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combination products are therapeutic and diagnostic products that combine drugs devices and or biological products according to the us food and drug administration fda a combination product is one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products this handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market the authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices this handbook brings clarity of understanding for global combination products guidance and regulations reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market reviews medical product classification and assignment issues faced by global regulatory authorities and industry the editor is a recognized international combination products and medical device expert with over 35 years of industry experience and has an outstanding team of contributors endorsed by aami association for the advancement of medical instrumentation

specification of drug substances and drug products is a fully comprehensive reference on specification setting for pharmaceuticals there have been several recent developments in the ich guidelines which were not captured in previous editions notably the new guideline on development of analytical procedure and the revisions to the validation guidelines and the specification guidelines this edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mrna based products this substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products presents critical assessment potential impact and application of the recent revisions to ich guidelines on method validation q2 as well as the latest guideline on analytical method development q14 and the special regional requirements in non ich regions addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nrna based drugs vaccines and gene therapy this book will also address drug device combinationproducts such as digital drug delivery systems transdermal systems and inhalation products presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data

when a synthetic chemical is released into the environment it may be degraded by abiotic and biotic processes these degradation processes usually involve a cascade of reactions resulting in the formation of a number of transformation products while we usually know a great deal about the environmental properties fate and effects of parent synthetic chemicals our understanding of the impacts of transformation products is much less developed as such this volume brings together chapters from leading researchers in the field of transformation products in the environment and describes how these products are formed how they move through the environment and their environmental effects the book also presents modelling and analytical approaches for understanding the occurrence fate and effects of transformation products in the environment it is of interest to scientists in academia the chemicals industry and regulators as well as graduate students in environmental chemistry and ecotoxicology

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