DATE: 14TH SEPTEMBER 2023 **TIME: 01.30 P.M. – 03.30 P.M.**

Part B – Short Answer Questions (20 Marks)

1.

1.1 What is analytical method validation? (01 mark)

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1.2 State the three (03) main categories of analytical tests according to International Council for Harmonization (ICH) quality guidelines. (03 marks)

I.....

II.....

III.....

1.3 State the purpose of following quality control tests conducted for semi-solid dosage forms. (06 marks)

a. Minimum fill

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b. Spreadability

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c. In vitro release test

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Index No.....

2.

2.1 Define tablet hardness. (02 marks)

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2.2 State two (02) tests used to confirm the uniformity of dosage units. (02 marks)

I.....

II.....

2.3 What is the significance of pH testing in the quality control of oral liquid preparations? (02 marks)

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2.4 State four (04) quality control tests conducted specially for suppositories. (04 marks)

I.....

II.....

III.....

IV.....

Index No.....

Part C – Structured Essay Questions (60 Marks)

1.

1.1. State four (04) visual identification tests conducted for solid dosage forms. (04 marks)

1.2. Differentiate between limit testing and sterility testing as microbiological quality tests for solid dosage forms. (06 marks)

1.3. Explain the method of interpreting dissolution test results for a tablet dosage form. (08 marks)

1.4. Briefly explain the following quality control tests conducted for the liquid dosage form. (12 marks)

a. Microbiological tests
b. Redispersibility
c. Droplet size

2.

2.1. What are pharmaceutical impurities? (03 marks)

2.2. Briefly describe four (04) methods use to overcome impurity related problems for a dosage form. (08 marks)

2.3. Write a short note on types of pharmaceutical impurities based on ICH classification. (09 marks)

2.4. Discuss the objectives of quality control in pharmaceutical industry. (10 marks)