

Bioequivalence Study

A bioequivalence study is a study conducted to show that two medicines, or two different dosages of the same medicine, are equally absorbed after administration and produce the same effect at the required site.

For generic medicinal products, the concept of bioequivalence is fundamental since the bioequivalence with the reference (original) medicinal product must be demonstrated for a generic to be approved. Regulatory authorities evaluate bioequivalence by considering two standards: the rate of absorption and the extent of absorption. If a medicine formulation differs in one or both parameters, the authorities would determine that this medicine is not bioequivalent to the original product.