Lesson 3.

Task 1.

Oral dosage form of indomethacin (25 mg dosage) has been evaluated. For a more complete assessment of the obtained picture, the calculation of the main pharmacokinetic parameters was carried out by a model-independent method using the Kinetica™ 5 program, the results of which are presented in the table.

Table – Main pharmacokinetic parameters of indomethacin tablet samples compared to the standard oral dosage form of indomethacin (25 mg).

| № | Sample | $C_{max,}$ ug/mL | $T_{max,}$ h | $AUC_{0-24h}$, ug×h/mL | MRT, h |
|---|---|---|---|---|---|
| 1 | **Sample 1** | 2.91 ± 0.13 | 8 | 33.46 ± 1.34 | 9.15 ± 0.39 |
| 2 | **Sample 2** | 0.87 ± 0.02 | 4 | 11.90 ± 0.46 | 9.89 ± 0.42 |
| 3 | **Sample 3** | 2.27 ± 0.10 | 4 | 24.96 ± 1.08 | 20.58± 0.93 |
| 4 | **Sample 4** | 1.62 ± 0.08 | 4 | 19.44 ± 0.76 | 27.57± 1.14 |
| 5 | **Standard dosage form of indomethacin** | 4.45 ± 0.19 | 2 | 23.48 ± 0.84 | 7.34± 0.32 |

Calculate the relative bioavailability for the test samples of indomethacin.

Lesson 2.

Oral dosage form of sodium diclofenac (100 mg dosage) has been evaluated. For a more complete assessment of the obtained picture, the calculation of the main pharmacokinetic parameters was carried out by a model-independent method using the Kinetica™ 5 program, the results of which are presented in the table.

Table – The main pharmacokinetic parameters of the developed dosage forms of diclofenac sodium in comparison with the standard dosage form - Voltaren® retard

| № | Sample | $C_{max}$ (ug/mL) | $t_{max}$(h) | $AUC_{0-\tau}$(ug×h/mL) | MRT (h) |
|---|---|---|---|---|---|
| 1 | Sample 1 | 0.98 | 2 | 16.83 | 9.231 |
| 2 | Sample 2 | 2.43 | 12 | 30.76 | 10.23 |
| 3 | Sample 3 | 3.26 | 4 | 38.84 | 13.99 |
| 4 | Sample 4 | 10.58 | 2 | 30.22 | 9.305 |
| 5 | Sample 5 | 7.56 | 1 | 39.38 | 10.029 |

| № | Sample | $C_{max}$ (ug/mL) | $t_{max}$(h) | $AUC_{0-\tau}$(ug×h/mL) | MRT (h) |
|---|---|---|---|---|---|
| 6 | Sample 6 | 5.36 | 4 | 62.29 | 32.90 |
| 7 | Sample 7 | 8.40 | 8 | 56.05 | 9.78 |
| 8 | Sample 8 | 3.90 | 1 | 30.20 | 30.92 |
| 9 | Sample 9 | 7.17 | 2 | 87.49 | 11.58 |
| 10 | Voltaren® retard | 2.96 | 8 | 39.9 | 13.6 |

Calculate the relative bioavailability for the test samples of diclofenac sodium.