Con. 2329–11.

P. eutics - VII

Sem VIII

(REVISED COURSE)

RS–8399

20/4/11

(2 Hours)

[Total Marks : 40

N.B. :- (1) Question No. **1** is **compulsory**.
(2) Attempt any **four** of remaining **six** questions.
(3) **Figures** to the **right** indicate **full** marks.

1. (a) Define process validation. Discuss steps for validating a stem sterilization method. **4**
   (b) Give a typical layout scheme for large scale manufacture of a film coated tablet. **4**

2. Discuss Pilot plant scale up for manufacture of a liquid oral product. **8**

3. (a) State importance of Documentation in large scale manufacturing. What is an SOP ? Give a typical SOP for operating a single punch tablet machine. **5**
   (b) Write a note on Warehousing. **3**

4. (a) Discuss IPQC testing for a terminally sterilized injection. **4**
   (b) Discuss IQ and OQ for a Mixer Granulator. **4**

5. (a) Discuss the concepts of Vendor Audit and ABC analysis. **5**
   (b) Give a specimen document for 'Paracetamol' as a raw material. **3**

6. (a) Give a typical BMR for manufacture of an effervescent granules formulation. **4**
   (b) Write a note on Q. C. charts. **4**

7. Write notes on (any **two**) :– **8**
   (a) Sampling and sampling plans
   (b) Elements of Cost
   (c) Sales forecasting.

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Con. 2189–11. (REVISED COURSE) RS–8414

3/5/11 (2 Hours) [Total Marks : 40

N.B. : (1) Question No.**5** is **compulsory**.
(2) Attempt any **three** questions from the remaining **four** questions.
(3) **All** questions carry **equal** marks.

1. Discuss the various phases of 'Clinical Trials' in the drug discovery process.

2. Enumerate the various problems encountered in 'Paediatric drug therapy' with suitable examples.

3. Mention various types of drug-drug interactions. Elaborate on 'Pharmacokinetic drug interactions.'

4. Discuss with suitable examples the need to monitor 'drug usage' and 'timing of drug exposure' in pregnancy.

5. Write short notes on (any **two**) :–
   (a) Detection and Prevention of Adverse Drug Reactions
   (b) Patient Compliance
   (c) Scope and Objectives of Hospital Pharmacy.

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Pharm. & Med. Chem. IV Sem VIII (R)

Con. 2153–11. **(REVISED COURSE)** **RS–8396**

18/4/11 (2 Hours) **[Total Marks : 40**

N.B. :- (1) Question No. **1** is **compulsory**.
(2) Answer any **four** questions from the remaining **six** questions.

1. (a) Draw neat structures and mention the therapeutic use for the following :– **4**
   (i) 6-Methoxy alpha-methyl-2-naphthalene-acetic acid.
   (ii) 7-Nitro-5-(2-chlorophenyl) 1, 3-dihydro-2H-1, 4-benzodiazepine-2-one.
   (iii) 5-(3-Dimethylaminopropylidene)-10, 11-dihydro-5H-dibenzo [a, d] cycloheptene hydrochloride.
   (iv) 3, 5-Diamino-6-(2, 3-dichlorophenyl)-1, 2, 4-triazine.
   (b) Draw neat structures and indicate the therapeutic use for the following :– **4**
   (i) a carbamate derivative used for its CNS depressant activity.
   (ii) a cyclic sulfonamide derivative having CoX enzyme inhibitory activity.
   (iii) an enthranilic acid derivative used in therapy.
   (iv) a phenyl piperidine derivative with greater selectivity for serotonin reuptake inhibition.

2. (a) Give specific reasons for the following and support your answers with structures : **6**
   (i) 3-Hydroxy benzodiazepines are usually prescribed for sedation in the elderly.
   (ii) Carbamazepine shows selectivity against electrically induced seizures and is useful in treating generalised grand mal seizures.
   (iii) acetylmethadol has better profile of activity than methadone.
   (iv) Heterocodeine is a more potent mu receptor agonist than codeine.
   (b) Discuss the importance of 5, 5-disubstitution and lipophilicity for the therapeutic activity among barbiturates. **2**

3. (a) Give the schematic synthesis of any **two** and write names of reactants and reaction conditions for each step : **6**
   (i) Doxepine (ii) Diclofenac (iii) Glutethimide.
   (b) Explain with specific reasons why monoamine oxidase inhibitors are useful in treating both depression and Parkinsonism. **2**

4. (a) Give the schematic metabolism of any **two** and label metabolites as active/inactive. **4**
   (i) Indomethacin (ii) Mephobarbital (iii) Haloperidol.
   (b) Using examples explain the changes in profile achieved when the barbiturate ring system is replaced or modified to a hydantoin or an oxazolidinedione or a succinimide. **4**

5. (a) Write a detailed note on binding of agonists at the mu receptor. **4**
   (b) What is psychosis ? Describe the structural requirement for exhibiting antipsychotic activity. Further explain how drugs belonging to different chemical classes satisfy this. **4**

6. (a) Explain the importance of the following structural features/changes : **4**
   (i) Vinyl substitution in gaba
   (ii) Oxo substitution in central ring of carbamazepine
   (iii) N-allyl substitution in morphine
   (iv) Reversing the ester group in meperidine.
   (b) Explain MPTP neurotoxicity and its significance. **2**
   (c) Write the structure of amantadine and account for its CNS activity and mention its mechanisms of action. **2**

7. (a) Give structures and comment on any **two** of the following :– **4**
   (i) Combination of levodopa and carbidopa is useful in Parkinson's disease.
   (ii) Combination of a mild mu receptor agonist and an antagonist is used in deaddiction.
   (iii) Combination of sulfinpyrazone and allopurional is used in treating gout.
   (b) Mention the therapeutic uses of CoX-2 inhibition and explain why such inhibitors are favoured. Also give reasons for the with drawal of important inhibitors from the market. **2**
   (c) Mention the important structural features required for antiinflammatory activity and explain the importance of alpa methyl substitution in p-isobutyl phenylacetic acid. **2**

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Pharm. Anal. V

Con. 2494-11. **(REVISED COURSE)** **RS-8412**

30/4/11 Sem VIII (R)

(2 Hours) **[Total Marks : 40**

N.B. : (1) Question No. **1** is **compulsory**.
(2) Attempt any **four** questions from remaining **six** questions.
(3) Draw **neat** labelled diagrams wherever **necessary**.
(4) **Figures** to the **right** indicate **full** marks.

1. (a) Explain the following terms in brief (any **two**) :– **4**
   (i) Radioisotope
   (ii) Overtones
   (iii) Metastable ions.

   (b) Name the following (any **four**) :– **4**
   (i) Any one solvent used in NMR spectroscopy
   (ii) Any one type of burner used in flame photometry
   (iii) Any one radiation source for near IR
   (iv) Peak with highest intensity in mass
   (v) Any one spectrum interface used in GC-MS.

2. (a) Enlist any four interfaces used in LC-MS. Explain any one in detail. **4**

   (b) A compound with molecular formula $C_9 H_{10} O_2$ has the following spectral characteristics : **4**

   IR : 1745cm $^{-1}$, 3025cm $^{-1}$, 749cm $^{-1}$, 697cm $^{-1}$

   UV : λ_{max} 257nm.

   ^{1}HNMR : δ = 2·1 (singlet) 31·0 squares
   δ = 4·0 (singlet) 20·0 squares
   δ = 7·22 (singlet) 49·9 squares.

   Predict the structure and justify your answer.

3. (a) Explain the principle and advantages for near IR spectroscopy. **4**

   (b) Distinguish between the followng pair of compounds by giving suitable spectral characteristics. **4**

   $H-C\equiv C-CH_2-\overset{O}{\overset{\|}{C}}-CH_3$ and

   $CH_3-C\equiv C-CH_2-\overset{O}{\overset{\|}{C}}-CH_3$

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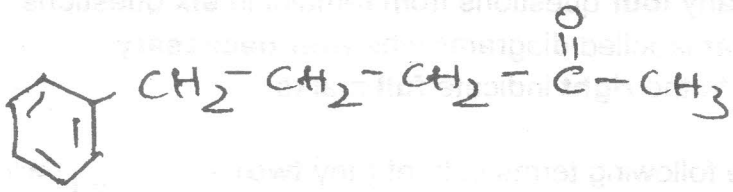
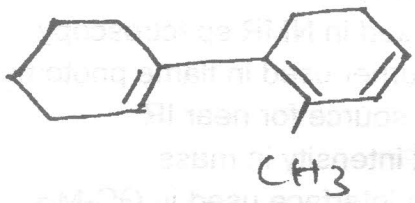
4. (a) With the help of diagram, derive Bragg's equation. Explain any one pharmaceutical application of X ray diffraction in detail. 4

(b) Depict two fragmentation pathways in mass spectrum of : 4



5. (a) Write a note on Quality control of radiopharmaceuticals. 4

(b) Predict the λ_{max} in UV spectrum of following compound. 4



6. (a) Discuss various factors influencing chemical shift values. 4

(b) A compound having molecular formula of C_5H_9ON has following spectral characteristics – 4

UV : No significant absorption

IR : 2910 cm^{-1}, 2235cm^{-1}, 1470cm^{-1},1400cm^{-1}

NMR (i) 1·1 δ triplet J = 6Hz

(ii) 2·7 δ triplet J = 7Hz

(iii) 3·7 δ triplet J = 7Hz

(iv) 4·7 δ quartet J = 6Hz

Predict the structure and justify your answer.

7. Write short notes on any **two** :– 8

(a) Isotope dilution analysis

(b) Spin-Spin Coupling

(c) Atomic Absorption Spectroscopy

(d) Chemical ionization in mass spectrometry.

Forensic Pharm. Sem VIII

Con. 2183-11. **(REVISED COURSE)** **RS-8408**

28/4/11

(2 Hours) **[Total Marks : 40**

N.B.: (1) Question No. **1** is **compulsory**.
(2) Attempt any **three** questions of the **remaining**.
(3) **Figures** to the **right** indicate **full** marks.

1. (a) Define (Any **Four**) :— 4
   (i) 'Misbranded Drug' under D and C Act.
   (ii) 'Bulk Drug' under DPCO.
   (iii) 'Cannabis, under NDPS Act.
   (iv) 'Food' under PFA Act.
   (v) 'Advertisement' under D.M.R. (O.A.) Act.

   (b) Answer the following (Any **Three**) :— 6
   (i) Write a note on 'Education Regulation'.
   (ii) Write a note on 'Central Food Laboratory'.
   (iii) List offences under D and C Act w.r.t. manufacture and sale of drugs.
   (iv) What is Drug Prices Equalisation Account ?

2. (a) Attempt any **Four** of the following :— 4
   (i) List ex-officio members of P.C. I.
   (ii) Give composition and functions of DCC.
   (iii) Define 'Dutiable Goods' under M.T.P. (E.D.) Act.
   (iv) Explain patent co-operative Treaty (PCT).
   (v) Define 'Factory' under factories act.

   (b) Answer the following (Any **Two**) :— 6
   (i) Explain the procedure to be followed for Grant of a Patent.
   (ii) What is an 'Adulterated Food Article' ?
   (iii) Give the following :—
      (1) Punishment for possession of small quantity of narcotic.
      (2) Measures for safety of factory workers under Factories Act.
      (3) Criteria for patentability of an Invention.

3. (a) Answer any **two** of the following :— 4
   (i) What were the terms of reference of Drugs Enquiry Committee ?
   (ii) How is sale price of Bulkdrug fixed ?
   (iii) Discuss the duties of Insecticide Inspector.

   (b) Attempt any **two** of the following :— 6
   (i) Define 'New Drug' under D and C Act.
   (ii) Define 'Bonded Loboratory' under M.T.P.(E.D) Act. Write note on manufactured in Bond.
   (iii) Define 'Ilicit Traffic' under N.D.P.S. Act.

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4. (a) (i) Describe the procedures to be followed by Drug Inspector 2
   (ii) Differentiate between— 2
      (1) Cognizable and Non Cognizable offence.
      (2) Drug store and Pharmacy.
   (b) Answer of the following :— 6
      (i) Describe savings under D.M. R. (O.A.) Act
      (ii) State objectives of :—
         (1) Bombay shops and establishments Act.
         (2) Pharmacy Act
         (3) D.P.C.O.

5. (a) Answer in brief (Any **Two**) :— 4
      (i) What the following schedules state ?
         (1) Schedule B
         (2) Schedule P
         (3) Schedule O
         (4) Schedule H
      (ii) What are the conditions to be followed for manufacture of drugs for examination test and analysis ?
      (iii) Classify the following as Drug, Cosmetic or Food and Justify.
         (1) Boroline Antiseptic Cream
         (2) I.V. Infusion Set
         (3) Cardamom
         (4) Tooth Paste.
   (b) Attempt the following (Any **Two**) :— 6
      (i) Write a note on 'Schedule Y'
      (ii) Give qualifications for entry into :—
         (1) First register
         (2) Subsequent register
         (3) Register after implementation of Education Regulation.
      (iii) Give labelling requirements for ophthalmic preparations.