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## **Practical Considerations for Topical Drug Formulations With and Without Enhancers**

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### I. INTRODUCTION

The purpose of topical dosage forms is to conveniently deliver drugs across a localized area of the skin. To develop an ideal dosage form one must take into account the flux of drug across skin, retention of the dosage form on the skin's surface, the reservoir capacity of the dosage form, and the patients' acceptability of the formulation. The problem of formulating a drug is complex because of the wide diversity of drug solubility in vehicle components and the vast range in cutaneous fluxes (six orders of magnitude).

The objective of this chapter is to simplify and make more efficient the development of optimum topical dosage forms. There is always a certain amount of empiricism to this process, but a strategy based upon fundamental principles of thermodynamics and diffusion can greatly reduce the time required to develop good topical dosage forms. Another topic to be addressed in this chapter is how to compare two different topical dosage forms. In some organizations, physical and chemical stabilities, plus the formulator's opinion of aesthetics, are all that is required of a formulation. The science and technology available today make this approach obsolete, and one must have a quantitative measure of delivery to develop a competitive topical dosage form.

### II. VEHICLE DESIGN

#### A. General Considerations

The purpose of dissolving a drug in a solvent or mixture of solvents is to facilitate the transport of drug to the surface of the