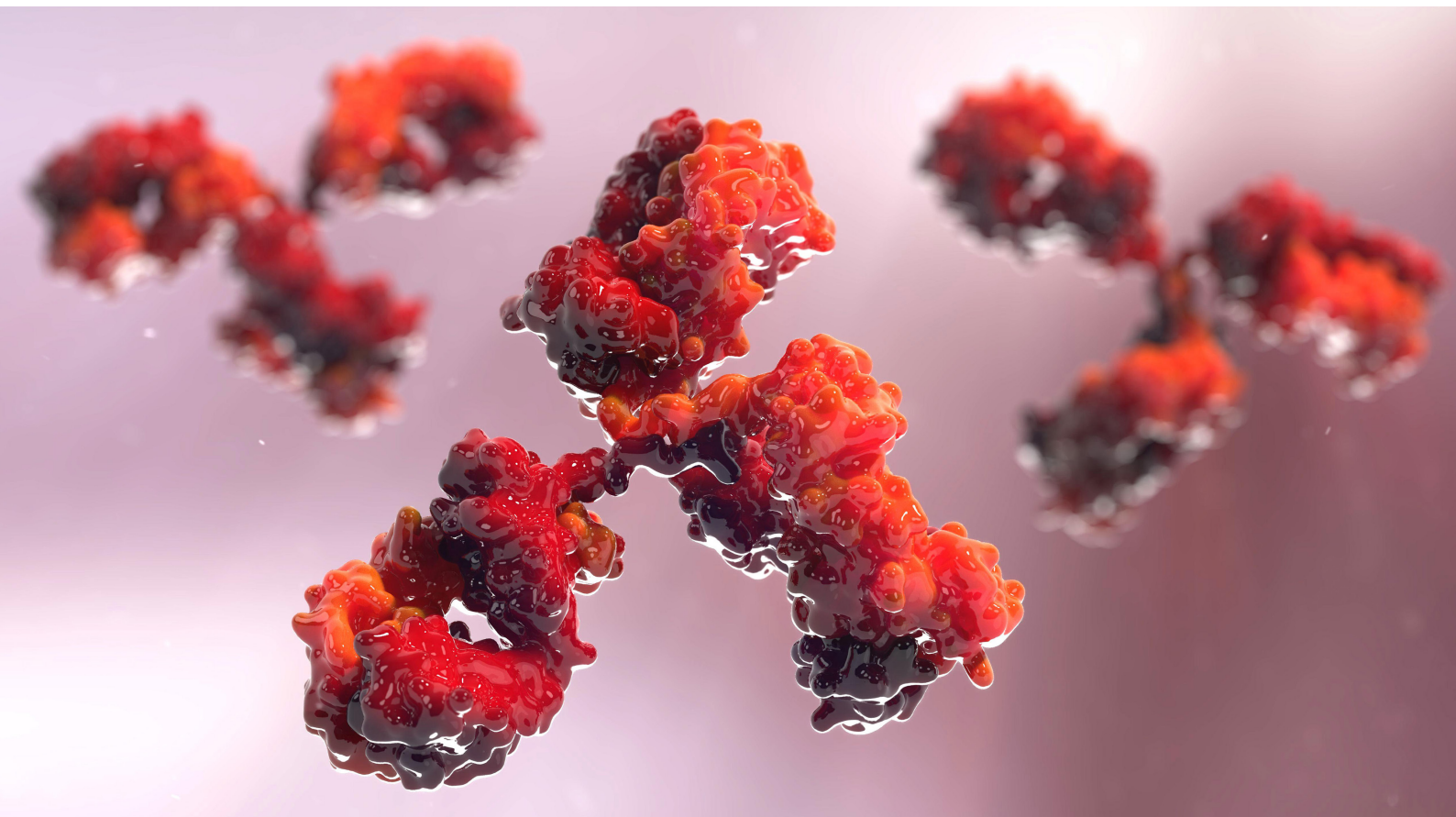




TOSOH

# Antibody Capture and Analysis



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## TOSOH RESINS AND COLUMNS SPECIFICALLY OPTIMIZED TO MEET YOUR NEEDS

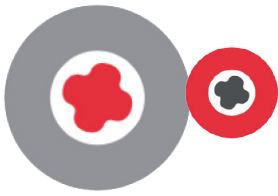
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Tosoh purification resins and analysis columns have a long set standard in industrial manufacturing of biopharmaceuticals. Sustained investment in research and development maintains our position at the technological frontier.

Over the past decades, we have brought to market successive generations of resins and columns that anticipate our clients' evolving needs in response to growing pressures on time-to-market, needs for control of production price, tightened safety controls and increasing titers.

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**TOSOH BIOSCIENCE**



**PROTEIN A HC LEACHING REMAINS UNDER THE 10 NG/ML LIMIT IN ALL TESTING CONDITIONS**

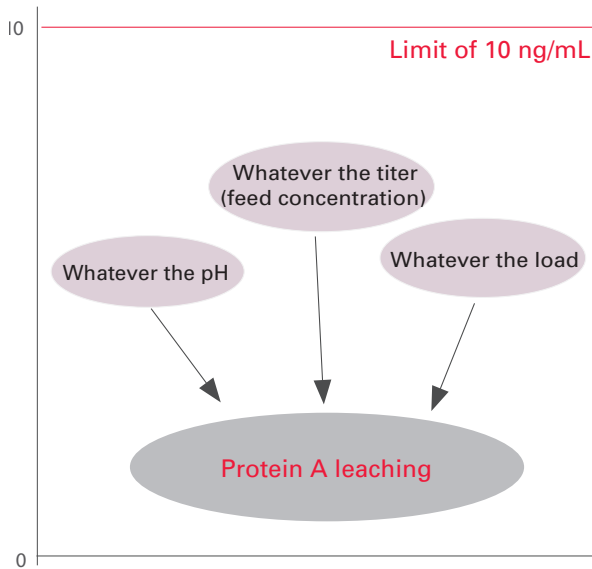


Figure 1

**HIGH STABILITY TO ENSURE A LOW DEGREE OF PROTEIN A LEACHING FOR GREATER SAFETY**

Regardless of the initial load and pH, Protein A leaching is typically kept well beneath the limit of 10 ng/mL, guaranteeing high purity and safety; the leaching even diminishes slightly as the titers are increased. This low leakage is due to the ligands' multipoint attachment to the TOYOPEARL® polymer matrix.

Tosoh Protein A HC\* chromatography:

An optimized combination of high stability and high binding capacity

**HIGH ALKALINE STABILITY TO PERMIT MULTIPLE REUSE AND THEREFORE REDUCED COSTS**

The Protein A HC resin's chemical and thermal stability allows at least 300 Cleaning-in-Place (CIP) cycles (at 0,2 M NaOH) without significant reduction in dynamic binding capacity (DBC). The caustic stability during cleaning, due to its multipoint attachment, considerably reduces operating costs.

**NO SIGNIFICANT REDUCTION IN DBC AFTER 300 CIP CYCLES**

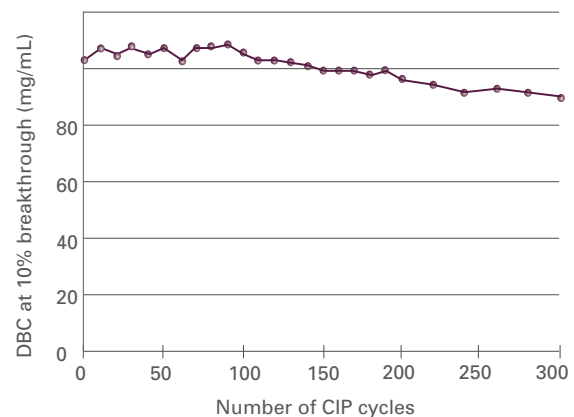
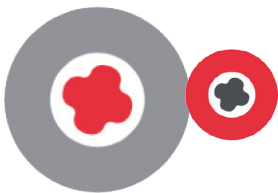


Figure 2



## HIGH BINDING CAPACITY TO REDUCE THE COST OF PURIFICATION

The TOYOPEARL Protein A HC resin displays a binding capacity of > 68 g IgG/L. This exceeds the typical binding capacity of 30-50 g/L on competitor Protein A resins. Since the share in the overall cost of purification accounted for by Protein A capturing diminishes as resin capacity increases (due to even smaller in-process pools, reduced buffer consumption, etc.) this reduces total operating costs substantially.

## THE COST OF PURIFICATION STEP DROPS FROM 43% TO 21%

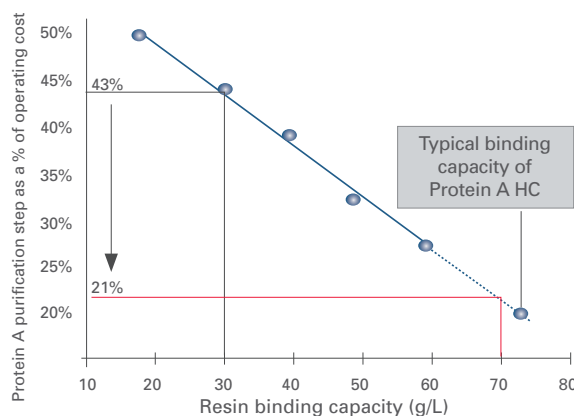


Figure 3

## MORE THAN 50 g IgG/L IS ALREADY CAPTURED AFTER ONLY 2 MIN

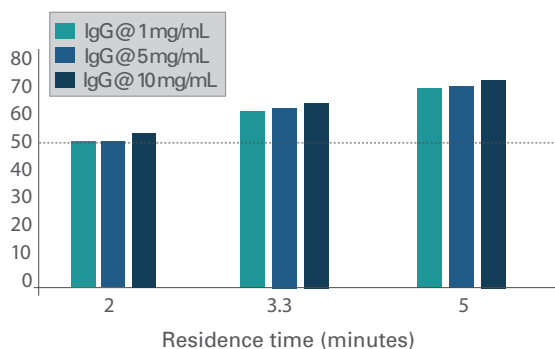


Figure 4

## HIGH BINDING CAPACITY TO MEET INCREASING UPSTREAM PROCESSING LOADS AND REDUCE COSTS

The rising titers that result from improvements in upstream efficiency are a challenge for downstream processing (DSP), especially at the Protein A-capturing step. The protein adsorption capacity of the Protein A HC resin prevents DSP bottlenecks at the highest possible titers (10 g/L), even at short residence times. A Protein A HC resin capacity of even more than 100 g/L has been achieved. This exceeds the dynamic binding capacity of all other commercially available alkaline-stable Protein A resins. This outstanding characteristics reduces both the volume of resin needed and the footprint, which minimizes the costs.

## HIGH BINDING CAPACITY EVEN AT VERY SHORT RESIDENCE TIMES TO REDUCE PROCESS TIME

In contrast to many Protein A resins on the market, the binding capacity of the Protein A HC resin is high even at residence times as short as two minutes, reducing total process time.

## LESS RESIN IS NEEDED TO TREAT THE SAME AMOUNT OF FEEDSTOCK

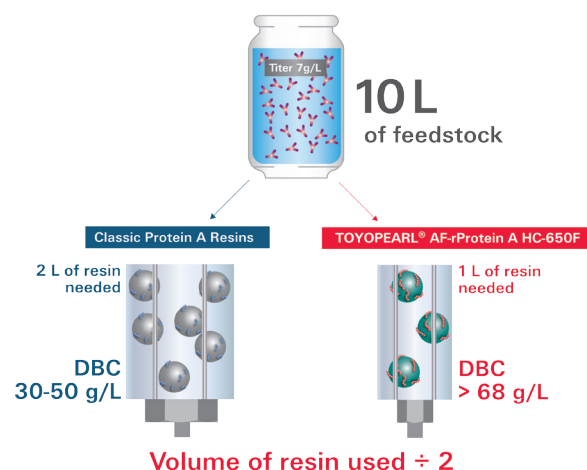
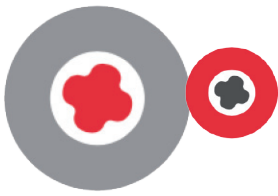


Figure 5



## TSKgel® SW SERIES, THE GOLD STANDARD FOR QUALITY CONTROL ANALYSIS OF ANTIBODY THERAPEUTICS

For decades, TSKgel G3000SW<sub>XL</sub> columns have been the industry's standard for antibody analysis and quality control of monoclonal antibodies by size exclusion chromatography (SEC). We have developed new series of silica-based SEC columns for HPLC and UHPLC providing shorter analysis time and higher resolution. Their principal characteristics are:

- Higher resolution with SuperSW mAb HR
- Faster separation with SuperSW mAb HTP
- Higher molecular weight range with UltraSW Aggregate
- Highest resolution and fastest separation with UP-SW3000 UHPLC columns

### AN ALWAYS HIGHER RESOLUTION

Tosoh TSKgel columns are designed to improve resolution of antibody fragments, monomers and dimers. The SuperSW mAb HR, the TSKgel UltraSW Aggregate and the TSKgel UP-SW3000 column offer superior resolution over the whole molecular weight range, from fragments to aggregates.

#### BETTER RESOLUTION IN HALF THE TIME

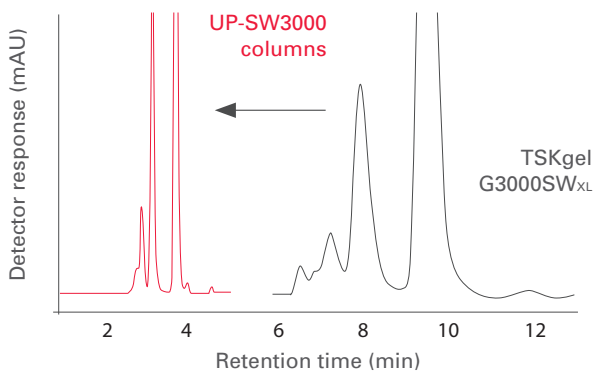


Figure 7

### LOT-TO-LOT REPRODUCIBILITY

TSKgel SW SEC columns are known for their outstanding quality and reproducibility. The new series columns are highly reproducible for HPLC as well as for UHPLC systems. This allows straight forward method validation and routine implementation.

Tosoh columns for quality control of mAbs by SEC:

a range tailored to meet your needs

#### TSKgel UP-SW3000 OFFER HIGHER RESOLUTION ACROSS THE WHOLE MOLECULAR RANGE

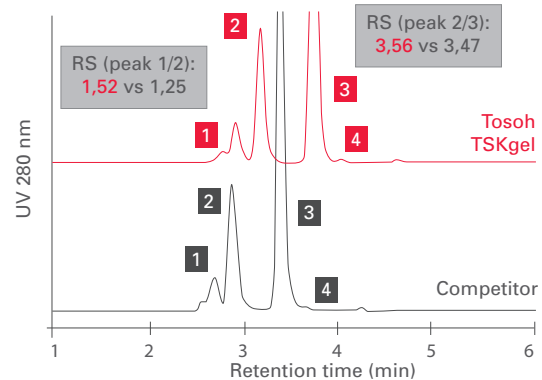


Figure 6

### ANALYSIS TIME TWICE AS FAST

The new series of Tosoh columns were also engineered to provide shorter analysis time by:

- Increasing the throughput without compromising resolution with SuperSW mAb HTP (HTP for "High ThroughPut")
- Completing the analysis in half the usual run time and increasing resolution with the use of the UP-SW3000 column on a UHPLC system.

#### HIGH LOT-TO-LOT REPRODUCIBILITY

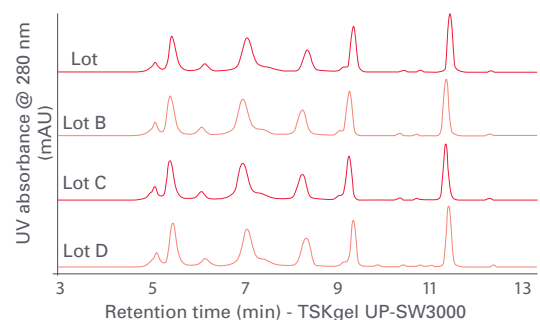


Figure 8