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*Chapter 3*

# STATISTICAL APPROACHES FOR BIOEQUIVALENCE OF HIGHLY VARIABLE DRUGS AND DRUG PRODUCTS

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## GENERAL BACKGROUND

Bioequivalence studies play a major role in the development of new drugs and in the marketing of generic formulations; such trials also contribute in to access to low-cost and effective medicines in developing countries. At present, with the loss of patents of novel molecules, the difficulty in designing interchangeability trials has increased.

Several factors contribute to the complexity of bioequivalence studies. Some new drugs are more potent, and their concentrations in biological fluids

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