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"Troubleshooting and trouble avoiding for topical semi-solid formulations"

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ABSTRACT For topical semi-solid formulations, it is not uncommon for troubleshooting needs to arise late in development or after commercialization. This can be due to chemical or physical instability, insufficient robustness, scale-up and manufacturing issues, or excipient quality and variability. The reasons for this can be explained by the often complex nature and thermodynamic instability of the systems, the use of complex excipients, and the fact that the active ingredients are typically present in a dissolved state, resulting in a higher risk of chemical degradation. In addition, the development of topicals is often still based on empirical approaches that lead to a poor understanding of the product. The goal of troubleshooting is typically to make as few changes to the product as possible. However, sometimes problems cannot be solved without significant changes. As a result, costly and time-consuming activities may be required: in late clinical development, stability studies or even clinical trials may need to be repeated. Post-approval changes may require extensive studies to demonstrate equivalence to the original product.

I will present typical examples of troubleshooting problems for commercial semi-solids and systematic approaches to their resolution. In addition, it will be shown how rational design approaches, based on a systematic understanding of the underlying thermodynamic and physicochemical principles, drastically reduce the risk of needing to troubleshoot later in development and during commercialization.