# M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM): WINTER - 2018

SUBJECT: ADVANCED DRUG RUGULATORY AFFAIRS - I

Time: 10.00 A.M. TO 01.00 P.M. Day W-2018-4160 Monday Date Max. Marks: 60 07/01/2019 N. B. : Attempt ANY THREE questions from Section - I and ANY THREE questions 1) from Section – II. 2) Figures to the right indicate FULL marks. Answers to both the sections should be written in **SEPARATE** answer books. 3) Draw neat and labelled diagram WHEREVER necessary. 4) **SECTION - I** Q. 1 Discuss the basic principles of Material Management (10)Q. 2 Discuss the WHO good practices in production and quality control. (10)Q. 3 Discuss in details, fundamentals of Quality Management System as per ISO. (10)Q. 4 Write short notes on **ANY TWO** of the following: (10)ANVISA guidelines for GMP a) Market complaints and product recall b) **Documentation Control** c) Discuss various steps involved in pharmaceutical development. Q. 5 (10)Discuss Quality Risk Management in detail. Q. 6 (10)Discuss roles and responsibilities of various stakeholders in conducting a (10) **Q.** 7 clinical trial. Write short notes on **ANY TWO** of the following: Q. 8 (10)Accuracy, precision and robustness of analytical method Reporting of ADR in clinical trial b) Components of a CTD dossier

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#### M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM): WINTER-2018

SUBJECT: ADVANCED PHARMACEUTICAL CHEMISTRY-I

Time: 10.00 A.M. TO 01.00 P.M. Day: Monday W-2018-4156 Max Marks: 60 Date: 07/01/2019 N.B: 1) Attempt ANY THREE questions from section- I and ANY THREE questions from section-II Answers to both the sections should be written in the **SEPARATE** answer books. 2) 3) Give reactions, structures, schemes WHEREVER necessary. 4) Figures to the right indicate FULL marks. **SECTION-I** 0.1 Discuss various methods for the protection and deprotection of -OH and -NH<sub>2</sub> (10)group Discuss the concept of catalysis with its classification. Explain mechanism of (10) Q.2 surface catalyzed reaction. Discuss the importance of fluorine, -CF<sub>3</sub> and -OCF<sub>3</sub> group in organic (05) Q.3 molecule Discuss in detail nucleophic fluorination reactions. (05)b) Write short notes on any TWO of the following: **Q.4** (10)Hoffman degradation a) Benzil - benzillic acid rearrangement b) Homogeneous and heterogeneous reduction **SECTION-II Q.5** Classify pericyclic reactions and discuss cycloaddition reactions in detail. (10)**Q.6** Discuss in detail stereochemistry of allenes and biphenyls. (10)**Q.7** Discuss IUPAC nomenclature of hetero cyclic compounds with examples. a) (05)Describe Fisher indole synthesis and Hinsberg thiophene synthesis. (05)**Q.8** Write short notes on any **TWO** of the following: (10)a) Methods of preparations for  $\alpha$  methylene lactones b) Stereochemistry of Spiro compounds Curtin Hammet principle c)

#### M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM): WINTER-2018

SUBJECT: ADVANCED PHARMACEUTICS - I

Time: 10.00 A.M. TO 01.00 P.M. Day: Monday W-2018-4154 07/01/2019 Date: Max. Marks: 60 N.B. 1) Answer any THREE questions from Section – I any THREE questions from 2) Both the sections should be written in separate answer books. Figures to the right indicate FULL marks. 3) **SECTION - I Q.1** Enlist the various parameters to be considered during preformulation (10) study. Comment on the interrelationship of drug properties in preformulation. Explain the model based and model independent approaches to compare (10) **Q.2** dissolution profile. the various approaches employed Q.3 Enlist for optimization of (10) pharmaceutical formulations. Write short notes on: **Q.4** (10)Principle, Instrumentation and application of DSC. a) b) Q.1 ICH guideline for stability study of pharmaceuticals. SECTION - II Give an account of the different mathematical approaches to study the (10) Q.5 compressional behavior of solids. Define CMC. Elaborate on the factors affecting CMC. Q.6 (10)Explain the different mechanisms of biodegradation of polymers with (10) **Q.7** examples. Write notes on: (10)**Q.8** 

Thermodynamics of polymer solutions

a)

b)

**Dendrimers** 

### M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM): WINTER-2018

SUBJECT: ADVANCED PHARMACOGNOSY-I

Time: 10.00 A.M. TO 01.00 P.M. Day: Monday W-2018-4157 Max. Marks. 60 Date: 07/01/2019 N.B. 1) There are **FOUR** questions in each section. Attempt any **THREE** questions from each section. Answers to the two sections should be written in **SEPARATE** answer books. 2) Figures to the RIGHT indicate full marks. 3) SECTION - I Q.1 Write an exhaustive note on Gymnema sylvestre and Ocimum sanctum. (10)Give the detailed phytochemical and pharmacological profile of Azadirachta indica (10) Q.2 and Tylophora asthematica. Describe ex-situ and in situ methods of cultivation. Elaborate the advantages and (10) 0.3 disadvantages of these techniques with respect to the cultivation on medicinal plants. Write elaborate note on ANY TWO 0.4 (10)Plant Breeders Right b) Biodiversity law Indian patent law applicable to natural products. SECTION - II Write a detailed note on Food guide pyramid. 0.5 (10)What are nutraceuticals? Classify them and explain their roles in healthcare. (10)Q.6 Write a detailed note on Marine CVS drugs. Explain the Pharmacognosy of any **Q.**7 (10)one in detail (10)Write a short note on ANY TWO **Q.8** Recent trends in Marine drug research Antioxidants b) c) FPO

#### M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM): WINTER - 2018

	SYSTEM): WINTER - 2018 SUBJECT: ADVANCED PHARMACOLOGY-I							
ay:	I	Monday		Time: 10.00 A.M. TO				
)ate:	07	7/01/2019	W-2018-4155 Ma					
N.B.:	1) 2) 3)	from Section-II. Answers to the two sections should be written in SEPARATE answer books.						
		de recent de sate al vers	SECTION - I					
Q.1		Describe the OECI	guidelines for performing experi	ment on animals. [10]				
Q.2		Describe the screening of analgesic, anti-inflammatory drugs in detail.						
Q.3		Explain in detail high throughput screening.						
Q.4		Write short notes on <b>ANY TWO</b> of the following:						
	a)	Microarrays						
	b)	Screening of CNS stimulants						
			SECTION - II					
Q.5		Explain the screeni	ng of bronchodialators.	[10]				
Q.6		Describe the screen	ning of antihistamines.	[10]				
<b>Q.</b> 7		Explain the screeni	ng of cholinergics.	[10]				
Q.8		Write short notes o	n ANY TWO of the following:	[10]				
	a)	Screening of antithyroid drugs.						
	b)	Screening of andro	genic drugs.					
	c)	Animal cell lines a	nd their uses.					

# M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE SYSTEM): WINTER - 2018

### SUBJECT: ADVANCED QUALITY ASSURANCE TECHNIQUES - I

Day Monday Time: 10.00 A.M. TO 01.00 P.M. W-2018-4159 Date: 07/01/2019 Max. Marks: 60 N. B.: Attempt ANY THREE questions from Section - I and ANY THREE questions 1) from Section – II. Figures to the right indicate FULL marks. 2) Answers to both the sections should be written in **SEPARATE** answer books. 3) Draw neat and labelled diagram WHEREVER necessary. 4) **SECTION - I** Q. 1 Discuss important aspects related to Materials Management in Pharma (10) Industry. Q. 2 Discuss the requirements for buildings and facilities of a pharma (10) manufacturing unit. What are the responsibilities of heads of QC and production? Also add a note (10) Q. 3 on their combined responsibilities. Write short notes on ANY TWO of the following: (10)Q. 4 a) Personnel Training and Personnel Hygiene in pharmaceutical industry Design and construction of process equipment b) Factors in contractor selection for outsourcing of pharma operations **SECTION - II** Discuss in detail manufacturing of Q. A. aspects of sterile pharmaceutical (10) Q. 5 products. Elaborate on recalled, returned rejected and recovered product. Add note on (10) Q. 6 product complaint. Discuss I.P.Q.C. activities in production and calculation of yields with its (10) **Q.** 7 importance. (10)Write short notes on ANY TWO of the following: Q. 8 a) WHO guidelines on inspection of Pharma MFG facilities b) Concept of QA and QC Release of finished products c)

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#### M. PHARM. SEM-I (CHOICE BASED CREDIT & GRADE

SYSTEM): WINTER - 2018

## SUBJECT: Elective- I: a) PHARMACEUTICAL ADMINISTRATION

				ADMINISTRATION	01
	Day Date		nesday 1/2019	W-2018-4161	Time: 10.00 A.M. TO 01 Max Marks: 60
	N.B	1) 2) 3)	All questi	any <b>THREE</b> questions questions from ons carry <b>EQUAL</b> marks. sections should be written in <b>SEPA</b> .	
				SECTION-I	
Q.1		Discuss	concept of s	social responsibilities of manageme	nt. (10)
Q.2		Explain	with examp	les various steps involved in strateg	ric planning process. (10)
Q.3		Discuss	salient featu	ares of formal and informal organiza	ations. (10)
Q.4		Write sh	ort notes on	ANY TWO	(10)
	<b>b</b> )	Process	e and proces of Decision ance Apprai	_	
Q.5		Discuss	s various Hu	ıman factors in managing.	(10)
Q.6		How do	oes pitfalls i	n communication process damage o	organizations? (10)
Q.7		Discuss	s various req	uirements for effective control.	(10)
Q.8	a) b)	Product	tion and Ope	n <b>ANY TWO</b> : erations Management g Productivity	(10)
	c)		ive Control		

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