Table 11.1 In Vitro Study Design

Human skin source	Number of replicates	
	Formulation 1	Formulation 2
A	4	4
B	4	4
C	4	4
Total	12	12

Assay: Reservoir fluid
Skin
Skin surface wash
Apparatus wash
Material balance

1. All formulations should be compared within the same skin samples.
2. Variability exists between skin sources, and thus a minimum of three skin sources is desired.
3. Reservoir fluid, skin, skin surface wash, and apparatus wash should be assayed for material balance.

Obviously, the abbreviated study design depicted in Table 1 will not meet all needs. However, it will avoid pitfalls of human skin variability, and the material balance is a check on scientific quality. In addition, as will be discussed later in this chapter, assay of chemicals within skin may be a viable alternative when solubility in reservoir fluid is a problem.

III. FACTORS

A. Membranes

The literature is full of reports showing that skin absorption is different in most animals than in humans (Table 2; 3). Human skin is available, so it should be the membrane of choice.

Human skin should be used as soon as possible. Obviously, freshness is best. Reports suggest that the freezing of skin changes its permeability characteristics. If skin metabolism data are warranted, then appropriate procedures and verifications are warranted.