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Past Papers

Faculty of Health Sciences

Higher diploma in Pharmaceutical & cosmetic sciences

(Year 2 – Semester I)

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PAST PAPERS

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Faculty of Health Sciences

Higher Diploma in Pharmaceutical & Cosmetic Sciences

HD 2153 – Sterile Pharmaceutical & Cosmeceutical Manufacturing

Batch – 01- 2nd year 1st semester -Repeat SEQ Examination

Date : **07th February 2023**
Time : **09.00 a.m to 11.00 a.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.
- You are not allowed to take out the examination papers.

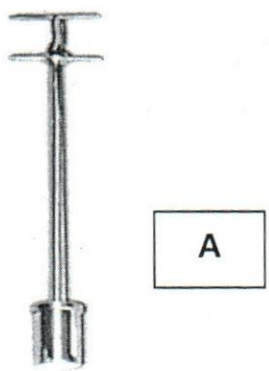
Question 01 **(100 marks)**

1.1. What is meant by the sterility of a pharmaceutical or cosmeceutical product? (10 marks)

1.2. Differentiate between aseptic processing and terminal sterilization. (10 marks)

1.3.

1.3.1. Identify the following sampling tool (**A**). (20 marks)



A

1.3.2. State the purpose of using this sampling tool. (20 marks)

1.4. Describe the dye ingress test. (40 marks)

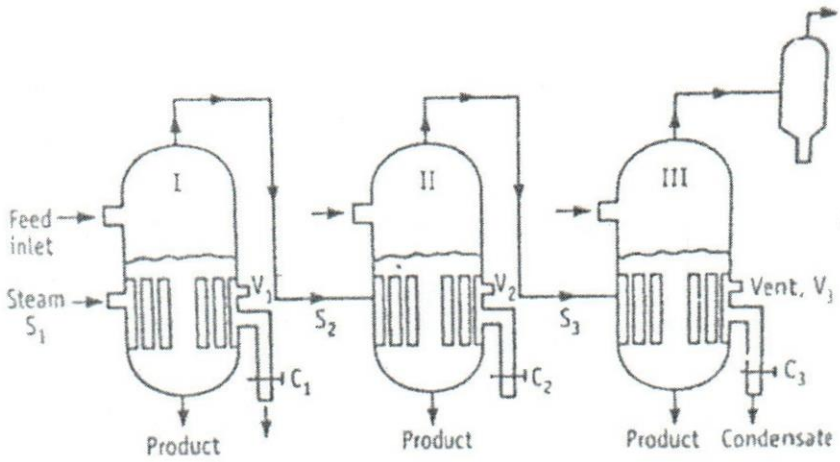
Question 02 **(100 marks)**

2.1. State **03** types of water for injections. (15 marks)

2.2. What is the importance of using water for injections? (25 marks)

2.3. Identify the following apparatus used in the pharmaceutical industry. (25 marks)

2.3.1.



2.4. Describe the Limulus Amebocyte Lysate test (LAL test). (35 marks)

Question 03 **(100 marks)**

3.1. List the sterile dosage forms. (10 marks)

3.2. Briefly describe the characteristics of a sterile dosage form. (25 marks)

3.3. Classify the main categories of sterilization methods. (15 marks)

3.4. What are the advantages, disadvantages and applications of dry heat sterilization? (20 marks)

3.5. Describe the challenges and the solutions in sterile dosage form manufacturing. (30 marks)

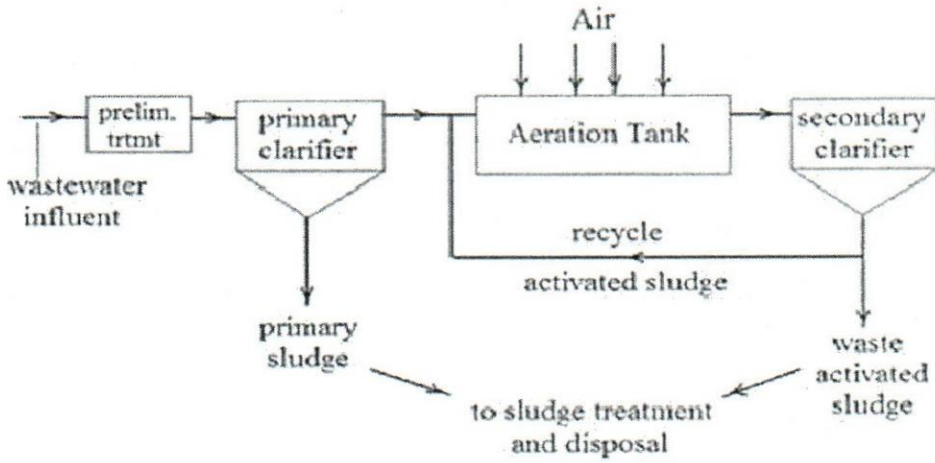
Question 04 **(100 marks)**

4.1. List **03** types of powder conveying systems. (15 marks)

4.2. Briefly describe the importance of powder conveying systems in pharmaceutical and cosmeceutical industry. (25 marks)

4.3.

4.3.1. Identify the following method of effluent water treatment. (10 marks)



4.3.2. What is the basis of this method? (20 marks)

4.4. Describe the "encapsulation" method used in solid waste management. (30 marks)

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CINEC CAMPUS
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Faculty of Health Sciences

Higher Diploma in Pharmaceutical & Cosmetic Sciences

HD 2133 - Pharmaceutical & Cosmeceutical Packaging

Batch - 01

2nd Year 1st semester

Repeat Examination -Assignment

INDEX NUMBER: .....

Date : **03rd February 2023**
Time : **01.00 p.m. – 02.00 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.
- You are not allowed to take out the examination papers.

01 **(100 marks)**

1.1. Draw a typical manufacturer label for the drug paracetamol with the brand name of paragon including all the legal requirements.

02 **(100 marks)**

2.1. You are provided with a tablet containing an active ingredient which get degraded when it contacts with water. Discuss how you would design the packaging of the given product.

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Faculty of Health Sciences

Higher Diploma in Pharmaceutical & Cosmetic Sciences

HD 2133 - Pharmaceutical & Cosmeceutical Packaging

Batch - 01

2nd Year 1st semester

SEQ Repeat Examination

INDEX NUMBER: .....

Date : **03rd of February 2023**
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 **03** selection criteria for pharmaceutical packaging. (15 marks)

1.2. State **05** functions of pharmaceutical packaging. (20 marks)

1.3. Briefly describe the main **03** types of pharmaceutical packaging. (25 marks)

1.4. Discuss advantages & disadvantages of using glass as a packaging material. (40 marks)

02 **(100 marks)**

2.1. State the importance of pharmaceutical label reconciliation. (15 marks)

2.2. Write **04** inspection criteria to be considered during label reconciliation. (20 marks)

2.3. State **05** advantages of label reconciliation in related to pharmaceutical industry. (25 marks)

2.4. State **04** legal requirements of a manufacturer label and describe them. (40 marks)

03 **(100 marks)**

3.1. What are the **02** main factors need to be considered before counting solid dosage forms? (10 marks)

3.2. Briefly describe the method of using counting triangles during the process of tablet counting. (25 marks)

3.3. List **05** commonly used desiccants in pharmaceutical packaging. (25 marks)

3.4. Discuss about the usage of desiccants in pharmaceutical and cosmeceutical packaging. (40 marks)

04 **(100 marks)**

4.1. Briefly describe the importance of quality control and quality assurance in related to pharmaceutical packaging. (15 marks)

4.2. Improper pharmaceutical packaging can be resulted in deficiencies in quality assurance system for packaging and it can be resulted in drug recalls. To prevent the occurrence of any default in packaging, line clearance is implemented in most of the manufacturing plants as a main process.

4.2.1. Briefly describe the process line clearance. (15 marks)

4.2.2. Outline the main sections consist in line clearance. (25 marks)

4.3. State **05** chemical tests conduct to access the quality of pharmaceutical glass containers. (20 marks)

4.4. Describe **03** different types of quality control tests carry out for pharmaceutical finished products. (25 marks)

05 **(100 marks)**

5.1. List the types of tamper resistant packaging. (20 marks)

5.2. What is meant by thermoforming? (15 marks)

5.3. State the importance of tamper resistant packaging. (25 marks)

5.4. Describe why blister packaging is preferred by pharmaceutical companies. (40 marks)

06 **(100 marks)**

6.1. Compare and contrast the end folded wrapper and fin seal wrapper used in pharmaceutical packaging. (20 marks)

6.2. "The primary and secondary packaging materials should pass the quality control tests before they are issued for the packaging process." Comment on this statement. (20 marks)

6.3. State the different types of electric counters used in pharmaceutical and cosmeceutical packaging. (25 marks)

6.4. Describe different types of bottle packaging and closure systems used in tamper resistant packaging. (35 marks)

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Faculty of Health Sciences

Higher Diploma in Pharmaceutical & Cosmetic Sciences

HD 2143 - Pharmaceutical & Cosmeceutical Maintenance Sciences

Batch - 01

2nd Year 1st semester

Repeat SEQ Examination

Date : **06th February 2023**
Time : **9.00 a.m. – 11.00 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.
- You are not allowed to take out the examination papers.

01 **(100 marks)**

1.1. List **03** manufacturing machines and **02** utilities used in pharmaceutical manufacturing industry. (10 marks)

1.2. Explain **04** principles of maintenance carried out in a pharmaceutical manufacturing plant. (40 marks)

1.3. Briefly describe one advantage and one disadvantage of following least matured type of maintenance. (30 marks)

1.4. List **02** GMP practices to be followed during maintenance process. (20 marks)

02 **(100 marks)**

2.1. List **05** steps of Preventive Maintenance (PM) process. (25 marks)

2.2. What are the actions to be followed during an overdue PM? (20 marks)

2.3. Name **03** factors to be considered when defining preventive maintenance frequencies. (15 marks)

2.4. Describe **02** quality critical maintenance requirements and **02** safety critical maintenance requirements in a tablet compression machine. (40 marks)

03 **(100 marks)**

3.1. List **03** criteria to identify GxP critical spare parts. (30 marks)

3.2. State **02** basic requirements to be fulfilled by any maintenance equipment before using it inside a manufacturing facility for maintenance activities. (20 marks)

3.3. Name **02** pre-requisites to be fulfilled by a mechanical technician to conduct routine maintenance in a liquid manufacturing equipment. (10 marks)

3.4. Describe the difference of identical and equivalent spare parts. (40 marks)

04 **(100 marks)**

4.1. List **04** engineering maintenance activities which require to go through change control process. (20 marks)

4.2. State **03** benefits of engineering change management process for pharmaceutical and cosmetics industries. (25 marks)

4.3. Mention **04** important factors to be considered during pharmaceutical and cosmetic facility design. (20 marks)

4.4. Describe how to prevent product contamination during facility design and maintenance activities in pharmaceutical and cosmetics industries providing **02** examples. (35 marks)

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CINEC CAMPUS
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Faculty of Health Sciences

Higher Diploma in Pharmaceutical & Cosmetic Sciences

HD 2143 - Pharmaceutical & Cosmeceutical Maintenance Sciences

Batch - 01

2nd Year 1st semester

Repeat Practical Based Assignment

Date : **06th February 2023**
Time : **1.00 p.m. – 4.00 p.m. (Three Hours)**

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **THREE** 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. The cosmetics company XYZ plans to purchase a new double cone blender for powder mixing.

1.1.1. Describe **02** impact areas of this change which could be identified during quality and safety change impact assessments. (30 marks)

1.1.2. What kind of actions should be taken for each type of impact area mentioned in 1.1.1.? (10 marks)

1.1.3. List **04** equipment qualification/validation processes which are applicable for this equipment and explain what happens at each stage. (40 marks)

1.1.4. When you are going to add this to equipment maintenance schedule? describe how maintenance frequency should be decided. (20 marks)

02 **(100 marks)**

2.1. You are auditing maintenance program of liquid products manufacturing department of PQR organization. List **05** questions you may ask during the audit. (50 marks)

2.2. While you were conducting the audit on 20th August 2022, you found below information for a packing machine.

Next planned date of maintenance: 05-Aug-2022

Last completed maintenance: 05-Jun-2022

Grace period: ±7days

Maintenance frequency: Once in 2 months

The maintenance technician informed that they could not carry out planned maintenance on 05th August 2022 and still in pending status by the date you are conducting the audit.

Is this acceptable with maintenance schedule? Describe how you derive the answer. (50 marks)

03 **(100 marks)**

3.1. List **05** engineering documents and mention applications of each. (20 marks)

3.2. List **05** causes which can lead to a machine breakdown. (20 marks)

3.3. Describe below terms and how they help to minimize breakdowns. (30 marks)

3.3.1. Root cause analysis for machine breakdowns

3.3.2. Machine downtime analysis

3.3.3. Key performance indicators

3.4. Assume there is maintenance work to be carried out by a contractor inside an area which product is exposed. Mention **03** facility control procedures available in pharmaceutical and cosmetic industries to prevent product contamination during this type of maintenance activity. (30 marks)