



# AJEENKYA

## D Y PATIL UNIVERSITY

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### End Term Examinations (April/May 2019)

School : SOM-ICRI      Program: M.Sc Clinical research

Course: Good Manufacturing and laboratory practices      Course Code: MGT561

Semester: II      Max Marks: 50      Duration (mins) : 150 mins

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Note : 1. Figures to the right indicates full marks.  
2. Answer all the questions.

Q 1. What is good manufacturing practice (GMP) and what is its objective? (5)

Q 2. Describe phase 4 in drug development and drug approval process? (5)

Q 3. Describe in detail the preclinical and phase 1 of drug development and drug approval process. (10)

Or

Describe in detail the phase 2 and 3 of drug development and drug approval process (10)

Q 4. What are the basic elements of GLP and describe them briefly? (10)

Or

Describe in detail Good clinical practice (GCP). (10)

Q 5. State and describe the Principles of good manufacturing practice? (10)

Or

Describe Abbreviated new drug application (ANDA) and Investigational New drug (IND) and what are their goals? (10)

Q 6. What is New Drug Application (NDA) and what is the content of NDA and describe them briefly? (10)

Or

What is Investigational New drug (IND) and what is the content of IND and describe them briefly? (10)

\*\*\*All the best\*\*\*