

FDA Procedures for Standardization of Retail Food Safety Inspection Officers

U.S. Public Health Service



Procedures Manual

*Updated to the 2013 FDA Food Code and
The Supplements to the 2013 Food Code*

**U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
College Park, MD 20740**

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Roseann B. Termini

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practical methods and regulatory considerations pertaining to formulations development with poorly water soluble molecules A pharmaceutical scientist's approach toward solubility enhancement of a poorly water soluble molecule typically includes detailed characterization of the compound's physiochemical properties solid state modifications advanced formulation design non conventional process technologies advanced analytical characterization and specialized product performance analysis techniques The scientist must also be aware of the unique regulatory considerations pertaining to the non conventional approaches often utilized for poorly water soluble drugs One faced with the challenge of developing a drug product from a poorly soluble compound must possess at a minimum a working knowledge of each of the above mentioned facets and detailed knowledge of most In light of the magnitude of the growing solubility problem to drug development this is a significant burden especially when considering that knowledge in most of these areas is relatively new and continues to develop

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