Register Number									

Question Paper

Exam Date & Time: 04 April 2021 (9:30 am to 12:30 pm)

MANIPAL ACADEMY OF HIGHER EDUCATION

Industrial Pharmacy II [PCE-BP702T]

Marks: 75, Duration: 180 mins.

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins (9:30 am to 10 am)

No.	Question
1	For import/manufacture of a new drug, an Indian pharmaceutical company has to seek permission from ___ a) DCGI b) ICMR c) DBT d) DST
2	If a drug is approved in a geography other than India, its clinical trial in India is ____ a) Always necessary b) Never required c) May be waived off based on the decision of licensing authority d) Is required only for anticancer drugs
3	Along with the application for permission to import a new drug, data has to be submitted by applicant as per ____ a) Schedule A b) Schedule Y c) Schedule B d) Schedule Z
4	Give the full form of CTD, in the context of pharmaceutical regulatory affairs: a) Clinical Trial Document b) Common Technical Document c) Common Trial Document d) Central Trial Database
5	Data to be submitted along with application to manufacture new drug in India includes ____ a) Chemical and pharmaceutical information b) Animal pharmacology data c) Human clinical pharmacology data d) All the above
6	While scaling up a tablet formulation batch, the disintegrant level was changed by 0.3% w/w. Which of the following levels applies to this change, under SUPAC? a) Level 1 b) Level 2 c) Level 3 d) Outside the ranges of SUPAC
7	Which of the following is true with respect to scale-up of dry blending? a) It is preferable to maintain geometric similarity of equipment between scales b) Low-dose API is preferably added to the blender before addition of excipients c) Mixing efficiency is highest below 10% fill level of the blender d) Blender rpm should never be same between two scales
8	Which of these is applicable to scale-up of fluid bed granulation operation? a) Roller pressure b) Spray rate c) Impeller diameter d) Roller speed
9	If the data shows that the process performs consistently at critical step to produce a product that falls within release specification, then that process is said to be _____ a) Qualified b) Calibrated c) Validated d) Installed

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10	Which of these is not a part of the GMP checklist with respect to scale-up of a new product or process? a) Equipment qualification b) Availability of SOPs c) Training of personnel d) Modification of product specification
11	TQM stands for -------- a) Total Quality Assurance Management b) Total Industry Quality Management c) Total Quantity Management d) Total Quality Management
12	ISO 9000 is related to -------- a) Quality Management b) Quality Assurance c) Quality Management and Quality Assurance d) Quality Management and Scale up
13	Which one of the following options is wrong with respect to quality management? a) ISO 9000 b) ISO 14000 c) ISO 14001 d) ISO 90001
14	Full form of GLP is ---------- a) Good Laboratory Practices b) Good Language Practices c) Good Learning Practices d) Good Local Practices
15	What is OOS? a) Out of Stability b) Out of Specification c) Out of Storage d) Out of Specific Condition
16	Technology Transfer process is for ---------- a) API b) Method c) Documentation d) All of the above
17	Six sigma is related to --------- a) QMS b) TT c) CDSCO d) BRDC
18	NABL is related to ---------- a) Technology transfer b) Production c) Packaging d) QMS
19	CDSCO is concerned with ---------- a) Packaging of drugs b) Packaging of tablets c) Packaging of Injectable d) None of the above
20	State licensing authority regulates a) Selling drugs in USA b) Purchasing drugs in South Africa c) Packaging drug in India d) Indian Regulatory Requirements

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& Time: 04 April 2021 (9:30 am to 12:30 pm)

MANIPAL ACADEMY OF HIGHER EDUCATION

Industrial Pharmacy II [PCE-BP702T]

Section Duration: 150 mins (10 am to 12:30 pm)

II Long Answers

l the questions.

the pharmaceutical regulatory agencies of any five geographies. Write a note on 'drug ery project-team' and the disciplines associated with this team. (10)

ɔlain technology transfer process for excipients (10)

III Short Answers

ll the questions.

ɜ SUPAC and its three levels of changes. Explain level 1 and 2 changes in pharmaceutical ct composition. (5)

e pilot plant scale in the manufacture of pharmaceuticals and write its importance. (5)

ibe the space requirements for a pilot plant set-up.

cribe any five elements of a clinical trial protocol checklist. (5)

·ibe the procedure and data to be submitted for application to import/ manufacture a new already approved in India. (5)

rite a short note on approved regulatory bodies (5)

Explain QbD in detail (5)

Add a note on COPP

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