

# *Advanced Technologies and Evolving Paradigms: Characterization of Topical Semisolid Dosage Forms*

*FDA Regulatory Updates for Topical Drug Products*  
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# Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

# What are Topical Products?



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Ointment



Gel



Lotion



**Bright field micrographs of metronidazole crystal structures formed after drying from a solution, or from the reference listed drug (RLD) MetroGel® on either a glass slide or on human skin**

# Characterization of Topical Products

1. Characterization of appearance and texture
2. Characterization of phase states
3. Characterization of structural organization of matter
4. Characterization of polymorphic form of the active ingredient
5. Characterization of rheological behavior
6. Characterization of water activity and/or drying rate
7. Characterization of pH and buffering
8. Characterization of oleaginous components
9. Characterization of specific gravity
10. Characterization of metamorphosis-related changes



# Characterization - **Single** Phase Systems

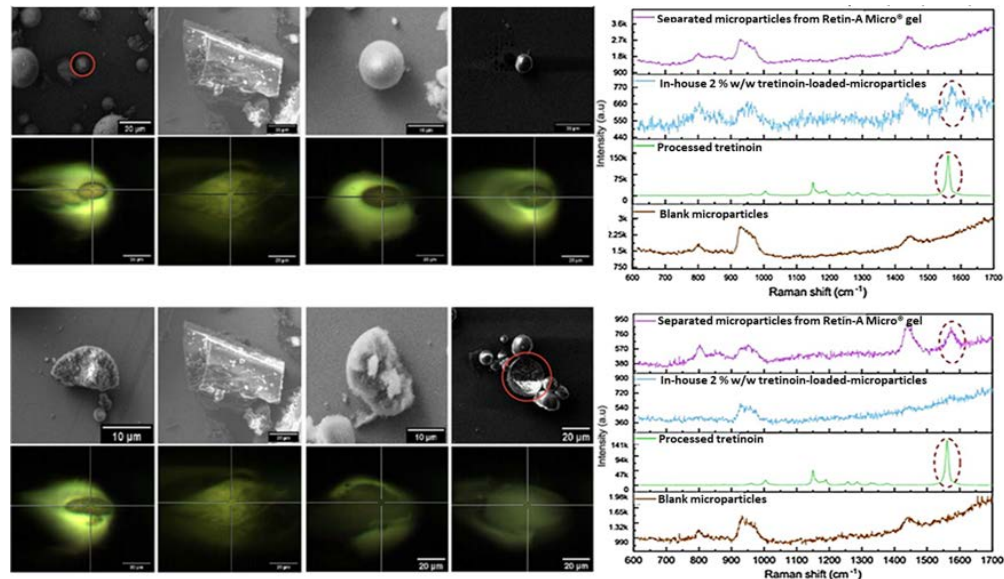
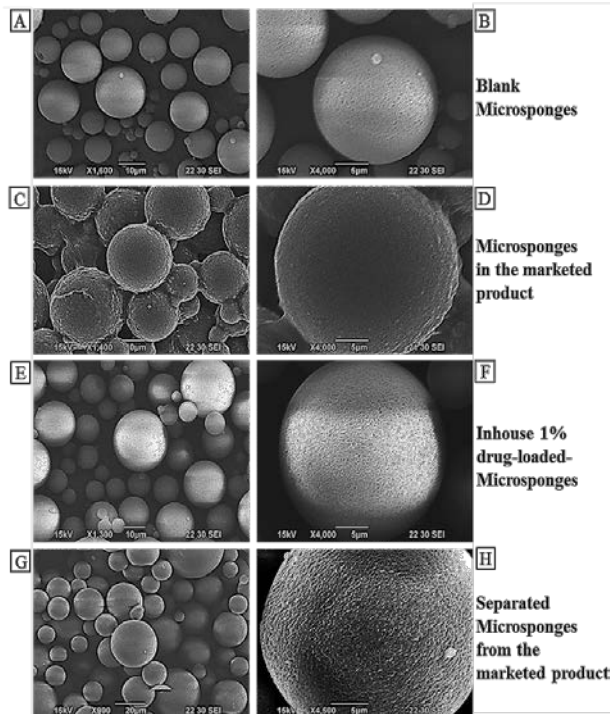
- *Visual Appearance*
- *Microscopy*
- *Particle size*
- *Polymorphic form*
- *Drying rate (weight loss)*
- *Specific gravity*
- *Rheology*
- *pH*
- *Etc.*



# Characterization- **Multi** Phase Systems

- *Appearance*
- *Microscopy*
- *Particle size*
- *Polymorphic form*
- *Drying rate*
- *Specific gravity*
- *Rheology*
- *pH*
- ***Water activity***
- ***Globule size***
- ***Impact of container closure system***
- ***Etc.***

# Characterization- Unique Microstructure



In-SEM SCA Raman analysis of Microsponges® at the surface and inside broken Microsponges®.



# Summary

- Topical dermatological drug products are generally complex dosage forms
- Drug product characterization data can enhance our understanding of the drug product microstructure and thereby facilitate the development of topical drug products for its intended purpose
- Goal of the GDUFA regulatory science research program is to facilitate the development of strategies that can be utilized as a tool to facilitate drug development and/or assess bioequivalence

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