conventional dosage forms. Efficacy, safety, scaleup, stability, raw materials supply and purity, process control, and validated analytical methods must all be achieved. Selected parameters that are germane to formulating with liposomes will be noted in the following section.

A. Vehicle Selection for the Active Ingredient

An active ingredient can be situated in the aqueous compartments, hydrophobic phase, or oriented at the water–bilayer interface. The selection of the appropriate liposome vehicle (MLV, SUV, or other) should be based on a careful analysis of the physical properties of the drug and its tendency to associate with the lipid components. Additional factors, such as buffer composition, pH, ionic strength, and lipid composition, all will influence the distribution of active ingredient. Cost of goods is also germane when selecting a liposome vehicle. A very costly, water-soluble ingredient may require maximum captured volume of the formulation. A process that results in an LUV to OLV preparation should be employed. However, MLVs are more cost-effective at incorporating lipophilic active ingredients at considerable savings, because a simpler process can be used and a clean up step to remove unincorporated drug may be omitted.

B. Process Selection

Liposomes have their own unique problems of scaleup and process control. These are concerned with adequate supplies of phospholipid raw materials, lipid hydration to achieve the desired capture volume and particle size, use of pharmaceutically acceptable organic solvents, removal of solvents (organic phase addition–removal processes; 22) or detergent (detergent dialysis; 20), and clean up of unentrapped drug.

Selection of a process should be based on the solubility properties of the drug in aqueous solution and appropriate solvents, the liposome / buffer partition coefficient, and the required percentage entrapment or incorporation.

Topical liposome formulations have the advantage of not requiring the stringent particle size specifications of parenteral products. If liposome size or heterogeneity does not affect in vivo performance, the specifications can be kept quite broad and the process simplified considerably.

C. Characterization

The characterization of bulk properties of liposome formulations, such as color, pH, rheology, are very similar to those commonly employed for other types of dispersions and suspensions.