TF Instruments

Publication on the Rapid Prediction of Nano-Emulsion Stability using Ultrasonic Resonator Technology

Monmouth Junction, New Jersey April 20th, 2007: TF Instruments Inc. the developer of Ultrasonic Resonator Technology (URT) today announced the publication of a paper with the Division of Product Quality Research of the Center for Drug Evaluation of the US Food and Drug Administration (CDER-FDA). The paper, entitled: "Quality by Design: Characterization of Self Nano-Emulsified Drug Delivery Systems (SNEDDs) using ultrasonic resonator technology", was accepted by the peer-reviewed *International Journal of Pharmaceutics*.

Characterization of formulation stability is a key step in the design of safe, stable, and effective drugs. Since current analytical techniques often lack sufficient resolution or require dilution of the drug, URT and the *ResoScan™ Research System* were evaluated as analytical tools to predict stability of nano-emulsions and determine the influence of composition on formulation stability. The benefits of the *ResoScan™ Research System* include the abilities to measure from low to high concentration, rapid analysis and high resolution combined with low sample consumption.

The authors investigated the formation of stable Cyclosporine A containing SNEDDs. In particular, the influence of oil, surfactant and co-surfactant ratio was analyzed with respect to particle stability. The results suggest that the prediction of optimal ratios of components for stable SNEDDs is possible. Moreover, quality of nano-emulsion preparation may be rapidly controlled using URT.

Richard G. Morris, CEO of TF Instruments, Inc, commented: "this publication confirms the potential of URT to contribute to the new *Quality-by-Design* initiative of drug regulators. It is an important step in establishing the *ResoScan™ Research System* as important analytical tool in the pharmaceutical industry for both research and quality control."

About TF Instruments

TF Instruments is a recognized leader for the Ultrasonic Resonator Technology; a fundamental ultrasound based analytical methodology for the physical characterization of aggregation, phase transitions and concentration in pharmaceutical and chemical samples. Among other applications, URT and the *ResoScan™ Research System* have recently

been adopted for the physical characterization of nano-particle and nano-emulsions and other drug delivery systems. The Company maintains offices near Princeton, NJ, USA and in Heidelberg, Germany. More information can be found at www.tf-instruments.com.

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