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Title: Comparative Assessment of the Effect of Glyco-engineering on the Pattern and Kinetics of Aggregate Formation of Darbepoetin Alfa using a Stability-Indicating Orthogonal Testing Protocol



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## ACCEPTED MANUSCRIPT

Comparative Assessment of the Effect of Glyco-engineering on the Pattern and Kinetics of Aggregate Formation of Darbepoetin Alfa using a Stability-Indicating Orthogonal Testing Protocol

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## Highlights

- Effects of hyper-glycosylation on stability of erythropoietin was investigated.
- Stress-induced degradation of Erythropoietin alfa and Darbepoetin alfa was performed.
- Stability-indicating orthogonal stability-indicating protocol was developed and validated.
- Darbepoetin alfa showed high stability under the studied stress conditions.

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