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Roll No

MPY-DRA(B)
M.Pharmacy III Semester Examination, June 2020
Generic Drug Approval
(Elective)
Time : Three Hours

Maximum Marks : 70

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

1. a) Discuss various regulatory considerations for generic drug approval.
b) Explain in detail patent certification in drug approval.
2. a) What is an ANDA filing? Write the differences between NDA and ANDA.
b) What is the life of patent? Explain patent term extension.
3. Describe in detail USFDA regulations. Differentiate between patent and trademark with suitable example.
4. a) What is a biologics approval process in FDA, explain.
b) What is the differences between BLA and NDA, explain with suitable example.
5. a) Discuss in detail FDA drug approval process for new drugs.
b) Explain in detail Hybrid NDA.
6. Explain in detail about:
 - a) Orange book
 - b) Follow on Biologics
7. a) Elaborate antitrust issues in pharmaceutical patent litigation settlements.
b) Discuss the automatic 30 month stay of ANDA approval.
8. Write notes on:
 - a) Eligibility for ANDA approval based on discontinued innovator drug.
 - b) The paragraph IV certification and notice requirement.
