



Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2153 Quality Assurance & Quality control
Batch - 02
2nd Year 1st Semester
End Semester SEQ Repeat Examination

Date : 24th of September 2024
Time : 9.00 am. - 12.00 pm. (Three Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of SIX questions.
Answer ALL questions.
You should write legibly in black or blue ink.

Question 01 (100 marks)

1.1 State the difference between accuracy and precision. (25 marks)

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1.2 Briefly describe the importance of Quality Management System (QMS) concept. (25 marks)

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1.3 In a laboratory experiment calculation, the approximate value of R/10 is taken as
0.8500 J mol-1 K-1
(R = 8.314 J mol-1 K-1)

1.3.1 Calculate the absolute error of this calculation. (25 marks)

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1.3.2 Calculate the relative error of this calculation. (25 marks)

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Question 02

(100 marks)

2.1 What is internal quality control?

(25 marks)

2.2 What is external quality control.

(25 marks)

2.3 State **three (03)** characteristics of "Normal Distribution Curve"

(25 marks)

2.4 The life span of an analytical equipment manufactured by "Xenon Company" has a normal distribution with a mean of 54 months a standard deviation of 8 months, the company guarantee of any equipment that starts malfunctioning within 36 months of the purchase will be replaced by a new one.

2.4.1 Calculate the Z-score value.

(25 marks)

Question 03

(100 marks)

3.1 State **three (03)** types of audits.

(15 marks)

3.2 For a given process the upper specification limit is 33.20 g and the lower specification limit is 32.71 g. The standard deviation (σ) is 0.042 g and the average value is 32.88 g.

3.2.1 Find the **Process Capability** (C_p) value.

(15 marks)

3.2.2 Find the **Process Capability Index** (C_{pk}) value.

(20 marks)

3.3.3 Comment on the capability of the given process.

(20 marks)

3.3 State the difference between standards and regulations.

(30 marks)

Question 04

(100 marks)

4.1 Define record retention.

(25 marks)

4.2 Mention the different laboratory documents that are required to be archived.

(25 marks)

4.3 State the purposes of laboratory records.

(25 marks)

4.4 State the documents that are maintained for each major laboratory instrument.

(25 marks)

Question 05

(100 marks)

5.1 State the below three main phases of the laboratory testing process and activities involved in each phase.

5.1.1 Pre-analytical phase

(25 marks)

5.1.2 Analytical phase

(25 marks)

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5.2 State the errors that can occur during analytical phase

(50 marks)

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Question 06

(100 marks)

6.1 Define the term Standard Operating Procedure (SOP).

(25 marks)

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6.2 State the purpose of a SOP.

(25 marks)

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6.3 the character of writing style of a SOP.

(25 marks)

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6.4 Outline the one type of SOPs.

(25 marks)

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Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2153 Quality Assurance & Quality control
Batch – 02
2nd Year 1st Semester
End Semester Assignment Repeat Examination

Date : 24th of September 2024
Time : 1.30 am. – 2.30 pm. (One Hour)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **Two** questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.

Question 01

1.1 You have been given two data sets. Calculate the following parameters for each data set.

- 1.1.1 Mean (20 marks)
1.1.2 Standard deviation (50 marks)
1.1.3 Variance (30 marks)

A	B
2.7	70.24
3.0	70.22
2.6	70.10
2.8	70.15

Question 02

- 2.1 Define Cause and Effective Diagram. (10 marks)
2.2 Develop a Cause and effective Diagram for haematology laboratory currently facing loss of profit. (60 marks)
2.3 Describe the advantages of the cause and effective diagram to analyse the case scenario mentioned in above question. (30 marks)



Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2143 Introduction to Immunology
Batch - 02
2nd Year 1st Semester
End Semester SEQ Repeat Examination

Date : 19th of September 2024
Time : 1.30 pm. - 3.30 pm. (Two Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of FOUR questions.
Answer ALL questions.
You should write legibly in black or blue ink.

Question 01

1.1 Define the adaptive immune response. (100 marks) (25 marks)

Dotted lines for answer writing

1.2 State classification of the adaptive immune system. (25 marks)

Dotted lines for answer writing

1.3 State the mechanism of humoral immune response. (25 marks)

Dotted lines for answer writing

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1.4 List the types of immune cells involved in inflammatory response. (25 marks)

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Question 02 (100 marks)

2.1 Define the term of active immunity. (25 marks)

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2.2 Differentiate the active and passive immunity. (25 marks)

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2.3 State the steps of immune response initiation under the adaptive immunity. (25 marks)

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2.4 State the types of passive immunity. (25 marks)

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Question 03 (100 marks)

3.1 Define the term of antigen-antibody complex. (25 marks)

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3.2 State the primary and secondary immune response mechanisms. (25 marks)

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3.3 State three types of MHC class molecules. (25 marks)

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3.4 State the action of MHC class II molecule. (25 marks)

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Question 04 (100 marks)

4.1 Define the term of immunogenicity. (25 marks)

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4.2 State the characteristics of complete antigen. (25 marks)

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4.3 Outline the factors that influence the antigenicity. (25 marks)

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4.4 Outline the function of the linear epitope. (25 marks)

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Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2133 Clinical Biochemistry
Batch - 02
2nd Year 1st Semester
End Semester SEQ Repeat Examination

Date : 19th of September 2024
Time : 9.00 am. - 11.00 am. (Two Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of FOUR questions.
Answer ALL questions.
You should write legibly in black or blue ink.

Question 1 (100 marks)

1.1 List three (03) methods which we can identify acidity or basicity of a solution (25 marks)

Dotted lines for answer to question 1.1

1.2 List three (03) body mechanisms important in regulating acid-base balance in human body. (25 marks)

Dotted lines for answer to question 1.2

1.3 A 55-year-old man, complained of intractable vomiting suspected of suffering from pyloric stenosis receiving treatment showed following acid base data on second day of the treatment.

Table with 2 columns: Laboratory data and Reference. Rows include pH, pCO2, and HCO3-.

1.3.1 Interpret the lab report and identify the acid-base disorder. (25 marks)

Dotted lines for answer to question 1.3.1

1.3.2 State how vomiting induced this acid-base disorder? (25 marks)

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Question 2 (100 marks)

2.1 Define the liver profile test. (25 marks)

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2.2 List three commonly measured biomarkers for liver health. (25 marks)

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2.3 State the indications for lipid profile. (25 marks)

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2.4 State the patient advices before lipid profile test. (25 marks)

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Question 03

(100 Marks)

A 69-year-old female presented at the hospital to carry out her annual blood serum urea, serum creatinine and blood cholesterol levels.

3.1 Illustrate the clinical laboratory path flow of a laboratory from patient sample submission step to test results dispatch. (25 marks)

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3.2 Define the terms of sensitivity, specificity and false negative results. (25 marks)

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3.3 State the blood collection method. (25 marks)

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3.4 Based on the laboratory test results blood serum urea, creatinine level and blood cholesterol levels indicated as above the reference range. State the expected results of a patient. (25 marks)

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Question 04 (100 marks)
4.1 Define the term of erythropoiesis. (25 marks)

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4.2 Outline the hemoglobin structure. (25 marks)

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4.3 Mention the cyanmethemoglobin method. (25 marks)

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Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2123 – Molecular Biology
2nd Year 1st Semester
HD BMS Batch 02
End Semester Special Repeat SEQ Examination

Date : 18th of September 2024
Time : 01.30 p.m. – 03.30 p.m. (Two Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **FOUR** questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.

QUESTION 01

(100 marks)

1.1. Mention the parts of a nucleotide.

(10 marks)

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1.2. Write two types of spontaneous DNA damages.

(30 marks)

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1.3. Write a short note on base excision repair mechanism.

(30 marks)

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1.4. What is known as deamination DNA damage? (30 marks)

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QUESTION 02 (100 marks)

2.1. State five enzymes involved in DNA replication process. (15 marks)

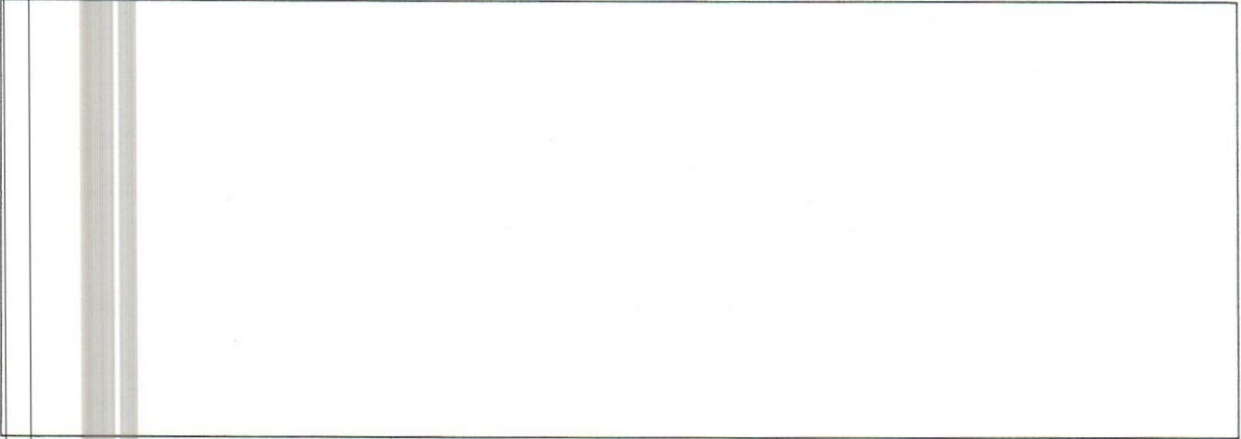
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2.2. Differentiate between replication and translation. (25 marks)

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2.3. Draw a diagram to illustrate the DNA replication of eukaryotes. (30 marks)

2.4. Imagine that you are about to initiate a molecular biology laboratory at your hometown. Draw a laboratory floor plan to set up the laboratory. (30 marks)



QUESTION 03

(100 marks)

3.1. List the RNA secondary structures.

(20 marks)

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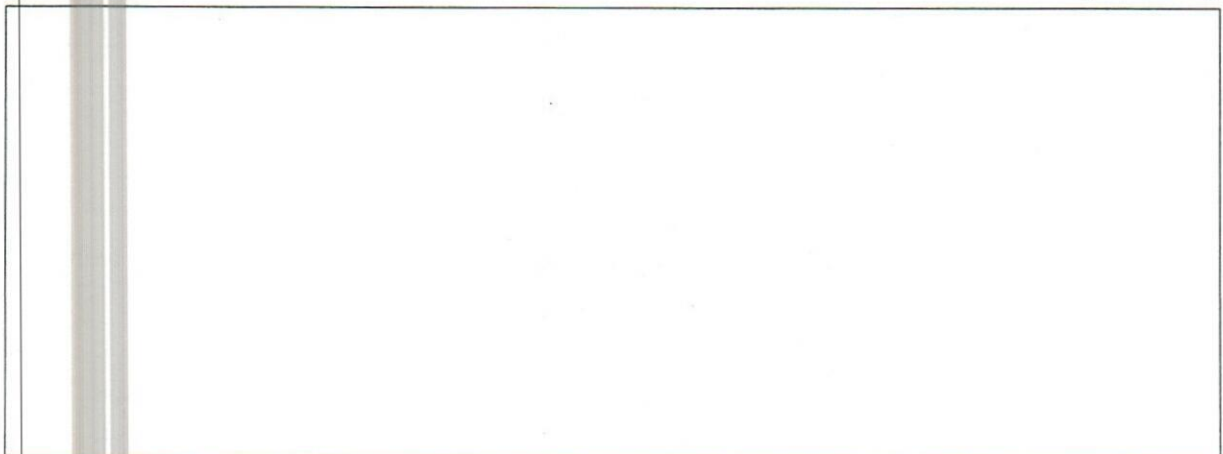
3.2. Mention three types of RNA seen in eukaryotic cells and their functions.

(20 marks)

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3.3. Draw a diagrammatic representation of *Lac operon* and label the different regions of the operon.

(30 marks)



3.4. State the role of *Lac operon* under the presence of Lactose within the cell. (30 marks)

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QUESTION 04 (100 marks)

4.1. State the protein purification methods which could separate extracted proteins **based on size**. (40 marks)

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4.2. State the “**Selection**” step for PUC 18/PUC 19 plasmids using a media containing X-gal, if you have used them for recombinant DNA technology. (40 marks)

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4.3. What are the criteria that should be present in vectors used for recombinant DNA technology? (20 marks)

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Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2113- Haematology and Transfusion Science
Batch - 02
2nd Year 1st Semester
End Semester SEQ Repeat Examination

Date :18th of September 2024
Time : 9.00 am. - 12.00 pm. (Three Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of SIX questions.
Answer ALL questions.
You should write legibly in black or blue ink.

Question 01 (100 marks)

1.1 Define the term of stem cells. (25 marks)

Dotted lines for answer to question 1.1

1.2 State the sites of haemopoiesis. (25 marks)

Dotted lines for answer to question 1.2

1.3 State the characteristics of pluripotent stem cell. (25 marks)

Dotted lines for answer to question 1.3

1.4 What is the mechanism of haemopoiesis take place within the bone marrow. (25 marks)

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Question 02 (100 marks)

2.1 Define the term of peripheral blood cells. (25 marks)

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2.2 State the component of whole blood. (25 marks)

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2.3 Briefly outline the composition of plasma in blood. (25 marks)

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2.4 Briefly outline the composition of white blood cells.

(25 marks)

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Question 03

(100 marks)

3.1 Define the term of anaemia.

(25 marks)

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3.2 State the process of fibrinolysis.

(25 marks)

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3.3 Define the following terms.

3.3.1 Anti-thrombin

(25 marks)

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3.3.2 Protein S

(25 marks)

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Question 04

(100 marks)

4.1 Define the term of haemostasis.

(25 marks)

4.2 State the functions of haemostatic mechanism.

(25 marks)

4.3 State the information which can be obtained from automated hematology counter report.

(25 marks)

4.4 Outline the principle of erythrocyte sedimentation rate.

(25 marks)

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Question 05

(100 marks)

5.1 Define the term of extrinsic pathway of coagulation.

(25 marks)

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5.2 State the intrinsic pathway.

(25 marks)

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5.3 State the blood ABO group compatibility patterns.

(25 marks)

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5.4 State the importance of ABO blood grouping.

(25 marks)

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Question 06 **(100 marks)**

6.1 State the purpose of donor selection. (25 marks)

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6.2 State the steps involved in donor selection process. (25 marks)

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6.3 List the steps of donor blood collection. (25 marks)

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6.4 State laboratory investigation use for acute lymphoblastic leukemia. (25 marks)

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Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2153 Quality Assurance & Quality control
Batch – 02
2nd Year 1st Semester
End Semester Assignment Examination

Date : 2024.04.05
Time : 1.30 am. – 2.30 pm. (One Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of ~~5~~ ^{two} questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.

Question 01

1.1 You have been given three data sets. Calculate the following parameters for each data set.

- 1.1.1 Mean (40 marks)
 1.1.2 Standard deviation (60 marks)

	A	B	C
	2.7	0.514	70.24
	3.0	0.503	70.22
	2.6	0.486	70.10
	2.8	0.497	70.15

Question 02

- 2.1 Define Cause and Effective Diagram. (10 marks)
- 2.2 Develop a Cause and effective Diagram for haematology laboratory currently facing loss of profit. (60 marks)
- 2.3 Describe the advantages and disadvantages of the cause and effective diagram to analyse the case scenario mentioned in above question. (30 marks)



Faculty of Health Sciences
Higher Diploma in Biomedical Sciences
HD 2153 Quality Assurance & Quality control
Batch – 02
2nd Year 1st Semester
End Semester SEQ Examination

Date : 2024.04.05
Time : 9.00 am. – 12.00 pm. (Three Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.

Question 01 (100 marks)

- 1.1 State the difference between accuracy and precision. (15 marks)
- 1.2 The quality management system is very important for achieving good laboratory performance.
- 1.2.1 List the **seven (07)** Quality Management Principles. (07 marks)
- 1.2.2 Briefly describe the importance of Quality Management System (QMS) concept. (13 marks)
- 1.2.3 Discuss how you use “**customer focus**” principle in an organization to establish a quality management culture. (15 marks)
- 1.3 In a laboratory experiment calculation, the approximate value of $\pi/4$ is taken as 0.7854 ($\pi = 3.14$)
- 1.3.1 Calculate the absolute error of this calculation. (25 marks)
- 1.3.2 Calculate the relative error of this calculation. (25 marks)

Question 02 (100 marks)

- 1.1. State the difference between internal quality control and external quality control. (20 marks)
- 1.2 Briefly describe the importance of certified reference materials with regard to quality control. (20 marks)
- 1.3 State **three (03)** characteristics of “Normal Distribution Curve” (15 marks)
- 1.4 The life span of an analytical equipment manufactured by “Xenon Company” has a normal distribution with a mean of 54 months a standard deviation of 8 months, the company guarantee of any equipment that starts malfunctioning within 36 months of the purchase will be replaced by a new one.
- 1.4.1 Calculate the Z-score value. (15 marks)
- 1.4.2 Calculate the percentage of equipment’s made by this company are expected to be replaced. (area equivalent to the z -score value is 0.489) (30 marks)

Question 03 (100 marks)

- 3.1 State **three (03)** types of audits. (15 marks)
- 3.2 For a given process the upper specification limit is 33.20 g and the lower specification limit is 32.71 g. The standard deviation (σ) is 0.042 g and the average value is 32.88 g.
- 3.2.1 Find the **Process Capability** (C_p) value. (10 marks)
- 3.2.2 Find the **Process Capability Index** (C_{pk}) value. (10 marks)
- 3.3.3 Comment on the capability of the given process. (10 marks)
- 3.3 State the difference between standards and regulations. (10 marks)
- 3.4 Briefly describe the main objectives of international standards. (15 marks)
- 3.5 Briefly describe the benefits of standards to consumers and organizations. (30 marks)

Question 04 (100 marks)

- 4.1 Define record retention. (10 marks)
- 4.2 Mention the different laboratory documents that are required to be archived. (20 marks)
- 4.3 Describe the purposes of laboratory records. (30 marks)
- 4.4 State the documents that are maintained for each major laboratory instrument. (20 marks)
- 4.5 Differentiate calibration and adjustment. (20 marks)

Question 05 (100 marks)

- 5.1 Describe the below three main phases of the laboratory testing process and activities involved in each phase.
- 5.1.1 Pre-analytical phase (25 marks)
- 5.1.2 Analytical phase (25 marks)
- 5.1.3 Post-analytical phases (25 marks)
- 5.2 State the errors that can occur during each phase and how do these errors impact the accuracy of test results? (25 marks)

Question 06 (100 marks)

- 6.1 Define the "Four P's Models" when developing a Standard Operating Procedure (SOP)? (20 marks)
- 6.2 State the purpose of a SOP? (20 marks)
- 6.3 Briefly describe the characters of following elements of a SOP.
- 6.3.1 Writing style of a SOP. (10 marks)
- 6.3.2 General format of a SOP. (10 marks)
- 6.3.3 Title page. (10 marks)
- 6.4 Discuss three types of SOPs. (30 marks)