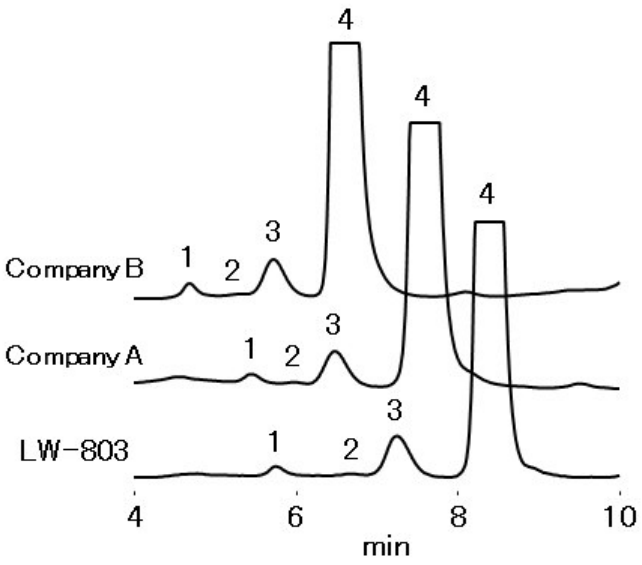
Comparison of SEC Separation of Monoclonal Antibody

Antibody drugs have been spotlighted as therapeutic agents which have a high specificity to the target molecule with few side effects. It is known that dimer and/or larger aggregates may be produced during the manufacturing process or storage of antibody drugs. Since it is possible that these aggregates may become immunogenic to induce antibody production and/or cellular immunity in the body and cause side effects, it is important for quality control to analyze these impurities. Monomers and dimers can be separated effectively using PROTEIN LW-803. Therefore, LW-803 is suitable for monitoring impurities.



Sample : 20µL
IgG from recombinant CHO cell
1mg/mL
1. Aggregates
2. Trimer
3. Dimer
4. Monomer

	Resolution	
	monomer/dimer	dimer/trimer
Company B	2.1	2.6
Company A	2.5	2.4
LW-803	2.6	3.4

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Columns      : Shodex PROTEIN LW-803 (8.0mmI.D. x 300mm)
               Silica-based SEC column from other manufacturer (7.8mmI.D. x 300mm each)
Eluent       : 50mM Sodium phosphate buffer (pH7.0) + 0.3M NaCl
Flow rate    : 1.0mL/min
Detector     : UV(280nm)
Column temp. : Room temp.
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