

# TOYOPEARL GigaCap® DEAE-650M Preserving Resolution at Increased Protein Loads

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PERFORMANCE DATA

TOYOPEARL GigaCap DEAE-650M, a very high capacity anion exchange resin for process scale applications, was recently introduced by Tosoh Corporation. This resin, with dynamic binding capacities of over 150 g/L for bovine serum albumin (BSA), is the newest member of the TOYOPEARL® product line.

## Introduction

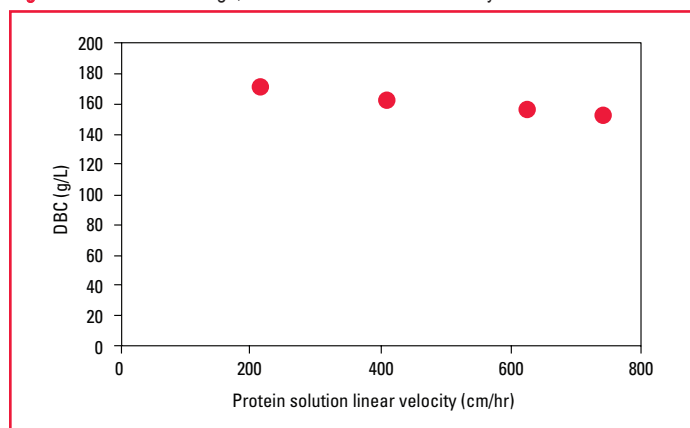
Advances in upstream processes allow the manufacture of biotherapeutic proteins in increasing titers. As a result, downstream unit operation demands are increased. Binding capacity of a chromatography resin is one potential bottleneck. However, the bottleneck can be resolved by using a higher capacity chromatography resin. A higher capacity resin will also allow for smaller column volume, increased throughput, and decreased buffer consumption.

TOYOPEARL GigaCap DEAE-650M chromatography resin is a new anion exchange resin with a very high binding capacity designed to alleviate the bottleneck created by increased titers. This chromatography resin has a dynamic binding capacity of greater than 150 g/L for BSA. In addition to a high dynamic binding capacity, TOYOPEARL GigaCap DEAE-650M has the ability to separate proteins up to 96 g/L protein. This new resin uses the same polymethacrylate backbone as all other TOYOPEARL chromatography resins. Thus, it will have similar pressure-flow and chemical stability characteristics.

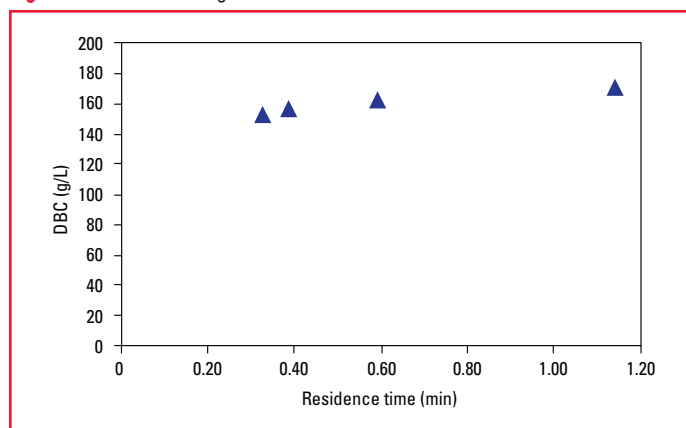
## Experimental Conditions/Results

TOYOPEARL HW-65 size exclusion resin was functionalized with diethylaminoethanol groups using a proprietary spacer group to create TOYOPEARL GigaCap DEAE-650M. To determine the dynamic binding capacity (DBC), a 6 mm ID × 4 cm column was packed with this new resin. A 1 g/L BSA solution was loaded onto the column at 212 cm/hr until 10% breakthrough as measured by UV at 280 nm. *Figures 1 and 2* demonstrate that the dynamic binding capacity of the TOYOPEARL GigaCap DEAE-650M remains high at increased linear velocity and with low residence times.

**Figure 1.** DBC remains high, even at increased linear velocity



**Figure 2.** DBC remains high with low residence times



For static binding capacity (SBC), a total protein concentration of 210 mg BSA/mL resin was used. *Table 1* shows the increased capacities of TOYOPEARL GigaCap DEAE-650M compared to the TOYOPEARL DEAE-650M resin.

**Table 1.** Typical properties of TOYOPEARL GigaCap DEAE-650M

|                                      | TOYOPEARL DEAE-650M | TOYOPEARL GigaCap DEAE-650M |
|--------------------------------------|---------------------|-----------------------------|
| Particle Size (µm)                   | 40-90               | 50-100                      |
| Ion Exchange Capacity (meq/mL resin) | 0.11                | 0.23                        |
| SBC (g/L resin)                      | 30                  | 179                         |
| DBC (g/L resin)                      | 25                  | 165                         |

For the protein loading experiments, a 1.0 cm ID × 14.7 cm column was packed with TOYOPEARL GigaCap DEAE-650M. The column was first sanitized with 2.5 column volumes (CV) of 1.0 mol/L NaOH. Then 50 mmol/L Tris-HCl (Buffer A) was used to equilibrate the column for 5 CV. An injection of 10 g/L ovalbumin and 10 g/L trypsin inhibitor was then loaded onto the column, and the column was washed with Buffer A. A 10 CV gradient going from 0-100% Buffer B (Buffer A with 0.5 mol/L NaCl) was then completed. After the gradient, the column was again sanitized with 1.0 mol/L NaOH. The results of this experiment are shown in *Figure 3*.

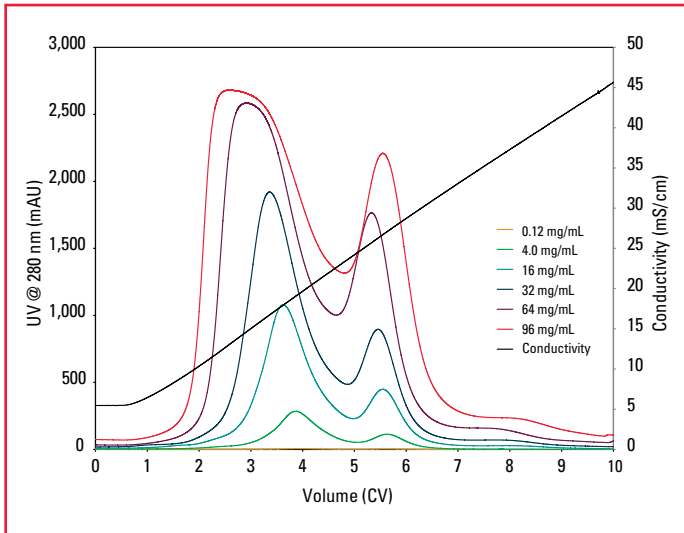
To determine the clean in place (CIP) stability of TOYOPEARL GigaCap DEAE-650M, it was exposed to 0.5 mol/L NaOH for 1 hour (27 CV) and then washed with 10 CV per cycle. The DBC was tested before CIP and compared to the DBC after every 20 CIP cycles. As shown in *Figure 4*, TOYOPEARL GigaCap DEAE-650M retains DBC stability after 100 clean in place (CIP) cycles.



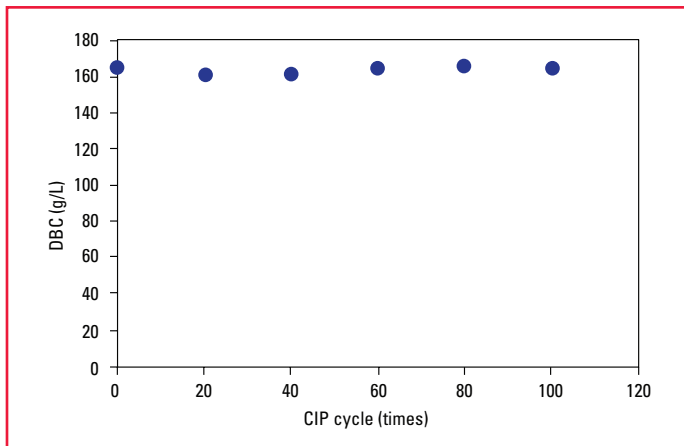
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**Figure 3.** Protein loading studies with ovalbumin and trypsin inhibitor



**Figure 4.** TOYOPEARL GigaCap DEAE-650M retains DBC stability after 100 clean in place (CIP) cycles



## Conclusions

TOYOPEARL GigaCap DEAE-650M is an ideal anion exchange resin for the chromatographic purification of biotherapeutic products. Since the TOYOPEARL GigaCap DEAE-650M has such a high dynamic binding capacity, the need for very large columns and massive buffer consumption is minimized, particularly for proteins expressed at higher levels due to upstream improvements. The increased capacity is evident even with low residence time or increased flow rate as well as over many CIP cycles. In addition to a high binding capacity, the TOYOPEARL GigaCap DEAE-650M resin has the ability to separate proteins, including those at very high loading concentrations.

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