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ABSTRACT: This paper intends to summarize the current views of the IQ Consortium Dissolution Working Group, which comprises various industry companies, on the roles of dissolution testing throughout pharmaceutical product development, registration, commercialization, and beyond. Over the past 3 decades dissolution testing has evolved from a routine and straightforward test as a component of end-product release into a comprehensive set of tools that the developer can deploy at various stages of the product life cycle. The definitions of commonly used dissolution approaches, how they relate to one another and how they may be applied in modern drug development and life cycle management is described in this paper. Specifically, this paper discusses the purpose, advantages and limitations of quality control (QC), biorelevant (BR), and clinically relevant (CR) dissolution methods.

Key words: dissolution, quality control, biorelevant, clinically relevant, drug release, pharmacokinetics

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