Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-I) (New) (CBCS) Examination: March/April - 2026
Environmental Health and Safety in Pharmaceutical Manufacturing (G20-0101)

Day & Date: Thursday, 23-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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

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

1) GMP ensures which of the following parameters?
a) Quality b) Safety
c) Efficacy d) All the above

2) What is a biological hazard?
a) Old Age b) Fatigue
c) Virus d) Alcoholism

3) SOPs are used to ensure consistency in daily operations. What does ‘S’ stand for in SOP’s?
a) Special b) Standard
c) Safety d) Sustainable

4) 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

5) Methods that maintain sterility products _____.
a) Aseptic techniques b) Bleaching
c) A clean person d) Admixture

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) For sterilization to occur, steam must _____
   a) Make direct contact with all surface
   b) Be superheated
   c) Be flushed into each package
   d) Trap air inside the package

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

1) Aseptic techniques are the methods that maintain sterility products.
2) Autoclave works on hot air sterilization principle.
3) Chlorination of water kills the pathogens present in it.
4) Filtration helps in purification of water.

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

a) What is meant by ‘portable water’, and why is it necessary in pharmaceutical processes?
b) Explain the term ‘softening of water’. Why is it important in pharmaceutical manufacturing?
c) Name any two responsibilities of employees to follow safety rules at work.
d) Mention two common hazards in pharmaceutical manufacturing.
e) What should you do in case of a chemical spill at work?
f) Name one impurity found in water and explain how it can be removed.
g) What is sterilization, and why is it important in pharmaceutical manufacturing?

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

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

Q.4 Answer the following. (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?

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

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

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Semester - I) (New) (CBCS) Examination: March/April - 2026
GMP Compliance for Pharmaceutical Manufacturing (G20-0102)

Day & Date: Friday, 24-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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

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

1) Quality assurance refers to ensuring purity, quality of product in _____.
   a) RM selection b) Stages of manufacture
   c) By QC d) Every stage

2) Sanitation / cleaning as per USFDA is dealt under CFR 21 _____.
   211.42-48 211.134-138
   211.12-18 None of these

3) Cleaning by chemical, physical methods remove _____ types of impurities.
   a) Invisible b) Visible
   c) Soluble d) All of these

4) A manufacturing facility can be located _____.
   a) on a river bank
   b) Near a thermal power plant
   c) Near a nuclear power plant
   d) Away from a city

5) The grade of clean room suitable for filling of an ointment is _____.
   a) D b) B
   c) C d) A

6) _____ is a process of ensuring proper performance of a method process.
   a) Validation b) Assurance
   c) Calibration d) None of these

7) Quality products ensure _____ to the company.
   a) Recognition b) Profit
   c) Acceptance d) Regulatory approval

8) Medical services in a manufacturing facility is for _____.
   a) First-aid b) Routine check-up
   c) Emergency d) Any of these

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

1) Documents help in identifying and _____ of errors.
2) Waste products generated in _____ plant are difficult to treat.
3) Contamination may not occur from pests, dust, metal, soil, or foreign material if the vessel is covered.
4) Head of QC is the key person of manufacturing drugs as per Schedule-M.

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

a) Chemicals used in sanitization of clean areas
b) Role of HEPA filters
c) Discuss about environmental contamination during API manufacture.
d) Write a short note on Schedule T.
e) Write a short note on “Pharmaceutical wastes”.
f) What is GLP? Mention its usefulness.
g) Batch Manufacturing Records
h) Site Master File

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

a) Write a short note on the contents of documentation related to maintenance of pharma manufacturing facility.
b) Explain the rationale behind determining BOD of an effluent.
c) Discuss the consequences of non-compliance to cGMP.
d) Elaborate on GMP for cosmetic products.

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

a) ICH-guidelines on documentation practice.
b) Describe GMP regulations related to premises and equipment of products of Indian System of Medicine.
c) Discuss WHO regulations related to maintenance of manufacturing equipment.

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

a) WHO regulations related to instrument maintenance and calibration.
b) Write a note on “Land fill” as a method of waste disposal.
c) Discuss about the typical SOP related to entry into Grade A clean room.

Seat No.	

Set | P

B.Sc. (Pharmaceutical Manufacturing & Quality) (Semester - I) (New) (CBCS) Examination: March/April - 2026 Pharmaceutics (G20-0104)

Day & Date: Saturday, 25-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 PM

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

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

1) Tablets are placed under the tongue are _____.
   a) Enteric coated b) Implant
   c) Film coated d) Sublingual

2) In hammer mill property of free flowing depends on the _____.
   a) Speed of mill b) Size of mill
   c) Both a & b d) None of above

3) In which type of packaging system, the product is direct contact with packing material _____.
   a) Secondary Packing b) Primary Packing
   c) Tertiary Packing d) All of above

4) The process in which the particle size of a substance is reduced from its smaller size to finer state is known as?
   a) Size reduction b) Extraction
   c) Size separation d) Filtration

5) Chemical substance added to pharmaceutical dosage form to prevent & inhibit microbial growth is known as _____
   a) Coloring agent b) Flavoring agent
   c) Sweetening agent d) Preservatives

6) Sieves are used for _____.
   a) Mixing b) Size reduction
   c) Drying d) Size separation

7) Unit operations used in pharmaceutical manufacturing are _____.
   a) Size Separation b) Filtration
   c) Size reduction d) All of above

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) Syrups are liquid dosage form.
2) Treated soda lime glass is Type I packing material.
3) Maceration is the type of extraction.
4) First edition of British Pharmacopoeia was published in 1955.

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

a) Write standards of sieves.
b) Write advantages of Liquid dosage form.
c) Classify Solid dosage form.
d) Draw neat labeled diagram of Double cone blender.
e) Write definition of Drying and Mixing.
f) Write different types of rubber as packaging material.
g) Write working of fluidized bed dryer.
h) Classify powders according to IP.

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

a) Write a note on British Pharmacopoeia.
b) Write the principle, construction of Ball mill.
c) Write advantages and disadvantages of glass as packaging material.
d) Write definition of
   i) Capsules
   ii) Elixirs
   iii) Suppositories
   iv) Dentifrices

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

a) Write a note on Indian Pharmacopoeia.
b) Draw a neat labeled diagram of Fluidized bed dryer and write its principle and working.
c) Write types of packing material and write a detailed note on rubber packing material.

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

a) What is size reduction, write note on Hammer mill?
b) Write a note Glass as packaging material.
c) Define and Classify Pharmaceutical dosage form.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Semester - I) (New) (CBCS) Examination: March/April – 2026
Biochemistry (G20-0105)

Day & Date: Monday, 27-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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 an imino acid?
   a) Serine b) Proline
   c) Aspartate d) Glutamine

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) Electron transport system (ETS) is present in which of the following parts of mitochondria?
   a) Inner membrane b) Outer membrane
   c) Matrix d) Stroma

5) The Tricarboxylic acid cycle is also known as _____.
   a) Citric acid cycle b) Glycolysis
   c) Gluconeogenesis d) EMP

6) 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

7) The nature of an enzyme is _____.
   a) Lipid b) Vitamin
   c) Carbohydrate d) Protein

8) The electron transport system occurs in _____.
   a) Thylakoid membrane b) Stroma
   c) Cytosol d) Mitochondria

B) True or False. **04**

1) Lipids consist of repeating units called fatty acids.
2) The nature of an enzyme is a protein.
3) The Priming function in glycogen synthesis is carried by glycogenin.
4) Any chemical reaction could be inhibited or accelerated by an enzyme.

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

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

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

a) Explain in detail what is meant by transamination and deamination.
b) Explain in detail the Metabolic disorder albinism.
c) Explain the synthesis of Dopamine.
d) Explain in detail the decarboxylation of Urea cycle.

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

a) Explain the mechanism of De novo synthesis of Palmitic acid.
b) Explain in detail the oxidative phosphorylation.
c) Explain the conversion of Cholesterol into bile acid and its biological significance.

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

a) Define what is meant by adrenaline and give its significance.
b) Explain the biological significance of cholesterol.
c) Explain the Hormonal regulation of blood glucose level and Diabetes mellitus.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing & Quality) (Sem-I) (New) (CBCS) Examination: March/April - 2026
English Language - I (G20-0106)

Day & Date: Tuesday, 28-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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 an example of a suffix?
   a) Re- b) -ness
   c) Pre- d) Un-

2) What is the antonym of "sad"?
   a) Joyful b) Angry
   c) Quiet d) Nervous

3) The word “unhappy” has the prefix _____.
   a) un- b) re
   c) pre- d) in-

4) Which of these is a verb?
   a) Walk b) Beautiful
   c) Happiness d) Red

5) Which punctuation mark shows strong feeling or emotion?
   a) Comma b) Period
   c) Exclamation mark d) Question mark

6) The opposite of "hot" is: _____.
   a) Warm b) Cold
   c) Cool d) Sunny

7) Which word is a noun in the sentence “The cat is sleeping”?
   a) Sleeping b) Cat
   c) The d) Is

8) What is the purpose of using a question mark?
   a) To ask a question b) To show excitement
   c) To separate ideas d) To end a sentence

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

1) A noun refers to a _____.
2) The suffix “-ly” is used to form _____.
3) True or False: "Jump" is a noun.
4) True or False: The word “help” is a verb.

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

a) Write a sentence using a noun and verb.
b) What is the antonym of “strong”?
c) What is a prefix? Provide an example.
d) Write a letter to your friend inviting them for a picnic.
e) What is the role of punctuation in a sentence?
f) What is the definition of an adjective? Give an example.
g) What is the synonym for the word “bright”?
h) Write a short letter to your teacher thanking them for their help.

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

a) What is the difference between formal and informal letters? Explain with examples.
b) Write a letter to your school principal requesting leave for an event.
c) Explain the different types of language functions.
d) How do reading and comprehension help in better communication?

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

a) Explain the role of communication in an organization.
b) Write an essay on your favorite book.
c) Discuss the importance of punctuation marks like commas and periods in writing.

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

a) Write an essay on the importance of reading.
b) Describe how prefixes and suffixes change the meaning of words.
c) Write a letter describing a recent event in your life.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Semester - I) (New) (CBCS) Examination: March/April - 2026
Environmental Science (G20-0107)

Day & Date: Wednesday, 29-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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

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

1) What is the main feature of Hydrosere succession?
a) It occurs in dry, arid areas
b) It begins in a water body like a pond or lake
c) It starts on bare rock
d) It is associated with desert ecosystems

2) Which of the following is a common symptom of Chickenpox?
a) Severe headache b) Rashes and blisters
c) Swelling of the joints d) Loss of appetite

3) Which of the following factors is NOT represented by an ecological pyramid?
a) Energy flow b) Biomass distribution
c) Number of individuals d) Genetic diversity

4) Which of the following is the causative agent of cholera?
a) *Vibrio cholerae* b) *Escherichia coli*
c) *Salmonella typhi* d) *Shigella dysenteriae*

5) Which of the following human activities contributes most to global warming?
a) Deforestation b) Industrial emissions
c) Burning fossil fuels d) All of the above

6) 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

7) In which year, Wildlife Protection Act was implemented in India?
a) 1972 b) 1927
c) 1729 d) 1980

8) The National Green Tribunal (NGT) is headquartered in which city?

a) Kolkata b) Mumbai
c) New Delhi d) Bengaluru

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

1) The meaning of the word ecology was given by German biologist Hackle in 1869.
2) Noise pollution only impacts human health and does not affect animal behavior or migration.
3) A pyramid of energy is always upright because energy is transferred from one trophic level to another, with significant loss at each level.
4) AIDS is primarily transmitted through airborne particles, similar to the flu or cold virus.

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

a) Explain the term Ecosystem.
b) Define Pollution. Enlist the different types of pollution.
c) What is the main purpose of the Environment Protection Act 1986?
d) What are the different common symptoms observed during bacterial infection?
e) What is environmental ethics?
f) Explain the concept of Synecology.
g) Write a note on control measures of solid waste management.
h) Write a note on causes of Drug addiction.

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

a) Write a note on Food web.
b) Describe in detail about Acid rain.
c) Give silent features of Air (Prevention and Control of Pollution) Act 1981.
d) Write a note on Pyramid of biomass.

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

a) Write in brief about Malaria.
b) Write in detail about Environmental Protection Act, 1986.
c) Describe in detail about Nitrogen cycle.

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

a) Write a note on structure and function of ecosystem.
b) Discuss causes, effects and control measures of Noise pollution.
c) Write an account on AIDS.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - II) (CBCS)
Examination: March/April - 2026
Sterile Manufacturing in Pharma (G20-0201)

Day & Date: Saturday, 04-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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) Plastics 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 operating.

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.

SLR-OE-9

Seat No.		Set	P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS)
Examination: March/April – 2026
Pharmaceutical Packaging (G20-0202)

Day & Date: Monday, 06-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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

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

1) Which color glass containers provide protection to light-sensitive products?
a) Red b) Brown
c) Pink d) Yellow

2) How many types of glass are used in pharmaceutical industry?
a) Five b) Three
c) Four d) One

3) Lime Stone is?
a) Magnesium carbonate b) Calcium carbonate
c) Potassium d) Sodium carbonate

4) Type II glass is called as _____.
a) General soda lime glass b) NP glass
c) BS glass d) Treated Soda lime glass

5) The package that comes in contact with formulation directly is called _____.
a) Primary package
b) Secondary package
c) Primary and Secondary package
d) Tertiary package

6) Uncoated steel is called _____.
a) Black plate b) White plate
c) Tin plate d) Steel plate

7) Double wall corrugated fiberboard has _____.
a) One liner b) Two liner
c) Three liner d) Four line

8) Aerosol containers are manufactured using which metal ____.
a) Tin plate b) Aluminum
c) Brass d) None

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

1) Packaging and materials handling decisions can be made in isolation from other logistics activities.
2) The physical characteristics of some goods change while they are moving in the logistics channel.
3) Certain products should not for safety or health reasons, be packaged together.
4) One general function of packaging is to identify the relevant product.

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

a) Define Pharmaceutical Packaging. Give its advantages.
b) What are the criteria for selection of packaging materials?
c) Differentiate between Blister and Strip Packaging.
d) Write the different environmental issues consider for packaging materials.
e) Discuss in detail Quality Control test for Packaging Materials.
f) Write Note on: Routes of delivery of drugs.
g) Differentiate between packaging and labelling.
h) Discuss about different Closures used in pharmaceutical packaging.

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) Write the ideal characteristics of Pharmaceutical Packaging Materials.
d) Write Packaging materials:
   i) Metal
   ii) Plastics
   iii) Adhesives
   iv) Boards

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

a) What to mean by product recall. Discuss in detail Preventions.
b) Discuss in detail advantages of glass.
c) What are different types of glass materials used in Packaging?

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

a) Discuss in detail various types of synthetic rubbers used in pharmaceutical packaging.
b) Explain in detail types of Metal packaging materials.
c) Discuss in detail packaging protocol for pharmaceutical dosage form.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - II) (CBCS)
Examination: March/April - 2026
Pharmaceutical Engineering – I (G20-0203)

Day & Date: Tuesday, 07-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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

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

1) Material broken into smaller pieces. coarse or fine powder is _____.
a) Size Reduction b) Drying
c) Size Separation d) Evaporation

2) The separation of particles according to their size range is _____.
a) Distillation b) Size Reduction
c) Size Separation d) Filtration

3) Unit operations used in pharmaceutical manufacturing are _____.
a) Size reduction b) Size Separation
c) Evaporation d) All of above

4) Evaporation is _____ phenomenon.
a) Surface b) Bulk
c) Solid d) Sterile

5) Cyclone separator used in pharmaceutical manufacturing for _____.
a) Size reduction b) Mixing
c) Drying d) Size Separation

6) Grades of powder given in _____.
a) 1995 b) 1996
c) 1955 d) 1898

7) _____ is the methods of sieving.
a) Agitation b) Centrifugation
c) Brushing d) All of the above

8) Distillation assembly consist _____.
a) Flask b) Condenser
c) Receiver d) All of the above

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

1) Evaporation used for to get concentrated product.
2) Size separation based on size range of particles.
3) The product after distillation process is distilland.
4) Ball mill is used for separation of particles.

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

a) Write mechanisms of size reduction with example.
b) Give the objectives of size separation.
c) Discuss the factors affecting the evaporation.
d) Draw neat labeled diagram of Cyclone separator.
e) What is distillation and write its applications.
f) Construct the drying curve.
g) Write process involved in size reduction.
h) Give applications of size separation.

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

a) Draw the diagram of tray dryer.
b) Discuss the objectives of size reduction.
c) Elaborate objectives of drying.
d) Define the following:
   i) Size separation
   ii) Size reduction
   iii) Evaporation
   iv) Drying

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

a) Write a note on materials used for sieves.
b) Draw a neat labeled diagram of hammer mill and write its principle and working.
c) Differentiate between evaporation and other heat process.

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

a) Give grades of powders according to IP 1996.
b) Write a note Ball mill with a diagram.
c) Classify drying equipment's.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - II) (CBCS) Examination: March/April – 2026
Industrial Microbiology (G20-0204)

Day & Date: Wednesday, 08-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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

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

1) _____ is not used as Nitrogen source in fermentation medium.
a) Molasses b) Soyabean meal
c) Peptone d) Corn steep liquor

2) L lysine is an _____.
a) amino acid b) vitamin
c) antibiotic d) protein

3) Which ingredient is responsible for the bitter taste in beer?
a) Barley b) Yeast
c) Water d) Hops

4) Phenyl acetic acid is precursor used in _____ production.
a) Amylase b) Penicillin G
c) Vitamin B12 d) Lysine

5) _____ is used for streptomycin production.
a) *E. coli* b) *B. subtilis*
c) *Streptomyces griseus* d) *Penicillium*

6) Overheating of fermenter during fermentation process is controlled by _____.
a) Cooling jacket b) Steam
c) Ice d) Cold air

7) Which of the following process is used in the recovery of the product?
a) Downstream processing b) Upstream processing
c) Chromatograph d) Treatment process

8) Optimum sugar concentration in medium for alcohol production is ____%.
a) 30-40 b) 4-8
c) 50-60 d) 10-18

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

1) Genetic recombination is a method of microbial strain improvement.
   a) True b) False

2) Spargers are used for disruption of vortex formation.
   a) True b) False

3) Citric acid is commonly produced by microorganisms, particularly *Aspergillus niger.*
   a) True b) False

4) Beer is made by fermenting grains such as barley, while wine is made from fruits like grapes.
   a) True b) False

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

a) Give the names of organisms used for the production of vitamin B12.
b) Define fermenter.
c) Enlist different methods of downstream processing.
d) Give name of any two microorganisms used for production of citric acid and acetic acid.
e) What is Malt?
f) What is the role of sparger in a fermenter?
g) Define Continuous fermentation.
h) What are hops?

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

a) Draw a neat labelled diagram of fermenter.
b) Write a short note on different types of raw materials used in fermentation media.
c) Describe any two methods used for microbial strain development.
d) Write a note on batch fermentation process.

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

a) Write a note on wine production.
b) Difference between solid state and submerged fermentation.
c) Describe in detail penicillin fermentation process.

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

a) Give an account on citric acid production.
b) What is fermenter? Explain the function of different parts of a fermenter.
c) What is the downstream process? Explain in detail any one method used for recovery.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS) Examination: March/April - 2026
Engineering for Non-Engineer (G20-0205)

Day & Date: Thursday, 09-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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 audit 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.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-II) (CBCS)
Examination: March/April – 2026
Communication Skill (G20-0206)

Day & Date: Friday, 10-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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

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

1) The word 'communication' has been derived from the word _____.
a) Latin b) Greek
c) Roman d) None of the above

2) _____ is not a type of non-verbal communication.
a) Smiling b) Tone of voice
c) Interpersonal skills d) Eye contact

3) _____ of the following is not a type of verbal communication.
a) Intrapersonal skills b) Interpersonal skills
c) Public speaking d) Haptics

4) The circle of communication process can be incomplete without _____
a) Feedback b) Decoding
c) Channel d) Content

5) Decoding in the communication is related to _____.
a) Sender b) Source
c) Receiver d) Channel

6) 'Distance' is an example of _____.
a) physical barriers b) psychological barrier
c) linguistic barrier d) semantic barrier

7) 'Fear' is an example of _____.
a) physical barriers b) psychological barrier
c) linguistic barrier d) semantic barrier

8) _____ of the following is not the part of communication process.
a) Sender b) Message
c) Channel d) Recoding

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

1) Passive engagement with the speaker does not include basic listening skills.
2) 'Gestures' is an example of non-verbal communication.
3) GD in communication skills means Group Discussion.
4) Panel interview is not a type of interview.

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

a) Write a note on importance of communication.
b) What is verbal communication?
c) What is communication?
d) What is self-awareness?
e) What is non-verbal communication?
f) What is communication style matrix?
g) What is channel?
h) What is feedback?

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

a) What are the types of communication?
b) Explain the communication process.
c) What are the different communication style matrix?
d) Write a note on written communication.

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

a) Prepare and write presentation on communication process.
b) What are the various types of barriers in communication?
c) Suppose that you have completed your course of B. Sc (PMQ). Prepare and write interview for the post of drug inspector.

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

a) Suppose that you have completed your course of B. Sc (PMQ). Prepare and write interview for the post of quality controller.
b) Write a group discussion on the topic *One Nation and One Election.*
c) Write a group discussion on the topic *Save the Girl Child.*

SLR-OE-14

Seat No.		Set	P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - II) (CBCS) Examination: March/April – 2026
Diversity and Inclusion: Sensitivity towards All Genders and People with Disabilities (G20-0207)

Day & Date: Saturday, 11-04-2026 Max. Marks: 60
Time: 03:00 PM To 05:30 PM

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

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

1) _____ in the workplace refers to recognizing and respecting the diverse needs, rights, and roles of individuals, regardless of their gender.
a) Gender Sensitivity b) Gender Diversity
c) Gender Equality d) Gender Quality

2) In order to maintain Gender equality in the classroom a teacher should _____.
a) Provide same opportunity to the Boys and Girls
b) Discourage the girl to take part in curricular activity
c) Provide analytical work to the boys
d) None of the above

3) _____ refers to a person's biological and physiological characteristics
a) Sex b) Gender
c) Personality d) Behaviour

4) Women in India are discriminated in _____.
a) Political life b) Social life
c) Economic life d) All the above

5) From which year The Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act. came in to effect?
a) 2010 b) 2013
c) 2014 d) 2020

6) _____ year was declared 'International Disable Year' by UNO.
a) 1988 b) 1981
c) 1986 d) 1984

7) _____ lead to a multitude of negative consequences, impacting individuals and society as a whole.
a) Stereotypes b) Prejudices
c) Both a and b d) None of these

8) _____ can hinder economic growth by limiting the potential of individuals and business.

a) Unemployment b) Discrimination
c) Conflict d) Civil suit

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

1) The harmful effects of prejudice can be passed down through generations, impacting family dynamics and mental health.
2) The National Commission for women was set up in 1992.
3) Gender diversity refers to not an equal ratio of men and women. The main objective of Prevention of Sexual Harassment (PoSH).
4) Act. is protecting women from sexual harassment at the workplace.

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

a) Gender Sensitivity
b) Workplace
c) Work Environments
d) Equal Opportunity
e) Disabilities
f) Stereotypes and Prejudices
g) Diversity
h) Empowerment

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

a) Local Complaints Committee
b) Redressal
c) Interim Reliefs
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 procedure to Report Inappropriate Behaviour?
c) What is the meaning of Embracing Diversity in the Workplace?

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?

Seat No.	

Set P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - III) (New) (CBCS) Examination: March/April – 2026
Production Planning (G20-0301)

Day & Date: Thursday, 02-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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

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

1) Vendor-managed inventory (VMI) aims to _____.
   a) Allow suppliers to manage inventories
   b) Increase warehousing costs
   c) Outsource production completely
   d) Centralize all deliveries

2) What does ergonomic design improve in a manufacturing facility?
   a) Worker health and comfort
   b) Machine speed
   c) Lighting for displays
   d) Locker space

3) The role of automation in material handling primarily helps in _____.
   a) Improving workflow efficiency
   b) Increasing manual labour
   c) Adding more supervisors
   d) Prolonging storage time

4) Lead time in production scheduling refers to _____.
   a) Time taken to fulfil a production order
   b) Time to clean equipment
   c) Peak holiday scheduling
   d) Meeting room occupancy

5) Environmental monitoring in facility design is important for _____.
   a) Maintaining clean air and surfaces
   b) Increasing energy bills
   c) Staff leisure activities
   d) Decorating workspaces

6) In-process testing during batch release is conducted to _____.
   a) Ensure product quality and regulatory compliance
   b) Calibrate air conditioners
   c) Arrange staff training
   d) Announce new policies

7) Which technology helps minimize inventory waste?
   a) Automation b) Manual registers
   c) Filing cabinets d) Fax machines

8) Capacity planning ensure _____.
   a) Meeting production and market demands
   b) Reducing technical training
   c) Increasing payroll costs
   d) Enhancing cafeteria services

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

1) Automation cannot help in minimizing inventory waste.
2) Ergonomic design is not considered in sterile manufacturing facilities.
3) Lead time is the time between starting and ending production.
4) Documentation review occurs before batch release.

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

a) Describe efficient workflow planning.
b) State the importance of ergonomic design in facility layout.
c) What are consumables in inventory control?
d) Mention one benefit of automation in material handling.
e) Explain the concept of vendor-managed inventory (VMI).
f) What is demand forecasting?
g) Outline a procedure for batch release.
h) Why is in-process testing needed?

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

a) Discuss the role of automation in streamlining inventory control.
b) Explain the importance of batch release protocols for regulatory compliance.
c) Analyse how environmental monitoring ensures product safety.
d) Compare JIT and VMI inventory management systems.

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

a) Examine the importance of ergonomic design and space utilization in sterile facilities.
b) Discuss strategies for effective material management in sterile pharmaceutical production.
c) Compare different inventory control systems suitable for sterile manufacturing.

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

a) Analyse the role of automation and technology in material handling and minimizing inventory waste.

b) Evaluate production scheduling techniques based on demand forecasting and capacity constraints.

c) Discuss the impact and procedures of batch release in ensuring product quality and compliance.

SLR-OE-16

Seat No.	

Set P

B.Sc. (Pharmaceutical Manufacturing & Quality) (Sem - III) (New) (CBCS) Examination: March/April – 2026
Pharmaceutical Regulatory Affair (G20-0302)

Day & Date: Saturday, 04-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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) DCGI is Drug _____ General of India.
a) Control b) Controller
c) Capton d) All of the above

2) DMF Type II is _____.
a) Excipient b) Packing material
c) Drug Substance d) Reference

3) Pharmacovigilance is also known as _____.
a) Drug Safety Monitoring b) Post-marketing surveillance
c) Both d) None

4) Form _____: For bioequivalence study approval.
a) CT-22 b) CT-21
c) CZ-21 d) Above all

5) CDER is Center for Drug _____ and Research.
a) Biological b) Bio
c) Evaluation d) All

6) COA: Certificate of _____ for quality assurance.
a) Accuracy b) Analytical
c) Analysis d) All

7) The phrase 'process is the _____' as manufacturing process is tightly linked to product quality.
a) Drug b) RLD
c) Product d) All

8) Schedule _____ of the D and C Rules, 1945 outlines the framework for clinical trials and BA/BE studies.
a) Z b) Y
c) X d) Above all

B) Write True /False **04**

1) Hatch-Waxman Act of 1984, which aimed to increase prescription drug costs.
2) GMP Compliance is mentioned in 21 CFR Parts 210 & 211.
3) Paragraph IV -patent is invalid or will not be infringed by the generic product.
4) E6 is for Good PreClinical Practice (GCP).

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

a) What are Pivotal Roles of DMF?
b) Who Prepares and Maintains the MFR?
c) What are regulatory functions of BE studies?
d) What is 180-Day Exclusivity?
e) What are meant for SUPAC Guidelines?
f) Under which clauses can an ANDA be field?
g) Enlist the regulated markets with their Pharmaceutical regulatory bodies.
h) Why Outsource BA/BE Studies to CROs?

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

a) What are the Core Requirement for ANDA Submission.
b) What is a CRO?
c) Enlist the Quality Guidelines.
d) Give overview of regulatory pathway for IND.

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

a) What are regulatory requirements the EU?
b) What is the importance of industry and FDA liaison processes?
c) Discuss the relevant sections of the CFR governing generic drug development.

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

a) Discuss the overview of regulatory pathway for APIs.
b) What are the Best Practices for Documentation in Pharma Production?
c) What are regulatory requirements the MHRA?

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing & Quality) (Semester - III) (New) (CBCS) Examination: March/April – 2026
Bioprocess (G20-0303)

Day & Date: Monday, 06-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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

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

1) Which type of impeller is commonly used for high oxygen transfer?
a) Flat blade turbine b) Rushton turbine
c) Paddle impeller d) Marine propeller

2) Enzyme immobilization allows _____.
a) Enzyme reuse b) Faster nutrient depletion
c) Only batch production d) Foam reduction

3) Riboflavin (Vitamin B2) is mainly produced by _____.
a) *Ashbya gossypii*
b) *Saccharomyces cerevisiae*
c) *Corynebacterium glutamicum*
d) *Penicillium notatum*

4) Stock cultures are maintained mainly to _____.
a) Increase oxygen transfer
b) Preserve genetic stability of strains
c) Eliminate pH changes
d) Avoid crystallization

5) Enzyme engineering focuses on _____.
a) Improving enzyme stability and activity
b) Reducing pH
c) Eliminating foam
d) Increasing batch volume

6) Mechanical agitation is required only in _____.
a) Packed bed
b) Airlift reactor
c) Continuous stirred tank reactor
d) Bubble column

7) Rheology is the study of _____.
a) Microbial growth rate
b) Flow and deformation of materials
c) Heat transfer in bioreactors
d) Gas exchange in fermentation

8) In HTST sterilization, medium is sterilized by _____.
a) Passing through UV light
b) Direct exposure to flame
c) Dry heat oven
d) Rapid heating and cooling using heat exchangers

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

1) Immobilized systems can be reused for multiple cycles, making them cost-effective in industry.
a) True b) False
2) Scale-up in fermentation means transferring a process from small laboratory scale to large industrial scale.
a) True b) False
3) Foam produced during fermentation is harmless and does not affect the process.
a) True b) False
4) Air sampling is done to monitor microbial contamination in cleanrooms.
a) True b) False

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

a) What is the purpose of a cooling jacket in a fermenter?
b) Define bioreactor.
c) What is the role of enzyme engineering in immobilized systems?
d) Name two methods of culture preservation.
e) List two types of chromatography used in bioprocessing.
f) Name any two types of fermentation medium with example.
g) Mention the substrate for glycerol production and its application.
h) State any two carrier material used for enzyme immobilization.

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

a) Write and explain any two methods of filtration used in scale-down of fermentation process.
b) Explain microbial production of Riboflavin.
c) Explain adsorption technique of immobilization of enzyme/cell with an example.
d) Define scale-up of fermentation process and describe theoretical considerations involved.

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

a) Explain the design and operation of a bubble column bioreactor.

b) Explain the principle and process of High Temperature Short Time (HTST) sterilization. Discuss its advantages in fermentation.

c) Describe in detail the process of air treatment before supplying to fermenters.

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

a) Explain microbial production of citric acid.

b) Explain the concept of batch culture in fermentation. Draw a typical growth curve and describe each phase.

c) Explain the principle and working of gel filtration chromatography. State its applications.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-III) (New) (CBCS) Examination: March/April – 2026
Pharmaceutical Engineering – II (G20-0304)

Day & Date: Tuesday, 07-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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 _____ process force is one particle come in contact with another.
a) Mixing b) Sedimentation
c) Filtration d) None of these

2) _____ Separation process.
a) Filtration b) Centrifugation
c) Corrosion d) Both a & b

3) Tumbling is the mechanism of _____.
a) Liquid b) Semi solid
c) Solid d) None of these

4) Corrosion of metals _____ process.
a) Mixing b) Separation
c) Evaporation d) Erosion

5) Darcy's equation is for ____.
a) Filtration b) Corrosion
c) Mixing d) All of these

6) Non perforated basket centrifuge consists of _____.
a) Perforations b) Filter cloth
c) Skimming tube d) None of these

7) Perlite is the example of _____.
a) Filter media b) Filter aid
c) Filter paper d) None of these

8) Type – I glass is _____.
a) Simple b) Borosilicate
c) Treated soda lime d) None of these

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

1) Positive negative and neutral are types of mixtures.
2) Liquid mixing generates flow of current.
3) Tumbling is used for mixing of liquid.
4) Pressure is not a factor for filtration.

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

a) Define filter aids and filter media.
b) Draw diagram of perforated basket centrifuge.
c) Discuss the factors affecting on filtration.
d) Give Darcy's equation for filtration.
e) Define corrosion and give its types.
f) What are the types of plastic?
g) Distinguish between dry and wet 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 ribbon mixer.
b) Give the mechanism of solid mixing.
c) Give the applications of centrifugation.
d) Enlist the equipment used for manufacturing of semisolid and liquid mixing.

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

a) Define mixing. Give factors affecting on mixing.
b) Write a note on rubber as a non-metal material.
c) What are filter media? Give suitable examples.

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

a) Differentiate between dry and wet corrosion.
b) Give construction and working of double cone blender.
c) Discuss the mechanism of semi-solid mixing.

Seat No.		Set	P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - III) (New) (CBCS) Examination: March/April – 2026
Pharmaceutical Jurisprudence (G20-0305)

Day & Date: Wednesday, 08-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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

Q.1 A) Multiple choice questions: **08**

1) The Narcotic Drugs and Psychotropic Substances Act were passed in _____.
a) 1985 b) 1963
c) 1940 d) 1938

2) The ex-officio member of Pharmacy Council of India is _____.
a) Teacher in Pharmacology b) A member from MCI
c) A representative of UGC d) Director of CDL

3) A drug consisting in full or in whole or in part of any filthy, putrid or decomposed substance is called _____.
a) Adulterated drug b) Spurious drug
c) Misbranded drug d) Patent drug 1

4) The minimum required=area to open a retail drug store is _____.
a) 15 sq. m b) 10 sq.m
c) 40 sq. m d) 60 sq.m

5) The Pharmacy Act was passed in the year _____.
a) 1950 b) 1965
c) 1948 d) 1947

6) The function of central drug laboratory is _____.
a) To issue repacking license
b) To issue manufacturing license
c) To issue loan license
d) To analyse the samples of drugs or cosmetics

7) The study, of fundamental legal principles is _____.
a) Ethics b) Rules
c) Jurisprudence d) None

8) Which of the following schedule belongs to Blood Banks?
a) Schedule C b) Schedule F
c) Schedule C1 d) Schedule F1

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

1) Prevention of Cruelty to Animals Act, 1960 requires records and approval for transfer and acquisition of animals for experiments.
2) The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing the ceiling price of scheduled formulations as per DPCO-2013.
3) The Hathi committee and Mudaliar committee are purely legislative bodies, with no advisory roles in pharmaceutical law.
4) The National List of Essential Medicines (NLEM) is maintained to decide retail pricing under the Drugs Price Control Order.

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

a) Define the following terms under Drugs and Magic Remedies
   i) Advertisement
   ii) 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 the 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 Forensic Pharmacy, Act, Schedule, Ethics.

b) Write a note on export of alcoholic preparations.

c) Define Magic remedy, explains prohibition of certain advertisement under Drugs and Magic Remedies Act.

d) Write a note on import of drags.

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

a) Write a note on Central Drag Laboratory.

b) Explain Schedule Y.

c) Write the objectives of Drags and Magic Remedies Act 1955.

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

a) Write a note on licensing procedure under Medicinal and Toilet Preparation Act 1955.

b) Explain Schedule N.

c) Write a note on origin and nature of Pharmaceutical Legislation in India.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-III) (New) (CBCS) Examination: March/April – 2026
Biostatistics (G20-0306)

Day & Date: Thursday, 09-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 AM

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**

1) The middle value of a dataset, when arranged in ascending order, is called _____.
a) Mean b) Mode
c) Median d) Standard Deviation

2) A graphical representation that shows the relationship between two variables is called a _____.
a) Bar Graph b) Histogram
c) Scatter Diagram d) Pie Chart

3) The formula for Pearson's coefficient of correlation (r) lies between _____.
a) 0 and 1 b) -1 and 0
c) -1 and +1 d) $-\infty$ and $+\infty$

4) The probability of an event that is certain to happen is _____.
a) 0 b) 0.5
c) 1 d) 100

5) In a Binomial distribution, the probability of success is denoted by _____.
a) q b) n
c) x d) p

6) Which distribution is defined by its "mean" and "standard deviation" and has a bell-shaped curve?
a) Binomial Distribution b) Poisson Distribution
c) Normal Distribution d) Uniform Distribution

7) If a fair die is rolled, the probability of getting any number from 1 to 6 is equal. This is an example of _____.
a) Binomial Distribution b) Uniform Distribution
c) Normal Distribution d) Poisson Distribution

8) The square root of the variance is known as _____.

a) Mean b) Range
c) Standard Deviation d) Coefficient of Variation

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

a) In a grouped frequency distribution, the class interval 10-20 includes the value 20.

b) The two regression lines, X on Y and Y on X, are always the same.

c) The sum of all probabilities in a probability density function for a continuous random variable is 1.

d) The mean of a Poisson distribution is always equal to its variance.

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

a) Define the terms: Biostatistics and Frequency Distribution.

b) Calculate the mean of the following data: 5, 7, 9, 11, 13.

c) What is the difference between a discrete and a continuous random variable? Give one example of each.

d) Draw a scatter diagram showing a high positive correlation.

e) Write the probability mass function for a Binomial distribution.

f) List any two properties of a Normal distribution.

g) Find the median of the data: 22, 18, 30, 15, 25.

h) What is the principle of least squares in curve fitting?

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

a) Calculate the mode and median for the following grouped data:

Class interval	$0-10$	$10-20$	$20-30$	$30-40$
Frequency	5	8	12	5

b) Calculate the standard deviation for the dataset: 2, 4, 6, 8, 10.

c) Explain the concept of Rank Correlation. When is it preferred over Pearson's correlation?

d) A random variable X has the following probability distribution. Find the value of 'k'.

X	1	2	3	4
$P(X)$	k	$2k$	$3k$	$4k$

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

a) From the following data of the marks obtained by 20 students in a test, prepare a grouped frequency distribution with class intervals 0-10, 10-20, and so on. Then, calculate the mean marks.
Data: 5, 15, 25, 8, 32, 18, 12, 7, 28, 35, 22, 9, 11, 19, 30, 16, 4, 27, 13, 21.

b) Calculate the standard deviation for the following dataset which represents the daily wages (in ₹) of 10 workers: 120, 135, 140, 125, 150, 130, 145, 155, 125, 135.

c) Calculate Pearson's coefficient of correlation from the following data between the values of X (advertising expenditure) and Y (sales). Interpret your result.

X	10	12	15	18	20
Y	20	25	22	30	28

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

a) The following table shows the ranks given by two judges in a dance competition. Calculate Spearman's rank correlation coefficient.

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

b) A random variable X has the following probability distribution. Find:

a) The value of the constant 'k', and

b) the probability that X is greater than 1.

X	0	1	2	3
$P(X)$	k	$3k$	$5k$	$7k$

c) A fair coin is tossed 5 times. What is the probability of getting (a) exactly 3 heads, and (b) at least 4 heads?

SLR-OE-21

Seat No.	

Set P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - III) (New) (CBCS) Examination: March/April - 2026
Computer Applications in Pharmacy (G20-0307)

Day & Date: Saturday, 11-04-2026 Max. Marks: 60
Time: 09:00 AM To 11:30 PM

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) BDS b) CDS
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) Which is an interdisciplinary field that combines biology, computer science, and information technology to analyze and interpret biological data?
a) Informatics b) Bioinformatics
c) Biological Informatics d) Green Informatics

4) Which is Programming language?
a) Java b) Python
c) C++ 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) Base of binary Number system is _____.
a) 4 b) 5
c) 2 d) 6

7) Which of the following is not part of project management?
a) Supervision b) Interview
c) Input/Output Design d) Risk Management

8) A Pharmacy drug database is mainly used for _____.
   a) Storing and retrieving medicine related information
   b) Web Formatting
   c) Web hosting
   d) None

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) Gen Bank is type of Database. (True or False)
3) HTML is a not Markup Language. (True or False)
4) MySQL is a _____.

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

a) List the chromatographic methods used in sample analysis.
b) What is flowchart? What are the types of flowcharts?
c) What is Computer Network? List type of Networks.
d) Define Chromatography.
e) Define Database.
f) Define Topology.
g) Define Web-server.
h) Define Genomics.

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

a) Convert Decimal to Binary: 59
b) Convert Octal to Decimal: 15571
c) Explain different types of number systems with base values and examples.
d) Short note on E-Prescribing.

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

a) Short note on Applications of Bioinformatics.
b) Short note on CDS.
c) Describe the phases of the Software Development Life Cycle (SDLC) with a neat diagram.

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

a) Design an HTML form for pharmacy drug entry with fields: DrugID, Name, Price
b) Explain Vaccine discovery in detail.
c) Explain Information Retrieval.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing & Quality) (Semester - IV) (New) (CBCS) Examination: March/April - 2026
Documentation for Production Control and Quality (G20-0401)

Day & Date: Wednesday, 15-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

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

1) Which document is primarily used for recording actual production activities during manufacturing?
a) SOP
b) BMR (Batch Manufacturing Record)
c) BPR
d) Validation protocols

2) What does BPR stand for in the context of pharmaceutical documentation?
a) Batch Production Report
b) Batch Packaging Record
c) Batch Process Review
d) Bach Quality Record

3) Batch Manufacturing Records (BMR) and Batch Packaging Records (BPR) fall under which category?
a) Practical documentation
b) Risk management documentation
c) Training documentation
d) Validation documentation

4) What is a key purpose of SOPs in production control?
a) To record actual batch yields
b) To standardize procedures for consistent execution
c) To approve marketing authorizations
d) To handle customer complaints only

5) Key components of a BMR include _____.
a) Product and Batch Information
b) Bill of Materials (BOM)
c) Manufacturing Instructions
d) All of above

6) BMRs and BPRs are essential for _____.
a) Regulatory Compliance b) Traceability
c) Batch Release d) None of above

7) Which is a practical document for ensuring traceability?
a) Batch size determination
b) Complaint investigation procedures
c) SOPs for production
d) All of the above

8) Cleaning validation protocols are essential for _____.
a) Personnel training only
b) Preventing cross-contamination in sterile production
c) Packaging line clearance
d) Market complaint investigation

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

1) Batch Manufacturing Record (BMR) records actual production steps executed during a batch.
2) Batch Packaging Record (BPR) is used only for non-sterile products.
3) SOPs (Standard Operating Procedures) standardize manufacturing processes to ensure consistency.
4) Line clearance protocols check production area readiness before starting a batch.

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

a) What does BMR stand for, and what is its primary purpose?
b) Name the document used for Sterile Manufacturing.
c) What role do SOPs play in production?
e) List two quality assurance documents.
f) How do line clearance protocols contribute to GMP?
g) What is the purpose of market complaint investigation?
h) Name two validation areas in the documentation list.
i) How does self-inspection documentation aid continual improvement?

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

a) Explain the differences between BMR and BPR, including their key contents and roles in ensuring product quality.
b) Discuss how risk assessments in manufacturing and training records for change management contribute to GMP compliance.
c) Describe the scope of validation documents (e.g., cleaning and process) and their importance in sterile manufacturing
d) Outline practical documents like market complaint procedures and self-inspection for continual improvement.

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

a) How do documents (batch planning, complaint handling) ensure traceability? Give sterile example.

b) Discuss self-inspection and audit procedures. Frequency and outcomes in QA system.

c) Outline market complaint procedures. How integrated with production records for CAPA?

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

a) Explain validation documents' scope (process, cleaning). Role in technology transfer for sterile products.

b) Describe line clearance protocols. Why critical before sterile batch start? Include checklist items.

c) Explain SOPs' role in production control. Provide steps for SOP implementation in a sterile filling area.

Seat No.		Set	P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-IV) (New) (CBCS) Examination: March/April - 2026
Complaint Handling and Product Recall (G20-0402)

Day & Date: Thursday, 16-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

Q.1 A) Multiple choice question. **08**

1) What is the primary role of complaint handling in pharmaceutical production?
   a) Marketing product sales
   b) Ensuring product quality and patient safety
   c) Reducing manufacturing costs
   d) Training sales staff

2) Which document outlines procedures for receiving, recording, and investigating complaints in pharma?
   a) Batch Manufacturing Record (BMR)
   b) Standard Operating Procedure (SOP)
   c) Certificate of Analysis (COA)
   d) Product Label

3) Which technique is commonly used for conducting investigations into production-related complaints?
   a) Fishbone diagram or 5-Why analysis
   b) Cost-benefit analysis
   c) Market survey
   d) Employee polling

4) Which departments collaborate on complaint investigations?
   a) Only Quality Assurance
   b) Manufacturing, Quality Assurance, and other departments
   c) Sales and Marketing only
   d) Finance and HR

5) What must be documented for complaint investigations?
   a) Only customer contact details
   b) Investigation plans, data collection, root cause analysis, and risk assessment
   c) Sales figures
   d) Packaging samples

6) Which department is responsible for investigating production-related complaints?
   a) Marketing
   b) Manufacturing Department
   c) Legal
   d) IT

7) What is the primary role of complaint handling in pharmaceutical manufacturing?
   a) Marketing promotion
   b) Quality oversight
   c) Sales tracking
   d) Inventory control

8) What is a key method for investigating complaints in production?
   a) Random sampling
   b) Root cause analysis
   c) Cost estimation
   d) Supplier review only

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

1) Complaints must always include product samples to be processed.
2) Root cause analysis is utilized to identify underlying issues within production operations.
3) Documentation reporting for complaint investigations is conducted only by the QA department.
4) Product recalls are initiated solely based on equipment failures.

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

a) Define: Product Recall & Complaint.
b) Write regulatory requirements and guidelines for complaint handling.
c) Define: Critical Complaint, Non- Critical Complaint.
d) List and briefly describe the three main objectives for registering, documenting, and evaluating complaints within the production environment.
e) Define: Major Complaint, Minor Complaint.
f) What is the purpose of investigating complaints in production processes and their relation to complaint handling.
g) Name two root cause analysis methods used to identify underlying issues within production operations.
h) State two corrective actions involving production operations and regulatory compliance post-recall investigation.

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

a) Describe the roles and responsibilities of personnel in the pharmaceutical complaint handling environment.
b) Outline the overview of regulatory documents and guidelines for complaint handling within the applicable production environment.
c) Describe techniques for root cause analysis used to identify underlying issues within production operations, linking to production quality.
d) Outline practical documents like market complaint procedures and self-inspection for continual improvement.

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

a) Overview of product recall procedures.

b) Developing and executing a recall strategy specific to production processes, including line clearance, quarantine procedures, and batch disposition.

c) Outline market complaint procedures. How integrated with production records for CAPA.

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

a) Write Key Roles of Production in Complaint Handling.

b) Write Procedures for receiving, documenting, and escalating complaints within the production environment.

c) Write on their roles and responsibilities of production personnel in the complaint handling process.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-IV) (New) (CBCS) Examination: March/April - 2026
Process Equipment Design (G20-0403)

Day & Date: Friday, 17-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

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

1) The factor of safety in equipment design is used to _____.
   a) Reduce equipment cost
   b) Increase operating pressure
   c) Account for uncertainties in design and loading
   d) Eliminate maintenance

2) In heat exchanger design, fouling factor accounts for _____.
   a) Increase in temperature
   b) Resistance due to dirt or deposits
   c) Fluid velocity increase
   d) Pressure increase

3) In pharmaceutical equipment, a heat exchanger is primarily used to _____.
   a) Increase pressure
   b) Measure temperature
   c) Store chemicals
   d) Transfer heat between two fluids

4) A reactor in pharmaceutical manufacturing is primarily used for _____.
   a) Storage of chemicals
   b) Chemical reactions to produce products
   c) Cooling liquids
   d) Measuring pressure

5) Which parameter primarily affects pump selection?
   a) Flow rate and head b) Pipe colour
   c) Tank diameter d) Ambient temperature only

6) Which property is most important for materials used in pharmaceutical equipment?
   a) High weight b) Magnetic property
   c) Corrosion resistance d) Low melting point

7) Which type of reactor is most commonly used in pharmaceutical manufacturing?
   a) Batch reactor b) Plug flow reactor
   c) Fluidized bed reactor d) Fixed bed reactor

8) Which material is most commonly used for pharmaceutical equipment due to its corrosion resistance and cleanability?
   a) Carbon steel b) Stainless steel
   c) Cast iron d) Aluminium

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

1) Batch reactors are rarely used in pharmaceutical manufacturing processes.
2) Heat exchangers are used in pharmaceutical equipment to transfer heat between two fluids without mixing them.
3) Materials used in pharmaceutical equipment do not need to follow Good Manufacturing Practice (GMP) guidelines.
4) The main objective of process equipment design is to ensure safe, efficient, and economical operation of equipment.

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

a) What is a pressure relief valve and why is it important for safety in pharmaceutical equipment?
b) What is heat transfer? Name the three modes of heat transfer.
c) State any two methods used to improve energy efficiency in pharmaceutical equipment.
d) Why is stainless steel (SS 316L) commonly used in pharmaceutical equipment?
e) List any two important factors considered in the design of process equipment.
f) What are the important factors to be considered while selecting materials for pharmaceutical equipment?
g) What is a pharmaceutical reactor? Mention its main function in pharmaceutical manufacturing.
h) Give the concept process equipment design.

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

a) Discuss the importance of safety devices used in pharmaceutical equipment operating under high pressure.
b) Explain the working principle and applications of heat exchangers used in pharmaceutical equipment.
c) Discuss the importance of corrosion resistance and chemical compatibility in selecting materials for pharmaceutical equipment.
d) Explain the important steps involved in the design of process equipment.

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

a) Describe the working of a cooling tower and its role in maintaining temperature control in pharmaceutical industries.

b) Explain the safety considerations required while designing and operating pharmaceutical equipment working under pressure.

c) Explain the different modes of heat transfer and their application in pharmaceutical equipment.

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

a) Discuss the importance of safety devices used in pharmaceutical equipment operating under high pressure.

b) Explain the construction and working of a batch reactor used in pharmaceutical manufacturing.

c) Explain the basic principles of process equipment design and discuss the factors affecting the design of pharmaceutical process equipment.

Seat No.	

Set | P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem - IV) (New) (CBCS) Examination: March/April - 2026
Pharmaceutical Process Chemistry (G20-0404)

Day & Date: Saturday, 18-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

Q.1 A) Multiple choice questions: 08

1) Which of the following best defines pharmaceutical process chemistry?
   a) Study of natural products
   b) Study of drug design principles
   c) Study of large-scale synthesis of APIs
   d) Study of pharmacokinetics

2) The main objective of process chemistry is _____.
   a) Discovering new molecules
   b) Optimizing and scaling up synthetic routes
   c) Studying metabolism of drugs
   d) Determining pharmacological effects

3) Which of the following is not a step in process development?
   a) Route scouting
   b) Analytical method development
   c) Pharmacological testing
   d) Reaction optimization

4) Scale-up in process chemistry refers to _____.
   a) Reducing reaction size
   b) Increasing reaction volume from lab to production scale
   c) Decreasing temperature
   d) Increasing reagent purity

5) The term API stands for _____.
   a) Active Pharmaceutical Ingredient
   b) Applied Pharmaceutical Intermediate
   c) Active Process Integration
   d) Analytical Product Interface

6) The purpose of process validation is to _____.
   a) Check the color of the product
   b) Ensure consistent product quality
   c) Shorten production time
   d) Increase reaction yield only

7) Which of the following is an important parameter in reaction optimization?
   a) pH b) Temperature
   c) Solvent type d) All of the above

8) Process safety evaluation mainly deals with _____.
   a) Physical stability b) Thermal and chemical hazards
   c) Biological activity d) Regulatory filing

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

1) Filtration is a mechanical separation process.
2) In liquid-liquid extraction, separation is based on solubility differences in immiscible solvents.
3) The purpose of crystallization is drying solvents.
4) Evaporation is mainly used for separating volatile and non-volatile components.

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

a) Define pharmaceutical process chemistry.
b) What is the importance of process chemistry in drug manufacturing?
c) Define filtration and name any two types of filters.
d) What is extraction? Give one example from the pharmaceutical industry.
e) Define process optimization.
f) Mention any two parameters affecting reaction yield.
g) What is a pilot plant?
h) Write two differences between laboratory and pilot-scale production.

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

a) Explain the importance and scope of pharmaceutical process chemistry.
b) Explain the principle, construction, and working of filtration equipment used in pharma industries.
c) Explain the concept of process optimization with suitable examples.
d) Explain the scale-up process and its significance in pharmaceutical

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

a) Explain the role of process chemistry in ensuring product safety and regulatory compliance.
b) Discuss pilot plant design, operation, and safety aspects.
c) Discuss different parameters affecting reaction yield and selectivity.

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

a) Explain the importance of catalyst and solvent selection in process chemistry.
b) Explain in detail the concept of unit operation with pharmaceutical examples.
c) Discuss the differences between bench scale, pilot scale, and commercial scale production.

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Sem-IV) (New) (CBCS) Examination: March/April - 2026
Water for Pharmaceutical Use (G20-0405)

Day & Date: Monday, 20-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

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

1) Which of the following is NOT a type of water listed for pharmaceutical use?
   a) USP Purified Water
   b) USP Water for Injection (WFI)
   c) USP Sterile Water for Injection
   d) USP Distilled Drinking Water

2) USP Water for Injection (WFI) is primarily intended for use in ____.
   a) Equipment cleaning only b) Production of sterile injectables
   c) Oral solid dosage forms d) Non-sterile topical creams

3) Analytical tests for pharmaceutical water quality typically include ____.
   a) Only pH and conductivity b) Microbial limits and endotoxins
   c) Color and odor only d) Hardness and alkalinity

4) Material commonly used for PW/WFI pipelines to prevent corrosion is ____.
   a) Carbon steel
   b) 316L stainless steel with electropolishing
   c) PVC plastic
   d) Galvanized iron

5) Validation of Water systems involves ____.
   a) Only visual inspection b) IQ/OQ/PQ
   c) Annual cleaning only d) No documentation required

6) BMRs and BPRs are essential for _____.
   a) Regulatory Compliance b) Traceability
   c) Batch Release d) None of Above

7) The first stage in pharmaceutical water system qualification is ____.
   a) IQ b) OQ
   c) PQ d) Design Qualification (DQ)

8) What does URS stand for in water system design?
   a) User Requirement Specification
   b) Utility Release Standard
   c) Unit Risk Specification
   d) Ultimate Recovery System

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

1) Water for Injection (WFI) is used only for non-sterile products.
2) Distillation is the only USP-approved method for producing WFI.
3) Clean steam is used for sanitizing WFI distillation stills.
4) Design Qualification (DQ) is the first step in water system validation.

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

a) Define: Endotoxin & Distillation.
b) Write difference between PW & WFI.
c) Write Application of water in pharmaceutical.
d) Define Water for Pharmaceutical Use and state its primary importance in pharmaceutical manufacturing.
e) List the main types of water used in pharmaceutical processes.
f) What are the key material requirements for pipes and fittings in WPU systems to prevent contamination?
g) Name two chemical sanitization agents used in pharmaceutical water systems and their removal method.
h) Differentiate between drinking-water and Purified Water in terms of treatment and use.

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

a) Describe the User Requirement Specification (URS) and Design Qualification (DQ) stages for water purification systems used in pharmaceuticals.
b) Detail the root cause analysis and corrective actions for common deviations in water systems.
c) Discuss the manufacturing process for Water for Injection (WFI)
d) Explain the key design principles of Sterile Water for Injection.

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

a) Write Key Roles of Validation in Pharmaceutical Water System.
b) Explain the importance of water quality and compliance with pharmacopeial standards
c) Write significance of BET in pharmaceutical water testing.

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

a) Describe the key Pharmacopeial tests (e.g., conductivity, TOC, endotoxins, microbial limits) and specifications for validating purified water and WFI in pharmaceutical use.

b) Describe the different grades of water used in pharmaceutical manufacturing (e.g., purified water, WFI), including their key differences in production methods and applications.

c) Outline the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) process for a Water for Injection (WFI) system, with acceptance criteria for each stage.

Seat No.	

Set | P

B.Sc. (Pharmaceutical Manufacturing and Quality) (Semester - IV) (New) (CBCS) Examination: March/April - 2026
Design Thinking (G20-0406)

Day & Date: Tuesday, 21-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

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

1) The primary aim of Design Thinking is to develop _____.
   a) Technical systems b) User-focused solutions
   c) Advertising campaigns d) Financial reports

2) In Design Thinking, empathy refers to _____.
   a) Reducing product cost
   b) Ignoring complaints
   c) Understanding users' feelings and needs
   d) Quick product launch

3) The main purpose of brainstorming is to _____.
   a) Judge ideas b) Generate creative ideas
   c) Produce goods d) Finalize budget

4) An affinity diagram helps to _____.
   a) Test product quality b) Promote products
   c) Group related ideas d) Control manufacturing

5) Ergonomics is concerned with _____.
   a) Branding b) Packaging
   c) User comfort and efficiency d) Profit margin

6) A journey map illustrates _____.
   a) Sales performance
   b) Production process
   c) User's experience across stages
   d) Cost calculation

7) A prototype can be best described as _____.
   a) Completed final product b) Initial sample for evaluation
   c) Marketing strategy d) Advertisement model

8) Sustainable design mainly aims at _____.
   a) Increasing speed b) Reducing environmental harm
   c) Higher promotion d) Labour reduction

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

1) Journey map shows user experience.
2) Prototype is an early model.
3) Empathy ignores user feelings.
4) Ergonomics improves usability.

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

a) What is the basis of Design Thinking?
b) What is meant by a structured open-ended approach?
c) State the rules of brainstorming.
d) What is mind mapping?
e) What is scenario planning?
f) What is the Frog Design Concept?
g) What is product specification?
h) What is innovation culture?

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

a) Explain the principles of Design Thinking.
b) Explain the Empathy Mapping process.
c) Explain the different ideation methods used in Design Thinking
d) Explain the role of storytelling in innovation.

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

a) Explain any two important Design Thinking skills with suitable examples.
b) Differentiate between developer perspective and user perspective in Design Thinking.
c) Explain the stages of prototyping in the Design Thinking process.

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

a) Explain ergonomics and semantics in design with suitable examples.
b) Discuss the major challenges faced in sustainable design.
c) Who are the members of a Design Thinking team? Explain their roles briefly

Seat No.	

Set **P**

B.Sc. (Pharmaceutical Manufacturing and Quality) (Semester - IV) (New) (CBCS) Examination: March/April – 2026
Vedic mathematics (G20-0407)

Day & Date: Wednesday, 22-04-2026 Max. Marks: 60
Time: 12:00 PM To 02:30 PM

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

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

1) The sutra “Urdhva Tiryagbhyam” means _____.
   a) By observation b) One more than previous
   c) Vertically and crosswise d) All from 9 and last from 10

2) Beejank of the number 456 is _____.
   a) 6 b) 9
   c) 15 d) 5

3) Square of 55 using Vedic Mathematics is _____.
   a) 1125 b) 3025
   c) 1325 d) 2025

4) Ratio 2:4 is equal to _____.
   a) 1:4 b) 1:2
   c) 2:1 d) 4:2

5) Formula for Simple Interest is _____.
   a) P + RT b) PRT
   c) PRT/100 d) PR/T

6) Which sutra is used for general squaring?
   a) Dwandwayoga b) Nikhilam
   c) Paravartya d) Ekadhikena

7) Which sutra is used for fast division by numbers not near the base?
   a) Nikhilam b) Urdhva
   c) Paravartya Yojayet d) Anurupyena

8) LCM of 4 and 6 is _____.
   a) 6 b) 8
   c) 1 d) 12

B) Fill in the blanks. **04**

1) Vedic Mathematics encourages _____.
2) Urdhva Tiryagbhyam means _____.
3) Divisibility test of 9 depends on the _____.
4) Subtraction using Vinculum reduces _____.

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

a) Write importance of Vedic Mathematics.
b) Solve the Simultaneous addition and subtraction.
c) Write the multiplication table of 91.
d) Convert the recurring decimal 0.27.
e) Explain Method of finding cubes using Vedic Mathematics.
f) Find the cube of 12.
g) Find square root of 5625.
h) What is Vinculum? Give one example.

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

a) Explain the term Place Wise Addition and Shuddh Method.
b) Find HCF and LCM of 36 and 84 using Vedic Mathematics techniques
c) Solve the following percentage problem using Vedic Mathematics:
Find 12.5% of 640.

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

a) Solve the following using Vedic methods:
i) 48×52
ii) 97×103
b) Find the square of 995 using Nikhilam Sutra and verify the result.
c) Explain Vedic Mathematics and write any five important sutras with their meanings and one example each.

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

a) Multiply 657×937 using the Nikhilam Sutra.
Explain each step clearly.
b) Explain the Paravartya Sutra and solve. Divide 3456 by 9 using this sutra.
c) Write Divisibility test for 3, 5 and 7. Give their one example each.