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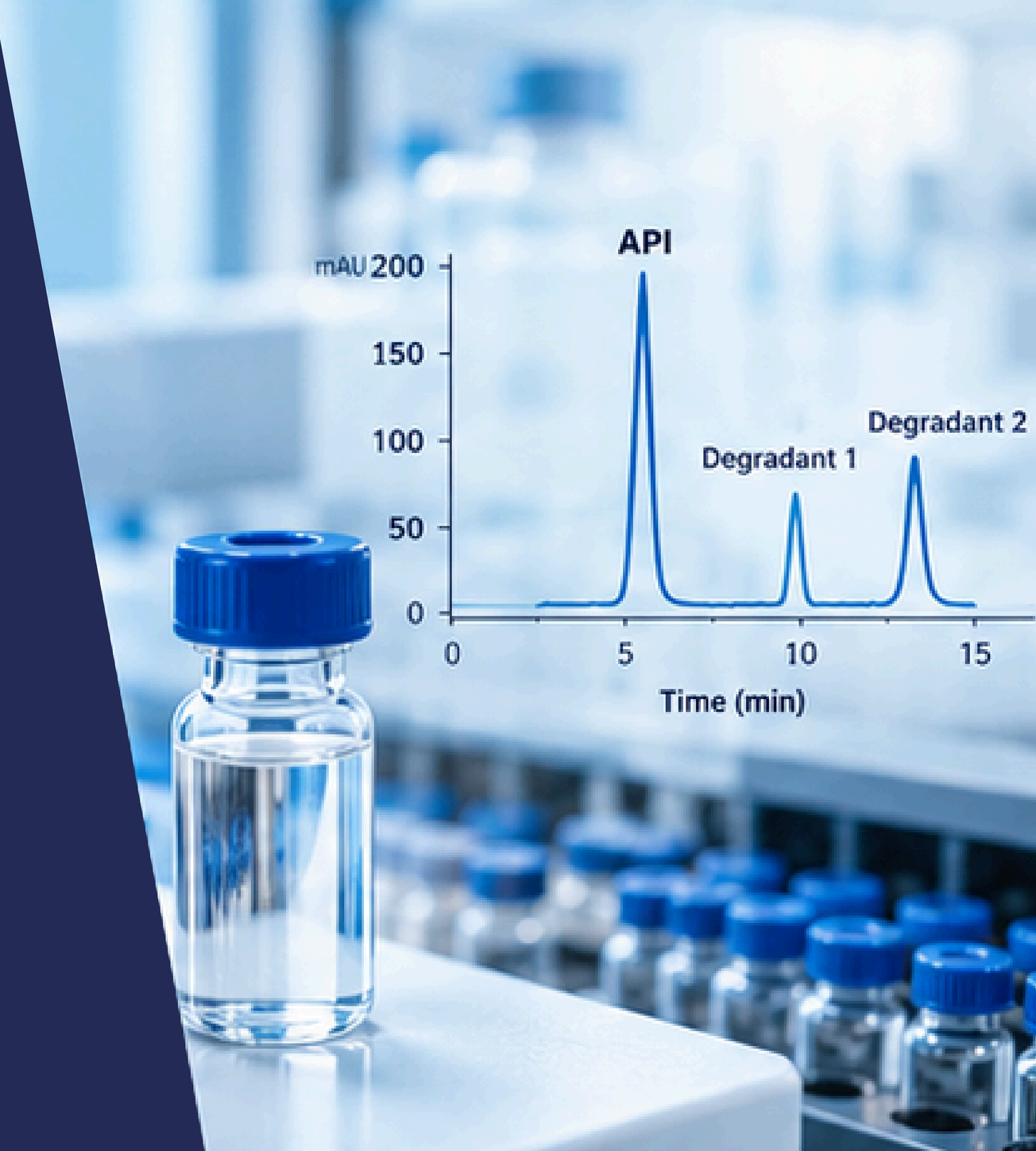
Stability-Indicating Methods vs. Solution Stability

Two different questions
behind reliable analytical results.

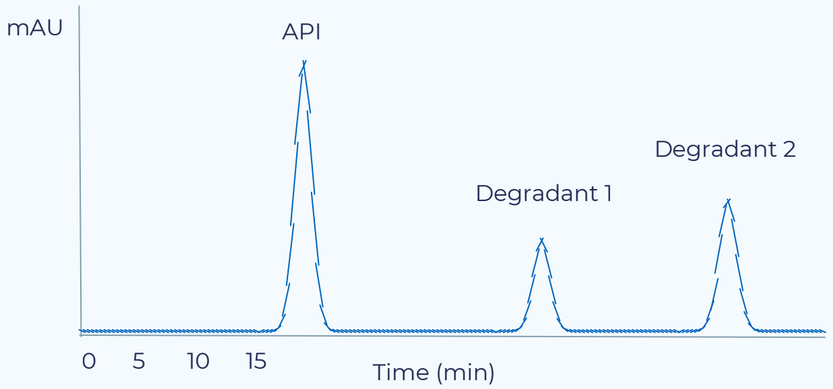


Two Different Assessments

A **stability-indicating method** demonstrates that the analyte can be measured specifically in the presence of relevant degradation products, process impurities, excipients, and other potential interferences. **Solution stability** establishes the period during which prepared samples and standards remain suitable for analysis under defined storage and handling conditions.

01 Stability-Indicating Method (SIM)

Can the analytical procedure distinguish the target analyte from relevant degradation products and other potential interferences?



- ✓ Assess specificity against relevant degradation products and interferences.
- ✓ Use forced-degradation studies to support specificity, as appropriate.
- ✓ Demonstrate reliable analyte measurement in the presence of relevant degradation products.

02 Solution Stability

Does the analyte remain sufficiently stable in prepared samples and standards under defined conditions throughout the intended analytical period?



Sample preparation



Storage and handling



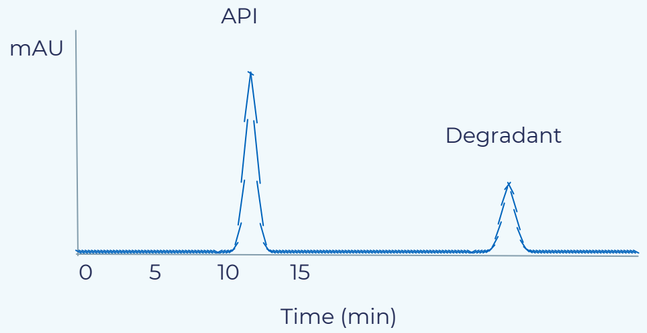
Sample Analysis

- ✓ Assess relevant storage and handling conditions.
- ✓ Establish justified solution hold times using appropriate data.
- ✓ Consider autosampler conditions and analytical sequence duration.

A Reliable Method Cannot Compensate for an Unstable Sample

Changes in analytical results may reflect product degradation, instability of the prepared sample, or other analytical factors. Distinguishing these possibilities is essential for reliable interpretation.

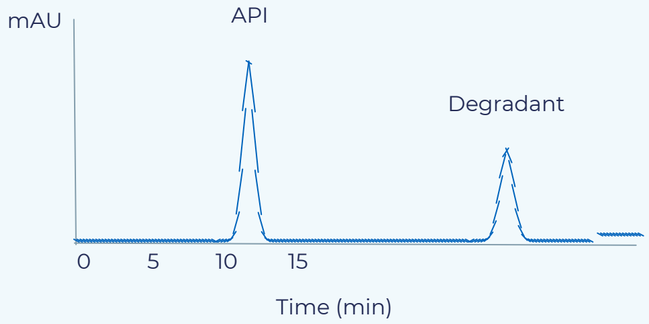
Scenario A. Sample Degradation After Preparation



What happened?

The drug product may be stable, but the prepared analytical sample changes before analysis. The method can distinguish the analyte from the degradant, but the result no longer reflects the intended sample at the time of preparation.

Scenario B. Product Degradation Detected by a Suitable Method



What happened?

The drug product undergoes degradation and the stability-indicating method can detect and distinguish degradation products from the analyte. A stable sample solution allows the result to accurately reflect the product.

Key takeaway

The analytical team needs to distinguish changes occurring in the product from changes occurring after sample preparation. Both a stability-indicating method and appropriate solution stability assessment are needed for reliable results.

What should be considered?

- ✓ Evidence supporting method specificity.
- ✓ Sample and standard solution stability.
- ✓ Defined handling, storage, and analysis conditions.
- ✓ Appropriate acceptance criteria and documented conclusions.

From Analytical Evidence to Reliable Decisions

nuvalore supports pharmaceutical and biotech teams with stability-indicating method development, solution stability assessments, and GMP analytical testing to help generate reliable data for pharmaceutical quality decisions.



Analytical method development and testing

Development, validation, and verification of robust, stability-indicating methods.

Pharmaceutical stability testing

Support for long-term, accelerated, and in-use stability studies with appropriate analytical methods.

GMP-compliant analytical testing and documentation

Reliable data and documentation to support your development and commercial programs.

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