MASENO UNIVERSITY

UNIVERSITY EXAMINATIONS 2016/2017

THIRD YEAR FIRST SEMESTER EXAMINATIONS FOR THE DEGREE OF BACHELOR OF SCIENCE IN PHARMACEUTICAL SCIENCES WITH INFORMATION TECHNOLOGY

MAIN CAMPUS

PPS 344: DRUG PRODUCT DEVELOPMENT I

Date: 6th December, 2016 Time: 12.00 - 3.00 pm

INSTRUCTIONS:

- Answer ALL questions in SECTION A and TWO questions in SECTION B.

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PPS 344: DRUG PRODUCT DEVELOPMENT I

BSC PHARMACEUTICAL SCIENCES

SECTION A: 40 MARKS

INSTRUCTIONS: Answer ALL Questions (4 marks each)

1. Give four examples of *molecules used in Drug Product* (dose form) Development
2. Differentiate *Efficacy* from *Biological tests*
3. List four *Sustained Release Formulation dosage forms*
4. State two goals *of Design and Optimization* of controlled Release Systems
5. Outline *advantages and disadvantages* of tablets
6. List four *granule properties* useful in tabletting
7. Give examples of;
   a) Aborbent b) Gladant c) Disintegrant d) Direct compression in tablets
8. State two examples of granulating agents and reason for their use
9. Classify membrane devises seen in dosage forms
10. Examine the *commercial reasons* for Controlled Drug Release System
11. Enumerate the *factors* that make difficult Drug Product Development Process

SECTION B: 30 MARKS

INSTRUCTIONS: Attempt two (2) questions only [15 marks each]

1. *Compare and contrast* the trend of New Drug Applications (NDA) and New Molecular Entities (NME) approved by Bureau of Drugs.
2. Discuss *the importance of Lubricants* as tablet excipient and give comprehensive list of examples.
3. Explain *the perfect sink solution* in diffusion-controlled system in Drug Product Development Process.
4. Explain the problems encountered in tabletting process
5. Discuss the purpose of each component in te formula below

   Spray dried lactose

   Starch (BP)

   Acacia

Talc

Essential oils

Methylcellulose

Boric acid

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