Exploring Topical Semisolid Microstructure

Topical microstructure is the microscale organization of matter in semisolid formulations such as creams, ointments, and gels. Driven by the selection of excipients, amount of excipients, quality of excipients, and processing parameters, the resulting microstructure has an impact on critical quality attributes and product performance. To keep up with the changing regulatory environment, it is crucial that both generic and pharmaceutical formulators understand the role of microstructure to enhance topical formulation bioavailability and stability.



Study Design

One brand and three generic clotrimazole 1% creams were identified for microstructure evaluation. The four clotrimazole creams were composed of the same listed excipients. Lots expiring within two months of one another were chosen to minimize microstructural differences resulting from various stages of product degradation. Following an equilibration period, the creams were imaged using bright field and polarized light microscopy under 100x magnification to evaluate the presence of microstructural differences.



Macrostructure images of brand (A) and generic (B, C, & D) clotrimazole creams.



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Results

While the four studied creams appeared to be macroscopically similar, the three generic clotrimazole creams were found to exhibit distinct microstructural differences in comparison to the reference listed drug.



Brand (A1) and generic (B1, C1, & D1) clotrimazole creams imaged under bright field microscopy at 100x magnification.



Brand (A2) and generic (B2, C2, & D2) clotrimazole creams imaged under polarized light microscopy at 100x magnification.

Conclusion

Excipients and processing methods play key roles in topical microstructure. As the regulations surrounding the role of microstructure in topical drug product development continue to change, a deep understanding of this continually developing science is imperative. BASF provides in-depth expertise to support Q1, Q2, and Q3 microstructure evaluations to assist with the optimization of critical quality attributes and product performance.

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