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Roll No

MPY-DRA(D)
M. Pharmacy III Semester Examination, June 2020
Regulations of Good Laboratory Practices
(Elective)
Time : Three Hours

Maximum Marks : 70

Note: i) Attempt any five questions.
ii) All questions carry equal marks.

1. Summarize the personnel requirements as per GLP guideline 21 cfr part 58.29. 14
2. a) Write a brief account on requirements of animal care facilities. 7
b) What are the requirements of facilities for handling test and control articles? 7
3. Describe the role of testing facility management for nonclinical laboratory study. 14
4. Give the procedure to be followed for caring animal as per 21 cfr part 58.90. 14
5. Outline the requirements for performing characterization of test and control substances for animal studies. 14
6. Describe the information to be included in protocol for animal study. 14
7. Point out the area which leads to disqualification of testing facilities. 14
8. Write short notes on (any three): 14
 - a) Sponsor
 - b) Study director
 - c) Quality assurance unit
 - d) Performance qualification
 - f) Standard Operating Procedure.
