LL.M/OC/01/004/23

ONE YEAR LL.M. DEGREE FIRST SEMESTER EXAMINATIONS, NOVEMBER, 2023

LAW RELATING TO DRUGS AND CLINICAL TRIALS

TIME: 3 HRS **MAX. MARKS 50**

Answer any 5 question (Each question carries 10 marks)

1. "The Indian pharmaceutical industry has seen a massive expansion over the last few years and is expected to reach about 13% of the size of the global pharma market while enhancing its quality, affordability, and innovation." Give an overview of the pharmaceutical industry in India.
2. Explain the law relating to manufacturing, storage, packaging and transportation of drugs in India
3. "Considering the complexity of the healthcare system in India, concerted efforts from all directions and a multi-pronged approach are needed to usher is the real challenge". Explain the Indian initiatives to ensure safe medicine.
4. The World Health Organization (WHO) recommends that s a limited number of essential medications should be available and accessible to everyone in a healthcare system. What are drugs and essential drugs? Explain the law relating drug pricing in India.
5. Explain the significance of Good Manufacturing Practices, nationally and internationally.
6. Explain the legal and ethical issues involved in clinical trials. What is the law relating to clinical trials in India
7. Explain the impact of digitalization in right to access medicine in India
8. Write Short note on
   i. Central Drugs Laboratory ii. Spurious drugs

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