W-2022

Seat Number | | | | | | |

PANKH-06

BP-7002-T
Industrial Pharmacy-II
(747704)

Total Pages : 3]

Time: 3 Hours Max. Marks : 75

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 Draw well labelled diagram, wherever necessary.
5 Figures to the right indicate full marks.

1. (A) Choose the correct answer of the following: (10)

a) Which of the following is NOT a stage in product life cycle?
   i) Scale up
   ii) Commercialization
   iii) Technology transfer
   iv) Product marketing

b) --- is a process of increasing batch size or applying the same process to different output volumes.
   i) Preformulation
   ii) Diffusion
   iii) Product scale up
   iv) Bioequivalence

c) A transfer of technology between sites of two different companies is called -- --
   i) Inter-company transfer
   ii) Intra-company transfer
   iii) Technology transfer protocol
   iv) None of these

d) Quality risk management activities are entitled to be undertaken by -- --
   i) Business development expert
   ii) Legal expert
   iii) Marketing and sales expert
   iv) All of the above

e) An agreement to enter collaborative relationship with outside parties is called -- --
   i) License
   ii) Memoranda of understanding
   iii) Confidentiality agreement
   iv) Legal tax agreement

f) A profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in different areas is -- --
   i) Pharmacovigilance
   ii) Regulatory affairs
   iii) Technology transfer
   iv) Risk management

g) An ------- filing is a formal process by which a sponsor requests the approval for testing of a drug in human subjects.
   i) INDA
   ii) NDA
   iii) ANDA
   iv) CTD

h) a legal document that declares a certain manufacturing company is legally allowed to sell their pharmaceutical product in the country they are producing.
   i) Investigator's brochure (IB)
   ii) Clinical trial protocol
   iii) Certificate of Pharmaceutical Product (COPP)
   iv) Master formula record (MFR)

i) QbD is a part of -- -- --
   i) DoE
   ii) QRM
   iii) TQM
   iv) FDA

j) number of human volunteers are involved in Phase III clinical studies.
   i) 1-10
   ii) 10-100
   iii) 100-300
   iv) 300-3000

(B) Answer the following: **(10)**

a) Mention different roles of regulatory affairs team.
b) Enlist types of platform technologies.
c) Illustrate different stages of technology transfer diagrammatically.
d) What is TQM? Mention benefits of TQM.
e) Write a brief note on NABL.

2. Solve any **Two:** (20)

a) Write a note on pilot plant scale up considerations for solids.
b) Explain in detail the drafting of clinical trial protocol.
c) Explain: SUPAC guidelines.

3. Solve any **Seven:** (35)

a) Write a brief note on QbD.
b) Explain in detail ISO.
c) Explain in detail the documents related to Technology transfer.
d) Explain in detail the COPP.
e) Write a brief note on ANDA.
f) Explain in detail the Quality risk management process.
g) Explain different phases of drug development process with neat, labelled diagram.
h) What is GLP ? Write a brief note on principles and benefits of GLP.
i) Explain with flowchart, the drug approval process for new drugs in India.