 6 points, 3 marks)** 1) To inspect at least twice a year all establishments licensed for sale of drugs in the area assigned to him and to check whether the conditions of the licenses are observed or not. 2) If he thinks necessary, to obtain and send the samples of imported drugs and cosmetics for test or analysis, which are being sold or stocked in contravention of the provisions of the Act. 3) To investigate any complaint in writing made to him. 4) To institute prosecutions in case of breach of the Act and Rules. 5) To maintain the records relating to all inspections and actions taken by him and to submit copies of such records to the controlling authority. 6) To make inquiries and inspections regarding the sale of drugs in contravention of the provisions of the Act. 7) To detain the imported packages, if he suspects to contain drugs, the import of which is prohibited	**3M**
	f)	**Discuss code of ethics for pharmacist in relation to medical profession.** **I)Limitation of professional activity:** A pharmacist under no circumstances, should practice medicines, that is diagnosing diseases and prescribing medicines. However, in case of accidents or emergencies, he may give first aid services. A pharmacist should not recommend any particular medical practioner, unless specially asked for. **II) Clandestine Arrangement:** A pharmacist should never enter into any secret agreements with the medical practioner physician, dentist, veterinary surgeons to offer them commission or gift by recommending his dispensary or drug store.	**3M**

Q. No.	Sub Q. N.	Answer	Marking Scheme
		Pharmacist should not have any clandestine or underhand arrangements with any physician. **III) Liaison between medical profession and public** Pharmacist is a link between medical profession and public. He should be constantly in touch with modern development in pharmacy and allied fields. He should be expert in the field of pharmacy so that he may advise the physicians on pharmaceutical matters. He should have sufficient knowledge to educate the public. Pharmacist should neither discuss physicians prescriptions with customers nor disclose to them the composition of prescriptions.	
3		**Answer any FOUR of the following:**	**12M**
	a)	**Explain the role of Pharmacist in health care system.** i) All the pharmacists working in different fields of profession are directly or indirectly related to nation's health. ii) Community pharmacist and hospital pharmacists are health professionals for the safe and effective use of drugs. iii) Pharmacy occupies an important position in the health care system. So the pharmacist should be well equipped with knowledge of drugs, their handling system & legal aspects as well as principles of quality assurance applied to medicine product. iv) Pharmacist is legally held responsible for the quality of product which is manufactured and distributed. v) They supply medicines against prescriptions. They counsel patients at the time of dispensing prescriptions. The pharmacists also participate in health programmes. vi) They provide link between Physician & Patient vii)They are able to advice patients with minor illness viii)The profession of Pharmacy presently consist of- • Industrial pharmacist	**3M**

		• Hospital pharmacist • Academic pharmacist • Community pharmacist ix)Pharmacist has to play an important role in areas such as: 1. Prescription adherence. 2. Storage and distribution of drugs. 3. Drug choice. 4. Drug monitoring. 5. Information and education. 6. Clinical pharmacokinetics. 7. Research and development and many other health activities.	
	b)	**Enlist ex-officio members of Drugs Technical Advisory Board.** The following are the ex-officio members: i) The Director General of Health Services, who shall be Chairman of the board. ii) The Drugs Controller of India. iii) The Director of the Central Drugs Laboratory, Calcutta. iv) The Director of the Central Research Institute, Kasauli. v) The Director of Indian Veterinary Research Institute, Izatnagar. vi) The Director of Central Drug Research Institute, Lucknow. vii) The President of Medical Council of India. viii) The President of the Pharmacy Council of India.	**3M**
	c)	**Give formula for calculation of retail price of drug formulation and explain the term involved in it as per DPCO, 1995. (Formula-1M, Explanation-2M)** By applying the following formula, the retail price of the formulation is calculated by the Government. R.P.= (M.C.+ C.C.+ P.M. + P.C.) x (1+ MAPE/100) + ED Where, **R.P.:-** Means retail price. **M.C.:-** Means material cost which includes the cost of drugs and other pharmaceutical	**3M**

		aids with overages, if any, plus process loss thereon in accordance with the norms specified from time to time by notification in the official Gazette. **C.C.:-** Means conversion cost worked out in accordance with such norms as may be specified by the Government from time to time by notification in the official Gazette. **P.M**.:- Means the cost of packing material including process loss thereon worked out in accordance with such norms as may be specified by the Government from time to time. **P.C.:-** Means packing charges worked out in accordance with such norms as may be specified by Government every year by notification in the Official Gazette. **MAPE:**-Maximum allowable post manufacturing expenses. In means all the cost incurred by the manufacturer from the stage of ex-factory cost of retailing. It also includes trade margin and margin of manufacturer. MAPE shall not exceed 100% for indigenously scheduled formulations. **E.D.:-** Means excise duty.	
	d)	**Define 'Coca leaf', 'Coca derivative' and 'Opium' under N.D.P.S. Act, 1985.** **Coca leaf (1M)** It includes 1. The leaf of coca (Erythroxylon) plant (excluding the leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed) 2. Any mixture thereof with or without any neutral material and does not include any preparations containing less than 0.1% of cocaine. **Coca Derivative (1M)** means i) Crude cocaine which can be used directly or indirectly for the manufacture of cocaine. ii) Ecgonine and all the derivatives from which it can be recovered. iii) Cocaine, which is methyl ester of benzoyl- ecgonine and its salts. iv) Preparations containing more than 0.1 percent of cocaine. **Opium(1M)** – It means the coagulated juice of the opium poppy and its mixture with or without neutral material (excluding the preparations containing less than 0.2% of morphine).	**3M**

	e)	**Write circumstances under which pregnancy can be terminated under Medical Termination of Pregnancy Act, 1971.** **1) Consent:-** No pregnancy shall be terminated by a RMP without the consent of the pregnant women except: i) When the pregnant woman is less than 18 yrs. of age or ii) The pregnant woman is lunatic. In case of pregnant woman who is minor or lunatic, the pregnancy may be terminated with a written consent of her guardian. **2) Duration of pregnancies:** 1) A pregnancy may be terminated if it is not more than 12 weeks old & a medical practitioner is of the opinion that continuation of such pregnancy i) May involve a serious risk to the life of pregnant woman, & would result into serious injury to the physical or mental health of the pregnant woman, ii) The child to be born would be seriously handicapped due to physical or mental abnormalities. 2) A pregnancy may be terminated when the length of the pregnancy is more than 12 weeks old but not more than 20 weeks old & not less than 2 RMPs are of the same opinion as above. 3) A pregnancy of any duration may be terminated by RMP when is of the opinion that such termination is immediately necessary to save the life of pregnant women. **3) Other cases:-** The pregnancy caused due to rape or due to failure of contraceptive device used by any married woman or her husband for the purpose of family planning.	**3M**
	f)	**What do you mean by Education Regulations and what it prescribe?** **Education Regulations:** Subject to the provision of section 10 of the Pharmacy Act, 1948, Central Council after approval of the Central Government may make regulations prescribing the minimum standard of education required for qualification as pharmacist called Education Regulations.	**3M**

		Education Regulations prescribe: 1. Minimum qualification for admission to the course. 2. Nature and period of course of study. 3. Nature and period of practical training to be undertaken after completion of regular course (Not less than 500 hours covered in a minimum of 3 months in an institution, hospital, pharmacy or dispensary recognized by Central Council). 4. Subjects of examination and standards attained therein. 5.Equipment and facilities to be provided by institutions for students undergoing approved Course of study. 6. Conditions to be fulfilled by institutions giving practical training. 7. Conditions to be fulfilled by authorities holding approved examinations.	
4		**Answer any FOUR of the following:**	**12M**
	a)	**Write qualifications of drug inspector.** A person who is appointed an Inspector should possess the following qualifications 1) Graduate in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized University. Provided that for the purpose of inspection of manufacture of substances specified in Schedule C, a person appointed as a Drug Inspector should have - i) Not less than 18 months experience in the manufacture of at least one of the substances specified in Schedule C, or ii) Not less than 18 months experience in testing of at least one of the substances in Schedule C in approved Laboratory, or iii) Not less than three year experience in the inspection of firms manufacturing any of the substances specified in Schedule C during the course of their services as Drugs Inspector. Provided further that the first 4 years from the date on which Chapter IV of the Act takes effect in the States, person whose qualification, training & experience are considered adequate may be appointed as Inspector & their appointments continued even after 4 years, if the State Govt. is satisfied.	**3M**

	b)	**Define 'Advertisement' & 'Magic Remedy' under Drugs & Magic Remedies Act, 1954.** **Advertisement**:(**1½ marks**)It includes i) any notice, circular, label, wrapper or otherwise such document, and ii) any announcement made orally or by means of producing or transmitting light, sound or smoke. **Magic Remedies**:(**1½ marks**) It includes a Talisman, Mantra, Kavacha and any other charm claiming to possess miraculous powers: i) for diagnosis, treatment and prevention of any disease in human beings or animals, or ii) for affecting or altering the structure or organic function of the body or animal.	**3M**
	c)	**What are the functions of Pharmacy Council of India under Pharmacy Act, 1948?** **Functions of PCI:- (any 3 functions)** **1)** To prescribe the minimum standard of education required for qualification as a Pharmacist (This can be provided by making rules as Education Regulation which prescribes minimum qualification for admission, duration of course, details of syllabus, practical training,& examination, minimum facilities required for the conduct of course, examination & practical training) **2)** To regulate minimum educational standard.(for this purpose, Council appoints Inspectors to inspect the institutions providing the minimum standards in education in pharmacy & report on the facilities available & decides whether the institution should be recognized or not) **3)** To recognize qualification granted outside the territories to which Pharmacy Act,1948 extends for the purpose of qualifying for registration under the said Act **4)** To compile & maintain a Central Register for Pharmacist containing names of all persons for the time being entered in the state register. **5**) Any other functions that may be assigned to the Central Council in the furtherance of the objective of the Pharmacy Act,1948.	**3M**

	d)	**Enlist the operations controlled by State Government under Narcotic Drugs & Psychotropic Substances Act, 1985. (Any 6)** i) Provide that the State Government shall fix from time to time the limits within which licences may be given for any cultivation of cannabis plant. ii) Make provision that, only the cultivators licensed by the prescribed authority of the State Government shall be authorized to engage in cultivation of any cannabis plant. iii) Require that all cannabis, the produce of the land cultivated with cannabis plant, shall be delivered by the cultivators to the officers of the State Government authorized on this behalf. iv) Empower the State Government to fix from time to time, the price to be paid to the cultivators for the cannabis delivered. v)Prescribe the forms and conditions of licences or permits licences or permits for some or all of the following: possession, transport, import inter-state, export inter-state, warehousing, sale, purchase, consumption and use of poppy straw, opium, cannabis (excluding charas). vi) Empower the state government to declare any place to be warehouse wherein it shall be the duty of the owners to deposit all such poppy straw as is legally imported inter-state and is intended for export inter-state or export from India; to regulate the safe custody of such poppy straw warehoused and the removal of such poppy straw for sale.	**3M**
	e)	**Write the procedure for taking samples of drugs for analysis and their dispatch to government analyst.** **Procedure for taking samples –(1½ marks)** Where an Inspector takes any sample of drug or cosmetic, he shall : 1. Intimate the purpose to a person from whom, he takes sample, in writing in a prescribed Form (Form-17) 2. Tender fair price of the sample and obtain acknowledgement thereof. If price is refused, by, such person, he has to tender receipt thereof in prescribed form (Form-17-A) 3. Divide the sample in the presence of such person in three parts unless he will fully	**3M**

		absents himself and effectively seals and mark the portions so sealed. 4. a) Restore one portion or container with a person from whom sample is taken. b) Send one portion/container to the Government analyst for test or analysis. c) Reserve one portion/container for production before the court if proceedings are instituted in case of such sample. d) Send remaining portion to a warrantor, if any, (whose name, address and other particulars have been disclosed) **Procedure for dispatch of sample to the Government Analyst from Drug Inspector- (1½ marks)** 1. The portion of sample or the container sent by an inspector to the government analyst for test or analysis under subsection(4) of section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in form 18,in an outer cover addressed to the Government Analyst. 2. A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.	
f)		**Define 'Registered Pharmacist' and 'Displaced Person' as per Pharmacy Act, 1948.** **Registered Pharmacist:(1½ marks)** Means a person whose name for the time being is entered in the register of the pharmacists of the state, in which he is for the time being residing or carrying on his profession or business of pharmacy. **Displaced person:-(1½ marks)** Displaced person means- i)A person who on account of setting up of dominions of India and Pakistan or on account of civil disturbances or the fear of such disturbances in area now forming part of Pakistan has on or after 1st day of March 1947, left or been displaced from his place of residence in such area and who has since then been residing in India. ii)Any person who on account of civil disturbances or the fear of such disturbances in area now forming part of Bangladesh, has after 14th day of April, 1957 but before 25th day	**3M**

		March 1971, left or has been displaced from his place of residence in such area and who has since then been residing in India.	
5		**Answer any FOUR of the following:**	**12M**
	a)	**What are 'Loan Licences' and 'Restricted Licences' under D & C Act, 1940 ?**	**3M**
		Loan licence:(1½ marks) It means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by another licensee/ manufacturer. (i)Application for the grant or renewal of loan licences to manufacture for sale or for distribution of drugs other than those specified in Schedule C, Schedule C (1) & Sch. X shall be made up to ten items for each category of drugs shall be made in Form 24-A accompanied by a licence fee of rupees 6000/- & an inspection fee of rupees 1500/- to the licensing authority. (ii)The Licensing Authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture, & facilities for testing, to undertake the manufacture on the behalf of the applicant for a loan licence (iii)Application for manufacture of more than ten items for each category of drug on a loan licence shall be accompanied by an addition fee of rupees 300/- per additional item specified in Schedule M.& M-III (iv)If the Licensing Authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless he may, on payment of a 1000/- Rs. issue a duplicate licence. (v)An original licence or a renewed licence in Form 25 valid for a period of five years on which it is granted or renewed. **Restricted licences :(1½ marks)** (i)Restricted licences shall be issued subject to the discretion of the Licensing Authority, to dealers or persons in respect of drugs whose sale does not require the supervision of a qualified person. (ii)Licences to itinerant vendors shall be issued only in exceptional circumstances for	

		bonafide traveling agents of firms dealing in drugs or for a vendor who purchases drugs from a licensed dealer for distribution in rural areas where other channels of distribution of drugs are not available. (iii)For restricted licence, applicant has to make an application in Form-19A and the licence issued for drugs other than those specified in schedule C,C(1),and X in Form 20A and for drugs specified in schedule C, C(1) in Form 21-A (iii)The restricted licence in Form 21-A may also issued to a travelling agent of a firm for drugs specified in Schedule C. (iv)Such licence is not needed for venders for the specific purpose of distribution to medical practioner or dealers. (v)Such licence in not needed to traveling agents of licensed manufacturers, agents of such manufacturers and importers of drugs engaged in free distribution of samples of medicine among members of the medical profession, hospitals, dispensaries and the medical or research institutions.	
	b)	**Give any six classes of drugs the manufacture and sale of which is prohibited under D & C Act, 1940. (Each point ½ marks, any 6)** 1) Any drug which is not of a standard quality, or is misbranded, adulterated or spurious. 2) Any patent or proprietary medicine which label does not display true formula. 3) Any drug which by means of any statement, design or device claims to cure or mitigate any disease or ailment specified in schedule J. 4) Any drug in contravention to any provisions of the Act and rules thereunder. 5) Any drug not intended for sale. 6) Any drug imported or manufacture in contravention to any of the provisions of the Act & rules made thereunder. 7) Any drug in contravention of the conditions of licence. 8) Any drug intended for free distribution to the members of the medical profession.	**3M**

	c)	**Discuss provisions for excise duty on Ayurvedic alcoholic preparations under M.T.P. (E.D.) Act, 1955.** (i)Ayurvedic preparations containing alcohol may be of two types- 1) Those containing self-generated alcohol e.g. Asavas and Aristas. 2) Those prepared by distillation or to which alcohol is added at any stage of manufacture. (ii)Ayurvedic preparation containing self-generated alcohol, in which the alcohol content does not exceed 2% , are deemed to be nonalcoholic for the purpose of this Act and therefore exempt from the payment of duty. (iii)In case of the preparation, the alcoholic content of which is more than 2 % but which are not capable of consumption as ordinary alcoholic beverages are also exempt from excise duty. (iv) The preparations which can be consumed as alcoholic drinks are liable to duty of Rs.1.00 per L.P. litre. (v) However, Registered Ayurvedic Practitioner are allowed to manufacture and dispense (except by distillation or by addition of alcohol during the process) such preparations are free of duty, provided they take licence from Excise authorities, on payment of Rs.1 and use such preparations only for the patients of the practitioners & not for sale to the general public. (vi)They should allow Excise Officer to draw samples of such preparations to ensure that the preparations contain only self-generated alcohol ; and (vii)They should maintain accounts of the preparations manufactured or dispensed to the patients together with the names and addresses of the patients. (viii) Ayurvedic preparations, which are either made by distillation or to which alcohol is added at any stage of their manufacture, are liable to a duty of Rs. 52.80 per litre of pure alcohol content. (ix)The Ayurvedic preparations may be manufactured in bond or without bond.	**3M**
	d)	**Define 'Misbranded drugs' and 'Cosmetics' under Drugs & Cosmetics Act, 1940. (each definition 1 ½ marks)** **Misbranded Drugs** -A drug shall be deemed to be misbranded if- i) It is so coloured, coated, powdered or polished that damage is concealed or if it is	**3M**

made to appear of better or greater therapeutic value than it really is; or

ii) It is not labelled in the prescribed manner; or

iii) Its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular

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

e) Give the object of Medicinal Termination of Pregnancy Act, 1971. Give the conditions for approval of places for termination of pregnancies. **3M**

Object of Medicinal Termination of Pregnancy Act – (1 Mark)

This act was passed with the object to provide for the termination of certain pregnancies by Registered Medical Practitioners at approved places for bonafied medical reason & the matters connected therewith

Conditions for approval of places for termination of pregnancies – (2 marks)

Places where pregnancy may be terminated-

i) A Govt. Hospital or

ii) A place approved for the purpose of this Act of Govt.

Place for the termination of pregnancies shall be approved only if -

1) The Government is satisfied that termination of pregnancies may be done therein under safe and hygienic conditions and

2) The following facilities are provided -

a) An operation table and instruments for performing abdominal or gynaecological surgery.

b) Anaesthetic equipment, resuscitation equipment and sterilization equipment.

c) Drugs and parenteral fluids for emergency use.

	f)	**Give the provisions for 'Possession and sale' of Poisons under Poisons Act, 1919.** **Possession for sale & sale of any Poison-** The State Govt. may regulate the possession for sale and the sale whether wholesale or retail of any specified poison. The State Govt. has power to make such rules in this connection which may provide for - i) The grant of licences to possess any specified poison for sale, wholesale or retail, & fixing of the fees to be charged for such licences. ii) The classes of persons to whom such licences may be granted. iii) The classes of persons to whom such poison may be sold. iv) The maximum quantity of any poison which may be sold to a person. v) The maintenance of the registers for sale of poisons and inspection of the same. vi) Safe custody of poisons and the labelling of the vessels, packages or coverings in which such poison is sold or possessed for sale. vii) Inspection & examination of any such poison possessed for sale by any vendor. Possession of any Poison- The State Govt. has power to make rules regarding the possession of any specified poison in local area where such poison can be used for murders or for poisoning cattle & in such local area where such occurrences are very frequent. Any break of this rule is punishable with imprisonment upto 1 year or with fine upto Rs. 1000/- or with both, together with confiscation of the poison in respect of which the breach has been committed.	**3M**
6		**Answer any FOUR of the following:**	**16M**
	a)	**Define 'Bonded Laboratory'. Write the requirements of bonded laboratory.** **Definition- 1 mark, requirements-3marks)** **Bonded Laboratory-** It means the premises or any part of the premises approved & licensed for the manufacture & storage of medicinal & toilet preparations containing alcohol, opium, Indian hemp & other narcotic drugs or narcotics on which duty has not been paid.	**4M**

		Requirements of bonded laboratory - 1) A spirit store (if distillery or a rectified spirit warehouse from which rectified spirit is made available, is not attached with the laboratory.) 2) One large room for manufacture of medicinal preparations. 3) One or more rooms for storage of finished medicinal products. 4) A Separate room or arrangement for the manufacture of toilet preparations 5) The storage room for the finished toilet preparations. 6) Accommodation near the entrance for the excise in-charge with necessary furniture. 7) There shall only one entrance in lab & one door to each of its compartments. 8) Every window shall be provided with malleable iron rod with prescribed dimension & the window should be covered from outside with strong wire netting of mesh not exceeding 25mm. 9) Every room should bear a board indicating a name of room & serial number. 10) All pipes, sinks, wash-basins inside the lab shall discharge into the general drainage directly. 11) The gas & electric connections shall be cut off at the end of work. 12) All vessels intended to hold alcohol & other liquid preparations should bear distinctive serial no. with their full capacity marked individually. 13) The alcohol storage vessel shall bear excise ticket lock. 14) The lab can be opened only in presence of excise officer in-charge, at the end of day work; it shall be closed with excise ticket-lock.	
	b)	**Write the offences and penalties under Pharmacy Act, 1948 (Any four).** **1) Penalty for falsely claiming to be Registered Pharmacist** Any person whose name is not entered into the register, falsely claims to be a registered pharmacist or uses in connection with his name or any words or letters to suggest that his name is entered in the register, he shall be punishable on First conviction with fine upto 500/- Rs. or Any subsequent conviction imprisonment upto six months or with fine upto 1000/- Rs. or with both. The use of words such as pharmacist, chemist, druggist, Pharmaceutist, dispenser, dispensing chemist, or any combination of such words by a person.	**4M**

		If a person who is a registered pharmacist in another state and who at the time of making claims to be registration in the State has filed an application for registration shall not to be guilty of the offence. **2) Dispensing by unregistered persons** The person other than a registered pharmacist shall dispense any medicine for patients liable for punishment with imprisonment upto six months or with fine upto 1000/- Rs. or with both. **3) Failure to surrender certificate of registration**- If any person whose name has been removed from the register fails to surrender his certificate of registration he shall be punishable with fine upto 50/- Rs. **4) Obstructing State Pharmacy Council Inspectors**:- Penalties: - Shall be deemed guilty of an offence & may be punished with imprisonment upto six month or fine upto 1000 Rs. or both.	
	c)	**Give functions of Central Drugs laboratory (Any four).** **(each function 1 mark, any 4)** **1)**To analyse or test the samples of drugs or cosmetics sent to it by Custom collectors or any other authorized officers or courts **2)**To carry out such other duties as may be entrusted to it by Central or State Govt. after consultation with the DTAB **3)** In case of the following drugs or classes of drugs, function of CDL carried out at the Central Research Institute, Kasauli, and such functions are exercised by the Director of the said Institute:- Sera, Solution of serum proteins intended for injection, Vaccines, Toxins, Antigens, Anti-toxins, Sterilized surgical ligature and sterilized surgical suture & Bacteriophages. **4)**The functions regarding Oral Polio Vaccine are exercised by the Deputy Director & Head of the Polio Vaccine Testing Laboratory in case of Central Research Institute Kasauli. **5)**In case of the following drugs or classes of drugs shall be carried out at the Indian Veterinary Research Institute, Izatnagar or Mukteshwar. Such functions are exercised by	**4M**

		the Director of either of the said institutes: Anti-sera, Vaccines, (Toxoids, Diagnostic Antigens for veterinary use. **6)** In case of condoms the functions of CDL are carried out at the Central Indian Pharmacopoeia Laboratory, Ghaziabad, and such functions are exercised by the Director of the said Laboratory. **7)** In case of **VDRL Antigen (Veneral Disease Ref. Lab.)** the functions of CDL are carried out at Laboratory of the Serologist and Chemical Examiner to the Government of India, Calcutta and the functions are exercised by Director of Serologist and Chemical Examiner of the said Laboratory. **8)** In respect of Intrauterine Devices and Felope Rings, the functions of laboratory shall be carried out at the Central Drug Testing Laboratory, Thane, Maharashtra and such functions shall be exercised by the Director of the said Laboratory. **9**)In respect of human blood and human blood products including components, to test for freedom of HIV antibodies, shall be carried out by the following Institutes, Hospitals and such functions are exercised by the head of the respective Institutes- a) National Institutes of Communicable Disease, Department of Microbiology, Delhi. b) National Institute of Virology, Pune c) Centre of Advanced Research in Virology, Christian Medical College, Vellore.] **10)**In respect of Homoeopathic medicines the function of CDL carried out at the Homoeopathic Pharmacopoeia Laboratory, Ghaziabad and such functions are exercised by the Director of the said laboratory **11)**In respect of Blood Grouping reagent and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B Surface Antigen and Hepatitis C Virus the function of CDL carried out at the National Institute of Biologicals, NOIDA and such functions are exercised by the Director of the said laboratory.	
	d)	**What are schedule H drugs? Give two examples. What special particulars are required to be mentioned on label of schedule H drugs? (Sch. H – 1 mark, examples Any 2– 1 mark, particulars – 2 marks)** **Schedule H-** Prescription drugs which are required to be sold by retail only on the prescription of a RMP.	**4M**

		Drugs from schedule H supplied to RMP, hospital, Dispensaries & Nursing Homes, shall be supplied only against signed written order & such order should be preserved at least for 2 years. **Examples-** Analgin, Cimetidine, Clindamycin, Diazepam, Heparin, Ibuprofen, Levodopa. etc. (Any e.g. specified under schedule H) **Schedule H-** Particulars on the label of the substance specified in schedule H – i) Symbol R_x conspicuously displayed on the left top corner of the label. ii) The words 'Schedule H drug, warning- to be sold by retail on the prescription of a RMP only'. It contains a drug specified in schedule H & comes under the Dangerous Drugs Act, 1930 (Now, Narcotic & Psychotropic substances Act, 1985)- i) Symbol NR_x, conspicuously displayed on the left top corner of the label in Red ink. ii) 'Schedule H drug, warning- To be sold by retail on the prescription of a RMP only'.	
e)		**Give the procedure for movement of dutiable goods under bond as per Medicinal and Toilet preparations (Excise Duties) Act, 1955.** (i)When the goods are to be removed from one warehouse to another, the consignor or the consignee should enter into a bond with surety or sufficient security. (ii)Such bond shall be furnished to the officer-in-charge of the warehouse of removal or the warehouse of destination as the case may be. (iii)Such bond shall remain valid until officer-in-charge of the warehouse of removal has received a re-warehousing certificate (stating that the goods have been re-warehoused) form the officer-in-charge of warehouse of destination. (iv)The consignor should make an application in triplicate for removal of goods from one warehouse to another warehouse to the officer-in-charge of the warehouse together with other necessary information as the Excise Commissioner may require at least 24 hours before the removal of goods. (v)The officer-in-charge shall take account of the goods and send the duplicate copy after giving remark for removal to the officer-in-charge of the warehouse of destination. And the triplicate shall be given to the consignor for dispatch to the consignee.	**4M**

		(vi)On arrival of the goods at the warehouse of destination, the consignee should present them such goods along with the triplicate application and the transport permit to the office-in-charge. (vii)Then he shall take account of the goods & complete the re-warehousing certificate on the duplicate and the triplicate application and return the duplicate to the officer-in-charge of the warehouse of removal and the triplicate to the consignee for the dispatch to the consignor. (viii)The consignor shall present such triplicate copy of the application with the warehousing certificate to the officer-in-charge of his within 90 days of the issue of the transport permit to him.	
	f)	**Define 'Bulk drugs' under Drugs (Price Control) Order. Explain in brief about Drugs price Equalisation Account (DPEA). (Definition- 2 marks, DPEA – 2 marks)** **Bulk Drug** means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 and which is used as such or as an ingredient in any formulation. **Drugs price Equalisation Account (DPEA) -** The Government may by recover the dues accrued under the provisions of the Drugs (Prices Control) Order, 1979 from the manufacturer, importer or distributor as the case maybe & deposit the same into an account known as Drugs Prices Equalization Account. The amount, from Drugs Prices Equalisation Account shall be utilized for : (i)Paying the shortfall between the retention price and the common selling price or the pooled price as the case may be to the manufacturer or importer or distributor, to increases the production, or to securing the equitable distribution and availability at fair prices, of drugs. (ii)Meeting the expenses incurred by the Government in discharging the functions under this provision & (iii)Promoting higher education and research in Pharmaceutical Sciences and Technology.	**4M**

WINTER– 16 EXAMINATION

Model Answer Subject Code: 0814