**Enrollment No: _____ Exam Seat No:_____**

# C.U.SHAH UNIVERSITY

## Summer Examination-2019

**Subject Name:** Drug Regulatory Aspects & IPR
**Subject Code:** 4PS08DRA1 **Branch:** B.Pharm
**Semester: 8** **Date: 01/05/2019** **Time: 10:30 To 01:30** **Marks: 70**

Instructions:
(1) Use of Programmable calculator & any other electronic instrument is prohibited.
(2) Instructions written on main answer book are strictly to be obeyed.
(3) Draw neat diagrams and figures (if necessary) at right places.
(4) Assume suitable data if needed.

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**Q-1** **Define the following terms with suitable examples** **(14)**

**a)** Patent
**b)** e-CTD
**c)** OTC Drugs
**d)** Trade mark
**e)** World Trade Organization (WTO)
**f)** Orange book
**g)** Dossier
**h)** Drug Information
**i)** Orphan drugs
**j)** Sponsor
**k)** Green book
**l)** Copyright
**m)** Trade-Related Aspects of Intellectual Property Rights (TRIPS)
**n)** Invention

**Attempt any four questions from Q-2 to Q-8**

**Q-2** **Attempt all Questions:** **(14)**

**a.** Discuss role of quality assurance. **07**
**b.** Discuss the phases of NDA. **07**

**Q-3** **Attempt all Questions:** **(14)**

**a.** What is CTD? Discuss structure of CTD. How does it differ from eCTD? **07**
**b.** Explain the format and type of INDA. **07**

**Q-4** **Attempt all Questions:** **(14)**

**a.** Discuss the role of clinical trials and B.E. studies in a drug discovery **07**
**b.** Write an introductory note on Orange Book. How changes to the orange book can be made? **07**

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| **Q-5** | | **Attempt all Questions:** | **(14)** |
| | **a.** | Write a note on IIG. | **07** |
| | **b.** | Write about GMP audits. | **07** |
| **Q-6** | | **Attempt all Questions:** | **(14)** |
| | **a.** | Explain the concept of ANDA and prepare the flow chart showing ANDA review process. | **07** |
| | **b.** | Explain in detail about Investigator Brochure | **07** |
| **Q-7** | | **Attempt all Questions:** | **(14)** |
| | **a.** | Explain non-patentable inventions as per Indian patent Act. | **07** |
| | **b.** | Define and explain the importance patent search. Discuss the different sources for patent search. | **07** |
| **Q-8** | | **Attempt all Questions:** | **(14)** |
| | **a.** | Write a note on TGA. | **07** |
| | **b.** | Explain various phases of Drug Development and Approval process as per USFDA | **07** |