**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY**

**[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2934**
**(OCTOBER 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-I (PCI New regulations 2016)**
**PHARMACEUTICS - MPH**
**PAPER IV – REGULATORY AFFAIR**
***Q.P. Code : 262934***

**Time : Three hours** **Answer ALL Questions** **Maximum : 75 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. a) Discuss about the Abbreviated NDA approval process.
   b) The Drug Price Competition and Patent Term Restoration Act.

2. Explain about the Institutional Review Board, Independent Ethics Committee & Pharmacovigilance Monitoring in Clinical Trials.

**II. Write notes on:** **(7 x 5 = 35)**

1. CTD for Dossiers.
2. MFR – Master Formula Record.
3. Investigational Brochure (IB).
4. International Conference on Harmonization Efficacy Guideline.
5. Code of Federal Regulation.
6. What are the problems facing by CRO in outsourcing BA and BE.
7. Regulatory requirements of ROW.

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