**437p Adapting Traditional Microemulsion Phase Behavior Techniques to Pharmaceutical Formulation**

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The phase behavior of many polar oil-surfactant mixtures appropriate for liquid encapsulation is generally unavailable. Establishing the phase behavior of these systems identifies carrier compositions that are physically stable and also represents an initial step towards understanding how these carriers may behave in vivo. This presentation examines the phase behavior of medium chain mono, di, and triglycerides with Polysorbate 80 and water.

The phase behavior measurements were made by visual observation using a thermostated water bath. Crossed polarizers were used to examine structures that appeared crystalline. Pseudo-binary and ternary systems were studied as a function of temperature. “Pseudo” is used here to denote the use of fractionated polar oils as a single component—these materials are actually mixtures and not pure components.

Many of the binary systems investigated exhibited crystallization at moderate and low temperatures over wide concentration ranges. A surprising miscibility gap with a lower consolute critical temperature was discovered in binary mixtures of medium chain triglycerides and Polysorbate 80 at low surfactant concentrations. The same miscibility gap did not appear in a similar system containing medium chain mono and diglycerides with Polysorbate 80. The evolution of this miscibility gap was systematically studied as a function of the polar oil composition (mono, di, and triglyceride content).

The behavior of these oils with Polysorbate 80 displays striking similarities to that of water and Polysorbate 80 (e.g., lower consolute temperature at low surfactant concentration). Phase behavior measurements clearly define compositional regions that are physically unstable and unsuitable for formulation in addition to providing insight into the potential physical instability of formulations as a function of temperature and/or compositional changes.