Platform Size Exclusion Chromatography (SEC) method development for a broad range of monoclonal antibodies

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Understanding of size heterogeneity in biotherapeutic proteins is essential since it is one of the Critical Quality Attributes (CQA) due to its impact on safety and e cacy. e size heterogeneity covers the product related species/impurities that includes fragments, monomers and aggregates. Size exclusion chromatography (SEC) has been widely used to separate aggregates, monomer and fragments of monoclonal antibodies (mAbs) that might form during manufacturing, storage and shipping. e progress in biologics pipeline and the urgency to reach rst-in-human (FIH) has provided an opportunity to develop a generic method that can serve as a platform method for monoclonal antibodies. is study describes platform SEC method development for monoclonal antibodies using commercially available highperformance liquid chromatography (HPLC) and ultra-performance liquid chromatography (UPLC) SEC columns. For this purpose, several antibodies covering a broad range of isoelectric points (pI) and hydrophobicity were analyzed. Initial comparison was performed using six di erent mAbs to understand the impact of mobile phase and organics on separation of aggregates and fragments.

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