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| 1. Record Nr.           | UNINA9910141229603321  |
| Titolo                  | Analysis of aggregates and particles in protein pharmaceuticals<br>[[electronic resource] /] / edited by Hanns-Christian Mahler, Wim Jiskoot   |
| Pubbl/distr/stampa      | Hoboken, N.J., : John Wiley & Sons, Inc., 2012   |
| ISBN                    | 1-283-40104-5<br>9786613401045<br>1-118-15056-2<br>1-118-15057-0<br>1-118-15054-6  |
| Descrizione fisica      | 1 online resource (474 p.)   |
| Altri autori (Persone)  | MahlerHanns-Christian<br>JiskootWim  |
| Disciplina              | 615.1/9  |
| Soggetti                | Pharmaceutical chemistry<br>Protein drugs - Analysis   |
| 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.   |
| Nota di contenuto       | The critical need for robust assays for quantitation and characterization of aggregates of therapeutic proteins -- Separation based analytical methods for measuring protein aggregation -- Laser light scattering-based techniques used for the characterization of protein therapeutics -- Online detection methods and emerging techniques for soluble aggregates in protein pharmaceuticals -- Analytical methods to measure sub-visible particulates -- Detection of visible particles in parenteral products -- Characterization of aggregates and particles using emerging techniques -- Ultraviolet absorption spectroscopy -- Fluorescence spectroscopy to characterize protein aggregates and particles -- Infrared spectroscopy to characterize protein aggregates -- Raman microscopy for characterization of particles -- Microscopic methods for particle characterization in protein pharmaceuticals -- Comparison of methods for soluble aggregate detection and size characterization -- Protein purification and its relation to protein aggregation and particles -- Formulation development and its relation |

to protein aggregation and particles.

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#### Sommario/riassunto

This book describes how to address the analysis of aggregates and particles in protein pharmaceuticals, provides a comprehensive overview of current methods and integrated approaches used to quantify and characterize aggregates and particles, and discusses regulatory requirements. Analytical methods covered in the book include separation, light scattering, microscopy, and spectroscopy.

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