15/12/23

Seat Number | | | | | | |

DAGDU-25

BP 702T : INDUSTRIAL PHARMACY - II

(747702)

Total Pages : 3] **Max. Marks : 75**

Time: 3 Hours

Instruction to candidates:

1) Do not write anything on question paper except Seat number.
2) Graph or diagram should be drawn with black ink pen being used for writing paper or black HB pencil.
3) Students should note, no supplement will be provided.
4) All questions are compulsory.
5) Figures to the right indicate full marks.
6) Draw a neat well labelled diagram wherever required.

1-A. Attempt all questions: 10

i.) Process of increasing the batch size is called as--------

a) Batch Incrimation
b) Size Enlargement
c) Scale Up
d.) All of Above

ii.) Which one is said to be corrective tool for process of quality?

a) Quality Management
b) Quality Control
c) Total Quality Management
d.) Six Sigma

iii.) A measurable term under which test is considered as acceptable

a) Bracketing
b) Acceptance Criteria
c) Commissioning
d.) Criteria Control Point

iv.) Which of the following is a multi functional processor for process of granulation

a) FBD
b) Sigma Blade Mixer
c) Planetary Mixer
d.) Rapid Mixer Granulator

v.) Head office of CDSCO is located in which city?

a) New Delhi
b) Mumbai
c) Pune
d.) Bangalore

vi.) IND stands for-----

a) International New Drug
b) Investigational New Drug
c) Indian New Drug
d.) None of above

vii) Which of the following describes about Formulation order and Manufacturing Instruction ?

a) Master Formula Card
b) Standard Testing Procedure
c) Master Formula
d.) Master Packaging Card

viii) Format for COPP is recommended by-----

a) i.) ICH
b) WHO
c) CDSCO
d.) US-FDA

ix.) Which of the following ISO 9000 remain concerned?

a) Quality Management
b) Environmental Management
c) Process Management
d.) Document Management

x.) The phase of clinical trial in which maximum number of human volunteers are involved is:

a) Phase- I
b) Phase- II
c) Phase- III
d.) Phase- IV

1-B. Attempt all questions.: **10**

xi.) What is New drug Application (NDA)

xii.) What is clinical trial protocol.

xiii.) What is Drug Master File (DMF).

xiv.) Define Quality Risk Management (QRM) and write its principle.

xv) Enlist the benefits of Quality Management System

2. Attempt any two of the following: **20**

i.) Explain briefly about typical processof Quality Risk Management (QRM).

ii.) Explain in brief about concept of QbD (Quality by Design) along with details of its elements.

iii.) Explain in briefly about in pilot plant scale up consideration for Solids?

3. Attempt any seven of the following: **35**

i.) Explain technology transfer protocol in pharmaceuticals

ii.) Discuss the role and responsibilities of Regulatory Affairs professional.

iii.) What are the objectives and significance of pilot plants

iv.) Discuss the different phase of clinical trial

v.) What are the basic reasons for the process of Technology Transfer?

vi.) Give the difference between Quality Assurance and Quality Control.

vii) Discuss the uses of platform technology?

viii.) Enlist and Explain objectives of SIX SIGMA

ix.) Explain brief about organization structure and functions of SLA (State Licensing Authority).