**PMY8111 Section B Question 2**

**PLEASE STATE YOUR FIVE DIGIT ANONYMOUS CODE:**

Naproxen is a popular nonsteroidal anti-inflammatory drug (NSAID) that is a widely used oral dosage form for mild-to-moderate pain. The chemical structure of naproxen is shown in Figure 1 (pKa = 4.15).

Diagram

Description automatically generated

***Figure 1 Chemical structure of naproxen.***

1. What is the % ionisation of naproxen at pH=5?

[20%]

1. According to the Merck Index, naproxen has a solubility of 0.0159 mg/mL in water and good membrane permeability. The maximum dose of naproxen for adult patients is 500mg (tablet) twice per day. Based on the given information, which BCS class is naproxen? Clearly explain your reasoning.

[20%]

1. Naproxen sodium is a modification of naproxen with greater water solubility at 250 gram/L. Please explain the reason behind the increase in water solubility for naproxen sodium. Also explain how the increased solubility of naproxen sodium would affect the bioavailability of the drug.

[20%]

1. Company A is trying to produce a generic product for naproxen sodium using a wet granulation process. Please explain the potential process-induced phase transformations that can occur and the methods used to characterise them.

[40%]

Please write your answer between the lines above and below this sentence (you may delete this text)

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