GUJARAT NATIONAL LAW UNIVERSITY
GANDHINAGAR
Course: **Pharmaceutical Sciences (including Medical devices)**
Semester- IV (Batch: 2018-23)

End Semester Online Examination: February 2021

Date: 12th February, 2021
Duration: 8 hours **Max. Marks: 40**

Instructions:

- The respective marks for each question are indicated in-line.
- Indicate correct question numbers in front of the answer.
- No questions or clarification can be sought during the exam period, answer as it is, giving reason, if any.
- Prescribed Word limit: 500-600 words.

Marks

Q.1 An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Visit FDA website and CDC website to briefly explain how COVID-19 vaccines have been developed. (8)

Q.2 Explain the roles and responsibilities of the CDSCO. (8)

Q.3 Explain the life cycle of medical devices from research and development until regulatory approval. (8)

Q.4 What are the minimum requirements of drug manufacturing units as per "Schedule M" under the Drugs and Cosmetics Act, 1940 and rules there under? (8)

Q.5 Read the following and answer the questions. (1+4+3=8)

This is a case of a 28-year-old male Mr. Y, a Futsal Premier League player in season 2014 – 2015. The player was provisionally banned from the team. He had no history of anti-doping rules violation. He was selected randomly for sampling during a match in mid-2014. His sample was positive for morphine, and it was violation of article 6 of FIFA (The Federation of International Football Association) anti-doping regulations. The player denied using narcotics including morphine in testimony but admitted that he had taken a number of acetaminophen-codeine tablets (300 mg and 10 mg, respectively), the day before match for controlling tooth pain. He did not remember the exact number or the exact time of ingesting the tablets. Codeine is not among the WADA 2015 prohibited list. Disciplinary committee came to a conclusion that the player had not consumed morphine and did not violate doping code based on morphine/codeine ratio.

a) What do you think was the reason for the disciplinary committee's conclusion? (1 mark)

b) Explain the human metabolic enzyme involved in the biotransformation of codeine? What are the clinical implications for patient's (also players) who have deficiency in the activity of this enzyme and are prescribed codeine containing product for analgesia. (4 marks)

c) How can Pharmacogenetic testing play an important role in drug therapy? Name any other drug for which FDA recommends pharmacogenetic testing of patient is required before prescribing the drug. Add a note on the metabolizing enzyme involved in its biotransformation. (3 marks)

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