the following sections, the robotics techniques required to complete each of these steps will be considered in detail. The discussion will be general enough to be applicable to any of the commercially available systems, but specific enough to be used as a guide for automation of the sample preparation required for establishing compositional ranges before formulation optimization.

1. Determination of Compositions to be Mixed

Successful preliminary formulation selection is dependent upon various factors: (1) the robotics system must be able to adequately dispense, process (mix), and evaluate the stability of each sample prepared; (2) the formulation should be as simple (i.e., contain as few components) as possible; (3) the formulation should consist of readily available raw materials that are as chemically pure as possible; (4) the attributes of the formulation that are important for consumer acceptance of the eventual product must be clearly defined and accommodated; and (5) manufacturability of the scaledup formulation must be considered. Once a preliminary formulation is selected, the components can be separated into two groups. The first grouping is for materials that will be used at a preset concentration, regardless of other formulation changes that may occur because of optimization. Concentrations of the active component, preservative, and fragrance may be examples of materials that will be added in small amounts, or over narrow ranges and, thus, are included in this first grouping. The second material group is for those components that may be used over a wide range of concentrations. Examples of this group of materials for topicals would usually include water and other excipients. The concentration ranges forming homogeneous phase regions for this second group of materials will provide the framework of the phase behavior studies. It is hoped that no more than three to five of the components will fall into this second material group.

Next, each of the components falling in this second grouping are divided into polar materials, nonpolar materials, and other materials. This allows pseudoternary diagrams to be constructed. If only two of the foregoing divisions of polarity exists, then a binary diagram may be more appropriate. Five weight percent increments of the component compositions is usually sufficient to obtain a rough diagram that can then be refined along the phase boundaries.

An example of this procedure for a hypothetical system should clarify the steps in determining the compositions to be mixed. The preliminary formulation selected is a cream consisting of 5% to 15% active (oil soluble), 6% emulsifier, 11% coemulsifier, 15% oil, 8% glycerin, and q.s. with water containing the preservative. Glycerin and water are the polar materials, the oil is nonpolar, and the emul-