TOSOH

TSKgel AFC Column

High Performance Affinity Chromatography Column

TSKgel® FcR-IIIA-NPR

The First-in-Class, rhFcγreceptor IIIA immobilized affinity chromatography column for separation/analysis of antibody based on the difference of ADCC activity.

Features

- Innovative high performance affinity chromatography column for analysis of antibody
- Recombinant human Fcγreceptor IIIA is immobilized on the surface of non-porous resin as ligand
- Discriminate conformational change of Fc region of antibody attributed by N-linked glycan, which enables to separate antibodies based on the difference of ADCC activity
- Applicable to intact antibodies without any time-consuming or burdensome pretreatment, purification
- Rapid separation of antibody in 30 min is available

Product

P/N	Description	Particle size	dimension
0023513	TSKgel FcR-IIIA-NPR	5 μm	4.6 mm I.D.×7.5 cm

＊Guard column is not available. ＊Recommend to install line filter between pump and injection valve, Line filter kit PEEK, P/N 0018014.

Target molecules and applications

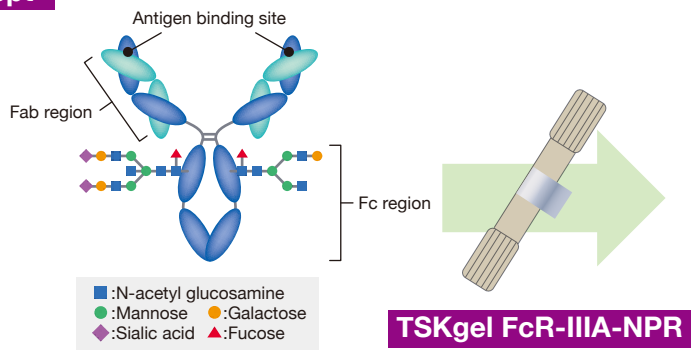
○ Antibody ○ Fc fusion protein

- Screening of cell line
- Optimization of culturing condition
- Monitoring of upstream process
- Quality control of mAb

Basic properties

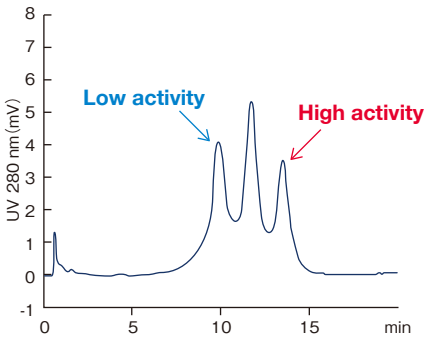
Description	TSKgel FcR-IIIA-NPR
Base materials	Hydrophilic non-porous polymer
Particle size	5 μm
Ligand	Recombinant human Fcγreceptor IIIA
Column size	4.6 mm I.D.×7.5 cm
Column hardware	PEEK

Concept



MAb therapeutics

N-glycan structures in Fc region would affect drug efficacy, and might cause lot-to-lot variation

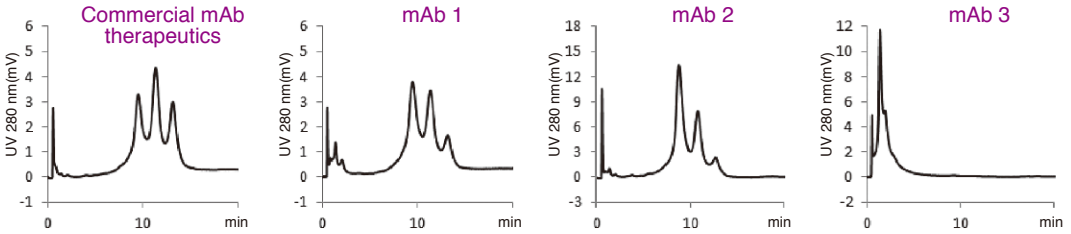


Chromatogram

TSKgel FcR-IIIA-NPR discriminates glycan structure and separates IgG based on ADCC activity

Applications

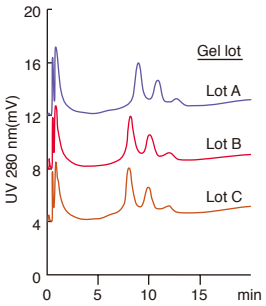
Separation of mAbs



Conditions 1
Column: TSKgel FcR-IIIA-NPR (4.6 mm I.D.×7.5 cm)
Eluent A: 50 mmol/L sodium citrate buffer (pH 6.5)
B: 50 mmol/L sodium citrate buffer (pH 4.5)
Gradient: B 0 – 100 % (2 – 20 min, linear)
Flow rate: 1.0 mL/min
Detection: UV (280 nm)
Temp.: 25 °C
Samples: monoclonal antibody

Distinctive chromatograms were obtained for all monoclonal antibodies applied on TSKgel FcR-IIIA-NPR column. (Typical monoclonal antibody therapeutics produced by CHO cell shows 3 peaks)

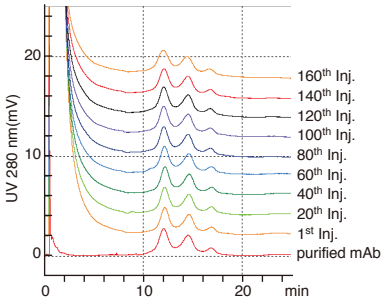
Lot-to-lot variability of packing materials



Conditions 2
Conditions are the same as conditions 1

Almost no difference in chromatogram was observed in gel lots

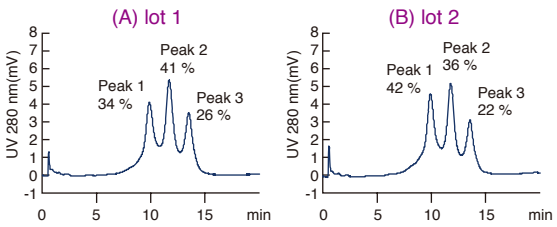
Column durability
(Separation of antibody in cell culture)



Conditions 3
Eluent A: 50 mmol/L sodium citrate buffer + 150 mmol/L NaCl (pH 6.5)
B: 50 mmol/L sodium citrate buffer + 150 mmol/L NaCl (pH 4.5)
Gradient: B 0 – 100 % (7 – 25 min, linear)
Temp.: 20 °C
Samples: CHO cell culture supernatant (1 g/L, mAb), purified mAb
*Sample was filtered and applied
*Other conditions were the same as conditions 1

Applicable to mAb in CHO cell culture with good reproducibility

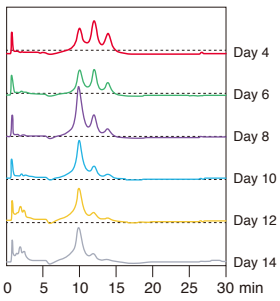
Application to quality control
(Monitoring of lot-to-lot variability of mAb therapeutics)



Conditions 4
Samples: Commercial mAb therapeutics (2 lots)
* Other conditions were the same as conditions 1

Applicable to lot-to-lot comparison with ease and rapidly

Application to process analysis
(Analysis of mAb cultured in CHO cell)



Conditions 5
Sample: mAb, 5 µg

* CHO cell culture was sampled periodically after starting culture, filtered, purified by protein A resin and applied on TSKgel FcR-IIIA-NPR
* Other conditions were the same as conditions 1
* CHO cell culture was kindly provided by Manufacturing Technology Association of Biologics

Applicable to monitor the time course of mAb during culture

TOSOH

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