On profile similarity in bioequivalence trials

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Abstract: For a typical bioequivalence trial, a general measure of area under the curve (AUC) is given to compare two formulations of a drug product. Thus we extend the recent method given by Mauger and Chinchilli (2000). For assessing bioequivalence over the entire profile which has a familiar interpretation and represents a compromise between the insensitivity to pattern difference of summary measures and the oversensitivity of pointwise comparisons.

Key words and phrases: clinical trial, area under curve, bioequivalence acceptance regions, test of average bioequivalence

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