

EXAMINANT

22 JUL 2024

20/07

CINEC

Library

00007



Faculty of Health Sciences
Higher Diploma in Pharmaceutical and Cosmetic Sciences
HD 2143 Maintenance Sciences
Batch 02
2nd Year 1st Semester
End Semester Examination – SEQ

INDEX NUMBER:

Date : 22nd July 2024
Time : 9.00 a.m. - 12.00 p.m. (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 (100 marks)

1.1 List **02** types of utilities used in the pharmaceutical industry. (10 marks)

.....
.....

1.2 State **02** pharmaceutical industry specific key maintenance practices. (20 marks)

.....
.....
.....
.....

1.3 List the least mature and the most mature types of maintenance. (10 marks)

.....
.....

1.4 Describe the importance of each type of maintenance mentioned in 1.3 above. (30 marks)

.....
.....
.....
.....
.....

1.5 Describe how to handle overdue preventive maintenance of a machine. (30 marks)

Question 02 (100 marks)

2.1 How do validation and maintenance interconnect in the pharmaceutical industry? (15 marks)

2.1 State 04 types of validation used in the pharmaceutical industry. (20 marks)

2.3 Briefly discuss the importance of a validation master plan. (20 marks)

1.4 Differentiate operational and performance qualifications. (20 marks)

2.5 What is the process of ‘installation qualification’. (25 marks)

Question 03 (100 marks)

3.1 Define the term ‘preventive maintenance’. (15 marks)

3.2 What are the advanced criteria to define frequencies in a maintenance schedule? (20 marks)

3.3 List 02 advantages and 02 disadvantages of preventive maintenance. (20 marks)

3.4 Briefly describe the asset identification in maintenance schedule. (20 marks)

.....
.....
.....
.....
.....

3.5 Write a short note on the process of machine handover in a manufacturing plant. (25 marks)

Question 04 (100 marks)

4.1 Define the term ‘machine breakdown’. (25 marks)

.....

4.2 List **02** causes each for ‘run to failure maintenance’ and ‘emergency breakdown maintenance’ in the pharmaceutical industry. (25 marks)

.....

4.3. State **05** actions that can be taken to effectively manage breakdown maintenance. (25 marks)

.....
.....
.....

4.4 Mention 05 types of facilities considered under facility maintenance. (25 marks)

Question 05 (100 marks)

5.1 List 03 criteria that maintenance equipment should fulfill. (25 marks)

5.2 What is meant by 'spare parts' in relation to maintenance science? (25 marks)

5.3 List **04** considerations you should take into account upon receiving new GxP and EHS critical spare parts in the pharmaceutical industry. (25 marks)

5.4 Write a short note on GxP lubricants. (25 marks)

Question 06**(100 marks)**6.1 List **03** types of maintenance related risk assessment.

(30 marks)

.....
.....
.....

6.2 State **04** observations you should make during risk assessment.

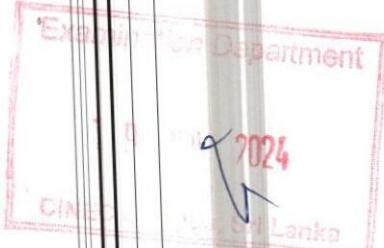
(35 marks)

.....
.....
.....
.....

6.3 Write the importance of risk assessment in cosmetic industry.

(35 marks)

.....
.....
.....
.....
.....
.....
.....
.....



00007



Faculty of Health Sciences
Higher Diploma in Pharmaceutical & Cosmetic Sciences
HD 2133 - Pharmaceutical & Cosmeceutical Packaging

Batch - 02

2nd Year 1st semester

End Semester SEQ Examination

INDEX NUMBER:

Date : 19th July 2024
Time : 9.00 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.
- You are not allowed to take out the examination papers.

01 (100 marks)

1.1. Write **04** selection criteria of pharmaceutical packaging. (20 marks)

.....
.....
.....

1.2. State **05** ideal pharmaceutical packaging requirements. (20 marks)

.....
.....
.....

1.3. Describe the main **03** types of pharmaceutical packaging by providing examples for each. (30 marks)

1.4. State **05** advantages and disadvantages of glass as a pharmaceutical packaging material. (30 marks)

02 (100 marks)

2.1. Define pharmaceutical label reconciliation. (10 marks)

2.2. Write the advantages of label reconciliation in related to pharmaceutical industry. (25 marks)

2.3. "Knowing what the labels and their packaging are made of will help in ensuring the disposing of them in a responsible and environmentally friendly manner." Based on this statement outline the structure of a pharmaceutical label that help understanding the proper disposal practice. (30 marks)

2.3. State **03** legal requirements of a manufacturer label and describe them. (35 marks)

03 (100 marks)

3.1. What are desiccants? (20 marks)

3.2. List two reasons to use desiccants in pharmaceutical packaging? (20 marks)

3.3. State how montmorillonite clay is used as a desiccant in the pharmaceutical industry.

3.4. "The primary and secondary packaging materials should pass the quality control tests before they are issued for the packaging process." Comment on this statement.

(30 marks)

04 (100 marks)

4.1. Write the process of line clearance in pharmaceutical packaging.

(30 marks)

4.2. State 05 general tests conduct to access the quality of pharmaceutical glass containers.

(30 marks)

4.3. Briefly describe the following test which is carried out for finished pharmaceutical products.

4.3.1. Carton drop test.

(40 marks)

.....
.....
05

(100 marks)

5.1. List 02 types of tamper resistant packages.

(20 marks)

.....
.....
.....

5.2. "Blister packaging is favored by pharmaceutical companies". Justify this statement giving 04 reasons.

(40 marks)

.....
.....
.....
.....
.....
.....

5.3. What is meant by thermoforming?

(40 marks)

.....
.....
.....
.....
.....
.....

06

(100 marks)

6.1. List 03 types of film wrappings used in pharmaceutical and cosmeceutical industry.

(40 marks)

.....
.....
.....

6.2. What are the commonly used materials for film wrapping? (20 marks)

6.3. Outline the mechanism used in photoelectric cell counters in tablet/capsule counting. (40 marks)