

International Islamic University Chittagong

Department of Pharmacy

Program: B. Pharm (Hons)

Examination: Final

Session: Spring-2018

Course Code: Pharm-3611

Course Title: Pharmaceutical Regulatory Affairs

Marks: 50

Time: 2 Hours and 30 Minutes

[N.B: Answers of separate groups must be written in separate script]

Group A

Answer any two questions

Marks: 20

1. a) Briefly state the membership of the National Intoxicant Control Board according to Drug Act 1990. 5
- b) Mention the classification of intoxicants. 3
- c) Brief the steps are taken to cure of intoxicated person? 2
2. a) Illustrate the composition pattern of Pharmacy Council in Bangladesh according to "Pharmacy Ordinance 1976". 4
- b) Describe the qualification for getting registration of "A grade" pharmacist. 3
- c) Elucidate the different functions of Pharmacy Council according to "Pharmacy Ordinance 1976". 3
3. a) Discuss the role of Pharmacy Council regarding issue of registration certificate. 3
- b) Illustrate the points of a registration form that are filled for registration as a pharmacist? 4
- c) Mention the function of inspector according to Pharmacy Council. 3

Group B

Answer any three questions

Marks: 30

4. a) Write short note on National Regulatory Authority according to National Drug Policy 2016. 3
- b) Discuss the area of drugs according to National Drug Policy 2016 4
- c) Explain the drugs and raw materials production. 3
5. a) Mention the control of drug advertising and promotion according to National Drug Policy 2016. 3
- b) Discuss about Joint collaborative research and development of drugs according to National Drug Policy 2016. 4
- c) Mention the registration criteria for drugs according to National Drug Policy 2016. 3
6. a) Descriptively point out the objectives of "Drug Act 1982". 3
- b) What are the penalties for unauthorized import of drugs and illegal advertisement of drugs under Drug (control) Ordinance 1982? 4
- c) Mention the functions of drug court according to "Drug Act 1982"? 3
7. a) Mention the elements of National Drug Policy-2005. 4
- b) Mention the criteria of drug production according to National Drug Policy 2005. 3
- c) Mention the quality assurance criteria of drug. 3