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

Authors: Eman M. Moenes, Medhat A. Al-Ghobashy, Abeer A. Mohamed, Maissa Y. Salem

PII: S1570-0232(17)30938-8
DOI: https://doi.org/10.1016/j.jchromb.2017.10.057
Reference: CHROMB 20887

To appear in: *Journal of Chromatography B*

Received date: 22-5-2017
Revised date: 21-10-2017
Accepted date: 29-10-2017

Please cite this article as: Eman M.Moenes, Medhat A.Al-Ghobashy, Abeer A.Mohamed, Maissa Y.Salem, 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, Journal of Chromatography B https://doi.org/10.1016/j.jchromb.2017.10.057

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

Eman M. Moenes[a], Medhat A. Al-Ghobashy[b,c*], Abeer A. Mohamed[a] and Maissa Y. Salem[b]

[a] National Organization for Research and Control of Biologicals, Egypt

[b] Analytical Chemistry Department, Faculty of Pharmacy, Cairo University, Egypt

[c] Bioanalysis Research Group, School of Pharmacy, New Giza University, Egypt

***Corresponding author at:**

Analytical Chemistry Department, Faculty of Pharmacy, Cairo University, Cairo 11562, Egypt.

E-mail address: medhat.alghobashy@cu.edu.eg (M. A. Al-Ghobashy)

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.