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SVKM'S NMIMS

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Programme: M. Pharm / M. Pharm + MBA (Pharmaceutics) **Year:** I **Semester:** I
Academic Year: 2019-20 **Marks:** 75
Subject: Regulatory Affairs **Time:** 2.00 pm to 5.00 pm
Duration: 3 hrs.
Date: 25 November 2019 **No. of Pages :** 2

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 **Attempt all the following**

a	Write the document title for given following code: (As per ICH) **i)** Q7 **ii)** Q6A **iii)** S2 **iv)** S4 **v)** E6(R2) **vi)** M8	**[3M]**
b	Distinguish carefully between stress degradation and formal stability studies.	**[3M]**
c	What is the difference between master formula record and batch manufacturing records?	**[3M]**
d	What is the full form of ARTG? What the TGA Regulate?	**[3M]**
e	What are the requirements for identification of appropriate CRO?	**[3M]**

Section (B)

Q.2	**a.** What are the several routes for the authorisation of drug products in European system? Explain significance, scope and benefits of centralized procedure.	**[8M]**
	b. What is CTD? Give its format. What are the different section in the module 2?	**[7M]**
Q.3	**a.** What is the M code in ICH? Provide important components included in M. Discuss in detail ICH guidelines to be referred for stability.	**[8M]**
	b. What data required for approval of marketing of new drug developed in India as an IND not marketed anywhere in world as per CDSCO.	**[7M]**

Q.4 **a.** Discuss in detail different elements required for developing clinical trial protocol. [8M]

b. Components of batch manufacturing records and describe them in a brief. [7M]

Q.5 **a.** Describe in detail methodology involved for NDA as per USFDA guidelines. [8M]

b. What is informed consent? Explain the challenges regarding informed consent. [7M]

Q.6 **a.** Write Short Note on Post Marketing Surveillance. [8M]

b. What is the investigator brochure? Discuss in detail table of content of investigator brochure. [7M]

Q.7 **Write short note on :** [15M]

a) Functions of MHLW

b) ANDA review process

c) 21 Code of Federal Regulation