

Exam Date & Time: 29-Sep-2020 (02:00 PM - 05:45 PM)



## PSG COLLEGE OF ARTS AND SCIENCE

Note: Writing 3hrs: Checking & Inserting Image : 30mins

MSc DEGREE EXAMINATION MAY 2020  
(Fourth Semester)

Branch - APPLIED MICROBIOLOGY  
MICROBIAL QUALITY CONTROL [19MBP22]

Marks: 75

Duration: 210 mins.

### SECTION - A

Answer all the questions.

- 1) Which of the following is a set of regulatory standards for clinical and medical labs that were created to help to make sure labs maintain quality assurance?  
(i) Clinical lab improvement amendments (CLIA)  
(ii) Health Insurance Portability and Accountability Act (HIPPA) (1)  
(iii) Procedure manual  
(iv) Standard operating procedures (SOPs)
- 2) Which laboratory design or process would allow the safe disposal of infectious material?  
(i) Red plastic bags for disposal of needles  
(ii) An exterior door that restricts access to non-employees (1)  
(iii) A Class II Biosafety Cabinet for preparing specimens  
(iv) An autoclave readily available in the laboratory
- 3) According to the Biosafety in Microbiological and Biomedical Laboratories (BMBL), culture isolate manipulation may be performed outside a biological safety cabinet for which infectious agent?  
(i) Mycobacterium fortuitum  
(ii) Neisseria meningitidis (1)  
(iii) Salmonella typhi  
(iv) Yersinia pestis
- 4) What action should be taken after failing a proficiency survey?  
(i) Repeat testing three times on three different days with new material  
(ii) Perform testing on quality control material and continue reporting if results are correct (1)  
(iii) Send the remaining proficiency material to a reference laboratory  
(iv) Determine the cause of the error, correct it, and document actions
- 5) What is the most common laboratory error present in pre-analytical processes? (1)  
(i) Instrument maintenance and calibration  
(ii) Patient and specimen identification  
(iii) Reporting and charting results  
(iv) Specimen preparation

- 6) Which of the following option is not correct in QA and QC procedure?  
 (i) Process capabilities should be monitored on intermittent basis  
 (ii) Measuring equipments must have a calibration certificate  
 (iii) Normally many inspections are done in the process of manufacturing  
 (iv) QA depends on activities of entire company (1)
- 7) Which of the following techniques are used by the FDA in determining the manner in which industry accepts its responsibilities?  
 (i) Establishment inspection  
 (ii) Sample Collection and analysis of product in process  
 (iii) Surveillance intended to identify new problems  
 (iv) All of the above (1)
- 8) FSSAI is located in 5 regions with head office located at  
 (i) Hyderabad  
 (ii) Mumbai  
 (iii) Bangalore  
 (iv) New Delhi (1)
- 9) What is HACCP system for  
 (i) Physical, Chemical and Biological Hazards  
 (ii) A systematic analysis of all steps and regular monitoring of the control points  
 (iii) Identifying the CCPs, including their location, procedure and process  
 (iv) Accurately monitoring food hygiene hazards (1)
- 10) \_\_\_\_\_ explains physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality.  
 (i) Q8 control strategy  
 (ii) Q8(R2)strategy  
 (iii) CQA  
 (iv) ICH information (1)

### SECTION - B

**Answer all the questions.**

- 11) Explain the features of GMP, cGMP, GLP and NABL. (5)
- a)  
 [OR] Sketch the significance of SOPs in clinical and R&D laboratory. (5)  
 b)
- 12) Explain how are QA and QC maintained in Clinical Microbiology laboratories. (5)
- a)  
 [OR] Illustrate the steps in ICH. (5)  
 b)
- 13) Describe the features of TQM. (5)
- a)

- [OR] Produce evidence to setup quality control check points in laboratory and industry. (5)  
b)
- 14) Analyze the suitable conditions to identify food toxins. (5)
- a)
- [OR] Compare the various sampling techniques in food. (5)  
b)
- 15) Recommend a suitable statistical method in quality assurance for food industries. (5)
- a)
- [OR] Discuss about the instrumental analysis of food for quality assessment. (5)  
b)

### SECTION - C

**Answer all the questions.**

- 16) Appraise the need for HACCP regulations in industries. (8)
- a)
- [OR] Determine how risk management and quality control parameters are monitored in food and pharmaceutical industries. (8)  
b)
- 17) Assess the different types of Quality testing methods and tools. (8)
- a)
- [OR] Construct a protocol/SOP for maintaining QA and QC in healthcare and pharma industries. (8)  
b)
- 18) How do you create quality control check points for inspection and audit. (8)
- a)
- [OR] Recommend the internal and external QC guidelines to comply with government regulations. (8)  
b)
- 19) Categorize the various food additives and give their applications. (8)
- a)
- [OR] Deduce the methods used for various physics and chemical analysis of food. (8)  
b)
- 20) Criticize the need for microbial quality analysis of food. (8)
- a)
- [OR] Discuss the mechanism of Food sensory evaluation. (8)  
b)