P-128-T

A Comparison of UPLC and CE-based Approaches for Glycan Profiling of B iotherapeutic Proteins- Challenges for the Fast Characterization of New Biological Entities (NBEs) and Biosimilar Candidates

Thomas Schröter, Michaela Wachs, Roland Moussa, Martin Blüggel

Protagen Protein Services GmbH, Dortmund, Germany

The characterization of biopharmaceuticals such as new biological entities (NBEs) and their biosimilars is a challenging field due to their structural complexity. When implementing a manufacturing process, variations in the protein structure or post-translational modifications occur. Therefore, a characterization program is required according to the guidelines of national authorities. When characterizing proteins from scratch, glycosylation is a central modification that has to be taken into account, as it can affect the half
-life and the stability of the protein.

As established standard UHPLC methods, such as HILIC with IPC or 2AB labeling are commonly used to detect different glycans in biopharmaceuticals. However, sample preparation takes up a large amount of the total analysis time, the method is not suitable for high-throughput analysis. In addition to that, sample analysis time takes up to 90 min per sample. In particular, for time sensitive development such as clone selections processes or assessing comparability of biosimilars to originators, those methods do not qualify for a quick screening process.

In this study, we evaluated a CE -based fast glycan labeling and analysis kit as a fast screening method to identify samples for subsequent detailed HILIC analysis. To assess the comparability the UHPLC method and CE method have been performed using the same sample. We analyzed a IgG market product and compared the obtained results with respect to identified glycans and the obtained relative peak areas.

As for the glycans identified by both methods, the relative areas were in the same value range with a certain degree of variance. All in all, the fast glycan analysis seems to be a suitable tool for fast screening of glycan composition and a decision support for selecting a reduced sample set for subsequent in-depth HILIC analysis.

NOTES: