BACHELOR OF PHARMACY HONOURS
FMU5205 – PHARMACEUTICAL ANALYSIS II – LEVEL5
ACADEMIC YEAR 2019/2020 – SEMSETER II
FINAL EXAMINATION

DATE: 11TH AUGUST 2021 **TIME: 1.30 P.M. – 3.30 P.M.**

Part B – SAQs (20 marks)

1.

1.1. List five (05) dimensions of 'Quality' from a customer's point of view. (05 marks)

I. .....

II. .....

III. .....

IV. .....

V. .....

1.2. State five (05) types of documentation required under 'Good Manufacturing Practices documentation'. (05 marks)

I. .....

II. .....

III. .....

IV. .....

V. .....

Index No: .....

2.

2.1. List two (02) international guidelines which instruct drug developers and regulatory agencies on how to evaluate and control impurities in drug substances and products. (02 marks)

I. .....

II. .....

2.2. List three (03) methods used in isolating and identifying process-related impurities and degradation products. (03 marks)

I. .....

II. .....

III. .....

2.3. State what is meant by analytical method validation. (05 marks)

.....

.....

Part C – SEQs (60 marks)

1.

1.1. Briefly explain five (05) basic requirements of 'Quality Control'. (10 marks)

1.2. Explain how 'Personal hygiene' is considered in Good Manufacturing Practices (GMP). (20 marks)

2.

2.1. Describe the GMP requirements of equipment and machinery used in a pharmaceutical manufacturing plant. (20 marks)

2.2. Briefly describe four (04) types of information which should be included in the 'Site Master File' of a manufacturing facility. (10 marks)