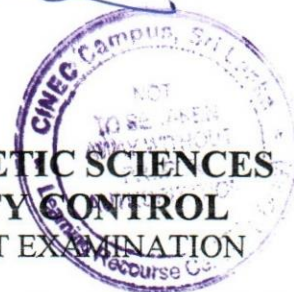


FACULTY OF HEALTH SCIENCES

HIGHER DIPLOMA IN PHARMACEUTICAL & COSMETIC SCIENCES

HD 2253 – VALIDATION, CALIBRATION & QUALITY CONTROL

BATCH – 01-2ND YEAR 2ND SEMESTER-END SEMESTER REPEAT EXAMINATION



Date : 30th April 2023
Time : 09.00 a.m. – 12.00 p.m. (Three Hours)

INSTRUCTIONS TO CANDIDATES

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

01 (100 marks)

- 1.1 Define the term validation in pharmaceutical industry. (10 marks)
- 1.2 State **05** benefits of conducting validation in pharmaceutical industry. (30 marks)
- 1.3 Describe **03** types of validation conducted in the pharmaceutical industry. (60 marks)

02 (100 marks)

- 2.1 Name **05** considerations (critical points) when conducting a cleaning validation activity for a manufacturing vessel which will be cleaned using a detergent and water. (30 marks)
- 2.2 State **05** situations which will require validation to be carried out in the pharmaceutical industry. (30 marks)
- 2.3 Describe **02** types used to process validation in pharmaceutical industry with examples. (40 marks)

03 (100 marks)

- 3.1 Briefly describe the purpose of a validation master plan. (20 marks)
- 3.2 State **04** parameters that should be considered during validation of a new liquid manufacturing process. (20 marks)
- 3.3 Describe **03** elements that should be included in a process validation protocol. (60 marks)

04 (100 marks)

- 4.1 Briefly describe equipment qualification. (20 marks)
- 4.2 State **05** reasons why equipment qualification is important. (30 marks)
- 4.3 Describe the main stages of the equipment qualification process. (50 marks)

05

(100 marks)

- 5.1 State **04** purposes of performing equipment calibration in pharmaceutical industry. (20 marks)
- 5.2 State **05** examples for measuring instruments which should be calibrated. (30 marks)
- 5.3 Outline the information which you can obtain from a calibration certificate. (50 marks)

06

(100 marks)

- 6.1 Calculate followings considering given data related to a calibration of a pressure measuring device.
Standard reading= 997 psi
Calibrating equipment reading= 1000 psi
Tolerance limit= ± 20
- 6.1.1. Error. (15 marks)
- 6.1.2. Accuracy. (15 marks)
- 6.1.3. Correction factor. (15 marks)
- 6.2 State **03** purposes of the change control program in Pharmaceuticals. (15 marks)
- 6.3 Describe **02** main categories of change in pharmaceutical industry with examples. (40 marks)



Faculty of Health Sciences

HIGHER DIPLOMA IN PHARMACEUTICAL & COSMETIC SCIENCES

HD 2243 – UTILITY AND CONTROL SYSTEMS

BATCH – 01-2ND YEAR 2ND SEMESTER- END SEMESTER SEQ REPEAT EXAMINATION

Date : 29th April 2023
Time : 09.00 a.m to 12.00 p.m. (Three Hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.
- You are not allowed to take out the examination papers.

Question 01

(100 marks)

- 1.1. State **03** advantages and disadvantages of a hydraulic system. (15 marks)
- 1.2. What are the main components of a hydraulic system? (20 marks)
- 1.3. Describe the primary fluid properties (30 marks)
- 1.4. A cylinder with a diameter of 7 cm and height of 20 cm is filled with an unknown fluid. A force of 16 kN is applied to a piston shifting on top of the fluid, which compresses the fluid column height to 19.99 cm.
 - 1.4.1. Calculate the bulk modulus of the unknown fluid. (35 marks)

Question 02

(100 marks)

- 2.1. State the reasons for the following systems. (20 marks)
 - 2.1.1 Single phase electrical supply
 - 2.1.2 Three phase electrical supply
- 2.2. State the importance to earth the bodies of electrical equipment. (20 marks)
- 2.3. What are the conditions that boost the generation of charge? (25 marks)
- 2.4. Compare the **02** types of wiring methods in three-phase wiring. (35 marks)

Question 03

(100 marks)

- 3.1. State the properties of steam. (20 marks)
- 3.2. Describe the types of boilers. (30 marks)
- 3.3. Describe the procedure that needs to be carried out before using an autoclave in sterilizing pharmaceutical products. (50 marks)

Question 04

- 4.1. What is Pneumatics? (20 marks)
4.2. State **03** advantages of compressed air. (25 marks)
4.3. What are the **03** elements of a pneumatic system? (25 marks)
4.4. Briefly describe how we can know when to change the filter element in an air filter. (30 marks)

Question 05

- 5.1. What is an air compressor? (20 marks)
5.2. What are the **02** main types of air compressors? (25 marks)
5.3. Briefly describe the pressure characteristics of the above-mentioned compressor types. (30 marks)
5.4. Differentiate between single-stage compressing and multi-stage compressing. (25 marks)

Question 06

- 6.1. State **04** methods of water purification. (20 marks)
6.2. What is BOD? (25 marks)
6.3. What are the **02** methods of reducing temporary hardness? (25 marks)
6.4. Describe how a water sample's turbidity is measured using light. (30 marks)

Faculty of Health Sciences

HIGHER DIPLOMA IN PHARMACEUTICAL & COSMETIC SCIENCES

HD 2253 - VALIDATION, CALIBRATION & QUALITY CONTROL

BATCH – 01-2ND YEAR 2ND SEMESTER-END SEMESTER REPEAT EXAMINATION - ASSIGNMENT

Date : 30th April 2023
Time : 01.30 p.m. – 02.30 p.m. (One Hour)

INSTRUCTIONS TO CANDIDATES

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

01

(100 marks)

1.1. Describe the main steps of the equipment qualification process considering the example of purchasing a balm/ointment manufacturing vessel for a pharmaceutical company ABC with batch size of 1000kg. Include important elements to be considered at each stage.

02

(100 marks)

2.1. Describe the parameters to be considered for a process validation to increase the batch size of a syrup product from 500L to 1000L.