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Nota di contenuto	Part I. General chapters -- Accelerated predictive stability: an introduction -- Regulatory expectations and industry practice on stability testing -- Theory and fundamentals of accelerated predictive stability (APS) studies -- Practical considerations -- The humidity exposure of packaged products -- Data evaluation and statistical methods -- Strategies for improving the reliability of accelerated predictive stability (APS) studies -- Integration of APS into a rapid, early clinical drug product development paradigm -- Accelerated predictive stability (APS) regulatory strategies -- Embedding APS within business -- Implementing an accelerated predictive stability program -- Part II. Industry practices -- Accelerated stability assessment program (ASAP) applications in a postapproval environment -- ASAP application: unstable drug candidate in early development -- ASAP application in suspension, liquid, lyophilized, and controlled-release drug products -- Applications of ASAP to generic drugs -- ASAP application: nicotine lozenges -- ASAP applications in clinical development: prediction of degradation and dissolution performance -- Accelerated predictive stability (APS) applications: packaging strategies for controlling dissolution performance -- Accelerated stability modeling: investigation of disintegration time of a drug product with sodium bicarbonate -- Accelerated stability modeling: an ionic liquid drug product -- Accelerated stability modeling: assay loss of nicotine

	lozenges -- Accelerated stability modeling: desolvation of a solvate drug product.
Sommario/riassunto	"Accelerated Predictive Stability (APS): Fundamentals and Pharmaceutical Industry Practices provides coverage of both the fundamental principles and pharmaceutical industry applications of the APS approach. Fundamental chapters explain the scientific basis of the APS approach, while case study chapters from many innovative pharmaceutical companies provide a thorough overview of the current status of APS applications in the pharmaceutical industry. In addition, up-to-date experiences in utilizing APS data for regulatory submissions in many regions and countries highlight the potential of APS in support of registration stability testing for certain regulatory submissions. This book provides high level strategies for the successful implementation of APS in a pharmaceutical company. It offers scientists and regulators a comprehensive resource on how the pharmaceutical industry can enhance their understanding of a product's stability and predict drug expiry more accurately and quickly. Provides a comprehensive, one-stop-shop resource for accelerated predictive stability (APS). Presents the scientific basis of different APS models. Includes the applications and utilities of APS that are demonstrated through numerous case studies. Covers up-to-date regulatory experience"--