KANEKA

KanCapA™ series

Affinity Chromatography Resins

KANEKA

KanCapA™ series

Purification of antibody drugs used to be high cost process due to using high-spec protein A resins. KANEKA KanCapA™ can provide a solution. Our affinity chromatography resins enable efficient purification with their unique combination of proprietary ligands and innovative highly cross-linked cellulose base matrix. The result is a series of resins that meet industry standards with good balance between cost and performance. Our resins enable monoclonal antibody manufacturers worldwide to reduce costs from development to commercial production of antibody drugs.

Our Promise

The needs of customers and patients come first. Providing the global pharmaceutical industry with a safe, reliable supply of resins for antibody purification is a responsibility we take very seriously. Sound business operations and responsible decision-making provide the foundation for KANEKA to fulfill its responsibility for many years to come.

Our Strengths

Suitable for newly developing mAbs and biosimilars

KANEKA KanCapA™ series offers good balance of price and performance with sufficient capability of antibody purification.

Reliable supply

Our dedicated production facilities give stable supply of resins with a short lead time when forecasted.

Scalable solutions

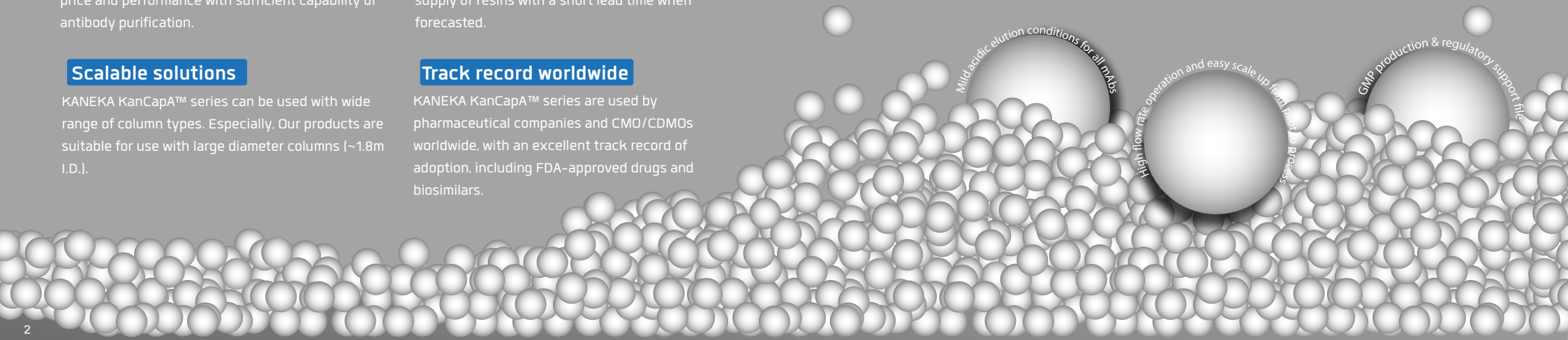
KANEKA KanCapA™ series can be used with wide range of column types. Especially, Our products are suitable for use with large diameter columns (~1.8m I.D.).

Track record worldwide

KANEKA KanCapA™ series are used by pharmaceutical companies and CMO/CDMOs worldwide, with an excellent track record of adoption, including FDA-approved drugs and biosimilars.

1. **KANEKA KanCapA™** is a Protein A resin intended for industrial scale purification of mAb's.

2. **KANEKA KanCapA™ 3G** is a Protein A resin with enhanced performance.



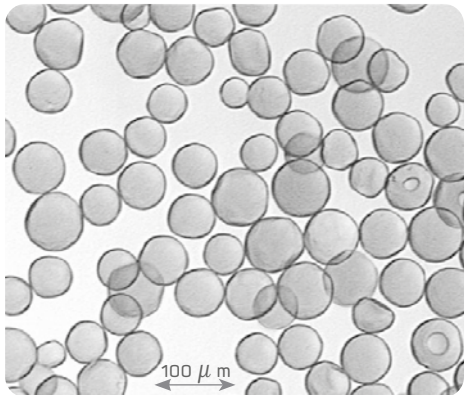
KANEKA
KanCapA™ series

A Resistant Base Matrix

Thanks to innovative technology, KANEKA KanCapA™ series uses a highly cross-linked cellulose base matrix with reduced non-specific binding properties when compared to other base matrices, polymers or glass.

The cellulose base matrix is biocompatible and has been used successfully for many years in KANEKA's plasmapheresis systems.

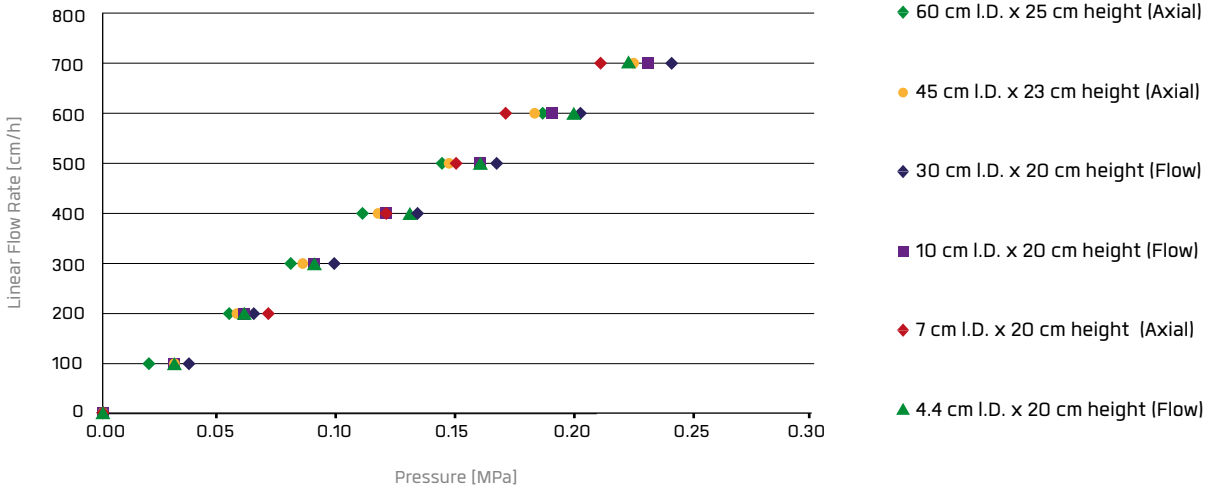
The combination of optimised cellulose base matrix with a novel Protein A ligand makes KANEKA KanCapA™ series an easy-to-use, durable resin ready for industrial-scale operations.



Cellulose Base Matrix Microscope image (x20k).

High Flow Rate Operation and Easy Scale Up from Pilot to Process

The KANEKA KanCapA™ series resin is suited for pilot and large scale purifications. The resin can be packed efficiently by normal flow or axial compression packing methods. Packed columns show excellent pressure/flow rate characteristics and excellent performance.



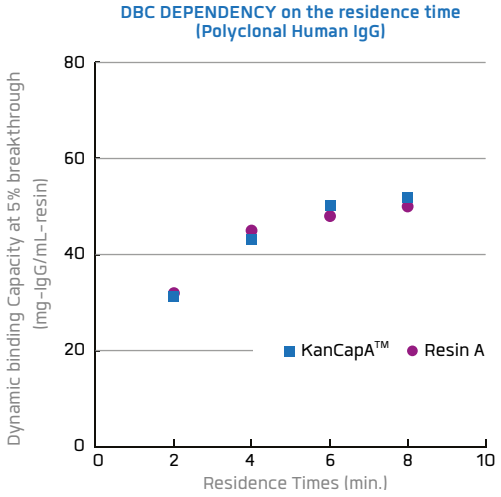
PRESSURE vs FLOW for packed columns of different diameters
The pressure generated by packed beds was calculated by subtracting the pressure of the system from total pressure.

KANEKA KanCapA™

High Binding Capacity

Dynamic binding capacity (DBC) is closely linked to productivity and production cost. It is a key parameter to consider when selecting an efficient chromatography resin.

KANEKA KanCapA™ has been designed and optimised to give a high binding capacity and productivity at a residence time of 4 to 6 minutes.



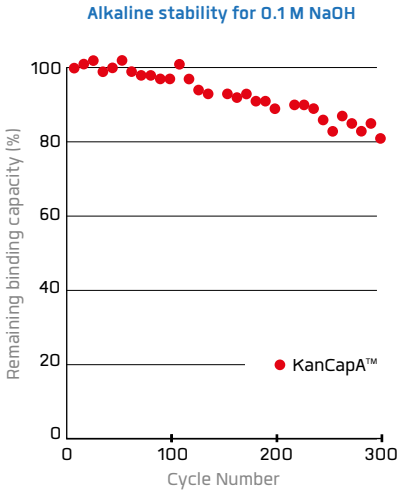
Alkaline Stability and Long Life Time

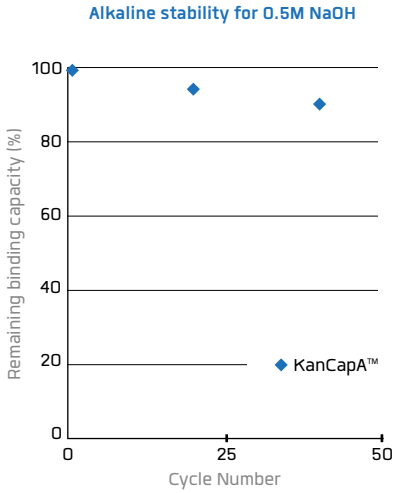
Sodium hydroxide is an efficient cleaning and sanitizing agent efficiently washing out proteins and lipids and rapidly inactivating viruses, bacteria, fungi and endotoxins.

Accordingly the alkaline resistance of KANEKA KanCapA™ protein A ligand was improved to be totally compatible with sodium hydroxide cleaning.

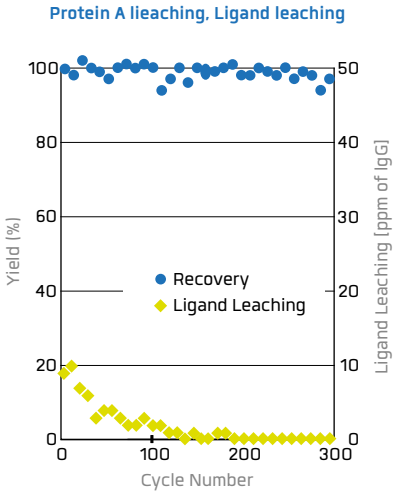
KANEKA KanCapA™ can be safely used up to 300 cycles with 0.1 M sodium hydroxide as the CIP solution with 15 minutes of contact time. Only limited loss of binding capacity (~20%) is observed. In addition, 0.5 M sodium hydroxide can be used for up to 100 cycles.

The elution yields are stable over the CIP cycles and no increase in protein A leaching was observed.





RESIN LIFETIME EVALUATION after alkaline CIP with 0.1M or 0.5M NaOH for 15 min contact time
Remaining dynamic binding capacity at 5% breakthrough



Protein A leaching
Ligand leaching: values less than the detection limit (1 ppm) are plotted as 1ppm

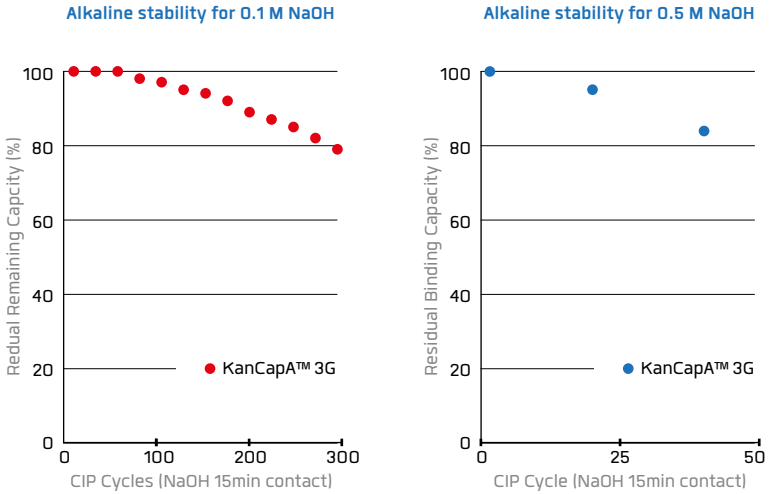
KANEKA KanCapA™ 3G

Alkaline Stability

KANEKA KanCapA™ 3G protein A ligand was developed to have both alkaline stability and high capacity.

KANEKA KanCapA™ 3G can be used up to 300 cycles with sodium hydroxide as the CIP solution with 15 minutes of contact time.

In addition, 0.5 M sodium hydroxide can be used for up to 50 cycles.

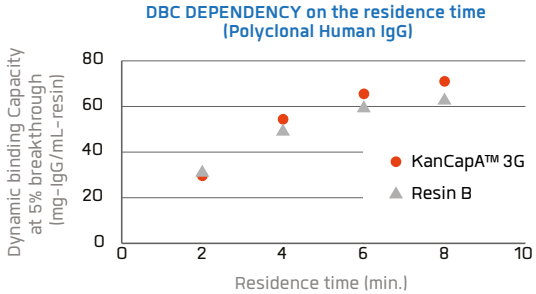


RESIN LIFETIME EVALUATION after alkaline CIP with 0.1M or 0.5M NaOH for 15 min contact time.
Remaining dynamic binding capacity at 5% breakthrough

Enhanced binding capacity

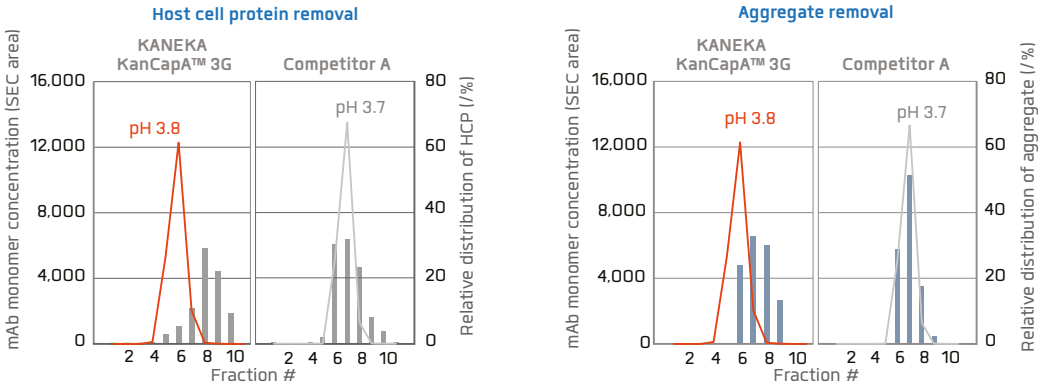
Dynamic binding capacity (DBC) is closely linked to productivity and production costs. It is a key parameter to consider when selecting an efficient chromatography resin.

KANEKA KanCapA™ 3G shows enhanced binding capacity which makes it suitable for monoclonal antibody purification from high titer feedstocks.



Unique impurity removal properties

KANEKA KanCapA™ 3G is a new generation of Protein A affinity chromatography resins carrying a recombinant protein A ligand with enhanced properties. The resin has a better potential for impurity removal compared to current commercially available resins.



Efficient HCP (left) and aggregates (right) separation during mAb elution by linear pH gradient
■ Host cell protein (HCP) ■ Aggreagates
Molecules: IgG1 CCCF), Load: 5 mg/mL resin Elution: 50 mM Citrate buffer, (gradient pH from 4.5 to 3, 10 CV)

KANEKA KanCapA™ series

Industrial Scale Packing

KANEKA supports a smooth packing process from pilot scale (~30cm I.D.) to industrial scale (~180cm I.D.) based on our years of experience and the exceptional flow characteristics of the KANEKA KanCapA™ series. We can provide packing support documentation and technical support, In addition, our comprehensive supply ststem including strategic reserved stocks assist your purification project totally.

Properties

Product	KANEKA KanCapA™	KANEKA KanCapA™ 3G
Base matrix	Highly cross-linked cellulose	
Average particles size[1]	65-85 µm	
Ligand	Recombinant Protein A (Alkaline Resistant)	
Coupling chemistry	Reductive amination	
Dynamic binding capacity[2]	≥ 35 mg human polyclonal	≥ 58 mg human polyclonal
Chemical stability	Stable in solution commonly used in affinity chromatography	
Working pH range	pH 2~13	
CIP condition	0.1 ~ 0.5 M sodium hydroxide	
Operational flow rate	Up to 500cm / h (bed height : 20~25 cm)	
Residence time	≥ 3 min. (4 ~ 6 min. is recommended)	
Storage condition[3]	Slurry in 20% ethanol at 1~10°C	
Product size	1 mL[4], 5 mL[4], 25 mL, 500 mL, 5 L & 10 L	
Regulatory support file	Available	

NOTES

[1] Average particle size is medium particle size of the cumulative volume distribution.

[2] 5% dynamic binding capacity is determined by frontal analysis at a resistance time of 3 minutes. Residence time of 6 min (KanKapA™ 3G)

[3] Prevent from freezing.

[4] Pre-packed column format.

Ordering Information

CATALOGUE NUMBERS AND FORMATS

Format	Pack Size	KANEKA KanCapA™	KANEKA KanCapA™ 3G
Pre-packed column	1 mL	KPA02-C001	KPA03-C001
	1 mL x 3 pcs	KPA02-C001-3P	KPA03-C001-3P
	1 mL x 5 pcs	KPA02-C001-5P	KPA03-C001-5P
	5 mL	KPA02-C005	KPA03-C005
RoboColumn®	200 µL x 8 rows	KPA02-S200	KPA03-S200
	600 µL x 8 rows	KPS02-S600	KPA03-S600
Bulk Resin	25 mL	KPA02-B025	KPA03-B025
	500 mL	KPA02-B500	KPA03-B500
	5 L	KPA02-B05K	KPA03-B05K
	10 L	KPA02-B10K	KPA03-B10K
ELISA Kit		Please contact us	

FAQ

Viral clearance?

Model tests have confirmed that our resins meet standard requirements for viral clearance. Details are available on request.

Regulatory Support?

We can provide you with Regulatory Support Files, certificates and documents you require.

Manufacturing control?

The resins are manufactured in an ISO 14644-1 class 8 level cleanroom under a quality system based on ICHQ7. Our facilities are regularly audited and satisfy all our customer requirements.

Support for ligand assays?

An ELISA kit is commercially available. We also offer standard ligands for process validation and in-process control. Details are available on request.

kaneka

CONTACT INFORMATION

JAPAN
Kaneka Corporation
1-12-32, Akasaka, Minato-ku,
Tokyo 107-6028, Japan
bioproducts@kaneka.co.jp

USA
Kaneka US Innovation Center
7979 Gateway Blvd., Suite 220,
Newark, CA 94560
bioproducts@kaneka.com

EUROPE
Kaneka Eurogentec S.A.
Rue du bois Saint-Jean, 14
4102 Seraing, Belgium
bioseparation@eurogentec.com

www.bioseparation.kaneka.com