Practical control of polysorbate

Degradation is manageable

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EFPIA session - CASSS Europe

Inspired by **patients.**
Driven by **science.**

Context and objective

- EFPIA published 3 papers on polysorbate
- Industry message: degradation is common and is manageable

- Objective: **Demonstrate this in a real UCB case**

EFPIA position paper

- Provides industry perspective with case studies
- Supports science-based control strategies
- In line with UCB control strategy

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General Commentary

Do we worry too much about polysorbate degradation? An industry-wide perspective with real-life case studies☆

Klaus Wuchner[a,*], Felix Nikels[b], Patrick Garidel[b], Karoline Bechtold-Peters[c], Sanjay Gupta[d], Pierre Guibal[e], Linda Yi[f], Neil Steinmeyer[g], Cyrille Chery[h], Sebastian Peuker[i], Ryan E Mould[j], Shousong Jason Zhang[j], Charlie Bupp[k], Felix Wiggers[l], Yogita Krishnamachari[m], Indira Prajapati[n], Stefan Bleher[o]

Check for updates

[Do we worry too much about polysorbate degradation? An industry-wide perspective with real-life case studies - Journal of Pharmaceutical Sciences]

Rationale

A B S T R A C T

[...]

For PS20 and PS80, the levels of FAs generated were estimated and translated into predicted SVP levels based on theoretical assumptions. Additionally, the current understanding of PS degradation in biopharmaceuticals, based on the latest literature, is summarized, with consideration of safety and immunogenicity aspects related to the primary PS degradation products. Overall, PS degradation is considered manageable and not problematic under practical conditions. Enzymatic hydrolysis of PS is generally deemed acceptable, provided that all CQAs are maintained within specified limits. If FA-related particles are formed it is recommended that the PS degradation pathway is well characterized, and an appropriate control strategy be implemented.

Polysorbate content on stability can decrease and that is not the end of the world

UCB case study:

- Drug product, mAb in solution
- Content of Polysorbate 80 on specification
  - At release and on stability
- Polysorbate content decreases on stability
  - Release: not less than *ca.* 0.2 µg/mL
  - End of shelf life: not less than *ca.* 0.15 µg/mL
  - Typical decrease between release target value and end of shelf life: ca. 50%

You can add references here.

Rational

- The mechanism of PS decrease is understood:
  - Evidence supports enzymatic degradation (not oxidation)
    - Formation of free fatty acids
    - Formation of POE sorbitan (=de-esterified PS)

- The degradation does not impact CQA:
  - No formation of sub-visible or visible particles
  - No impact on aggregates: enough PS left to still be effective

- The likely cause of the degradation (i.e., an enzyme, which is a host cell protein) does not impact CQA:
  - Host-cell proteins constant in quantity and identity across clinical pivotal batches and process performance qualification batches
  - Proved by quantitative data by ELISA and mass spectrometry

You can add references here.

Consequences (or lack thereof)

- UCB does not intend to change its process:
  - No intention to remove more HCPs (enzymes)

- UCB does not intend to change its formulation:
  - No need to change polysorbate for another excipient: It does its job as intended
  - The benefits of switching to another excipient are null

- Filed and accepted by EMA (on-going process)

You can add references here.

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