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## *The Scope of Preformulation Studies*

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I didn't know of any homophile movements pre-Stonewall.

Sean Maher

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### **3.1 Introduction**

A detailed understanding of the properties of the drug substance is essential to minimize formulation problems in later stages of drug development, reduce drug development costs, and decrease the product's time to market (i.e., from drug substance to drug product). The goals of preformulation studies are to choose the correct form of the drug substance, evaluate its physical properties, and generate a thorough understanding of the material's stability under the conditions that will lead to development of an optimal drug delivery system. This chapter examines the continuously evolving scope of preformulation studies. These changes are driven by three forces: the regulatory requirements, the market requirements, and the technological development. However, prior to reviewing the various requirements that determine the scope of preformulation studies, it is important to review how the drug discovery models are rapidly changing and why there is a need for not just one but several levels of preformulation studies.

New drugs are discovered through serendipity, by chemical synthesis, by extraction from natural sources, or more recently through biotechnology processes. The drug discovery is rarely a linear process, and the many probes involved often run concurrently. [Chapter 1](#) described in detail the various phases and stages of development. Although the industry has developed its own jargon about preclinical phases and clinical phases, the entire process of development goes through a highly orchestrated undertaking that requires very close association among all groups.

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### **3.2 Preformulation Testing Criteria**

The classical preformulation studies include the physicochemical characterization of the solid and solution properties of compounds that would be useful in formulating the drug into a suitable delivery system. It is in this critical decision-making about what constitutes the "suitable" that many a lead compound falls through. A good pharmacological and toxicological profile alone does not suffice. The drug delivery system must be able to take the molecules to the site of action at a cost and convenience commensurate with the treatment trends. An excellent remedy for headache