

In-use Stability and Compatibility Studies

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Abstract

In-Use Compatibility and Stability Studies will be discussed with a major focus on biologics. The topics at the roundtable will be centered on key quality attributes and risk factors that impact the in-use stability period: for example, the number of subvisible particles, microbial challenge data, extractable & leachables of off-the-shelf ancillary components (IV bags, IV lines, syringes, etc), and different routes of administration.

Discussion Questions

- What is your company's overall approach to any of these topics?
- What general questions have you received from Authorities (HAs) globally regarding any of these studies?
- What are other scientifically-sound approaches that you may use to support your in-use stability regarding any of these topics?
- What country-specific requirements impact your company's in-use study design and filing strategy?
- For products recommended for "immediate use", where in-use stability period is 4 hours or less, does your company perform the microbial challenge studies and file the microbial challenge data?
- Are companies generally following the guidance provided in the PDA paper or the FDA guidance, or are they adopting a different approach?
- PDA Journal of Pharmaceutical Science and Technology October 2023, pdajpst.2022.012806; DOI: <https://doi.org/10.5731/pdajpst.2022.012806> (Best Practices for Microbial Challenge In-use Studies to Evaluate the Microbial Growth Potential of Parenteral Biological Products; Industry and Regulatory Considerations)