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Autore	Levin, Harry
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Collana	Harvard studies in comparative literature ; 22
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Descrizione fisica	1 online resource (315 pages)
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## Sommario/riassunto

"In the mid 1960s people realized that drug dissolution/release has a significant impact on the therapeutic effect of orally administered drugs. Both the United States Food and Drug Administration (FDA) and United States Pharmacopoeia introduced dissolution requirements for oral drug products and the first dissolution tests became a quality control (QC) tool to ensure batch-to-batch consistency. As a consequence, from the 1970s on, several dissolution test methods were adopted as official QC methods for solid oral dosage forms. In the late 1990s, the increasing number of official dissolution apparatus and dissolution methods in the USP was complemented by the release of various FDA guidances pertaining to in vitro dissolution testing of solid oral dosage forms and its application from a regulatory point of view. Since then dissolution/drug release testing has expanded considerably with a variety of apparatus and methods in international pharmacopoeia and numerous international guidances and nowadays not only addresses questions of quality control but also plays an important role in screening of formulations and is also an important tool in proving bioequivalence of different drug products"--

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