THOMSON Solutions ™ At Work
INSTRUMENT COMPANY

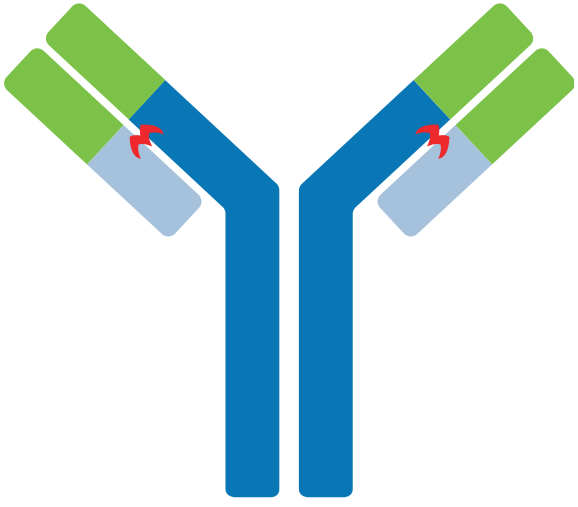
series	cap color	membrane	pore size	part #
nanoIFilter Vial™	●	PES	0.2µm	15535

Aggregation Determination using nanoIFilter Vials® by SEC

Introduction

The aggregation of protein therapeutics has become a major concern for the pharmaceutical industry and regulatory agencies. Protein aggregates can cause an adverse immune response and are typically monitored throughout the formulation and production of bio-therapeutics. Monitoring aggregates helps to minimize risks from therapeutic proteins in clinical applications by optimizing early formulations to reduce aggregation during production, storage, handling, and shipping.

Antibodies are clarified using Thomson nanoIFilter Vials®, 0.2 µm PES Membrane (Part#: 15535-200 or 500) and analyzed for purity using SEC (Size Exclusion Chromatography). 10 µL of purified antibody was placed into the nanoIFilter Vials® and 2 µL was injected onto the HPLC. Fig. 1 & 2 show a chromatogram of mAb1 with low abundance multimers. Fig. 3 & 4 show a chromatogram of mAb2 with dissociated antibody fragments.



Method & Sample Preparation

Method

- Agilent 1260 Infinity HPLC
- Column: 4.6x300 mm Bio-SEC3
- Buffer: 1x PBS (Phosphate Buffered Saline)
- Flow Rate: 0.2 mL/min
- Injection: 2 µL

Sample Prep

- 10 µL of purified antibody
- Thomson nanoIFilter Vials®, 0.2 µm PES Membrane

Chromatograms

Fig 1. Chromatogram of Antibody mAb1

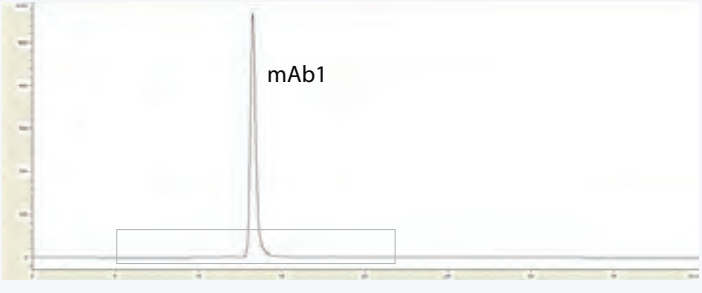


Fig 2. Chromatogram of Antibody mAb2

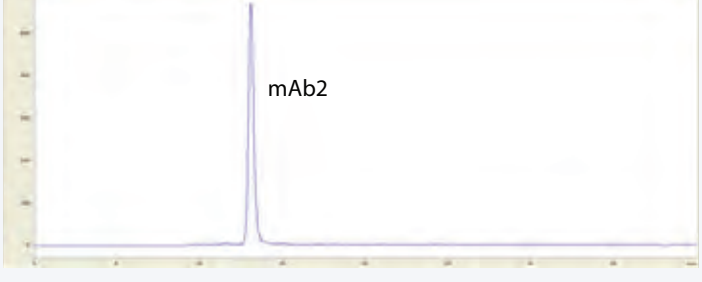


Fig 3. Zoomed in version of the chromatogram in Fig. 2 of Antibody mAb1 to better visualize low abundance dimer.

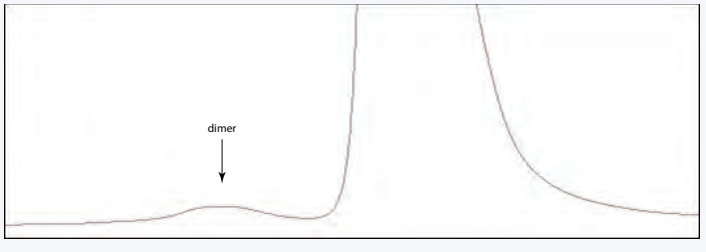


Fig 4. Zoomed in version of the chromatogram in Fig. 3 of Antibody mAb2 to better visualize aggregate peak.

Thomson nanoIFilter Vials®, 0.2 µm PES Membrane Part#: 15535-200 (qty 200) | 15535-500 (qty 500)