1. Record Nr. UNINA9910349449203321

Titolo	The Role of Microstructure in Topical Drug Product Development / / edited by Nigel Langley, Bozena Michniak-Kohn, David W. Osborne
Pubbl/distr/stampa	Cham : , : Springer International Publishing : , : Imprint : Springer, , 2019
ISBN	3-030-17355-0
Edizione	[1st ed. 2019.]
Descrizione fisica	1 online resource (207 pages)
Collana	AAPS Advances in the Pharmaceutical Sciences Series, , 2210-7371 ; ; 36
Disciplina	615.19
Soggetti	Pharmaceutical technology Pharmacy Pharmaceutical Sciences/Technology
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Nota di contenuto	Part I - Critical Quality Attributes: 1. Rheological Characterization in the Development of Topical Drug Products -- 2. In Vitro Release & Permeation Tests as Critical Quality Attributes in Topical Product Development -- 3. Determination of Particle Size and Microstructure in Topical Pharmaceuticals -- Part II - Role of API and Excipients: 4. Quality Assessment of API in Semisolid Topical Drug Products -- 5. The Role of Excipients in the Microstructure of Topical Semi-solid Drug Products.
Sommario/riassunto	Following the Semi-solid Microstructure Workshop sponsored by BASF and hosted by the Rutgers Center for Dermal Research, a pharmaceutical product development working group was formed. The group, known as the Q3 Working Group, selected the following five areas of focus: Particle/Globule Size and Distribution, Viscosity/Rheology/Spreadability, In Vitro Testing, State of API, State of Excipients. A committee was appointed for each of these five areas. The committees were tasked to review the literature, identify best practices, list experimental details required for an independent lab to duplicate the test, and propose scientific studies that may meaningfully advance this specific area of focus. Each committee has a chair (or co-chairs) that are the lead author(s) of the chapter. The Q3 Working Group

members serve as the critical reviewers of each chapter, making suggestions that improve the quality of the document and that make each of the five chapters uniform in scope and content. Pharmaceutical development scientists that formulate topical products (creams, lotions, gels suspensions, foams, etc) and all the allied raw material suppliers, packaging suppliers, contract laboratories including CROs, CMOs and regulators need access to this book. Overall, the topic of semisolid microstructure is of equal importance to the generic pharmaceutical companies (filing Abbreviated New Drug Applications or ANDAs) and pharmaceutical companies filing New Drug Applications (NDAs). In addition to products applied to the skin, hair, and nails, The Role of Microstructure in Topical Drug Product Development crosses over and is essential reading to developers of oral suspensions, ophthalmic ointments and gels, otic suspension, vaginal semisolids and retention enemas. .