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**Faculty of Health Sciences**  
**Bachelor of Science Honours in Industrial Pharmaceutical Science**  
**IPS 4123 – Pharmaceutical Quality Control**  
Batch – 02 & 03  
4<sup>th</sup> year 1<sup>st</sup> semester  
Special Repeat SEQ Examination

**INDEX NUMBER:** .....

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**Date** : 27<sup>th</sup> June 2024  
**Time** : 09.00 a.m. – 12.00 p.m. (Three hours)

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**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. What is the importance of the Quality Assurance (QA) department in a pharmaceutical manufacturing plant? (30 marks)

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1.2. State **05** main areas in which you have to follow Good Manufacturing Practices in a pharmaceutical manufacturing plant. (25 marks)

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1.3. State **03** objectives of following Good Laboratory Practices. (15 marks)

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1.4. What is the importance of following GMP in a pharmaceutical manufacturing area?

(30 marks)

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**Question 02**

(100 marks)

2.1. What are pharmacopeial appendices?

(10 marks)

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2.2. State **05** responsibilities of British Pharmacopoeia Commission (BPC). (20 marks)

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2.3. State the elements of pharmaceutical products distribution system and describe **01** of them.

(30 marks)

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**3.4. State the distribution channels used in pharmaceutical products distribution system.**  
**(40 marks)**

**Question 03** **(100 marks)**

**3.1. What is a quality management system in a quality control laboratory?** **(20 marks)**

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**3.2. How you are going to control your documents as a head of the quality control laboratory?**  
**(30 marks)**

3.3. How do you do quality analysis of incoming samples? (20 marks)

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3.4. What is the importance of retained samples of a particular pharmaceutical product?

(30 marks)

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**Question 04 (100 marks)**

4.1. State **02** devices currently used to check the hardness of solid dosage forms. (30 marks)

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4.2. State the importance of conducting friability and hardness tests for tablets.

(30 marks)

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4.3. State all the quality test parameters considered in the following quality control tests according to United States Pharmacopeia.

4.3.1. Dissolution test for hard gelatin capsules.

(30 marks)

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- 4.4. State the reason for conducting the following quality control tests for liquid dosage forms.  
4.4.1. Re-dispersibility test for pharmaceutical suspensions. (10 marks)

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**Question 05 (100 marks)**

- 5.1. State 05 advantages of the LAL test over the rabbit test when testing pyrogens.

(25 marks)

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- 5.2. What is the importance of conducting a growth promotion test when you are doing the sterility test? (20 marks)

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- 5.3. There is a complaint with severe adverse reactions after using a certain type of drug containing vial in a hospital. Investigators found that there are tiny cracks on those used vials.

5.3.1 What is the main defect you can come across with this investigation? (20 marks)

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5.3.2. State **one (01)** test method to identify this defect. (30 marks)  
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**Question 06** (100 marks)

6.1. State the importance of quality assurance relates to pharmaceutical packaging. (30 marks)  
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6.2. Write **05** quality control tests available to check the quality of packaging materials.  
(25 marks)  
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6.3. What is drug recalling? (20 marks)  
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6.4. What is CAPA in modern quality systems of pharmaceutical products? (25 marks)  
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00002

**Faculty of Health Sciences**  
**Bachelor of Science Honors in Industrial Pharmaceutical Science**  
**IPS 4143 Pharmacognosy I**  
**Batch 02 and 03**  
**4<sup>th</sup> Year 1<sup>st</sup> Semester**  
**Special Repeat Examination - SEQ**

**INDEX NUMBER:** .....

**Date :** 26<sup>th</sup> June 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 Briefly describe the term 'Pharmacognosy'.

**(25 marks)**

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1.2 What are crude drugs? Describe with giving **two (02)** examples.

**(25 marks)**

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1.3 List the advantages of using crude drugs for medicinal purposes.

**(25 marks)**

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1.4 List five (05) important alkaloids extracted from *Cinchona* spp. (25 marks)

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**Question 02** (100 marks)

2.1 What is 'Phyllotaxy'? (25 marks)

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2.2 "Members of the plant kingdom possess some key features compared to members in other kingdoms". Briefly describe this statement. (25 marks)

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2.3 What are the different functions of modified plant stems? (25 marks)

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2.5 Briefly describe why the stomata absent in roots. (25 marks)

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**Question 03****(100 marks)**

3.1 Classify different polysaccharides with suitable examples.

(25 marks)

3.2 State **three (03)** pharmaceutical importances of starch.

(15 marks)

3.3 Lipids are biologically important macro-molecules found in organisms.

3.3.1 List **three (03)** plant sources of lipids.

(15 marks)

3.3.2 Briefly describe the common method of extracting lipids from plant sources.

(20 marks)

3.4 What is the differences between fats and oils?

(25 marks)

**Question 04**

(100 marks)

4.1 What is 'asexual propagation of plants'?

(25 marks)

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4.2 List **four (04)** types of growth promoters.

(20 marks)

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4.3 State **five (05)** environmental factors that affect cultivation of medicinal plants.

(25 marks)

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4.4 State the importance of good harvesting practices in herbal medicine industry.

(30 marks)

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**Question 05**

(100 marks)

5.1 Differentiate primary and secondary metabolites.

(20 marks)

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5.2 List two (02) examples for different types of tannins. (10 marks)

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5.3 Name four (04) chemical tests for tannins. (20 marks)

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5.4 State the chemical nature of tannins. (20 marks)

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5.5 Discuss the medicinal value of different types of resins. (30 marks)

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### Question 06 (100 marks)

6.1 List four (04) animal-based crude drugs. (20 marks)

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6.2 Differentiate between organized and unorganized drugs. (20 marks)

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6.3 How you would classify crude drugs? (20 marks)

6.4 Adulteration is a common issue in herbal drug marketing field. Define the following terms.

6.4.1 Adulterants (20 marks)

6.4.2 Direct adulteration (20 marks)

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