Rajiv Gandhi University of Health Sciences

First Semester M. Pharm Degree Examination - Dec-2017

[Time: 3 Hours] [Max. Marks: 75]

Product Development and Technology Transfer

Q.P. CODE: 5104

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. What are the contents of Investigational New Drugs Application (IND).
2. Write in detail about Pre-formulation protocol for Tablet dosage forms.
3. Explain various parameters to be considered during selection of container closure system for Parenteral formulation.
4. What controls need to be ensured when a technical process is transferred from development site to client site?

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Discus the requirement of Supplemental New Drug Application (SNDA).
6. Discuss the Product registration guidelines as per CDSCO.
7. Write a note on Stability testing during product development.
8. How pre-formulation study for purity, impurity profiling is carried out?
9. What is a pilot plant? Explain the factors to be considered in the organization of pharmaceutical pilot plant.
10. Explain how the development of master formula records and batch manufacturing records play an important role in pilot plant scale up studies.
11. Explain the protocol for pilot plant scale up for tablets production.
12. List and explain QC tests for blister packaged products.
13. Explain metal as the container for the pharmaceutical packaging.
14. Explain various Qualitative and quantitative models of technology Transfer.

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