18 *In Vitro* Release from Semisolid Dosage Forms
What Is Its Value?

Vinod P. Shah
VPS Consulting, LLC, North Potomac, Maryland

CONTENTS

18.1 INTRODUCTION

A key aspect of any new drug product is its safety and efficacy as demonstrated in controlled clinical trials. The time and expense associated with such trials make them unsuitable as routine quality control methods to reestablish comparability in quality and performance following a change in formulation or method of manufacture. Therefore, in vitro and in vivo surrogate tests are often used to assure that product quality and performance are maintained over time. The focus of this chapter is the application of in vitro release (IVR) approaches in the documentation of the performance of semisolid dosage forms. In vitro approaches, such dissolution, are standard methods used to assess performance characteristics of a solid oral dosage formulation. It has evolved as a critical test method in the field of drug development. In vitro dissolution is used specifically to guide formulation development, monitor manufacturing process, ensure batch-to-batch quality, and possibly predict in vivo performance. When used as a quality control procedure, in vitro dissolution testing can signal an inadvertent change in drug and/or excipient characteristics or in the manufacturing process. Dissolution tests are used to provide a biowaiver for drug products containing highly soluble, highly permeable drug substances with rapid dissolution characteristics (Biopharmaceutics Classification System [BCS]) and for lower-strength dosage forms under certain conditions. Extension of in vitro dissolution methodology to semisolid dosage forms (topical dermatological drug products such as creams, ointments, gels, and lotions) has been the subject of both substantial research efforts and debate. A simple, reliable, reproducible, relevant, and generally acceptable in vitro method to assess drug release from a semisolid dosage form is highly valuable for the same reasons that such methodology has proved valuable in the development, manufacture, and batch-to-batch quality control of solid oral dosage forms. The quality control tests for semisolid dosage forms include identification, assay, strength,