SVKM'S NMIMS

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Programme: M. Pharm / M. Pharm + MBA (PQA) **Year:** I **Semester:** I
Academic Year: 2019-20 **Marks:** 75
Subject: Quality Control and Quality Assurance **Time:** 2.00 pm to 5.00 pm
Date: 25 November 2019 **Duration:** 3 hrs.
No. of Pages : 02

FINAL EXAMINATION

Instructions: Candidates should read carefully the instructions printed on the question paper and on the cover of the Answer Book, which is provided for their use.

1) Question No. 1 is compulsory.
2) Out of remaining questions, attempt any 4 questions.
3) **In all 5 questions to be attempted.**
4) All questions carry equal marks.
5) **Answer to each new question to be started on a fresh page.**
6) **Figures in brackets on the right hand side indicate full marks.**
7) **Assume suitable data if necessary.**

Section A

Q 1. Answer the following Questions **(15 M)**

1. Why change control is necessary?
2. How the product quality review is conducted?
3. What are the objectives of ICH Q8 Guidelines?
4. What is the significance of time limitations on production?
5. What is the GMP guidelines on Salvaging?

Section B

Q 2. A) What is CTD? Give its format. Describe the contents of clinical overview and module 5 of CTD **(8 M)**

B) What is the objective, scope and general principles of ICH Q3 guidelines? **(7 M)**

Q 3. A). What is the significance of cross contamination? How will you prevent mix ups and cross contamination? **(8 M)**

B) Describe the protocol for conduct of non-clinical testing as per OECD guidelines. **(7 M)**

Q 4. A) Describe content uniformity test as per USP **(8 M)**

B) What is the purpose of Master manufacturing record? Describe its contents **(7 M)**

Q 5. A) What are the Pharmacopoeial standards for parenterals? Explain bacterial endotoxin test. **(8 M)**

B) What is the objective of SOP? What are the important factors to be considered while writing SOP? **(7 M)**

Q 6. A) Give the overview of Organization and personnel responsibilities. **(8 M)**

B) What are the different grades of clean air? Discuss GMP requirements for aseptic manufacturing.**(7 M)**

Q 7. Write a short note on **any 3 (15 M)**

A. Importance of intellectual property right
B. CPCSEA guidelines
C. Expiry date calculation
D. Standards for surgical dressings