



SkillPak™ 1k MAX Super A Instruction Manual

Introduction

SkillPak 1k MAX Super A columns are GMP-ready pre-packed chromatography columns packed with TOYOPEARL® Super A resin. These columns were designed to deliver optimal biomolecule separation on a variety of liquid chromatography systems. Using state-of-the-art design criteria, superior chromatographic media, and proprietary packing conditions, Tosoh Bioscience offers GMP-ready pre-packed columns that combine superior chromatographic performance in a cost-effective and easily disposable column hardware.

Product Description

SkillPak columns are characterized by their simplicity, and ability to function under a variety of conditions. SkillPak 1k MAX columns are 8 cm ID × 20 cm length, which contain approximately 1 liter of resin. Using standard ¾ inch sanitary fittings, these columns are easily attached to any mid- to process-scale chromatography system.

Tosoh Bioscience also offers an optional stand for SkillPak 1k MAX pre-packed columns. The column easily locks into the stand to attach hose connections more easily. The stand stabilizes the column to reduce the risk of the column tipping over during operation. Once packed with TOYOPEARL Super A resin, the columns are tested for strict performance criteria and verified for minimal bioburden and endotoxin levels (listed on the Certificate of Analysis). Next, the columns are packaged in shipping containers which are designed and tested in accordance with the International Safe Transit Association (ISTA) 3A Protocol to ensure the end-user will receive a pre-packed column of superior quality.

Figure 1 and *Figure 2* show the column and the stand with the individual components numbered. *Table 1* lists the individual components, what material is used to construct the column, and whether the components are considered wetted parts or not.

➤ **Figure 1. SkillPak 1k MAX Column**



Not shown in Figure: 2, 4, 5, 6, 10, 14, 15

➤ **Figure 2. Column Stand**



All wetted components are composed of materials which conform to USP <88> Class VI and to 21 CFR 177 and are free of animal derived materials. The construction materials for the SkillPak 1k MAX column hardware are listed in [Table 1](#).

Table 1. Materials of Construction for SkillPak 1k MAX hardware

ID	Part list	Material	Wetted
1	Inlet/Outlet ports	Polyether ether ketone (PEEK)	Yes
2	Upper/Lower Adapters	Polypropylene (PP)	Yes
3	Column Body	Polypropylene (PP)	Yes
4	O-rings (internal)	Ethylene propylene diene monomer (EPDM)	Yes
5	Frits	Ultra-High Molecular Weight Polyethylene (UHMWPE)	Yes
6	Sanitary Gaskets (for Shipping)*	Platinum Cured Silicone	Yes
7	Sanitary Flanged End Caps (for Shipping)*	Polypropylene (PP)	Yes
8	Tamperproof Sanitary Clamp and Ties (for Shipping)*	Nylon	No
9	Tension Rod	Polyoxymethylene (POM)	No
10	Upper Retaining Ring	Polyoxymethylene (POM)	No
11	Skirt	Polypropylene (PP)	No
12	Bottom Retaining Ring (with Handles)	Polyoxymethylene (POM)	No
13	Top Cap	Polyoxymethylene (POM)	No
14	Screws/Bolts	Polyether ether ketone (PEEK)	No
15	Potting	Solvent resistant Epoxy Resin	No
16	Optional Stand	Acrylonitrile Butadiene Styrene (ABS), Polyurethane Rubber, and Stainless Steel	No

* These components provide for sealing during shipping. The end user shall replace or discard these items with items well suited for the processes and solvents in use.

Solvent compatibility

The SkillPak 1k MAX columns are designed to withstand most process scale chromatography solvents and buffers. [Table 2](#) lists common solutions compatible with the SkillPak hardware. Please contact Tosoh Bioscience Technical Support if you have any questions about solvents not listed in [Table 2](#). Specific conditions for the TOYOPEARL Super A resin may differ from these conditions.


Table 2. Solvent compatibility for SkillPak 1k MAX hardware

Solvent	Compatible with Integral Wetted Materials	Compatible with Non-Wetted Materials
Water (pH ~7)	Yes	Yes
1.0 mol/L NaCl (pH ~7)	Yes	Yes
3.0 mol/L NaCl (pH ~7)	Yes	Yes
Sodium Phosphate solutions (pH ~4 – 8)	Yes	Yes
1.0 mol/L NaOH (pH ~14.0)	Yes	Yes
10% Acetic Acid (pH ~2.5)	Yes	No
20% HCl (pH ~0)	Yes	No
2% Benzyl Alcohol (pH ~8)	Yes	No
20% Ethanol (pH ~7)	Yes	Yes*
70% Ethanol (pH ~7)	Yes	Yes*
70% Isopropyl Alcohol (pH ~7.7)	Yes	Yes*
Peracetic Acid	Yes	No

*These solvents may be acceptable for short periods of time. The exposed material should be immediately dried after contact with the solvent.

Column specifications

Tosoh Bioscience manufactures SkillPak columns to the highest quality. This allows the columns to be used in a wide range of end-user applications. *Table 3* lists the specifications and operating conditions of SkillPak 1k MAX Super A columns.

 **Table 3.** SkillPak 1k MAX Super A specifications and operating conditions

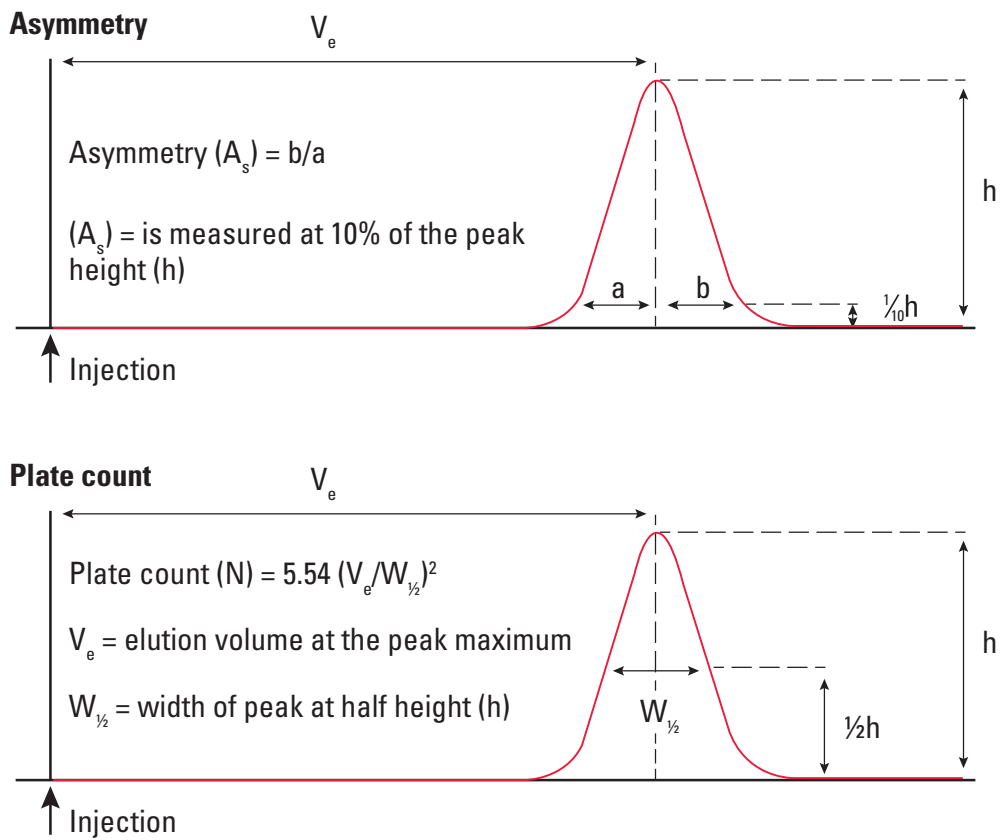
Dimensional Specification	Value
Internal Diameter	8.0 cm
Bed Height	20 cm
Volume	1.0 L
Frit Porosity	10 µm
Outer Diameter including handles	18.8 cm
Height	39.4 cm (includes skirt but not optional stand)
Optional Stand Height	18.2 cm
Product Release Specification	Value
Asymmetry Factor** (A _s)	0.80–1.40
Reduced Plate Height** (h)	≤ 8.0
Microbial Bioburden	≤ 100 CFU/mL
Endotoxin Activity	≤ 10 EU/mL
Operating Condition	Value
Storage Temperature	2–8 °C
Maximum Recommended System Pressure*	4 bar
Maximum Recommended Delta Column Pressure	3 bar
Maximum Recommended Flow Rate	250 cm/h
Connections	¾" sanitary tri-clamp
Shipping Solvent	20% ethanol
Shelf Life	3 months***

*Tosoh Bioscience does not recommend using some chromatographic systems, (e.g. AKTA 150s) at flow rates about 100 cm/h due to very high system pressures approaching 10 bar.

**Testing conditions for asymmetry and reduced plate height are determined by a 1% CV injection of 3 mol/L NaCl in a mobile phase of 1.0 mol/L NaCl.

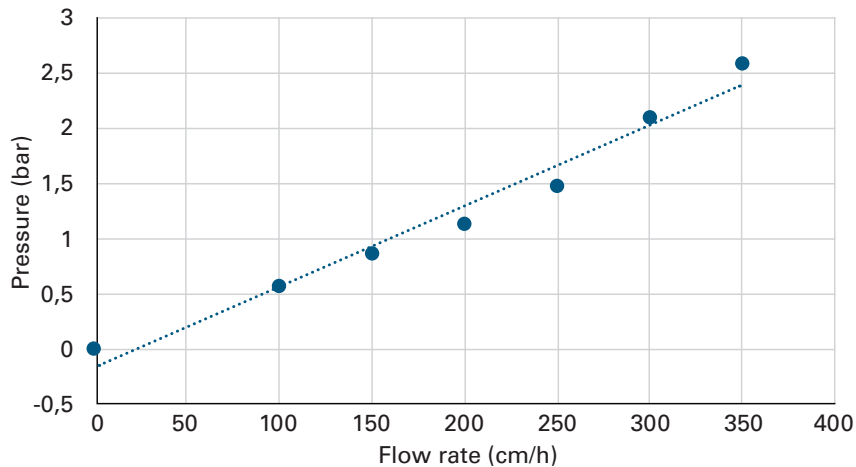
*** Testing for additional time points is ongoing.

Please refer to the Tosoh Bioscience documents PD0110A_PD23 and IM20 for additional information specific to TOYOPEARL Super A resin. These documents are available at www.tosohbioscience.com.



Plates per meter are calculated by taking the number of plates and dividing by the column bed height. HETP is the inverse of plates per meter often reported in cm^{-1} . Reduced plate height (h) is a measure of column efficiency that includes HETP and particle size (d_p) and is used to compare columns of different lengths and particle sizes ($h = \text{HETP}/d_p$). Typical pressure - flow data for SkillPak 1k MAX Super A column is shown in [Figure 3](#).

Figure 3. Average pressure - flow data (3 columns) for SkillPak 1k MAX Super A columns. Mobile phase is 1.0 mol/L NaCl at ambient temperature.



Instructions for Use

1. Installation

- a. Carefully open the outer container and remove the inner box.
- b. *Note: Do not use sharp objects to open the inner box or damage to the plastic bag may occur.* Open the inner box and remove the sealed bag that contains the column.
- c. If requested, remove the small bottle containing the sample of bulk resin. This sample may be used for resin ID or application-specific verification tests.
- d. If the column is going to be used in a clean room, wipe or spray down the clear plastic bag with 70% ethanol prior to opening.
- e. Open the clear plastic bag and inspect the column for any cracks or leaks.
- f. If using the optional stand, lock the skirt of the column into the stand by rotating clockwise about $\frac{1}{4}$ turn. Attach the column to the chromatography system according to the flow direction indicated by the arrow on the label, taking extreme care to prevent the introduction of air into the column. Do not attach heavy valves to the top or bottom of the column, as this may place undue mechanical stress on the column. When connected to the chromatography system, the column must remain upright and stable, even without the column stand. Ensure that hoses and tubing are properly supported and do not cause the column to be unbalanced.

2. Equilibration

- a. Best practices for pre-packed chromatography columns recommend that the new column be performance tested prior to use. Tosoh Bioscience performs this test by injecting a 1% CV of 3 mol/L NaCl onto the column running in a mobile phase of 1.0 mol/L NaCl at 100 cm/h. Tosoh Bioscience has optimized testing systems in our laboratory, so the results obtained by the end user may be slightly different than those results listed on the Certificate of Analysis. If the results of testing are significantly different or out of specification, please contact Tosoh Bioscience Technical Support before returning the column.
- b. Once the column is attached to the chromatography system, remove the shipping solvent (20% ethanol) with purified water by flowing at approximately 100 cm/hr for 2 CVs. After 2 column volumes of water, the column can be equilibrated with the appropriate mobile phase. This step prevents over-pressuring of the system due to the viscosity differences in the mobile phases.
- c. After the column passes incoming specifications, and before the first sample injection, the column should be equilibrated with at least 3 CV of the respective loading buffer. Slowly increase flow until it reaches the desired running flow rate but do not exceed the maximum flow rate (*see Table 3*). Buffer composition and gradient design are dependent on the resin type and resin chemistry. Please refer to the TOYOPEARL Super A documentation for information about recommended mobile phases (Tosoh Bioscience Documents PD23 and IM20).

3. Operation

TOYOPEARL Super A resin is a high-capacity Protein A resin that is ideally suited for capture of monoclonal antibodies or fusion proteins containing the Fc portion of an IgG molecule. Most applications involve a capture at neutral pH, followed by a wash step at intermediate pH. Elution is affected with a low pH treatment of citrate or acetate buffers. Once the product is eluted the resin is typically washed with neutral salt solutions. The column hardware is designed to be able to withstand many chromatographic cycles of the binding and elution of proteins onto the resin.

4. Regeneration & storage

SkillPak 1k MAX columns can be washed, regenerated and sanitized with typical buffers such as 0.5 mol/L NaOH. The columns can also be returned to the shipping buffer for storage after a water washing step. Please refer to the TOYOPEARL Super A product documentation for information about cleaning and storage solutions. SkillPak 1k MAX Super A columns are reusable if the plate counts and asymmetry remain in the desired range, which will largely depend on the care taken, the cleaning performed, and the tolerance of the resin to the applied conditions. The columns are not designed to be repacked.

Reduce, Recycle



Always store the column in its original packaging. It will prolong its lifetime, thus reducing the number of columns you will need.



The box and the foam inserts can be recycled following local regulations. The column can be disposed of as single-use waste according to local regulations.

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This chromatography column is supplied pre packed and is intended for use in bioprocessing applications within facilities operating in accordance with applicable Good Manufacturing Practice (GMP) guidelines. It is the sole responsibility of the end user to determine the column's suitability for its intended use, including integration with upstream or downstream unit operations.

Tosoh Bioscience LLC and its affiliates neither guarantee performance in any particular purification process, nor warrant that the column will achieve specific yield, purity, or scalability outcomes. All warranties, representations, conditions, and guarantees of any kind, whether express, implied, statutory, or otherwise, including, without limitation, implied warranties or conditions of satisfactory quality, merchantability, or fitness for a particular purpose; any warranty that the column will meet the user's specific requirements or intended use, whether or not communicated to the Tosoh Bioscience LLC; and any warranties arising from course of dealing, usage of trade, or prior performance, are expressly excluded and disclaimed.

The user assumes all risks associated with the handling, installation, operation, cleaning, storage, and disposal of the column.

This product is not intended for diagnostic, therapeutic, or clinical use. All operations must be performed by appropriately trained personnel in accordance with applicable safety procedures, including the use of suitable personal protective equipment (PPE) and adherence to facility specific safety requirements. The user is responsible for ensuring that use of this column complies with all applicable standards and guidelines.

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