Seat No.: _____ Enrolment No._____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**M. Pharm. – SEMESTER – III • EXAMINATION – SUMMER • 2015**

**Subject Code: 1931501 Date: 13-05-2015**

**Subject Name: Drug Regulation and Regulatory Authority**

**Time: 02:30 pm - 05:30 pm Total Marks: 80**

**Instructions:**

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

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|---|---|---|---|
| **Q.1** | **(a)** | Give an account on fixation of retail price of formulations as per drug price control Order, 1955. Explain the formula used for calculation of retail price of drug formulations. | **06** |
| | **(b)** | Give historical outline for Indian Pharmacopoeia. Discuss role of IP committee in publication of Indian Pharmacopoeia. | **05** |
| | **(c)** | Discuss a common framework required in medical device regulation. | **05** |
| **Q.2** | **(a)** | Write objectives of ICH E8 guidelines. Discuss development plan for clinical trials for special population. | **06** |
| | **(b)** | Write a brief note on IP reference substance and its spectra. | **05** |
| | **(c)** | Write eligibility criteria required for participating in WHO certification scheme. | **05** |
| **Q.3** | **(a)** | Give an account on FDA guidelines on clinical trials, review and approval of clinical study. | **06** |
| | **(b)** | Discuss drug pharmacokinetic studies on elderly patients as per ICH E7 guidelines. | **05** |
| | **(c)** | Write principle and goals of Good clinical practice. | **05** |
| **Q.4** | **(a)** | What is Drug Technical Advisory Board? Discuss their constitution and functions. | **06** |
| | **(b)** | Write a note on WHO certification scheme | **05** |
| | **(c)** | Write in detail objectives and function of Pharmacy Act 1948 | **05** |
| **Q.5** | **(a)** | What are the objectives of Drug master file (DMF)? Compare US and European Drug master file preparation. | **06** |
| | **(b)** | Describe the organization of the Common Technical Document. | **05** |
| | **(c)** | Write a note on Haemovigilance programme in India. | **05** |
| **Q. 6** | **(a)** | Discuss content and format of NDA as per the US FDA. | **06** |
| | **(b)** | What should Member States and regional organizations possess in order to issue a Certificate for a Pharmaceutical Product (CPP) to support the export pharmaceutical products? | **05** |
| | **(c)** | Write provisions of import of drug as per D& C act, 1940. | **05** |
| **Q.7** | **(a)** | Classify medial devices and discuss in brief registration process of medical device in India. | **06** |
| | **(b)** | Discuss the process of IP monographs development. | **05** |
| | **(c)** | Define Site master file. Explain the structure of Site master file. | **05** |

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