

1. Record Nr.	UNINA9910135046203321
Titolo	Metabolite safety in drug development // edited by Suzanne L. Iverson, Dennis A. Smith
Pubbl/distr/stampa	Hoboken, New Jersey : , : Wiley, , 2016 ©2016
ISBN	1-118-94967-6 1-118-94966-8 1-118-94968-4
Descrizione fisica	1 online resource (350 p.)
Classificazione	SCI013010MED071000
Disciplina	615.1
Soggetti	Drugs - Metabolism Drugs - Safety measures Pharmacology
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	6.3.2 The First Clinical Studies
Sommario/riassunto	"A reference on drug metabolism and metabolite safety in the development phase, this book reviews the analytical techniques and experimental designs critical for metabolite studies. It features case studies of lessons learned and real world examples, along with regulatory perspectives from the US FDA and EMA. ••• •••Reviews the analytical techniques and experimental designs critical for metabolite studies ••••••••••Covers methods including chirality, species differences, mass spectrometry, radiolabels, and in vitro / in vivo correlation ••••••••••••••••Discusses target pharmacology, in vitro systems aligned to toxicity tests, and drug-drug interactions ••••••••••••••••Includes perspectives from authors with firsthand involvement in industry and the study of drug metabolites, including viewpoints that have influenced regulatory guidelines"-- "This book focuses on the characterization of metabolites once a drug candidate is selected, featuring case studies to illustrate lessons learned and a perspective on future directions"--

