CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences

Bachelor of Science Honours in Industrial Pharmaceutical Sciences

BSM 1153 - General Pharmaceutics

Batch - 05

1st year 1st semester

End Semester SEQ Examination

INDEX NUMBER: .....

Date : **27th September 2021**
Time : **09.00 am – 12.00 pm (To answer the questions)**
12.00 pm- 12.30 pm (To upload and email the compiled answer sheet)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **all** questions.
- The paper will be for three hours (9.00 am-12.00 pm). You will be given an extra 30 minutes for submission. Any submission after 12.30 pm will not be accepted.
- You should write the answers in **lined** sheets legibly in black or blue ink.
- You MUST write **examination name, module code and index number** on each answer script.
- Answer script should be numbered (right bottom) clearly.
- Use a suitable mobile scanner (e.g. Cam Scanner) to scan your answer scripts. This app allows to convert the document into PDF format.
- **Label the PDF: Your Index No- General Pharmaceutics: End Semester Examination**
- **Upload** the labelled **PDF to LMS AND** also **email** the PDF to Fohs.exams@cinec.edu

01 **(100 marks)**

1.1. State the composition of effervescent tablets. (10 marks)

1.2. Differentiate two phased system from single phase gels. (10 marks)

1.3. Briefly describe the importance of powders as a dosage form. (15 marks)

1.4. Emulsions and suspensions are categorized as dispersed systems. Illustrate this statement. (15 marks)

1.5. Indicate the advantage/s of novel oral drug delivery technologies over typical oral dosage forms. (15 marks)

1.6. Describe briefly on,

1.6.1. Suppositories. (15 marks)

1.6.2. Non-aqueous solutions. (20 marks)

02 **(100 marks)**

2.1. What are the importance of GMP? (15 marks)

2.2. State different GMP guidelines found around the world. (10 marks)

2.3. Briefly describe the GMP requirements in location and surrounding, warehouses and quality control area. (15 marks)

2.4. Differentiate the quality assurance and quality control. (20 marks)

2.5. Describe any 05 basic principles of GMP. (40 marks)

03 **(100 marks)**

3.1. Indicate 02 quality specification tests available in pharmacopoeia for medicines. (10 marks)

3.2. Briefly describe the importance of pharmacopoeia. (20 marks)

3.3. Differentiate pharmacopoeia and drug formulary. (20 marks)

3.4. Drug can have either positive or negative effect while medicines impart only a positive medicinal effect on the patient. Comment on this statement. (15 marks)

3.5. "Newly developed medicine must address a new need or should provide a significant added benefit over an existing medicine". Based on this statement, **state** the facts need to consider when introducing new medicines to the market. (15 marks)

3.6. List out the requirements for unique facility design and operation for an injectable bio-drugs manufacturing facility. (20 marks)

04 **(100 marks)**

4.1. State 03 unique characteristic features of borosilicate glass. (15 marks)

4.2. Briefly describe the advantage/s of device packaging. (15 marks)

4.3. Indicate the importance of having proper closure system in primary packaging. (15 marks)

4.4. Comment on the importance of quality assurance aspects of packaging. (20 marks)

4.5. Write a descriptive account on blister packaging. (35 marks)

05 **(100 marks)**

5.1. Briefly describe the function of anti-oxidants as an excipient. (10 marks)
5.2. Compare and contrast glidants and lubricants aid in tablet manufacturing. (20 marks)
5.3. Comment on the functional role of excipients. (25 marks)
5.4. Differentiate the precautions and warnings available in a manufacturer label. (15 marks)
5.5. Outline the information should available in a dispensing label. (30 marks)

06 **(100 marks)**

6.1. State the uses of reference standards. (10 marks)
6.2. What is pharmaceutical layout? (15 marks)
6.2. Classify the reference standards according to the purity. (20 marks)
6.4. State 05 factors that would affect on manufacturing plant layout. (25 marks)
6.5. Describe the advantages and disadvantages of a Good Manufacturing Plant layout. (30 marks)

CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences

Bachelor of Science Honours in Industrial Pharmaceutical Sciences

BSM 1153 - General Pharmaceutics

Batch - 04

1st year 1st semester

End Semester SEQ Examination

INDEX NUMBER: .....

Date	**:**	**13th January 2021**
Time	**:**	**09.00 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.
- You are not allowed to take out the examination papers.

01 **(100 marks)**

1.1. Classify the dosage forms according to the route of drug administration. (10 marks)
1.2. Differentiate buccal and sublingual tablets. (10 marks)
1.3. State **03** (Three) uses of plasters. (15 marks)
1.4. Draw the schematic representation of the cumulative amount of drug released from immediate, extended and delayed-release tablets. (15 marks)
1.5. State **05** (Five) types of novel and advanced dosage forms, delivery systems and devices. (15 marks)
1.6. Describe the following.
a). Pharmaceutical inserts (15 marks)
b). Dispersed systems (20 marks)

02 **(100 marks)**

2.1. List down the **05** (Five) basic principles of Good Manufacturing Practices. (20 marks)
2.2. Briefly describe the basic requirements of the quality control area of a pharmaceutical manufacturing area. (25 marks)
2.3. What are the importance of GMP? (20 marks)
2.4. Discuss the common problems in GMP execution. (25 marks)
2.5. Compare and contrast Quality Assurance and Quality Control. (10 marks)

03 **(100 marks)**

3.1. State the phases of drug development. (10 marks)
3.2. Differentiate general monographs and specific monographs. (20 marks)
3.3. Define the following.
a). Standards (10 marks)
b). Quality specifications (10 marks)
3.4. Write a descriptive account on clean room technology. (50 marks)

04 **(100 marks)**

4.1. Write down **05** (Five) ideal requirements of packaging. (20 marks)
4.2. State **03** (Three) advantages of device packaging. (15 marks)
4.3. Comment on the quality assurance aspect of packaging. (15 marks)

4.4. Write short notes on following.
a). Type I – Borosilicate glass (15 marks)
b). Pharmaceutical closures (15 marks)
c). Strip package (20 marks)

05 **(100 marks)**

5.1. Classify the excipients based on their origin by giving **02** (Two) examples per each. (20 marks)

5.2. State **05** (Five) functional roles of excipients. (15 marks)

5.3. Define the following types of excipients.

a). Disintegrants (10 marks)

b). Glidants (10 marks)

c). Preservatives (10 marks)

5.4. State **05** (Five) advantages of a proper dispensing label. (15 marks)

5.5. Draw a typical dispensing label including the most important information should contain on it. (20 marks)

06 **(100 marks)**

6.1. What is a pharmaceutical reference standard? (10 marks)

6.2. What are the uses of reference standards? (15 marks)

6.3. State the types of reference standards and briefly mention it's characteristics. (30 marks)

6.4. List down the components included in a certificate of analysis of reference standards. (10 marks)

6.5. What are the advantages of a properly designed manufacturing plant layout? (25 marks)

6.6. State the factors influencing manufacturing plant layout design. (10 marks)

CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences

Bachelor of Science Honours in Industrial Pharmaceutical Sciences

BSM 1153 - General Pharmaceutics

Batch - 03

1st year 1st semester

End Semester SEQ Examination

INDEX NUMBER: .....

Date : **25th August 2020**
Time : **09.00 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.
- You are not allowed to take out the examination papers.

QUESTION 01 **(100 marks)**

1.1. Define the term "**Standards**". (10 marks)

1.2. State **05** (Five) types of drugs. (10 marks)

1.3. Pharmacopoeia is an official publication containing a list of medicinal drugs with their effects and directions for their use.

1.3.1. State **04** (Four) world renowned pharmacopoeias. (10 marks)

1.3.2. Differentiate General Monographs and Specific Monographs. (20 marks)

1.4. Environmentally controlled areas are important to be considered when manufacturing sterile biopharmaceuticals.

1.4.1. Define "**Clean Room**" considering biological drug manufacturing facility. (10 marks)

1.4.2. Briefly describe the structure and the function of HEPA filters in related to clean room technology. (15 marks)

1.4.3. Write a descriptive account on **categories** involving in documentation process of biopharmaceutical product manufacturing. (25 marks)

QUESTION 02 **(100 marks)**

2.1. What is meant by GMP? (20 marks)

2.2. Briefly explain the importance of GMP. (25 marks)

2.3. Briefly differentiate Quality Control and Quality Assurance. (20 marks)

2.4. Write down **05** (Five) basic principles of GMP. (10 marks)

2.5. Briefly explain the common problems in GMP execution. (25 marks)

QUESTION 03 **(100 marks)**

3.1. Define "**Powder**" dosage form. (10 marks)

3.2. Differentiate buccal and sublingual tablets. (10 marks)

3.3. Briefly describe **02** (Two) types of non- aqueous solutions. (15 marks)

3.4. State **03** (Three) uses of plasters. (15 marks)

3.5. Classify novel dosage forms and drug delivery technologies. (20 marks)

3.6. Write a descriptive account on semi-solid dosage forms. (30 marks)

QUESTION 04 **(100 marks)**

4.1. Write down **05** (Five) functions of packaging. (20 marks)

4.2. State **03** (Three) disadvantages of glass. (15 marks)

4.3. State **03** (Three) types of hazards encountered by package by giving **02** (Two) examples per each. (15 marks)

4.4. Write a detailed account on "blister packaging". (50 marks)

QUESTION 05 **(100 marks)**

5.1. Different types of pharmaceutical excipients are used in the manufacturing process of pharmaceutical dosage forms.

5.1.1. State **04** (Four) ideal characteristics of an excipient. (10 marks)

5.1.2. State **05** (Five) functional roles of excipients. (15 marks)

5.1.3. Classify the "excipients based on their origin" by giving **02** (Two) examples per each. (20 marks)

5.1.4. Define the following types of excipients. (15 marks)
a). Anti-adherents
b). Lubricants
c). Glidants

5.2. State the criteria to be fulfilled by a manufacturer or dispensing label. (10 marks)

5.3. State **05** (Five) advantages of a proper dispensing label. (15 marks)

5.4. Describe **05** (Five) legal requirements of a manufacturer label. (15 marks)

QUESTION 06 **(100 marks)**

6.1. What does pharmaceutical plant layout refer to? (10 marks)

6.2. What are the proper storage conditions of reference standards? (15 marks)

6.3. Differentiate Qualitative and Quantitative analysis. (20 marks)

6.4. Briefly describe the advantages of a good pharmaceutical plant layout. (25 marks)

6.5. Write a short note on following. (30 marks)
a). Employees' needs and safety
b). Plant environment/climate

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Faculty of Health Sciences

Bachelor of Science Honours in Industrial Pharmaceutical Sciences

BSM 1153 General Pharmaceutics

1st year 1st semester

End Semester SEQ Examination

Batch 02

INDEX NUMBER: .....

Date : **06th July 2020**
Time : **09.00 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.
- You are not allowed to take out the examination papers.

QUESTION 01 **(100 marks)**

1.1. Pharmacopoeia is an official publication containing a list of medicinal drugs with their effects and directions for their use.

1.1.1. Define Pharmacopoeia. (10 marks)

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1.1.2. State the purposes of having Pharmacopoeia. (20 marks)

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1.1.3. Briefly describe the difference between General Monographs and Specific Monographs. (20 marks)

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1.2. Differentiate the "Drug" and the "Medicine". (10 marks)

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1.3. State the phases of Drug Development. (10 marks)

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1.4. Write a descriptive account on cleanroom technology considering injectable bio drugs.

(30 marks)

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QUESTION 02 **(100 marks)**

2.1. State the **03** (Three) types of possibilities of pharmaceutical contaminations. (15 marks)

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2.2. What are the factors to be considered when designing of pharmaceutical production area in a manufacturing plant? (20 marks)

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2.3. Briefly describe the importance of a good pharmaceutical manufacturing layout.

(25 marks)

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2.4. Describe the important requirements of the premises of a good pharmaceutical manufacturing facility pertaining to good manufacturing practices (GMP) of the world health organization.

(40 marks)

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QUESTION 03 **(100 marks)**

3.1. Define the term "Dosage form". (05 marks)

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3.2. State the chemical composition of effervescent tablets. (10 marks)

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3.3. State **04** (Four) types of ointment bases. (10 marks)

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3.4. Mention **04** (Four) examples for Bulk powders. (10 marks)

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3.5. Draw the schematic representation of the cumulative amount of drug released from immediate, extended and delayed-release tablets. (15 marks)

3.6. Classify the dosage forms according to the physical forms and route of drug administration.

(20 marks)

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3.7. Write down a brief account on aqueous solutions. (30 marks)

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QUESTION 04 **(100 marks)**

4.1. The packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale and use.

4.1.1. Write down **05** (Five) selection criteria for packaging. (20 marks)

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4.1.2. State **03** (Three) advantages of "Device packaging". (15 marks)

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4.2. Briefly explain the importance of having proper closure system for containers. (15 marks)

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4.3. Write a detailed account on "types of glasses" including examples when necessary.

(50 marks)

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QUESTION 05 **(100 marks)**

5.1. Pharmaceutical excipients are playing a wide role in the manufacturing process of different types of dosage forms.

5.1.1. Define "Pharmaceutical Excipients". (10 marks)

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5.1.2. Classify the "excipients based on their origin" by giving **02** (Two) examples per each.

(20 marks)

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5.1.3. State **05** (Five) ideal properties of preservatives used in pharmaceutical manufacturing.

(15 marks)

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5.1.4. Define the following types of excipients. (15 marks)

a) Antioxidants

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b) Anti-adherents

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c) Disintegrants

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5.2. State **05** (Five) legal requirements of a manufacturer label. (10 marks)

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5.3. State **02** (Two) advantages of the proper dispensing label. (10 marks)

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5.4. Draw a dispensing label and mention the most important information should contain on it.

(20 marks)

QUESTION 06 **(100 marks)**

6.1. List the components included in a certificate of analysis of a reference standard. (10 marks)

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6.2. What are the basic requirements of quality of the reference standards? (20 marks)

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6.3. Briefly describe the uses of reference standards. (30 marks)

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6.4. Compare and contrast the quality control and quality assurance. (40 marks)