M. Pharm. Sem-II (2012 Course) (C.B.C.S.) : Winter 2019

SUBJECT : ADVANCED DRUG REGULATORY AFFAIRS - II

Day : Thursday
Date : 02-01-2020

Time : 10.00AM TO 1.00 P.M.
Max. Marks : 60

W-11653-2019

N. B. :

1) Attempt **ANY THREE** questions from Section – **I** and attempt **ANY THREE** questions from Section – **II**.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer books.

SECTION - I

Q. 1 Discuss the requirements for obtaining Biowaivers in US. **(10)**

Q. 2 US FDA cGMP requirements for pharmaceutical finished product manufacturing. **(10)**

Q. 3 Discuss 505 (b) (2) pathway in detail with applicable exclusivities. **(10)**

Q. 4 Write short notes on **ANY TWO** of the following: **(10)**

a) Types of DMF

b) Para I, II, III and IV filing

c) EU cGMP requirements for QC lab

SECTION - II

Q. 5 Discuss in detail provisions for scale up and post approval changes. **(10)**

Q. 6 Discuss important provisions for extended release oral dosage forms. **(10)**

Q. 7 Discuss preparation of drug product dossier in detail. **(10)**

Q. 8 Write short notes on **ANY TWO** of the following: **(10)**

a) *in vivo* BE documentation

b) Product approval in Europe

c) Product Development Report

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M.Pharm. Sem-II C.B.C.S (2012 Course): Winter 2019

SUBJECT: ADVANCED DRUG REGULATORY AFFAIRS- III

Day: Saturday
Date: 04-01-2020. W-11660-2019

Time: 10:00AM TO 1:00PM.
Max Marks: 60

N.B:

1) Attempt any **THREE** questions questions from each section.
2) All questions carry **EQUAL** marks.
3) Both the sections should be written in **SEPARATE** answer books.

SECTION-I

Q.1 Preparation of dossier for product registration as per Indian legislative. **(10)**

Q.2 Requirements of factory premises for manufacture of cosmetics (Schedule M-II). **(10)**

Q.3 Good manufacturing practices for homeopathic medicines (Schedule M-I). **(10)**

Q.4 Write short notes on **ANY TWO:** **(10)**

a) Executive administrative bodies under Drugs and Cosmetics Act, 1940
b) Compare then drug product dossier compilation and submission Process in India
c) Regulatory Requirements for Nutraceuticals

SECTION-II

Q.5 Describe in detail the importance of standard operating procedures in pharmaceutical industry? **(10)**

Q.6 What do you mean by T- License and describe its different types and forms. **(10)**

Q.7 Discuss different international regulatory guidelines. **(10)**

Q.8 Write short notes on **ANY TWO:** **(10)**

a) Packaging Records
b) Material safety data sheet and method of Analysis
c) DPCO Guidelines

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M. PHARM. (PHARMACEUTICAL CHEMISTRY) SEM-I
(CBCS- 2019 COURSE): WINTER-2019
SUBJECT: ADVANCED MEDICINAL CHEMISTRY

Day: Monday
Date: 06.01.2020

Time: 10:00AM-TO 1:00 P.M.
Max. Marks: 75

W-20727-2019

N.B.:

1) Attempt **ANY FIVE** questions.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** What are receptors? Classify and discuss about their activation mechanism. **(10)**

b) Write about Chemistry of prostaglandins with examples. **(05)**

Q.2 **a)** What are biososters? Explain its significance in analog based drug design. **(10)**

b) Write with examples on genetic principles of drug resistance. **(05)**

Q.3 **a)** What are antiviral agents? Write about reverse transcriptase inhibitors. **(07)**

b) Analyze the need of prodrug approach. Explain various types of prodrugs with suitable examples. **(08)**

Q.4 **a)** Write with examples stereo chemical aspects for drug action. **(07)**

b) Classify antihypertensive agents. Write Chemistry, MOA and SAR of ACE inhibitors. **(08)**

Q.5 **a)** Write about manipulation of conformational constraints locally or globally to peptidomimetic design. **(07)**

b) What is Combinatorial chemistry? Write in detail on different types of polymer supports in solid phase synthesis. **(08)**

Q.6 Write Short notes: **(15)**

a) Enzyme kinetics
b) Antineoplastic agents
c) Acetylcholine esterase inhibitors

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M.PHARM. (PHARMACEUTICAL CHEMISTRY) SEM. – I (CBCS – 2019 COURSE) : WINTER – 2019
SUBJECT: ADVANCED ORGANIC CHEMISTRY – I

Day : Friday
Date : 03-01-2020
Time : 10:00AM TO 1:00 P.M
Max. Marks : 75

W-20716-2019

N.B.

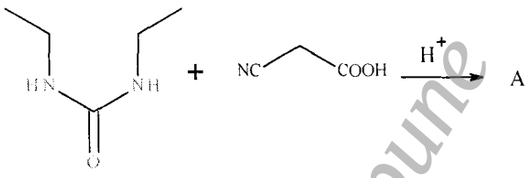
1) Attempt any **FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Draw the mechanism of Mannich reach and Vilsmeyer-Haack reaction. **(10)**

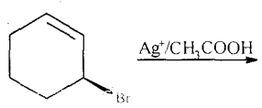
b) Write a note on Michael addition reaction. **(05)**

Q.2 **a)** Complete the reaction with mechanism. **(10)**

i)



ii)



b) Discuss the synthesis of Terconzole. **(05)**

Q.3 **a)** With examples describe the rules employed in the dissection of target molecules. **(07)**

b) Apply synthon approach and explain synthetic strategies for Indole and furan. **(08)**

Q.4 **a)** Describe the synthesis of Quinine. **(07)**

b) Outline the mechanism involved in Combes Quinoline synthesis and Traube Purine synthesis. **(08)**

Q.5 **a)** Explain with examples in each, the applications of Diazomethane and Dicyclohexyl carbodimide in organic synthesis. **(07)**

b) Write in detail protection and deprotection aminoacids with examples. **(08)**

Q.6 Write notes on the following: **(15)**

a) Free radical stability
b) Mechanism involving SN1
c) Compare E1 and E2 reaction

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M.PHARM. (PHARMACEUTICAL BIOTECHNOLOGY) SEM.-I (CBCS-2019 COURSE) : WINTER 2019

SUBJECT : ADVANCED PHARMACEUTIAL BIOTECHNOLOGY

Day : Thursday
Date : 09-01-2020

Time : 10:00AM TO 1:00P.M.
Max. Marks : 75

W-20737-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Describe extremophiles as source of important enzymes. **(10)**
b) Write a note on application of enzymes in food industry. **(05)**

Q.2 What are cloning vectors? Give important properties of a plasmid vector. **(15)**

Q.3 Define site-directed mutagenesis and describe the use of Oligo in bringing out desired change. **(15)**

Q.4 Describe with suitable diagram the procedure involved in producing therapeutic proteins. **(15)**

Q.5 **a)** What is GPCR signaling pathway? Explain with suitable example. **(15)**

Q.6 Write short notes. **(15)**
a) Cloning process in higher mammals
b) Bioremediation
c) Shotgun sequencing

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M. PHARM. (Pharmacology) SEM – I (CBCS -2019 COURSE): WINTER 2019
SUBJECT: ADVANCED PHARMACOLOGY - I

Day : Friday
Date : 03-01-2020

Time: 10:00AM TO 01:00PM.
Max. Marks: 75

WI-20719-2019

N.B.:

1) Attempt any **FIVE** questions.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Describe the second messenger concept of transducer mechanism. What are the objections raised to this concept and explanations given to support the concept? **(10)**

b) What are the signs, symptoms and treatment of anticholinesterase poisoning? **(05)**

Q.2 **a)** Classify non-steroidal anti-inflammatory drugs. Explain the mechanism of action, pharmacological effects, adverse reactions and uses of aspirin? **(10)**

b) Explain the atypical (second generation) antipsychotics with reference to their advantages, adverse effects and therapeutic uses. **(05)**

Q.3 **a)** Explain the mechanism of action, toxicity and uses of digitalis. **(07)**

b) Classify hypolipidaemic drugs. Justify the use of statins as hypolipidaemic agents. **(08)**

Q.4 **a)** Classify antiepileptic drugs. Describe the mechanism of action, adverse effects and uses of phenytoin. **(07)**

b) Classify adrenergic beta receptor antagonists. Explain the mechanism of action, pharmacological effects, toxicity and uses of propranolol. Which drugs were introduced as cardioselective beta receptor antagonisis? **(08)**

Q.5 **a)** Define pharmacokinetics. Describe the process of drug absorption after oral route of administration. **(07)**

b) Explain the mechanism of action, adverse effects, uses and techniques of local anaesthesia. **(08)**

Q.6 Write short notes on the following: **(15)**

a) Drug excretion

b) Prolongation of drug action

c) Second generation antitistaminics

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M.PHARM. (PHARMACEUTICAL BIOTECHNOLOGY) SEM.-I (CBCS-2019 COURSE) : WINTER 2019

SUBJECT : BIOPROCESS ENGINEERING AND TECHNOLOGY

Day : Monday
Date : 06-01-2020

Time : 10:00AM-TO 1:00PM.
Max. Marks : 75

1N-20726-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Explain different techniques used for isolation and screening of important microbial strains. **(10)**

b) Explain bacterial growth curve . **(05)**

Q.2 Explain in details, design, operation and control of bioreactor. **(15)**

Q.3 **a)** How will you synthesize glutamic acid by process of fermentation? **(07)**

b) Explain microbial transformation with suitable example. **(08)**

Q.4 **a)** Explain steps in down-stream processing of streptomycin in process of fermentation. **(07)**

b) Explain important rules and regulations in manufacturing of biological products. **(08)**

Q.5 **a)** Explain in detail rheological properties of fermentation system. **(07)**

b) Write the advantages and disadvantages of liquid sterilization. **(08)**

Q.6 Write short notes. **(15)**

a) Surface sterilization
b) Bubble column bioreactor
c) Slant and Stab culture

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M. PHARM. (PHARMACOLOGY) SEM – I (CBCS-2019 COURSE): WINTER 2019
SUBJECT: CELLULAR AND MOLECULAR PHARMACOLOGY

Day : Thursday
Date : 09-01-2020

Time: 10:00AM-TO 1:00PM.
Max. Marks: 75

IN-20741-2019

N.B.:

1) Attempt any **FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Classify receptors. Describe Enzymes as receptors. **(10)**

b) Write in detail about PCR technique; enlist its applications in molecular pharmacology. **(05)**

Q.2 **a)** Discuss the basic principles of recombinant DNA technology. Enlist its applications. **(10)**

b) Discuss the pathways of apoptosis. **(05)**

Q.3 **a)** Describe basic equipments and procedures involved in cell culture lab. **(10)**

b) Write the principle and applications of Flow-cytometry. **(05)**

Q.4 **a)** Describe ligand gated ion channels. **(10)**

b) Elaborate 'Gene sequencing'. **(05)**

Q.5 **a)** Discuss types, procedure and application of ELISA **(10)**

b) Explain the concept of second messengers via 3' 5' cyclic AMP. **(05)**

Q.6 Write short notes on **(15)**

a) Biosimilars

b) Gene mapping and cloning of disease gene

c) Necrosis

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M. Pharm. (Pharmaceutical Chemistry) SEM – I (CBCS – 2019 COURSE): WINTER 2019
SUBJECT: CHEMISTRY OF NATURAL PRODUCTS

Day: Thursday
Date: 09.01.2020

Time: 10:00AM TO 1:00 PM.
Max Marks. 75

W- 20738-2019

N.B.

1) Attempt any **FIVE** questions from the following
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Discuss Morphine alkaloids as leads for new pharmaceutical agents in detail. **(10)**

b) Write with examples chemistry and SAR of Neuro muscular blocking drugs. **(05)**

Q.2 **a)** Describe structural elucidation and stereochemistry of ephedrine. **(10)**

b) Discuss SAR of Quinine. **(05)**

Q.3 **a)** Give an account of sources, chemistry functions and deficiency manifestations of Niacin. **(07)**

b) Discuss in detail about general methods for chemical elucidation of terpenoids. **(08)**

Q.4 **a)** Describe new pharmaceuticals derived from biotechnology. **(07)**

b) Write in detail active constituents of curcuma longa. **(08)**

Q.5 **a)** Write in detail about structural modification of lead drug podophycotoxin resulted in new anticancer agents. **(07)**

b) Discuss stereochemistry and nomenclature of steroids. **(08)**

Q.6 Write short notes on the following: **(15)**

a) Artemisinin and their derivatives
b) Macrolide antibiotics
c) Isolation and purification of flavonoids

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M.PHARM. (PHARMACEUTICAL REGULATORY AFFAIRS) SEM. – I
(CBCS – 2019 COURSE) : WINTER – 2019
SUBJECT : CLINICAL RESEARCH REGULATIONS

Day : Monday
Date : 06-01-2020.
Time : 10:00 AM TO 1:00 P.M.
Max. Marks : 75

W-20733-2019

N.B.

1) Attempt any **FIVE** questions out of **SIX.**
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Discuss the key concepts in medical device clinical evaluation. **(10)**

b) Add a note on 'Informed Consent Process.' **(05)**

Q.2 **a)** Write in detail about types of clinical trials. **(10)**

b) Add a note on role of 'placebo' in clinical trials. **(05)**

Q.3 **a)** Write a note on general biostatistics principles applied in clinical trials. **(07)**

b) Elaborate about clinical trials in Paediatric populations. **(08)**

Q.4 **a)** What does Good Pharmacovigilance Practices guidance document state? **(07)**

b) Discuss :Belmont Report and declaration of Helsinki. **(08)**

Q.5 **a)** Write a note on 21 CFR Part 312 : IND application. **(07)**

b) Write a note on 21 CFR Part 822 : Post marketing Surveillance. **(08)**

Q.6 Write notes on the following: **(15)**

a) Ethics in clinical research
b) Composition of Institutional Review Board
c) Responsibilities of principal investigator in a clinical trial

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M. PHARM. (Regulatory Affairs) SEM – I (CBCS - 2019 COURSE): WINTER – 2019
SUBJECT: DOCUMENTATION AND REGULATORY WRITING

Day: Friday
Date: 03-01-2020

Time: 10:00AM TO 1:00PM
Max. Marks: 75

W-20722-2019

N.B.:

1) Attempt any **FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Write in detail about the content of CTD. **(10)**

b) Add a note on advantages of eCTD. **(05)**

Q.2 **a)** Discuss in details about various types of audits in pharma industry. **(10)**

b) Add a note on internal audit. **(05)**

Q.3 **a)** Describe SUPAC documentation required for changes to components of modified release oral dosage forms. **(07)**

b) Describe SUPAC documentation required for manufacturing process related changes to modified release oral dosage forms. **(08)**

Q.4 **a)** Discuss importance of Product Lifecycle Management (PLM) in detail. **(07)**

b) Describe Filing strategies for SUPAC changes to a product or process. **(08)**

Q.5 **a)** Discuss PDR contents. **(07)**

b) Discuss DMF contents. **(08)**

Q.6 Write short notes on the following: **(15)**

a) Certificate of Analysis

b) Master Formula Record

c) CAPA

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M. PHARM. (Pharmaceutics) SEM – I (CBCS -2019 COURSE): WINTER – 2019
SUBJECT: DRUG DELIVERY SYSTEMS

Day: Friday
Date: 03-01-2020

Time: 10:00AM TO 1:00PM
Max. Marks: 75

W-20717-2019.

N.B.:

1) Attempt any **FIVE** questions.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Explain any two approaches for increasing gastric retention time. **(10)**

b) What is Tg of polymers? Highlight its significance. **(05)**

Q.2 **a)** Explain the mechanisms of drug release from CRDDS. **(10)**

b) Explain the principle of ion exchange activated DDS. **(05)**

Q.3 **a)** Give an account of modulation of drug delivery using biochemical approaches. **(07)**

b) Discuss the strategies used to overcome the barriers in ocular drug delivery. **(08)**

Q.4 **a)** Explain the mechanisms for uptake of antigens. **(07)**

b) Give an account of different types of physiological barriers for protein delivery. **(08)**

Q.5 **a)** Describe in detail the approaches for mucosal delivery. **(07)**

b) Discuss the evaluation parameters for protein and macromolecular formulations. **(08)**

Q.6 Write notes on the following: Any two **(15)**

a) Evaluation of transdermal DDS

b) 3D printing of pharmaceuticals

c) Biodegradable polymers

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M.PHARM. (REGULATORY AFFAIRS) SEM.-I (CBCS-2019 COURSE) : WINTER 2019
SUBJECT : GOOD PHARMACEUTICAL PRACTICES

Day : Wednesday
Date : 01.01.2020

Time : 10:00AM TO 1:00 P.M.
Max. Marks : 75

W-20711-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Discuss on principles of cGMP with respect to USFDA. **(10)**

b) cGMP for medical devices. **(05)**

Q.2 **a)** Elaborate on GLP regulations with respective to USFDA requirements. **(10)**

b) Importance of documentation. **(05)**

Q.3 **a)** Discuss on principles of GALP. **(08)**

b) Checklist of 21 CFR part II with respective to GALP. **(07)**

Q.4 **a)** Discuss importance of GDP in USFDA. **(08)**

b) CDSCO guidelines with respective to GDP. **(07)**

Q.5 **a)** Importance of six sigma concept and its application. **(08)**

b) Analytical methods validations. **(07)**

Q.6 Write short notes on the following. **(15)**

a) TQM
b) VMP
c) Validation of Utilities

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M.PHARM. (PHARMACEUTICAL BIOTECHNOLOGY) SEM.-I (CBCS-2019 COURSE) : WINTER 2019

SUBJECT : MICROBIAL AND CELLULAR BIOLOGY

Day : Friday
Date : 03-01-2020

Time : 10:00AM TO 1:00PM.
Max. Marks : 75

W-20715-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Differentiate between Prokaryotes and Eukaryotes. Elaborate on the physiological, cultural and reproductive features of bacteria. **(10)**

b) Draw a neat labeled diagram of bacterial and animal cell. **(05)**

Q.2 **a)** Describe Griffith's experiment. **(10)**

b) Give significance of transformation. **(05)**

Q.3 **a)** Describe stem cells and their application. **(07)**

b) Discuss chord-cell banking. **(08)**

Q.4 **a)** With the help of T4 phage describe the life cycle and pathogenicity of virus. **(07)**

b) Write a detailed note on the economic significance of fungi with examples. **(08)**

Q.5 **a)** What is programmed cell death? **(07)**

b) Explain in detail necrosis and apoptosis. **(08)**

Q.6 Write notes on the following. **(15)**

a) Structure of DNA

b) Inheritance of mitochondrial DNA

c) Histone proteins

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M.PHARM. (PHARMACEUTICAL QUALITY ASSURANCE TECHNIQUES / PHARMACEUTICAL CHEMISTRY / PHARMACOLOGY) SEM-I (CBCS-2019 COURSE) : WINTER 2019

SUBJECT : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day : Wednesday
Date : 01-01-2020

Time : 10:00 AM TO 1:00 P.M.
Max. marks : 75

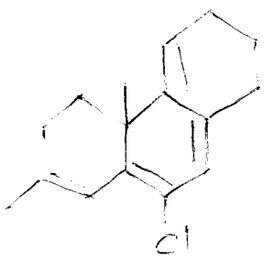
W-20708-2019

N.B.

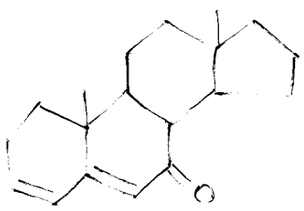
1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Calculate λ max for the following compounds using woodward-Fieser rule. **(10)**

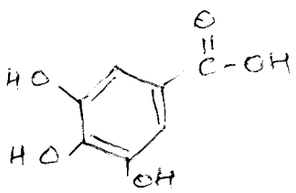
a)



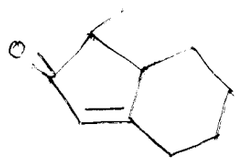
b)



c)



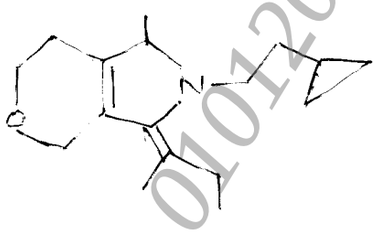
d)



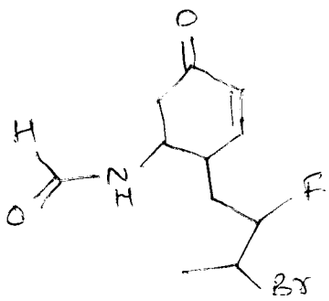
b) Explain the effect of conjugation on absorption (λmax) with example. **(05)**

Q.2 **a)** Write the chemical shift and multiplicities for the following compounds. **(10)**

i)



ii)



b) Write the fragmentation pattern for alcohols and phenols. **(05)**

Q.3 **a)** Explain the factors affecting fluorescence. **(07)**
b) Write an elaborate note on principle and instrumentation of Gas-Liquid chromatography. **(08)**

Q.4 **a)** What is electrophoresis? Classify. Write the principle and process involved in paper electrophoresis. **(07)**
b) Write the principle and instrumentations of flame emission spectroscopy. **(08)**

Q.5 **a)** Discuss the important regions of IR spectrum **(07)**
b) Discuss the principle, types and instrumentation of heat flux DSC **(08)**

Q.6 Write note on the following **(15)**

a) Potentiometric principle and applications
b) Interferences in FES
c) Modes of molecular vibrations

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M.PHARM. (PHARMACEUTICAL QUALITY ASSURANCE TECHNIQUES / PHARMACEUTICAL CHEMISTRY / PHARMACOLOGY) SEM-I (CBCS-2019 COURSE) : WINTER 2019

SUBJECT : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day : Wednesday
Date : 01-01-2020

Time : 10:00 AM TO 1:00 P.M.
Max. marks : 75

W-20708-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Calculate λ max for the following compounds using woodward-Fieser rule. **(10)**

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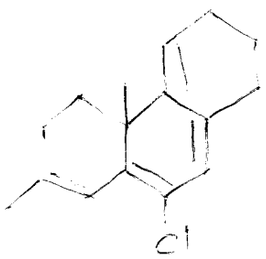
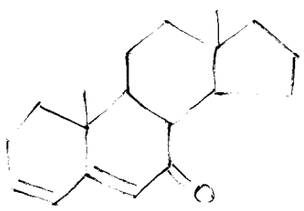
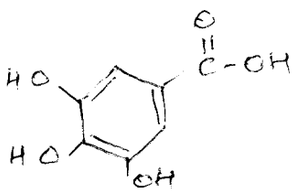


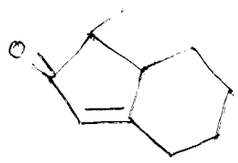
b)



c)



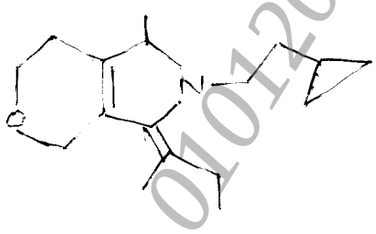
d)



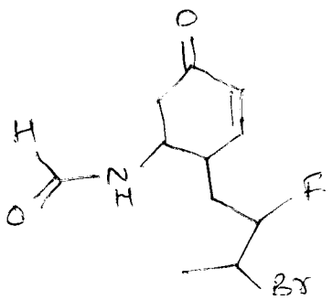
b) Explain the effect of conjugation on absorption (λmax) with example. **(05)**

Q.2 **a)** Write the chemical shift and multiplicities for the following compounds. **(10)**

i)



ii)



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Q.6 Write note on the following **(15)**

a) Potentiometric principle and applications
b) Interferences in FES
c) Modes of molecular vibrations

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M.PHARM. (PHARMACEUTICAL BIOTECHNOLOGY) SEM-I (CBCS-2019 COURSE) : WINTER 2019

SUBJECT : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day : Wednesday
Date : 01-01-2020

Time : 10:00AM TO 1:00 PM.
Max. marks : 75

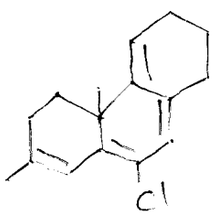
W-22409-2019

N.B.

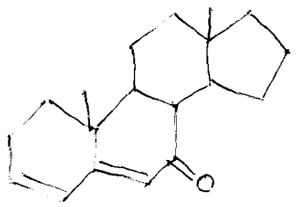
1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Calculate λ max for the following compounds using woodward-Fieser rule. **(10)**

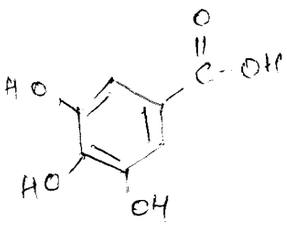
a)



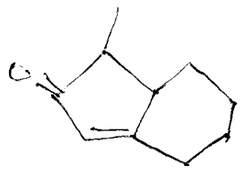
b)



c)



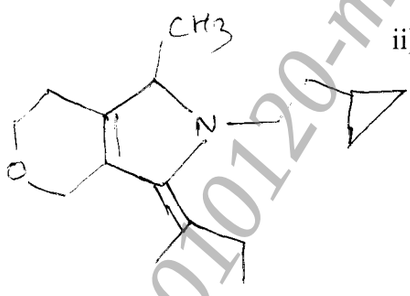
d)



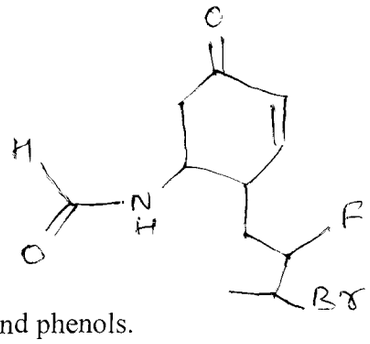
b) Explain the effect of conjugation on absorption (λmax) with example. **(05)**

Q.2 **a)** Write the chemical shift and multiplicities for the following compounds. **(10)**

i)



ii)



b) Write the fragmentation pattern for alcohols and phenols. **(05)**

Q.3 **a)** Explain the factors affecting fluorescence. **(07)**
b) Write an elaborate note on principle and instrumentation of Gas-Liquid chromatography. **(08)**

Q.4 **a)** What is electrophoresis? Classify. Write the principle and process involved in paper electrophoresis. **(07)**
b) Write the principle and instrumentations of flame emission spectroscopy. **(08)**

Q.5 **a)** Explain the mass analysers in brief. **(07)**
b) Discuss the important regions of IR spectrum **(08)**

Q.6 Write note on the following **(15)**

a) Thin layer chromatography
b) Interferences in FES
c) Modes of molecular vibrations

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M.PHARM. (PHARMACEUTICS) SEM.-I (CBCS-2019 COURSE) : WINTER 2019
SUBJECT : MODERN PHARMACEUTICS

Day : Monday
Date : 06-01-2020

Time : 10:00 AM TO 1:00 P.M.
Max. Marks : 75

W-20728-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** What is the need and concept of preformulation? Explain in brief preformulation studies of SMEDDS. **(10)**

b) Give the significance of Heckel plot. **(05)**

Q.2 **a)** Explain with suitable example of the three level factorial design to optimize the formulation. **(10)**

b) Explain validation master plan. **(05)**

Q.3 **a)** Discuss dissolution parameters of conventional tablet. **(08)**

b) Explain the physics of tablet compression. **(07)**

Q.4 **a)** Explain the concept of Total Quality Management. **(08)**

b) Explain the role of Higuchi and Peppas plot in the kinetics of drug release. **(07)**

Q.5 **a)** Elaborate objectives and policies of cGMP. **(08)**

b) Write in detail – Chi Square test, ANOVA Test and student t-test. **(07)**

Q.6 Write notes on the following. **(15)**

a) Similarity and dissimilarity factors of tablet
b) Stability testing of emulsion
c) IQ, OQ, PQ - Qualifications

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M.PHARM. (PHARMACEUTICS) SEM-I (CBCS-2019 COURSE) : WINTER 2019
SUBJECT : MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Day : Wednesday
Date : 01-01-2020

Time : 10:00AM TO 1:00 P.M.
Max. marks : 75

W1-20709-2019

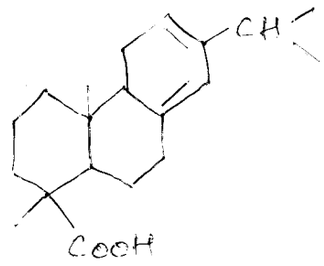
N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

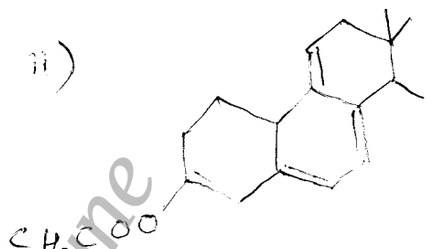
Q.1 **a)** Write a detailed note on interpretation aspects of IR spectrum. **(10)**

b) Calculate λ max for the following compounds. **(05)**

i)



ii)



Q.2 **a)** Write the chemical shift value and multiplicities of all protons in the given structures. **(10)**

i) 2-methyl propanol ii) propylamine
iii) Butylmethyl ether iv) 1-nitro butane

b) Write a note on choice of solvents in UV-spectroscopy. **(05)**

Q.3 **a)** Explain the principle of mass spectroscopy and discuss TOF mass analyzer. **(07)**

b) Write the principle, instrumentation and applications of atomic absorption spectroscopy. **(08)**

Q.4 **a)** Write a note on HPLC columns. **(07)**

b) Define chromatography, classify and explain the rate theory and plate theory of chromatography. **(08)**

Q.5 **a)** Discuss in detail capillary electrophoresis. **(07)**

b) Write the different methods of x-ray diffraction and explain any two in detail. **(08)**

Q.6 Write note on the following **(15)**

a) Radio Immunoassay
b) ELISA
c) Affinity chromatography

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BACHELOR OF PHARMACY (2011 COURSE) Final Year B. Pharm. Sem-VII: WINTER- 2019
SUBJECT: PHARMACOGNOSY-III (T T)

Monday 25-11-2019
02:00 PM-05:00 PM

W-7541-2019
Max. Marks: 80

N.B.:

1) **Q. No. 1** and **Q. No. 5** are **COMPULSORY**. Out of the remaining attempt any **TWO** questions from each section.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer books.
4) Draw neat and labelled diagram **WHEREVER** necessary.

SECTION-I

Q.1 Answer any **FIVE** of the following: **(10)**

a) Define tannins.
b) Give chemical test for Tea.
c) Give biological source and chemical constituents of Craneberry.
d) Give biological source and chemical constituents of Hops.
e) Differentiate between Indian Senna and Alexandrian Senna.
f) Give therapeutic uses of Orange.

Q.2 **a)** Write an exhaustive note on St.John's Worth. **(08)**
b) Give the general biosynthetic pathway of Shikimates. **(07)**

Q.3 **a)** Give pharmacognostic details of Ginger. **(08)**
b) Give pharmacognositc details of Hirda. **(07)**

Q.4 Attempt any **THREE** of the following: **(15)**

a) Discuss T S of Podophyllum.
b) Differentiate between Peru balsam and Tolu balsam.
c) Give pharmacognositc details of Turmeric.
d) Rosemary.

SECTION-II

Q.5 Answer any **FIVE** of the following: **(10)**

a) What are biological amines?
b) Differentiate between True alkaloids and Pseudo alkaloids.
c) Define Enflurage.
d) Give biological source and chemical constituents of Colchicum.
e) Give biological source and chemical constituents of Kola.
f) What is hydro distillation?

Q.6 **a)** What are saponins? Write an exhaustive note on Liquorice. **(08)**
b) Define volatile oils. Give biosynthetic pathway and classification of terpenoids **(07)**

Q.7 **a)** Give pharmacognostic details of Ma Huang and explain its extraction protocol. **(08)**
b) Give pharmacognostic details of Cinchona and explain its extraction protocol. **(07)**

Q.8 Attempt any **THREE** of the following: **(15)**

a) Give pharmacognostic details of Black pepper.
b) Draw transverse section of Datura.
c) Arnica.
d) Tropane alkaloid.

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BACHELOR OF PHARMACY (2011 COURSE) Final Year B. Pharm. Sem-VIII: WINTER- 2019

SUBJECT: PHARMACOGNOSY-IV (T T)

Tuesday 19-11-2019
02:00 PM-05:00 PM

W-7547-2019
Max. Marks: 80

N.B.:

1) Q. No. 1 and Q. No. 5 are **COMPULSORY.**
2) Out of the remaining solve any **TWO** questions from each section.
3) Figures to the **RIGHT** indicate full marks.
4) Answers to the two sections should be written in **SEPARATE** answer books.
5) Draw neat labeled diagrams **WHEREVER** necessary.

SECTION-I

Q.1 Answer any **FIVE** of the following: **(10)**

a) Give the uses of Bramhi
b) What is Marana Process?
c) What is Bhavana Process?
d) What is Putta?
e) Give the uses of Dashamularishta
f) What is Dhataki?

Q.2 **a)** Differentiate between Asawa and Arishta. Explain the method of preparation Ashokarishta and give its evaluation parameters. **(08)**

b) Explain the method of preparation of Shankh bhasma and give its evaluation process. **(07)**

Q.3 **a)** Give the uses of Lahsun and enlist the marketed preparations of Lahsun. **(08)**

b) Define Churna. Give method of preparation of Trikatu Churna. **(07)**

Q.4 Write short notes on any **THREE** of the following: **(15)**

a) Shatavari
b) Rajat bhasma
c) Karela kwath
d) Kumari Asava

SECTION-II

Q.5 Answer any **FIVE** of the following: **(10)**

a) Draw the structure of Artemisin
b) Give the uses of Etoposide
c) Give the uses of Camptothecin
d) Draw the structure of Hypericin
e) Define phyto pharmaceuticals
f) Give the importance of Omega 3 fatty acid

Q.6 **a)** Give the chemistry and therapeutic profile of Silymarin. **(08)**

b) Explain the method of isolation of Vinblastin. **(07)**

Q.7 **a)** Give the chemistry and therapeutic profile of Streptokinase. **(08)**

b) Explain the method of isolation of Resveretral. **(07)**

Q.8 Write short notes on any **THREE** of the following: **(15)**

a) Therapeutic uses of Colenol
b) Isolation of Taxol
c) Method of isolation of Valepotriates
d) Boswellic acid

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BACHELOR OF PHARMACY (B. PHARM.) (CBCS - 2015 COURSE) Final Year B. Pharm. Sem-VII: WINTER- 2019
SUBJECT: PHARMACOGNOSY-IV (T UE)

Wednesday 20-11-2019
02:00 PM-05:00 PM

W-13723-2019
Max. Marks: 60

N.B.

1) Q.1 and Q.5 are **COMPULSORY.** Out of the remaining attempt any **TWO** questions from each section.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer books.

SECTION – I

Q.1 Answer any **FIVE** of the following: **(10)**

a) Write biological source of Aloe.
b) Write chemical constituents of Neem.
c) What is AYUSH?
d) Write role of nutraceuticals in body.
e) Define the term nutraceutical.
f) What is use of Spirulina?

Q.2 **a)** Write in detail herbal skin care product. Add a note on production and quality control. **(06)**

b) Which are different wound healing agents from nature? **(04)**

Q.3 **a)** Explain impact of DSHEA on herbal drugs. **(06)**

b) Explain in detail role of different regulatory bodies regarding regulation of herbal drugs in India. **(04)**

Q.4 Write short notes on any **TWO** of the following: **(10)**

a) Oral bioavailability enhancer
b) Immunomodulators
c) FSSAI

SECTION – II

Q.5 Answer any **FIVE** of the following: **(10)**

a) Write biological source of Vinca.
b) Write chemical constituents of Taxus.
c) What is role of digoxin?
d) What is plant bitters? Give example.
e) What is use of Camptotheca?
f) Write names of any two natural flavoring agent.

Q.6 **a)** Write in detail process of drug discovery from natural products. **(06)**

b) Explain herb-drug interaction with suitable examples. **(04)**

Q.7 **a)** Which are different natural sweeteners? Give examples. **(06)**

b) Explain the term 'Liver tonic'. Give example. **(04)**

Q.8 Write short notes on any **TWO** of the following: **(10)**

a) Natural pesticides
b) Natural coloring agents
c) Pharmacovigilance of herbal drugs

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M.PHARM. (PHARMACOLOGY) SEM.-I (CBCS-2019 COURSE) : WINTER 2019
SUBJECT : PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I

Day : Monday
Date : 06-01-2020

Time : 10:00AM TO 1:00PM
Max. Marks : 75

W-20730-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Discuss the various methods employed in screening of anti-hypertensive agents. **(10)**

b) Write a note on limitations of animal experimentation. **(05)**

Q.2 **a)** Discuss in detail methods for screening of anti-Parkinson's agents. **(10)**

b) Discuss the various methods for screening of CNS stimulants. **(05)**

Q.3 **a)** Explain in detail the screening methods for of anti-fertility agents. **(07)**

b) Write a note on immunoassay methods and their applications. **(08)**

Q.4 **a)** Elaborate in detail methods for screening of laxatives. **(07)**

b) Elaborate on screening of hepatoprotective agents. **(08)**

Q.5 **a)** Explain in detail methods for screening of anti-hyperlipidemic agents. **(07)**

b) Discuss the general principles of immunoassays. **(08)**

Q.6 Write notes on the following. **(15)**

a) Types of Bioassay

b) Organisation of Preclinical Screening

c) Maintenance and Breeding of laboratory animals

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M.PHARM. (PHARMACEUTICAL QUALITY ASSURANCE) SEM.-I
(CBCS – 2019 COURSE) : WINTER 2019
SUBJECT : QUALITY CONTROL AND QUALITY ASSURANCE

Day : Monday
Date : 06-01-2020

Time : 10:00 AM TO 1:00 PM
Max. marks : 75

W-20732-2019

N.B.

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the **RIGHT** indicate **FULL** marks.

Q.1 **a)** Describe in detail ICH Quality guidelines. **(10)**

b) Add a note on ICH QSEM guidelines. **(05)**

Q.2 **a)** Discuss important provisions of Schedule M. **(10)**

b) Add a note on Good Warehousing Practices. **(05)**

Q.3 **a)** Write a note on CPCSEA guidelines. **(07)**

b) Discuss IPQC testing for raw materials. **(08)**

Q.4 **a)** Add a note on IPQC for tablets. **(07)**

b) Write a note on finished product testing of parenterals. **(08)**

Q.5 **a)** Discuss quality control testing for containers and closures. **(07)**

b) Write a note on audit planning. **(08)**

Q.6 Write notes on the following. **(15)**

a) IPQC of semisolids

b) Master Formula Record

c) Control of Mix ups and cross contamination during manufacturing

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M. PHARM. (PHARMACEUTICAL QUALITY ASSURANCE) SEM-I (CBCS-2019 COURSE): WINTER 2019

SUBJECT: QUALITY MANAGEMENT SYSTEMS

Day : Friday
Date : 03-01-2020

Time: 10:00AM TO 1:00PM.
Max. Marks: 75

W-20721

N.B.:

1) Attempt any **FIVE** questions from the following.
2) Figure to the right indicate FULL marks.

Q.1	**a)**	Discuss on the salient features of Quality as a strategic decision.	**(10)**
	b)	How do the Customer expectations are met with respect to complaints?	**(05)**
Q.2	**a)**	Elaborate on basic concepts of TQM.	**(10)**
	b)	Discuss on Quality Management Review.	**(05)**
Q.3	**a)**	Discuss on Six System Inspection Model.	**(08)**
	b)	Relevance of OOS and OOT.	**(07)**
Q.4	**a)**	Discuss on ICH Q8.	**(08)**
	b)	Importance of QRM in Pharmaceutical Quality Management.	**(07)**
Q.5	**a)**	Importance of SPC in Pharmaceutical Manufacturing.	**(08)**
	b)	Elaborate on various measurement tools in SPC.	**(07)**
Q.6		Write short notes on	**(15)**
	a)	Quality Culture	
	b)	Benchmarking	
	c)	Cost of Quality	

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M. PHARM. (REGULATORY AFFAIRS) SEM-I (CBCS- 2019 COURSE): WINTER-2019
SUBJECT: REGULATIONS AND LEGISLATION FOR DRUGS AND COSMETICS, MEDICAL DEVICES, BIOLOGICALS AND HERBALS AND FOOD AND NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS

Day: Thursday
Date: 09-01-2020

Time: 10:00AM TO 1:00PM.
Max. Marks: 75

W-20744-2019

N.B.:

1) Attempt **ANY FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Explain the ICMR-DBT Guidelines 2017 for Stem Cell Research and Therapy. **(10)**

b) Define: i) Schedule J ii) Schedule H **(05)**
iii) Schedule X iv) Schedule FF v) Schedule M-II

Q.2 **a)** Explain the format and contents of regulatory dossier filling for Biologicals and Herbals. **(10)**

b) Discuss the formula for calculation of retail price of formulations as under DPCO 1995. Explain each of the terms involved in detail. **(05)**

Q.3 **a)** Define Narcotic Drugs and Psychotropic Substances. Discuss power of Central Government to permit, control and regulate certain operations under NDPS 1985. **(07)**

b) Discuss regulatory requirements for Bioequivalence study. **(08)**

Q.4 **a)** Explain Education Regulations as per Pharmacy Act 1948. **(07)**

b) Discuss the general procedure for securing patents in India. **(08)**

Q.5 **a)** Discuss the guidelines for human participants in drug testing. **(07)**

b) Explain stability requirements as per ICH guidelines. **(08)**

Q.6 Write notes on the following: **(15)**

a) Process and Product Patent
b) Rationale for conducting animal studies
c) BIS standards

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M.PHARM. (PHARMACEUTICS) SEM. – I (CBCS – 2019 COURSE) : WINTER – 2019
SUBJECT : REGULATORY AFFAIRS

Day : Thursday
Date : 09.01.2020

Time : 10:00AM TO 1:00PM.
Max. Marks : 75

W-20739-2019

N.B.

1) Attempt any **FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Discuss Hatch Waxman Act. **(10)**

b) Add a note on post approval regulation USA. **(05)**

Q.2 **a)** Discuss in detail contents of CTD. **(10)**

b) Add a note on advantages of eCTD. **(05)**

Q.3 **a)** Discuss key aspects of clinical trial process. **(07)**

b) Add a note on global IND submission procedures. **(08)**

Q.4 **a)** Write a note on Investigator Brochure (IB). **(07)**

b) Write about Marketing Authorization procedures in EU. **(08)**

Q.5 **a)** Discuss Australian Regulatory framework. **(07)**

b) Discuss medical device regulation in USA. **(08)**

Q.6 Write notes on the following: **(15)**

a) ICH quality guidelines
b) DMF
c) EU IMPD

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