

Seat No.	
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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-I) (New)  
(CBCS) Examination: October/November - 2025  
Environmental Health and Safety in Pharmaceutical Manufacturing  
(G20-0101)**

Day & Date: Thursday, 06-11-2025  
Time: 12:00 PM To 02:00 PM

Max. Marks: 40

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative (MCQ)****08**

- 1) The scope of sanitation and hygiene covers \_\_\_\_\_.
  - a) Personnel
  - b) Premises
  - c) Equipments
  - d) All the above
- 2) What is a biological hazard.
  - a) Old Age
  - b) Fatigue
  - c) Virus
  - d) Alcoholism
- 3) GMP ensures which of the following parameters.
  - a) Quality
  - b) Safety
  - c) Efficacy
  - d) All the above
- 4) SOPs are used to ensure consistency in daily operations. What does 'S' stands for in SOP's?
  - a) Special
  - b) Standard
  - c) Safety
  - d) Sustainable
- 5) When are sterilized packs most likely to become contaminated?
  - a) After 30 days
  - b) After 60 days
  - c) Within the first hour of sterilization
  - d) Within the first day of sterilization
- 6) Chemical produced by microorganism that can cause fever reactions in patients \_\_\_\_\_.
  - a) Bacteria
  - b) Pyrogens
  - c) Viruses
  - d) Microorganisms
- 7) The three parameters of steam sterilization are: \_\_\_\_\_.
  - a) Steam under pressure, time, and temperature
  - b) Time, temperature, and concentration
  - c) Temperature, time, and humidity
  - d) All the above

- 8) Which of the following monitoring methods verifies that conditions within the load were adequate to kill bacterial spores?
- a) Mechanical
  - b) Biological
  - c) Chemical
  - d) none of the above

**B) Write true or false****04**

- 1) Autoclave works on hot air sterilization principle.
  - a) True
  - b) False
- 2) Boiling of water is one of the steps of disinfection of water.
  - a) True
  - b) False
- 3) Potable water is defined as water that is suitable for human consumption.
  - a) True
  - b) False
- 4) Aseptic techniques are the methods that maintain sterility products.
  - a) True
  - b) False

**Q.2 Answer the following questions (Any Six)****12**

- a) List two steps to follow during a fire emergency.
- b) Name two methods used for sterilizing pharmaceutical equipment.
- c) What is the difference between chemical and physical methods of water sterilization? Give one example of each.
- d) What should you do in case of a chemical spill at work?
- e) Who should be evacuated first during an emergency: employees or visitors? Why?
- f) How does cleaning and sanitation help reduce contamination in production areas?
- g) Name one impurity found in water and explain how it can be removed.

**Q.3 Answer the following questions (Any Three)****12**

- a) How should a medical emergency, such as an injury or illness, be handled in a workplace? List two key actions to ensure immediate safety.
- b) Define microbial control in pharmaceutical manufacturing.
- c) Describe the responsibilities of employees to ensure workplace safety and EHS compliance.
- d) Describe the process for identifying and reporting hazards in the workplace.

**Q.4 Answer the following questions (Any Two)****12**

- a) What are workplace hazards in pharmaceutical manufacturing? Explain the steps for identifying and reporting them.
- b) Describe the evacuation procedures for employees and visitors during an emergency in a pharmaceutical plant.
- c) Describe the methods used for cleaning equipment in pharmaceutical manufacturing.

**Q.5 Answer the following questions (Any Two)****12**

- a)** What are the differences between chemical and physical methods of sterilizing water? Give one example for each method.
- b)** What is pyrogen testing, and why is it essential in pharmaceutical production?
- c)** What is microbial control in pharmaceutical manufacturing and why is it important?

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-I) (New)  
(CBCS) Examination: October/November - 2025  
GMP Compliance for Pharmaceutical Manufacturing (G20-0102)**

Day & Date: Friday, 07-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Please choose correct alternatives (MCQ) 08**

- 1) It costs less to prevent a problem than it does to correct it' related more to \_\_\_\_\_.
 

a) QC	b) Quality Assurance
c) Quality Audit	d) In process QC
- 2) GXP refers to Good Practices related to \_\_\_\_\_.
 

a) GMP	b) GCP
c) GDP	d) All activities related to life sciences
- 3) Walls of a pharma manufacturing coated with epoxy paint such that, it \_\_\_\_\_.
 

a) Prevent microbes	b) Doesn't allow dust
c) Is smooth and washable	d) Is less sensitive to moisture.
- 4) Manufacturing facility of an antibiotic formulation is \_\_\_\_\_ with others.
 

a) Shared	b) Present, not-shared
c) Not-present	d) None of these
- 5) Non-sterile oral liquids are filled in cleanrooms of grade \_\_\_\_\_.
 

a) D	b) B
c) C	d) A
- 6) \_\_\_\_\_ is a process of ensuring proper performance of an Instrument.
 

a) Validation	b) Assurance
c) Calibration	d) None of these
- 7) The guidelines for manufacturing soaps is covered under \_\_\_\_\_.
 

a) Schedule M – 2	b) Schedule M
c) Schedule M1	d) Schedule M3

- 8) Solvent/s used for cleaning “clean room of B grade” is \_\_\_\_\_.  
 a) Sterile water                      b) Sterile 70% Isopropanol  
 c) Detergent                          d) Sterile sporicidal liquid.

**B) Fill in the blanks / State TRUE / FALSE**

04

- 1) Documents \_\_\_\_\_ the confidence in quality assurance system.
- 2) “An equipment looks clean, therefore it must be clean”.
- 3) A drug shall be deemed adulterated if: the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to GMP.
- 4) An equipment label as per cGMP should contain: Name of the product: Batch number: Batch size: Processing stage:

**Q.2 Answer the following. (Any Six)**

12

- a) Write a note on 21CFR 211 of USFDA-cGMP.
- b) Schedule M-2.
- c) Location of a Pharma manufacturing facility.
- d) Solid waste disposal methods.
- e) Components of SOP on clothing in clean areas.
- f) Documents that ensure achieving cGMP during manufacture.
- g) Justify “Regulatory compliance required for manufacturing equipment”.
- h) Measures used to prevent mix-ups and cross contamination.

**Q.3 Answer the following (Any Three)**

12

- Importance of cleaning validation in pharma waste management.
- Discuss about the revised Schedule M-2024.
- Elaborate on “Incineration” as a method of handling wastes.
- Explain GXP with an example.

**Q.4 Answer the following (Any Two)**

12

- How do you achieve GMP through maintenance of equipment?
- Explain components of a SOP for mixing process of a tablet formulation.
- Elaborate GMP standards and regulations related to premises of manufacture of Homeopathic products.

### Q.5 Long Answers (Any Two)

12

- a)** How can you achieve regulatory compliance for manufacturing equipment? Discuss.
- b)** Discuss the salient features of Schedule-M (old).
- c)** Explain the nature of and treatment done for liquid waste generated in an API / bulk drug industry.

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**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-I) (New)  
(CBCS) Examination: October/November - 2025  
General concept of Pharmacology (G20-0103)**

Day & Date: Saturday, 08-11-2025  
Time: 12:00 PM To 02:00 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right are marks allotted for each section.

**Q.1 A) Please choose correct alternatives (MCQ) 08**

- 1) Which of the following is NOT a phase of pharmacokinetics?
 

a) Absorption	b) Distribution
c) Metabolism	d) Synthesis
- 2) The term 'bioavailability' refers to: \_\_\_\_\_.
  - a) The rate at which a drug is eliminated from the body
  - b) The proportion of a drug that enters circulation when introduced into the body
  - c) The ability of a drug to bind to its target receptor
  - d) The duration of action of a drug
- 3) Which type of adverse drug reaction (ADR) is predictable and dose-dependent?
 

a) Type A	b) Type B
c) Type C	d) Type D
- 4) What is the primary goal of pharmacovigilance?
  - a) To develop new drugs
  - b) To monitor and evaluate adverse drug reactions
  - c) To enhance drug efficacy
  - d) To reduce drug costs
- 5) Drug interactions can lead to which of the following outcomes?
  - a) Enhanced therapeutic effect
  - b) Reduced therapeutic effect
  - c) Increased toxicity
  - d) All of the above
- 6) Cholinergic receptors primarily respond to which neurotransmitter?
 

a) Norepinephrine	b) Acetylcholine
c) Dopamine	d) Serotonin

- 7) Adrenergic receptors are primarily associated with which part of the nervous system?
- Central nervous system (CNS)
  - Parasympathetic nervous system
  - Sympathetic nervous system
  - Somatic nervous system
- 8) Which of the following factors does NOT affect drug absorption?
- pH of the environment
  - Blood flow to the absorption site
  - Drug solubility
  - Patient's age

**B) Fill in the blanks / State TRUE / FALSE****04**

- The process by which a drug is absorbed, distributed, metabolized, and excreted from the body is known as \_\_\_\_\_.
- The primary neurotransmitter associated with cholinergic receptors is \_\_\_\_\_.
- Adverse drug reactions that are unpredictable and not dose-dependent are classified as \_\_\_\_\_ reactions.
- Pharmacokinetics involves the study of how drugs affect the body. (True/ False)

**Q.2 Answer the following (Any Six)****12**

- Define bioavailability.
- Define pharmacokinetics and list its four main processes.
- What is the difference between first-pass metabolism and systemic circulation?
- Describe the mechanisms by which drug resistance can develop in bacterial infections.
- Enlist and explain sources of drugs with examples.
- Define Adverse reactions.
- Define pharmacodynamics and how it differs from pharmacokinetics.
- Define Essential medicines.

**Q.3 Answer the following (Any Three)****12**

- Discuss the pharmacokinetic parameters that influence drug dosing and how they can be altered in patients with liver disease.
- Explain the concept of receptor desensitization and its clinical implications in long-term drug therapy.
- Explain how genetic polymorphisms can affect drug metabolism.
- What is the primary function of the autonomic nervous system (ANS)?
- Name one common route of drug administration and elaborate.

**Q.4 Answer the following (Any Two) 12**

- a)** Discuss the pharmacokinetic processes of absorption, distribution, metabolism, and excretion (ADME) in detail, including factors that influence each process.
- b)** Explain the mechanisms of action of common classes of antihypertensive drugs, including their therapeutic uses and potential side effects.
- c)** Analyse the role of pharmacovigilance in ensuring drug safety, including the methods used.

**Q.5 Long Answers (Any Two) 12**

- a)** Enlist and describe various routes of drug administration.
- b)** Explain the role of the liver in drug metabolism, detailing the phases of metabolism and how liver function can affect drug clearance and dosing.
- c)** What is the scope of subject of pharmacology explain.



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Set **P**

**B.Sc. (Pharmaceutical Manufacturing & Quality) (Sem-I) (New)  
(CBCS) Examination: October/November - 2025  
Pharmaceutics (G20-0104)**

Day & Date: Monday, 10-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative. (MCQ)****08**

- 1) Emulsion is \_\_\_\_\_ type of dosage form.
  - a) Monophasic
  - b) Biphasic
  - c) Both A& B
  - d) None of the above
- 2) Enteric coated tablet is disintegrated in \_\_\_\_\_.
  - a) Stomach
  - b) Mouth
  - c) Intestine
  - d) Liver
- 3) Vial is \_\_\_\_\_.
  - a) Secondary Packing
  - b) Primary Packing
  - c) Tertiary Packing
  - d) All of above
- 4) Which is unit dosage form?
  - a) Suspension
  - b) Emulsion
  - c) Solid
  - d) Liquid
- 5) Syrup \_\_\_\_\_ type of dosage form.
  - a) Semisolid
  - b) Emulsion
  - c) Liquid
  - d) Suspension
- 6) Ball mill is used to \_\_\_\_\_.
  - a) Mixing
  - b) Size reduction
  - c) Drying
  - d) Size separation
- 7) Borosilicate glass is also known as \_\_\_\_\_ glass.
  - a) Type-I
  - b) Type- III
  - c) Type- II
  - d) Type-IV
- 8) Cyclone separator is based on the principle of \_\_\_\_\_.
  - a) Centrifugal force
  - b) Hydrogen force
  - c) Internal force
  - d) None of above

**B) Write True or False****04**

- 1) Creams are liquid dosage form.
- 2) Regular soda lime is Type I packing material.
- 3) Sieves are used for separation of particles.
- 4) First edition of Indian Pharmacopoeia was published in 1955.

**Q.2 Answer the following (Any Six)****12**

- a) Write applications of preservatives.
- b) Write advantages of Liquid dosage form.
- c) Classify Semisolid dosage form.
- d) Draw neat labeled diagram of Hammer mill.
- e) Write definition of Filtration and Extraction;
- f) Write different types of plastic as packaging material.
- g) Write theory of filtration.
- h) Enlist unit operations used in Pharmaceutical manufacturing.

**Q.3 Answer the following (Any Three)****12**

- a) Write a note on British Pharmacopoeia.
- b) Write the principle, construction of hammer mill.
- c) Write advantages and disadvantages of rubber as packaging material.
- d) Write definition of:
  - a) Powder
  - b) Linctus
  - c) Gargles
  - d) Suspension

**Q.4 Answer the following (Any Two)****12**

- a) Write a note on Indian Pharmacopoeia.
- b) Draw a neat labeled diagram of Cyclone separator and write its Principle and working.
- c) Write types of packing material and write a detailed note on plastic packing.

**Q.5 Answer the following (any two)****12**

- a) What is size reduction, write note on Ball mill?
- b) Write a note Preservatives.
- c) Define and Classify Pharmaceutical dosage form.

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-I) (New)  
(CBCS) Examination: October/November - 2025  
Biochemistry (G20-0105)**

Day & Date: Tuesday, 11-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose the correct alternative** **08**

- 1) Which of the following is the general formula of Carbo hydrates?
  - a)  $(C_4H_2O)_n$
  - b)  $(C_6H_2O)_n$
  - c)  $(CH_2O)_n$
  - d)  $(C_2H_2O)_n COOH$
- 2) Which of the following is the most abundant biomolecule on the earth?
  - a) Lipids
  - b) Proteins
  - c) Carbohydrates
  - d) Nucleic acids.
- 3) Diabetic mellitus occurs when the blood glucose level is \_\_\_\_\_.
  - a) High
  - b) Low
  - c) Medium
  - d) Absent
- 4) Which of the following is an imino acid \_\_\_\_\_.
  - a) Serine
  - b) Proline
  - c) Aspartate
  - d) Glutamine
- 5) The name of the scheme given to the transport of electrons is called as \_\_\_\_\_.
  - a) Z scheme
  - b) W scheme
  - c) Y scheme
  - d) E scheme
- 6) \_\_\_\_\_ accepts hydrogen from malate.
  - a) FAD
  - b) NAD
  - c) NADP
  - d) FMN
- 7) Glucose is converted into Glucose-6-Phosphate with the help of which enzyme \_\_\_\_\_.
  - a) Hexokinase
  - b) Keto-aldolase
  - c) Isomerase
  - d) Dehydrogenase
- 8) The Tricarboxylic acid cycle is also known as \_\_\_\_\_.
  - a) citric acid cycle
  - b) Glycolysis
  - c) Gluconeogenesis
  - d) EMP

**B) True or False.**

04

- Lipids consist of repeating units called fatty acids.  
a) True                      b) False
- The nature of an enzyme is a protein.  
a) True                      b) False
- Vitamin D helps the body absorb calcium, which is a key component of bone  
a) True                      b) False
- The Priming function in glycogen synthesis is carried by glycogenin.  
a) True                      b) False

**Q.2 Answer the following (Any Six)**

12

- a) Explain what is meant by electron transport chain.
- b) Write the significance of the citric acid cycle.
- c) Explain what is meant by coenzymes.
- d) State two causes of Vitamin D disorders.
- e) Explain the function of fatty acids in the human body.
- f) Explain any two diagnostic applications of enzymes.
- g) Define what is meant by glycogen storage disease and give one example of it.
- h) Explain what is ATP and state its function.

**Q.3 Answer the following (Any Three)**

12

- Explain in detail what is meant by transamination and deamination.
- Explain the synthesis of Dopamine.
- Explain what is meant by fatty liver and obesity.
- Explain in detail the Michaelis plot.

**Q.4 Answer the following (Any Two)**

12

- Explain the pathway of Glycolysis.
- Explain in detail the citric acid cycle pathway and mention its significance.
- Explain the Hormonal regulation of blood glucose level and Diabetes mellitus.

**Q.5 Answer the following (any two)**

12

- What is meant by HMP shut and explain its significance.
- Explain in detail the Metabolic disorder albinism.
- Explain what is meant by steroid hormone and Vitamin D.

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**B.Sc. (Pharmaceutical Manufacturing & Quality) (Sem-I) (New)  
(CBCS) Examination: October/November - 2025  
English Language - I (G20-0106)**

Day & Date: Wednesday, 12-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose Correct Alternatives.**

08

- 1) Which of the following is a synonym for "happy"?
  - a) Sad
  - b) Joyful
  - c) Angry
  - d) Tried
- 2) What is the antonym of "strong"?
  - a) Weak
  - b) Tall
  - c) Heavy
  - d) Soft
- 3) What does the prefix "un-" mean?
  - a) Not
  - b) Again
  - c) Before
  - d) After
- 4) Which of the following is a verb?
  - a) Quickly
  - b) Tall
  - c) Run
  - d) Book
- 5) Which punctuation mark is used at the end of a question?
  - a) Period/full stop (.)
  - b) Exclamation mark (!)
  - c) Question mark (?)
  - d) Comma (,)
- 6) Which word is the noun in the sentence "The dog ran fast"?
  - a) Dog
  - b) Ran
  - c) Fast
  - d) The
- 7) What is the antonym of "bright"?
  - a) Light
  - b) Dull
  - c) Large
  - d) Quick
- 8) What is the correct way to say "I will be go"?
  - a) I will go
  - b) I going
  - c) I will goes
  - d) I went

**B) Fill in the blanks/Write True or False.****04**

- 1) A noun represents a \_\_\_\_\_. (person/place/thing).
- 2) The antonym of "happy" is \_\_\_\_\_.
- 3) True or False: The word "happiness" is a noun.
- 4) True or False: "Quickly" is an adjective.

**Q.2 Answer the following (Any Six)****12**

- a) Write the synonym of the word "fast."
- b) What is a prefix? Give an example.
- c) Write a short formal letter inviting a friend to your birthday.
- d) What is a verb? Give one example.
- e) Write a sentence with a noun and an adjective.
- f) What does the word "comprehension" mean?
- g) How do you identify a verb in a sentence?
- h) What is the meaning of the word "prefix"? Provide one example.

**Q.3 Answer the following (Any Three)****12**

- a) Write a sentence using a noun, verb, and adjective.
- b) Write a letter to your teacher asking for permission to leave school early.
- c) What are the functions of language? Explain any two functions.
- d) How does punctuation help in understanding the meaning of a sentence?

**Q.4 Answer the following (Any Two)****12**

- a) Write a short essay on your favourite season.
- b) Explain the importance of reading comprehension and how it helps in understanding texts.
- c) Describe the types of communication that happen in an organization.

**Q.5 Answer the following (Any Two)****12**

- a) Write a passage (4-5 lines) describing your favourite hobby.
- b) Explain the process of skimming and scanning in reading.
- c) What is the importance of proper punctuation in writing? Explain with examples.

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - I) (New)  
(CBCS) Examination: October/November - 2025  
Environmental Science (G20-0107)**

Day & Date: Thursday, 13-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose Correct Alternatives.****08**

- 1) Which virus causes Chickenpox?
  - a) Herpes simplex virus
  - b) Varicella-zoster virus
  - c) Epstein-Barr virus
  - d) Hepatitis virus
- 2) Which of the following types of succession begins in an area where no soil is present?
  - a) Hydrosere
  - b) Xerosere
  - c) Lithosere
  - d) Psammosere
- 3) What is the primary cause of acid rain?
  - a) Carbon dioxide (CO<sub>2</sub>) emissions
  - b) Sulfur dioxide (SO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>) emissions
  - c) Methane (CH<sub>4</sub>) emissions
  - d) Ozone layer depletion
- 4) In an ecological pyramid, which of the following is represented by the base?
  - a) The primary consumers
  - b) The secondary consumers
  - c) The producers (autotrophs)
  - d) The decomposers
- 5) In which year was the Environmental Protection Act enacted?
  - a) 1984
  - b) 1986
  - c) 1990
  - d) 1992
- 6) The flow of energy in a food chain is \_\_\_\_\_.
  - a) Unidirectional
  - b) Bidirectional
  - c) Circular
  - d) Irregular
- 7) What is the primary source of radiation pollution?
  - a) Fossil fuel combustion
  - b) Radioactive substances and nuclear activities
  - c) Deforestation
  - d) Excessive use of fertilizers

8) Salmonellosis is caused by which type of microorganism?

- a) Bacteria
- b) Virus
- c) Fungus
- d) Protozoa

**B) Write True or false.**

**04**

- 1) Edaphology is the relationship between soil and living organisms.
  - a) True
  - b) False
- 2) An ecosystem is always stable and unaffected by external environmental changes.
  - a) True
  - b) False
- 3) Meningitis can be caused by viruses, bacteria, fungi, and parasites.
  - a) True
  - b) False
- 4) The Air (Prevention and Control of Pollution) Act. 1981 applies only to industries and does not cover vehicle emissions.
  - a) True
  - b) False

**Q.2 Answer the following (Any Six)**

**12**

- a) Explain the term Ecology.
- b) Write a note on functions of National Green Tribunal.
- c) What are the effects of Global warming?
- d) Define Food web.
- e) What is the mode of transmission of Malaria?
- f) What are the different causes of land pollution?
- g) Enlist any two air borne diseases with their mode of transmission.
- h) Enlist different important environmental protection acts in India.

**Q.3 Answer the following (Any Three)**

**12**

- a) Write a note on Global warming.
- b) Write a note on Pyramid of biomass.
- c) Describe in detail about National Green Tribunal.
- d) Write a note on Food Chain.

**Q.4 Answer the following (Any Two)**

**12**

- a) Write a note on Forest (Conservation) Act. 1980.
- b) Explain in detail about Tuberculosis.
- c) Write a note on causes, effects and control measures of Acid rain.

**Q.5 Answer the following (any two)**

**12**

- a) Write a note on Structure and Function of ecosystem.
- b) Describe in detail about Cholera.
- c) Discuss causes, effects and control measures of Water pollution.



**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS)**  
**Examination: October/November - 2025**  
**Sterile Manufacturing in Pharma (G20-0201)**

Day & Date: Thursday, 06-11-2025  
Time: 03:00 PM To 05:00 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative. (MCQ)**

08

- 1) Sterile dosage forms are usually \_\_\_\_\_.
  - a) Parenteral
  - b) Ophthalmic Preparation
  - c) Irrigating preparations
  - d) all of above
- 2) Ideal requirements of sterile dosage form are \_\_\_\_\_.
  - a) Sterility
  - b) free from particulate matter
  - c) Prepared under aseptic condition
  - d) all of above
- 3) Sterile preparation intended to be administered \_\_\_\_\_.
  - a) Orally
  - b) Parenterally
  - c) Both A & B
  - d) None of above
- 4) Which water is used for administration of Injection \_\_\_\_\_.
  - a) Purified water
  - b) Water for Injection
  - c) Distilled water
  - d) Sterile water for injection
- 5) For loading unloading and monitoring sterile intermediate products in manufacturing machine involves \_\_\_\_\_.
  - a) Aseptic practice
  - b) Environmental controls
  - c) Continuous monitoring
  - d) All of above
- 6) GDP ensures \_\_\_\_\_.
  - a) Integrity
  - b) Accuracy
  - c) Legibility
  - d) All of above
- 7) A high efficiency air filter is \_\_\_\_\_.
  - a) HEPA filter
  - b) Final filter
  - c) Diluents
  - d) Web filter
- 8) Methods that maintain sterility \_\_\_\_\_.
  - a) Aseptic technique
  - b) Bleaching
  - c) A clean person
  - d) Admixture

**B) Write True or false. 04**

- 1) Aseptic techniques are methods used to maintain pH.
- 2) Injectable liquids typically filled using aseptic technique.
- 3) Plastic are used for aseptic filling of injectable products.
- 4) Sterile products are administered orally.

**Q.2 Answer the following (Any Six) 12**

- a) Write definition of:
  - i) Sterilization.
  - ii) Pyrogen.
- b) Write techniques used for inspecting quality of raw material.
- c) Write potential contamination risks during machine operations.
- d) What is ALCOA+
- e) Write techniques used for inspecting quality of containers.
- f) Write role of machine operator in controlling and handling raw materials.
- g) Explain importance of maintain sterility.
- h) Write common issues encountered during machine operation.

**Q.3 Answer the following (Any Three) 12**

- a) Write techniques for inspecting and verifying the containers and closures.
- b) Write gowning procedure as per clean room guideline.
- c) Write and note on personal hygiene.
- d) Write the use of PPE during sterile formulation.

**Q.4 Answer the following (Any Two) 12**

- a) Write procedures for loading, unloading and monitoring sterile intermediate products in manufacturing machines.
- b) Write safe and efficient handling practices to prevent contamination and ensure product quality.
- c) How to operate pharmaceutical manufacturing equipment effectively and safely.

**Q.5 Answer the following (Any Two) 12**

- a) Write a note on GDP.
- b) Write cleanliness standards during machine operations.
- c) Write environmental conditions within manufacturing areas.

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS)**  
**Examination: October/November - 2025**  
**Pharmaceutical Packaging (G20-0202)**

Day & Date: Friday, 07-11-2025  
Time: 03:00 PM To 05:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative. (MCQ)**

**08**

- 1) What type of packaging comes into direct contact with the drug product?
  - a) Primary packaging
  - b) Secondary packaging
  - c) Tertiary packaging
  - d) Ancillary packaging
- 2) Which of the following is an example of a tertiary packaging material?
  - a) Glass bottles
  - b) Plastic blister packs
  - c) Carton for shipping
  - d) Metal tubes
- 3) What type of closure is used for glass vials?
  - a) Screw cap
  - b) Cork
  - c) Press-on cap
  - d) Foil Seal
- 4) Which of the following is a function of labeling in pharmaceutical Packaging?
  - a) To enhance the product's appearance
  - b) To provide information on the dosage and usage
  - c) To protect the drug product
  - d) To make the product easier to handle
- 5) What is the purpose of tamper-evident packaging?
  - a) To protect the product from environmental factors
  - b) To enhance the product's appearance
  - c) To prevent the product from being opened and tampered with during transit.
  - d) To make the product easier to handle.
- 6) Water attack test is used to test the limits of alkali particularly in \_\_\_\_\_.
  - a) Type-I
  - b) Type-II
  - c) Type-III
  - d) Amber colored glass

- 7) What are the major disadvantages of glass as a packing material?
- a) Fragility
  - b) Weight
  - c) Transparent
  - d) Can be easily labeled
- 8) Which of the following type is non-parental type of glass?
- a) I
  - b) II
  - c) III
  - d) IV

**B) Write True or false.****04**

- 1) Primary packaging comes into direct contact with the drug product.
- 2) Type II glass is also known as Treated Soda-Lime Glass.
- 3) Product packaging is the least important part of product planning because consumers simply throw it away.
- 4) Functions of packaging include protection of product.

**Q.2 Answer the following (Any Six)****12**

- a) Define Pharmaceutical Packaging. Give its advantages.
- b) What are the Ideal Characteristics of packaging materials?
- c) Differentiate between Blister and Strip Packaging.
- d) Write Note on: Routes of delivery of drugs.
- e) Define packaging and labelling.
- f) Define product recall. Why is product recall required?
- g) Discuss the advantages of metal as packaging materials.
- h) What are the adhesive materials used in Pharmaceutical Packing?

**Q.3 Answer the following (Any Three)****12**

- a) Explain in detail types of pharmaceutical packaging materials.
- b) What are the functions of pharmaceutical packaging materials?
- c) Discuss in detail ideal requirements of Pharmaceutical Packaging materials.
- d) Discuss in details different types of closures and closures liners.

**Q.4 Answer the following (Any Two)****12**

- a) Discuss in detail advantages of glass.
- b) What are different types of glass materials used in Packaging?
- c) What are the possible packaging forms of solid dosages forms?

**Q.5 Answer the following (Any Two)****12**

- a) Discuss in detail packaging protocol for pharmaceutical dosage form.
- b) What are the Quality Control tests for Pharmaceutical Packaging materials?
- c) Discuss in detail environmental issues for pharmaceutical packaging materials.

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS)**  
**Examination: October/November - 2025**  
**Pharmaceutical Engineering – I (G20-0203)**

Day & Date: Saturday, 08-11-2025  
 Time: 03:00 PM To 05:00 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
 2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative. (MCQ)****08**

- 1) The steam jacketed kettle is also called as \_\_\_\_\_.  
 a) Horizontal tube evaporator    b) Evaporating pan  
 c) vertical tube    d) None of these
- 2) Hammer mill based in \_\_\_\_\_ mechanism.  
 a) Impact    b) Cutting  
 c) Attrition    d) Compression
- 3) Mechanisms of size separation \_\_\_\_\_.  
 a) Agitation    b) Brushing  
 c) Centrifugation    d) All of these
- 4) Evaporation gives \_\_\_\_\_ product.  
 a) Concentrated    b) Dry  
 c) Both    d) None of these
- 5) Sieves used in pharmaceutical manufacturing for \_\_\_\_\_.  
 a) Size reduction    b) Mixing  
 c) Drying    d) Size Separation
- 6) In drying we get \_\_\_\_\_ product.  
 a) Semisolid    b) Wet  
 c) Dried    d) All of these
- 7) Which of the following is not the example of dryer?  
 a) Steam Jacketed    b) Tray  
 c) Spray    d) FBD
- 8) Which are the following p Process required heat energy \_\_\_\_\_.  
 a) Drying    b) Distillation  
 c) Evaporation    d) All of these

**B) Write True or false. 04**

- 1) Compression is the mechanism of size separation.
- 2) Metal and nonmetals used for preparation of sieves.
- 3) Distillation used for purification of liquids.
- 4) Hammer mill consist of rotor.

**Q.2 Answer the following (Any Six) 12**

- a) What are the objectives of size reduction?
- b) What are the objectives of size separation?
- c) Discuss the principle of distillation.
- d) Draw the well labeled diagram of horizontal tube evaporator.
- e) Write the principal and draw the diagram of hammer mill
- f) Discuss in short working of sieve shaker.
- g) Enlist factors affecting on evaporation
- h) Write the applications of drying

**Q.3 Answer the following (Any Three) 12**

- a) Write a note on process involved in size reduction.
- b) Write the advantages and disadvantages of steam jacked kettle.
- c) Write applications of size separation.
- d) Write definition of:
  - a) Size Separation.
  - b) Distill and.
  - c) Distillate.
  - d) Evaporators.

**Q.4 Answer the following (Any Two) 12**

- a) Elaborate different grades of powders.
- b) Draw a neat labeled diagram of cyclone separator give its working.
- c) Write methods of size separation. Discuss brushing method.

**Q.5 Answer the following (Any Two) 12**

- a) Discuss Fluidized bed dryer.
- b) Write a note Ball mill with a diagram.
- c) Define and Classify evaporation.

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (New)  
(CBCS) Examination: October/November - 2025  
Industrial Microbiology (G20-0204)**

Day & Date: Monday, 10-11-2025  
Time: 03:00 PM To 05:00 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative. (MCQ) 08**

- 1) The primary purpose of antifoaming agents in fermentation is to: \_\_\_\_\_.  
 a) Increase oxygen transfer  
 b) Stabilize pH  
 c) Prevent excessive foam formation  
 d) Enhance microbial growth
- 2) Which of the following is not a nitrogen source \_\_\_\_\_.  
 a) Glucose  
 b) Corn steep liquor  
 c) Yeast extract  
 d) Peptone
- 3) Streptomycin fermentation occurs in \_\_\_\_\_ phases.  
 a) 2  
 b) 3  
 c) 4  
 d) 5
- 4) The recovery of the fermentation products is also called as \_\_\_\_\_.  
 a) upstream processing  
 b) downstream processing  
 c) right stream processing  
 d) left stream processing
- 5) Batch fermentation is also called \_\_\_\_\_.  
 a) Closed system  
 b) Open system  
 c) Fed-Batch system  
 d) Sub-merger system
- 6) By crushing of grapes juice ready for fermentation is called \_\_\_\_\_.  
 a) Scud  
 b) Broth  
 c) Must  
 d) Fluid
- 7) Water coils around the fermenter are used to maintain the \_\_\_\_\_ of fermentation medium.  
 a) pH  
 b) Water level  
 c) Viscosity  
 d) Temperature
- 8) L lysine is an \_\_\_\_\_.  
 a) Amino acid  
 b) vitamin  
 c) Antibiotic  
 d) protein

**B) Write True or false.**

04

- 1) Penicillin is produced by the bacterium *Streptomyces griseus* in industrial fermentation,  
a) True                                      b) False
- 2) Genetic recombination is a method of microbial strain improvement.  
a) True                                        b) False
- 3) Acetic acid is made by bacteria such as *Acetobacter* species.  
a) True                                        b) False
- 4) Alcoholic beverages like beer and wine are produced through anaerobic fermentation,  
a) True                                        b) False

**Q.2 Answer the following (Any Six)**

12

- a) Give the name of the microorganisms used in streptomycin fermentation.
- b) Define batch fermentation?
- c) What is Malt?
- d) Enlist the different parts of the fermenter.
- e) Define biofuels with two examples.
- f) Enlist industrially important organisms with their products.
- g) Define fermenter.
- h) What are antifoaming agents? Give one example.

**Q.3 Answer the following (Any Three)**

12

- Describe the role of impeller and sparger in fermenter design.
- Describe any two methods used for microbial strain development.
- Describe the fermentation process for citric acid production.
- Differentiate between batch and continuous fermentation.

**Q.4 Answer the following (Any Two)**

12

- Explain in detail beer production.
- Describe in detail the Penicillin fermentation process.
- Describe the design of a fermenter with a diagram and its applications.

**Q.5 Answer the following (Any Two)**

12

- Explain in detail the production of vitamin B12.
- What is the downstream process? Explain in detail any one method used for recovery.
- Explain the various types of fermenters with examples and their specific uses.



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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS)  
Examination: October/November - 2025  
Engineering for Non-Engineer (G20-0205)**

Day & Date: Tuesday, 11-11-2025  
Time: 03:00 PM To 05:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Multiple Choice Questions****08**

- 1) cGMP Stands for \_\_\_\_\_.
  - a) Correct Good Manufacturing Practice
  - b) Good Manufacturing Practice
  - c) Current Good Manufacturing Practice
  - d) Good Medicine Practice
- 2) The environmental factors controlled in clean room are \_\_\_\_\_.
  - a) Humidity
  - b) Temperature
  - c) Pressure
  - d) all of above
- 3) A regulatory agency or independent body conducts an audit for compliance is known as \_\_\_\_\_.
  - a) Internal Audit
  - b) External audit
  - c) Regulatory
  - d) Customer audit
- 4) High probability of resulting in a product recall or in an adverse physiological response by customer is considered as \_\_\_\_\_.
  - a) Minor defect
  - b) Critical defect
  - c) Major defect
  - d) all of above
- 5) cGMP set of regulations published by \_\_\_\_\_.
  - a) FDA
  - b) ISO
  - c) CDSCO
  - d) WHO
- 6) Clean room provide for the control of \_\_\_\_\_.
  - a) Material
  - b) Equipment
  - c) airborne particles
  - d) Personal Hygiene
- 7) GDP ensures \_\_\_\_\_.
  - a) Integrity
  - b) Accuracy
  - c) Legibility
  - d) all of above
- 8) Preparation under aseptic condition are meant for \_\_\_\_\_.
  - a) Sterile formulation
  - b) Solid formulation
  - c) Food industry
  - d) Cosmetic

**B) Write True or false. 04**

- 1) Good documentation technique ensures the principles of ALCOA+
- 2) Airborne particles are not contamination source.
- 3) Personal hygiene is important parameter in clean room.
- 4) Internal audit conducted by regulatory bodies.

**Q.2 Answer the following (Any Six) 12**

- a) Write definition of:
  - i) Clean room.
  - ii) Particles.
- b) Write the type of contamination in clean room and contamination sources.
- c) Draw neat labelled diagram of HVAC
- d) Write different types of clean room walls system.
- e) Write principles of clean room design.
- f) Write importance of instrument calibration.
- g) Explain utilities management.
- h) Explain qualification test for enduring compliance

**Q.3 Answer the following (Any Three) 12**

- a) Write a note on Clean room.
- b) Explain examples and categorization of audit.
- c) Write a note on water treatment
- d) Write categorization of audit.

**Q.4 Answer the following (Any Two) 12**

- a) Write role of pharmaceutical engineering and its significance in the pharmaceutical industry
- b) Explain points considering during GMP audit.
- c) Explain GMP criteria for clean room walls and ceilings.

**Q.5 Answer the following (any two) 12**

- a) Elaborate fundamentals of engineering in HVAC.
- b) Write importance of avoiding critical and major findings.
- c) Explain importance of engineering in GMP maintenance.

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Set **P**

**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - II) (CBCS)  
Examination: October/November - 2025  
Diversity and Inclusion: Sensitivity towards All Genders and People  
with Disabilities (G20-0207)**

Day & Date: Thursday, 13-11-2025  
Time: 03:00 PM To 05:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Multiple Choice Questions****08**

- 1) \_\_\_\_\_ indicates the characteristics, positions and roles of man and woman in all social relationships.
  - a) Gender
  - b) Diversity
  - c) Equality
  - d) Quality
- 2) Women in India are discriminated in \_\_\_\_\_.
  - a) Political life
  - b) Social life
  - c) Economic life
  - d) All the above
- 3) In order to maintain Gender equality in the classroom a teacher should \_\_\_\_\_.
  - a) Discourage the boy to take part in curricular activity
  - b) Provide same opportunity to the Boys and Girls
  - c) Provide analytical work to the boys
  - d) None of the above
- \_\_\_\_\_ is negative and partial attitude acknowledgement and
  - 4) assessment of the characteristics, position, role and capacity of man or woman.
    - a) Gender stereotype
    - b) Gender equality
    - c) Personality
    - d) Gender sensitivity
- Which among the following is a "sexual harassment" as defined under Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act 2013?
  - 5)
    - a) physical contact and advances
    - b) a demand or request for sexual favours
    - c) showing pornography
    - d) All the above

- 6) The Sexual Harassment of Women at Workplace Act. 2013 covers \_\_\_\_\_.  
a) Workplace only  
b) Dwelling house only  
c) Both workplace and dwelling house  
d) None of the above
- 7) Chairperson for Local Complaint Committee to be nominated from amongst the \_\_\_\_\_ in the field of social work and committed to the cause of women.  
a) Retired Judges  
b) Eminent women  
c) Eminent person  
d) Any of the above
- 8) What is the purpose of Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act 2013?  
a) provide protection against sexual harassment of women at workplace  
b) prevention and redressal of complaints of sexual harassment  
c) Both a and b above  
d) None of these

**B) Write True or false.****04**

- 1) Gender sensitivity helps to generate respect for individual irrespective of sex
- 2) Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act extend to whole of India.
- 3) Gender diversity refers to not an equal ratio of men and women.
- 4) Disability includes physical, sensory, intellectual, and mental health.

**Q.2 Answer the following (Any Six)****12**

- a) What is the work place according to the Act?
- b) Who is an employee?
- c) Work Environments.
- d) Who is an employer?
- e) Types of Disabilities.
- f) What is a gender issue?
- g) Diversity.

**Q.3 Answer the following (Any Three)****12**

- a) What is the work of Local Complaints Committee?
- b) Redressal.
- c) Gender Sensitivity.
- d) How will Creating Supportive Environments for People with Disabilities?

**Q.4 Answer the following (Any Two)****12**

- a) Explain the concept of Sexual Harassment of Women at Workplace.
- b) What is the meaning of Embracing Diversity in the Workplace?
- c) What is the Procedure to Report Inappropriate Behaviour?

**Q.5 Answer the following (any two)**

**12**

- a)** What is Importance of Gender-Sensitive Behavior for Creating Safe and Inclusive Work Environments?
- b)** Explain in details the Significance of an Equal Opportunity Work Culture.
- c)** What are the Consequences of Stereotypes and Prejudices?

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<b>Set P</b>
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**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - III) (New)  
(CBCS) Examination: October/November - 2025  
Production Planning (G20-0301)**

Day & Date: Tuesday, 28-10-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose the correct alternative. 08**

- 1) Which of the following is a primary objective of production planning in sterile pharmaceutical manufacturing?
  - a) Maximizing advertising
  - b) Reducing staff leave
  - c) Ensuring product quality and safety
  - d) Increasing packaging variety
- 2) What does HVAC stand for in facility design for sterile pharmaceutical manufacturing?
  - a) High Value Analytical Chemistry
  - b) Heating, Ventilation, and Air Conditioning
  - c) High Velocity Airflow Control
  - d) Hazardous Vent Area Control
- 3) Which concept helps in optimizing resource utilization in production planning?
  - a) Batch sizing
  - b) Product labelling
  - c) Staff recruitment
  - d) Sales promotion
- 4) What is a key regulatory requirement for sterile manufacturing?
  - a) Stylish facility interiors
  - b) Compliance with regulatory standards
  - c) Increasing capacity annually
  - d) Regular corporate meetings
- 5) Batch sizing in sterile pharmaceutical production refers to \_\_\_\_\_.
  - a) Choosing packaging materials
  - b) Determining optimal quantity for production runs
  - c) Calculating retail prices
  - d) Marketing new products

- 6) Which principle is crucial for maintaining workflow efficiency in facility layout?
  - a) Storing obsolete equipment
  - b) Optimizing resource utilization
  - c) Increasing wall decorations
  - d) Installing vending machines
- 7) Air filtration systems in sterile manufacturing facilities are mainly used to \_\_\_\_\_.
  - a) Save power
  - b) Remove contaminants and maintain sterility
  - c) Add fragrance to air
  - d) Cool machinery
- 8) Inventory control systems like JIT help in \_\_\_\_\_.
  - a) Maintaining minimal stock and reducing waste
  - b) Extending shipment times
  - c) Increasing paperwork
  - d) Delaying procurement

**B) Write True or False. (One Mark Each)****04**

- 1) Batch sizing is unrelated to capacity planning.
- 2) HVAC systems are part of facility design in sterile pharmaceutical manufacturing
- 3) Inventory control does not affect production flow.
- 4) JIT stands for Just-in-Time inventory management

**Q.2 Answer the following questions. (Any Six)****12**

- a) Define sterile pharmaceutical production planning.
- b) What is the importance of regulatory compliance in sterile manufacturing?
- c) Briefly explain batch sizing.
- d) What does production scheduling involve?
- e) List key facility design principles for sterile manufacturing.
- f) Why is HVAC necessary in facility design?
- g) What is the role of air filtration in sterile pharmaceutical production?
- h) How does environmental monitoring benefit sterile manufacturing?

**Q.3 Answer the following (Any Three)****12**

- a) Discuss the significance of production planning in sterile pharmaceutical manufacturing.
- b) Explain the principles of cleanroom design and their impact on sterility.
- c) Describe the process of inventory control in sterile drug manufacturing.
- d) How does facility design impact workflow efficiency?

**Q.4 Answer the following. (Any Two)****12**

- a) Explain in detail the regulatory requirements governing sterile pharmaceutical manufacturing processes.
- b) Discuss the process and challenges of optimizing resource utilization in production planning.
- c) Analyse the key concepts of batch sizing and production scheduling in sterile manufacturing.

**Q.5 Answer the following. (Any Two)****12**

- a) Provide an extensive overview of facility design principles for sterile pharmaceutical production.
- b) Discuss considerations for cleanroom design, including HVAC, air filtration, and environmental monitoring.
- c) Evaluate the impact of layout planning for equipment, utilities, and personnel in a sterile environment.



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Set **P**

**B.Sc. (Pharmaceutical Manufacturing & Quality) (Sem - III) (New)  
(CBCS) Examination: October/November - 2025  
Pharmaceutical Regulatory Affair (G20-0302)**

Day & Date: Wednesday, 29-10-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figure to right indicate full marks.

**Q.1 A) Choose the correct alternatives from the options. 08**

- 1) ACTD stands for \_\_\_\_\_ Common Technical Dossier.
  - a) ASIAN
  - b) ASEAN
  - c) ASIA
  - d) All of the above
- 2) Once IND Submission is done then FDA has to review within \_\_\_\_\_ days.
  - a) 30
  - b) 45
  - c) 180
  - d) All of the above
- 3) ICH stands for International Council for \_\_\_\_\_.
  - a) Harmony
  - b) Harmonization
  - c) Humanity
  - d) None
- 4) MFR stands for Master \_\_\_\_\_ Record.
  - a) Formula
  - b) Formulation
  - c) Formal
  - d) About All
- 5) Biologics include \_\_\_\_\_.
  - a) Monoclonal antibodies
  - b) Therapeutic proteins
  - c) Vaccines
  - d) All
- 6) Generic drugs must be \_\_\_\_\_ to an approved NDA product.
  - a) Bioequivalent
  - b) Bioanalytical
  - c) Biopotent
  - d) All
- 7) In CTD Structure Module 2 is for \_\_\_\_\_ information.
  - a) Regional Administrative
  - b) Summaries of CMC
  - c) Clinical
  - d) All
- 8) TGA maintains ARTG which is a register for \_\_\_\_\_ products.
  - a) Marketed
  - b) IND
  - c) PMS
  - d) Above all

**B) Write True /False 04**

- a) WHO Guidelines: Promote international standards for generic drug quality and BE.
- b) ANDA Submission is done eCTD format via FDA ESG.
- c) CDSCO an apex body for drug approvals in India.
- d) One application to EMA is valid across all EU member states.

**Q.2 Answer the following questions. (Any Six) 12**

- a) What is Type III & V of DMFs meant for?
- b) What is Pivotal Role of BMR?
- c) Which are the Regulatory Centers of Biologics at USFDA?
- d) Which are the Expedited Programs for Novel Therapies?
- e) Which are the Key Regulatory Bodies?
- f) What is 180-Day Exclusivity?
- g) What are Biologics?
- h) What are Benefits of ANDAs?

**Q.3 Answer the following questions. (Any Three) 12**

- a) What is BLA & Biosimilar submission?
- b) What is Structure of an API DMF?
- c) What are Challenges in ROW Markets?
- d) What are NDA Submission Components?

**Q.4 Answer the following. (Any Two) 12**

- a) Discuss the pivotal role of MFR & DMF documentation.
- b) Discuss the TOC of Drug product of Module 3 in CTD.
- c) Discuss the Key Regulatory Pathways by Product Type.

**Q.5 Answer the following. (Any Two) 12**

- a) Discuss the Hatch-Waxman Act and its amendments.
- b) Discuss the BA/BE studies in outsourcing to CROs.
- c) Discuss regulatory requirements of TGA and ROW countries.

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**B.Sc. (Pharmaceutical Manufacturing & Quality) (Semester - III)  
(New) (CBCS) Examination: October/November – 2025  
Bioprocess (G20-0303)**

Day & Date: Thursday, 30-10-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative.**

**08**

- 1) Power requirement in a stirred tank reactor increases with: \_\_\_\_\_.
  - a) Medium viscosity and impeller speed
  - b) Airflow only
  - c) pH only
  - d) Foam level only
- 2) Antifoam agents in fermentation are used to: \_\_\_\_\_.
  - a) Increase oxygen transfer rate
  - b) Decrease heat generation
  - c) Prevent excessive foam formation
  - d) Neutralize acids
- 3) Secondary metabolites are primarily produced by microorganisms: \_\_\_\_\_.

a) During active growth	b) During stationary phase
c) During lag phase	d) During exponential growth
- 4) Enzyme engineering focuses on: \_\_\_\_\_.
  - a) Improving enzyme stability and activity
  - b) Reducing pH
  - c) Eliminating foam
  - d) Increasing batch volume
- 5) Glutamic acid is produced commercially by: \_\_\_\_\_.
  - a) *Bacillus subtilis*
  - b) *Corynebacterium glutamicum*
  - c) *Streptomyces griseus*
  - d) *Aspergillus terreus*
- 6) Common method for long-term maintenance of stock culture is: \_\_\_\_\_.

a) Lyophilization	b) Turbidity analysis
c) Solvent extraction	d) Bioautography

- 7) Immobilization of whole cells is preferred in industrial production because: \_\_\_\_\_.
  - a) Cells are easier to separate and reuse
  - b) Foam is reduced
  - c) Oxygen transfer is not needed
  - d) No sterilization is required
- 8) Synchronous cultures are used mainly to: \_\_\_\_\_.
  - a) Avoid aeration
  - b) Produce maximum product yield
  - c) Reduce foam formation
  - d) Study individual cell cycle events

**B) Write True or false.**

## 04

- 1) Scale-down studies are performed to replicate large-scale fermentation conditions in smaller systems.
  - a) True
  - b) False
- 2) Airlift and bubble column bioreactors use mechanical impellers for mixing.
  - a) True
  - b) False
- 3) The basic principle of affinity chromatography is specific binding between ligand and target molecule.
  - a) True
  - b) False
- 4) Foam produced during fermentation is harmless and does not affect the process.
  - a) True
  - b) False

**Q.2 Answer the following. (Any Six)**

12

- a) State the function of a sparger in a fermenter.
- b) Define immobilization in fermentation.
- c) State any two carrier material used for enzyme immobilization.
- d) State two applications of bubble column bioreactor.
- e) Mention the substrate for glycerol production and its application.
- f) What is the principle of enzymatic assay?
- g) Define fermentation. Name any two microorganisms used in industrial fermentation.
- h) Why is agitation important in a fermenter?

**Q.3 Answer the following. (Any Three)**

12

- What are the essential design considerations of a bioreactor?
- Explain microbial production of streptomycin.
- Describe industrial applications of immobilized enzymes.
- What is the principle of solvent extraction in fermentation, and give its applications?

**Q.4 Answer the following. (Any Two) 12**

- a) Explain the principle, configuration, and application of an airlift bioreactor.
- b) Explain the principle and process of High Temperature Short Time (HTST) sterilization. Discuss its advantages in fermentation.
- c) Write a note on immobilized culture system to prepare fine chemicals.

**Q.5 Answer the following. (Any Two) 12**

- a) Explain the key regulatory requirements governing the manufacturing of biological products.
- b) Explain the principle, process, and applications of ion-exchange chromatography in fermentation product recovery.
- c) Explain the concept of synchronous culture in fermentation. Draw a typical growth curve and discuss its significance.

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**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-III) (New)  
(CBCS) Examination: October/November - 2025  
Pharmaceutical engineering – II (G20-0304)**

Day & Date: Friday, 31-10-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose the correct alternative from the options. 08**

- 1) In centrifugation process \_\_\_\_\_ force is replaceable.
  - a) Gravitational
  - b) Sedimentation
  - c) Kinetic
  - d) None of these
- 2) \_\_\_\_\_ mm particle size can be separated with centrifugation process.
  - a) less than 0.5
  - b) less than 0.05
  - c) less than 5
  - d) less than 50
- 3) \_\_\_\_\_ centrifuge contains skimming tube.
  - a) Non perforated basket
  - b) Perforated basket
  - c) Both
  - d) None of these
- 4) Centrifugation is \_\_\_\_\_ process.
  - a) Separation
  - b) Reduction
  - c) Evaporation
  - d) None of these
- 5) Which of the following theory is not described the filtration?
  - a) Darcy
  - b) Noyes Whitney
  - c) Poiseulli
  - d) Konzy-Carman
- 6) \_\_\_\_\_ is the example of filter aids.
  - a) Perlite
  - b) Carbon
  - c) Asbestos
  - d) All of these
- 7) \_\_\_\_\_ is the not example of filter media.
  - a) Perlite
  - b) Filter paper
  - c) Cotton wool
  - d) None of these
- 8) Separation of solid from liquid is called as \_\_\_\_\_.
  - a) Mixing
  - b) Filtration
  - c) Centrifugation
  - d) Distillation

**B) Write True or False.****04**

- 1) Centrifugation is a separation process.
- 2) In filtration filter media is not used.
- 3) Tumbling is the mixing process.
- 4) Corrosion is erosion of metals.

**Q.2 Answer the following. (Any Six)****12**

- a) Write the factors affecting on mixing
- b) Define mixing. Give its types.
- c) Discuss the factors affecting on the filtration.
- d) Define filtration and filter aids.
- e) What is centrifugation and write its applications?
- f) Draw the neat labeled diagram of non-perforated basket centrifuge.
- g) What is corrosion? What are the types of corrosion?
- h) Give the list of equipment's used for manufacturing dosage forms.

**Q.3 Answer the following. (Any Three)****12**

- a) Draw the diagram of plate and frame filter.
- b) Discuss the objectives of mixing
- c) Elaborate applications of filtration.
- d) Define the following
  - i) Slurry
  - ii) Filter medium
  - iii) Filter cake
  - iv) filtrate

**Q.4 Answer the following. (Any Two)****12**

- a) Classify the materials used for pharmaceutical plant construction.
- b) Draw a neat labeled diagram of double cone blender and write its Principle and working.
- c) Differentiate between solid mixing and liquid mixing.

**Q.5 Answer the following. (Any Two)****12**

- a) Give the Darcy's equation of filtration.
- b) What are the types of mixture? Give suitable examples.
- c) Explain dry corrosion.

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**B.Sc. (Pharmaceutical Manufacturing & Quality) (Sem-III) (New)  
(CBCS) Examination: October/November - 2025  
Pharmaceutical Jurisprudence (G20-0305)**

Day & Date: Saturday, 01-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Rewrite the following sentences by choosing correct alternatives given below.**

08

- 1) The drugs and cosmetics rules were passed in \_\_\_\_\_.  
a) 1940                      b) 1944  
c) 1948                      d) 1945
- 2) Schedule H drug belongs to \_\_\_\_\_.  
a) List of prescription drug    b) Narcotic drug  
c) Misbranded drug          d) Imported drug
- 3) According to The Prevention of Cruelty to Animals Act, 1960 \_\_\_\_\_ non-official member/s who member/s who is/are actively engaged in the promotion animal welfare is nominated by Central Government.  
a) 5                                 b) 6  
c) 2                                 d) 1
- 4) Hatch Waxman Act is related to \_\_\_\_\_.  
a) Banned drugs                b) Over- the-counter drugs  
c) Dangerous drugs          d) Generic drugs
- 5) According to the Prevention of Cruelty to Animals Act, 1960, Experiment on animal is carried out for the purpose except \_\_\_\_\_.  
a) development of new drug  
b) to have practice  
c) production of vaccine and sera  
d) development of medical field
- 6) Which types of advertisement is not prohibited under Drug and magic remedies act?  
a) any advertisement published by government  
b) any advertisement in technical journal  
c) any advertisement contains information of disease  
d) all of the above



- 7) If it is so coloured, coated, powdered, or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is.
- |                     |                       |
|---------------------|-----------------------|
| a) Adulterated drug | b) Misbranded drug    |
| c) spurious drug    | d) spurious cosmetics |
- 8) What is Schedule M \_\_\_\_\_?
- |                                 |
|---------------------------------|
| a) Good Manufacturing Practice  |
| b) Only Registered practitioner |
| c) Only license                 |
| d) Standard for disinfectant    |

**B) Write True or False.****04**

- 1) The Drugs and Cosmetics Act, 1940 prohibits the manufacture and sale of all new drugs without a proper license.
- 2) Under Drugs and Cosmetics Act rules, permits are not required for the import of certain drugs and cosmetics.
- 3) Schedule G and Schedule H drugs require restricted licenses for wholesale and retail sale.
- 4) Drugs Consultative Committee and Drugs Technical Advisory Board are responsible for the administration of Drugs and Cosmetics Act and Rules.

**Q.2 Answer following question. (Any Six)****12**

- a) Define the following terms under Drugs and Magic Remedies
  - 1) Advertisement
  - 2) Magic remedy
- b) Define the terms Misbranded, Adulterated drug.
- c) What are the offences and penalties under the Narcotics drugs and psychotropic substances act?
- d) Write two constitution and function of DTAB as per D and C Act.
- e) What are the objectives of Pharmacy act
- f) Write offences and penalties under the Pharmacy act 1948
- g) What are the types of Intellectual property right?
- h) Define standards of quality describe the classes of drugs to import under license or permit.

**Q.3 Answer following question. (Any Three)****12**

- a) Define Minor, explain when pregnancies may be terminated by medical practitioners.
- b) Define contract research explain CPCSEA guidelines for breeding and stocking of animals.
- c) Define Magic remedy explains prohibition of certain advertisement under Drugs and magic remedies act.
- d) Give constitution of committee and offences and penalties involve under narcotic and psychotropic substances act.

**Q.4 Answer following question. (Any Two) 12**

- a) Explain about storage of alcoholic preparations and export of alcoholic preparations as per Medicinal and toilet preparation act.
- b) Define wholesale, describe conditions of wholesale license.
- c) Give Qualification and powers and duties of Drug Inspectors.

**Q.5 Answer following question. (Any Two) 12**

- a) Write the constitution and functions of the Pharmacy Council of India as per the Pharmacy act.
- b) Give constitution of committee and offences and penalties involve under narcotic and psychotropic substances act.
- c) Give an account of cultivation and production of poppy straw, manufacture, sale and export of opium.

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**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-III) (New)  
(CBCS) Examination: October/November – 2025  
Biostatistics (G20-0306)**

Day & Date: Monday, 03-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.  
3) Scientific calculator is allowed.

**Q.1 A) Choose the correct alternatives.**

08

- The value that appears most frequently in a data set is called the: \_\_\_\_\_.
  - Mean
  - Median
  - Mode
  - Range
- The line that gives the best estimate of one variable for any given value of the other variable is called the: \_\_\_\_\_.
  - Scatter Line
  - Regression Line
  - Frequency Line
  - Diagonal Line
- If the ranks of two sets of data are identical, the value of the Spearman's Rank Correlation Coefficient is: \_\_\_\_\_.
  - 0
  - +1
  - 1
  - 0.5
- For a continuous random variable, the probability at a single point is always: \_\_\_\_\_.
  - 1
  - 0.5
  - 0
  - Greater than 1
- The Binomial distribution is applicable when the number of trials 'n' is: \_\_\_\_\_.
  - Very large
  - Fixed and finite
  - Zero
  - Unknown
- The shape of the Normal distribution curve is often described as: \_\_\_\_\_.
  - Rectangular
  - J-shaped
  - Bell-shaped
  - Skewed
- In a Uniform distribution over the interval [a, b], the probability density function f(x) is: \_\_\_\_\_.
  - Different for each x
  - Highest at the mean
  - Constant
  - Zero

- 8) Which measure of dispersion is based on all the observations in a dataset?
- a) Range                      b) Standard Deviation  
c) Quartile Deviation     d) All of the above

**B) State whether the following statements are True or False. 04**

- a)** The sum of deviations of individual observations from their mean is always zero.
- b)** Correlation implies causation.
- c)** The mean of a Poisson distribution is equal to its standard deviation.
- d)** The total area under the probability density function (PDF) curve of a continuous random variable is 1.

**Q.2 Answer the following question. (Any Six)** **12**

- Differentiate between a simple frequency distribution and a grouped frequency distribution.
- Calculate the mode for the following data: 3, 5, 2, 5, 7, 9, 5, 2.
- Define a scatter diagram. What does a scatter diagram showing points scattered widely indicate?
- What is the purpose of using "Tied Ranks" in Rank Correlation?
- Write the probability mass function for the Poisson distribution.
- State any two properties of the Binomial distribution.
- Find the range of the data: 45, 32, 78, 15, 90, 65.
- What is a random variable? Give one example.

**Q.3 Answer the following question. (Any Three)** **12**

- The marks of 10 students are: 35, 42, 48, 25, 60, 72, 38, 45, 52, 65. Calculate the mean and range.
- Calculate Pearson's coefficient of correlation from the following results:  $n = 10$ ,  $\Sigma X = 60$ ,  $\Sigma Y = 50$ ,  $\Sigma XY = 350$ ,  $\Sigma X^2 = 450$ ,  $\Sigma Y^2 = 300$ .
- A fair coin is tossed twice. Let  $X$  be the number of heads. Construct the probability distribution of  $X$ .
- The mean of a Normal distribution is 70 and the standard deviation is 8. Between which two values would you expect approximately 95% of the data to lie? (Use Empirical Rule)

**Q.4 Answer following question. (Any Two) 12**

- a)** The following data shows the weights (in kg) of 20 students in a class. Construct a grouped frequency distribution with class intervals of 40-50, 50-60, and so on. Then, calculate the mean weight.  
Data:  
42, 55, 60, 48, 72, 58, 65, 53, 49, 61, 68, 74, 59, 63, 57, 70, 54, 67, 50, 66.
- b)** Calculate the standard deviation for the following data representing the monthly savings (in ?) of 10 individuals:  
2000, 2500, 1800, 2700, 3000, 2600, 2200, 2400, 2800, 2100.

- c) The following data shows the relationship between the number of study hours (X) and the marks obtained (Y) by five students. Calculate Pearson's coefficient of correlation and interpret the result.

X(Hours Studied)	2	4	6	8	10
Y(Marks Obtained)	40	50	65	80	90

**Q.5 Answer the following question. (Any Two)**

**12**

- a) The following table shows the ranks assigned by two judges in a singing competition.

Calculate Spearman's rank correlation coefficient.

Contestant	A	B	C	D	E
Judge1	1	2	3	4	5
Judge 2	2	1	4	3	5

- b) A discrete random variable X has the following probability distribution.

Find:

- a) The value of the constant  $k$ , and  
b) The probability that  $X \leq 2$ .

X	0	1	2	3
P(X)	2k	4k	6k	8k

- c) A fair die is thrown 4 times. Find the probability of getting:

- a) exactly two sixes, and  
b) at least one six

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**B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-III) (New)  
(CBCS) Examination: October/November - 2025  
Computer Applications In Pharmacy (G20-0307)**

Day & Date: Tuesday, 04-11-2025  
Time: 12:00 PM To 02:30 PM

Max. Marks: 60

**Instructions:** 1) All questions are compulsory.  
2) Figures to the right indicate full marks.

**Q.1 A) Choose correct alternative. (MCQ)**

**08**

- 1) Which is the type of chromatographic method?
  - a) CIMS
  - b) LIMS
  - c) DDS
  - d) None
- 2) Which is a separation technique used to identify and quantify the components of a mixture?
  - a) Chromatography
  - b) Demography
  - c) Geography
  - d) Oceanography
- 3) In binary multiplication,  $1 \times 1 = ?$ 
  - a) 0
  - b) 1
  - c) 2
  - d) Undefined
- 4) Which is Programming language?
  - a) Java
  - b) Pagemaker
  - c) Office
  - d) All
- 5) Which is the computer-based electronic generation, transmission, and filling of a medical prescription?
  - a) Prescription
  - b) Rx
  - c) E-Prescription
  - d) None
- 6) The decimal number 25 in binary is \_\_\_\_\_.
  - a) 10001
  - b) 11001
  - c) 11010
  - d) 10101
- 7) Which diagram is used to represent the flow of data in a system?
  - a) ER Diagram
  - b) Flowchart
  - c) Data Flow Diagram
  - d) UML Diagram
- 8) Feasibility analysis is done in which phase of software development?
  - a) Requirement analysis
  - b) System design
  - c) Project initiation
  - d) Maintenance

**B) Fill in the Blanks/Write true or False. 04**

- 1) \_\_\_\_\_ manages the entire lifecycle of samples, from their arrival to the lab to the reporting of result.
- 2) SWISSPROT is type of Database. True or False
- 3) XML is a not Markup Language. True or False
- 4) IIS is a \_\_\_\_\_.

**Q.2 Answer the following. (Any Six) 12**

- a) List the chromatographic methods used in sample analysis.
- b) What is the difference between 1's complement and 2's complement? Explain with example.
- c) What is a Data Flow Diagram (DFD)? Explain with example.
- d) Define Computer.
- e) Define Database.
- f) Define Topology.
- g) Define Web-Server.
- h) Explain the importance of a Pharmacy Drug Database.

**Q.3 Answer the following. (Any Three) 12**

- a) Convert Decimal to Binary.
- b) Convert Decimal to Octal.
- c) Convert Decimal to Hexadecimal.
- d) Short note on E-Prescribing.

**Q.4 Answer the following. (Any Two) 12**

- a) What is SQL? Write and explain commands for CREATE, INSERT, UPDATE, DELETE.
- b) Short note on CDS.
- c) Explain web servers with examples. How do they work?

**Q.5 Answer the following. (Any Two) 12**

- a) Explain the structure and importance of HTML with an example program.
- b) Short note on LIMS.
- c) Explain Information Retrieval.