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# In Vitro Testing of Topical Pharmaceutical Formulations

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## I. INTRODUCTION

The development of dermatological and transdermal drugs requires knowledge of the percutaneous permeation (local skin) and absorption (systemic) of the drug. The ultimate in both relevance and cost is in vivo human testing. To retain relevance, but compromise on cost, alternate test procedures are desired. One of these procedures is in vitro skin absorption using diffusion cells. A recent report (1) attempted to define principles and practices related to in vitro percutaneous penetration studies. This chapter will discuss and elaborate on those procedures and principles as they apply to drug testing in our laboratory.

We hold only one principle that relates to in vitro skin absorption studies: the system is artificial and subject to all variabilities of its parts. Relevance must be reserved until in vivo (preferably human) testing is done. On this principle, we build our in vitro studies.

We also offer an alternative study design for in vitro skin absorption drug screening that has proved valuable, especially for hydrophobic compounds that will not partition into reservoir fluid.

The information that follows is a small part of in vitro percutaneous absorption. The reader is referred to the fine work of Robert Bronaugh on in vitro percutaneous absorption (2).

## II. BASIC STUDY DESIGN

Table 1 gives the basic study design that we approach with in vitro absorption studies. We believe that