



International Islamic University Chittagong

Department of Pharmacy

B. Pharm (Hon's) Program

Final Examination

Spring Semester 2019

Course Code: **Pharm-3611**

Course Title: **Pharmaceutical Regulatory Affairs**

Time: 2 hours 30 minutes

Full Marks: 50

(Answer of separate groups should be given in separate scripts. Figures on right margin indicate marks)

Group A *(Answer any two questions from the followings)* **Marks: 20**

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|----|----|---|---|
| 1. | a) | Write down the composition of Pharmacy Council according to the Pharmacy Ordinance, 1976. | 4 |
| | b) | Mention the power of inspector according to Pharmacy Council. | 4 |
| | c) | Which particulars are needed for registration of a person? | 2 |
| 2. | a) | Explain the procedure for registration of pharmacists. | 3 |
| | b) | State the qualifications for register A, B and C grade pharmacists. | 4 |
| | c) | Mention the rules for revocation of certificates according to Pharmacy Ordinance, 1976. | 3 |
| 3. | a) | Explain the functions of pharmacy council according to the Pharmacy Ordinance, 1976. | 4 |
| | b) | Mention the power to make regulations according to the Pharmacy Council. | 3 |
| | c) | Discuss the role of Pharmacy Council regarding examination. | 3 |

Group B *(Answer any three questions from the followings)* **Marks: 30**

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|----|----|--|---|
| 4. | a) | State the registration criteria for drugs according to the National Drug Policy (NDP) 2005. | 3 |
| | b) | Explain about the drug production according to the NDP 2005. | 4 |
| | c) | Discuss the function of Drug Regulatory Authority. | 3 |
| 5. | a) | Explain the objectives and elements of the NDP 2005. | 4 |
| | b) | Describe about drug procurement according to the NDP 2005. | 4 |
| | c) | Define essential and OTC drug with example. | 2 |
| 6. | a) | Write note on National Regulatory Authority according to the NDP 2016. | 3 |
| | b) | Discuss about the rational and safe use of drugs according to the NDP 2016. | 4 |
| | c) | Mention the registration criteria for drugs according to the NDP 2016. | 3 |
| 7. | a) | Elucidate the National Control Laboratory according to National Drug Policy 2016. | 4 |
| | b) | Describe the transparent and rational pricing of drugs according to National Drug Policy 2016. | 3 |
| | c) | Mention the control of drug advertising and promotion according to National Drug Policy 2016. | 3 |