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active substance: non-clinical and clinical issues (EMEA/CHMP/BMWP/42832/05 Rev.1) lays down the non-clinical and clinical requirements for a similar biological medicinal product ("biosimilar"). The non-clinical section addresses the pharmaco-toxicological assessment. The clinical section

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Katzung Basic and Clinical Pharmacology by pharmacyStudent on Apr 06, 2015 Book Reviews: The thirteenth edition of Basic & Clinical Pharmacology continues the important changes inaugurated in the eleventh edition, with extensive use of full-color illustrations and expanded coverage of transporters, pharmacogenomics , and new drugs.

### Katzung Basic and Clinical Pharmacology

Statistical Principles of Clinical Trials Lecture Notes (Modified from Dr. A. Tsiatis' Lecture Notes) Daowen Zhang Department of Statistics North Carolina State University c 2009 by Anastasios A. Tsiatis and Daowen Zhang. TABLE OF CONTENTS ST 520, A. Tsiatis and D. Zhang Contents

### ST 520 Statistical Principles of Clinical Trials

GUIDANCE DOCUMENT. Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories October 2014

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