



Product Overview



SkillPak™ 1k MAX - Pre-packed Chromatography Columns for GMP Manufacturing

A Scalable Chromatography Platform from Development to GMP Manufacturing

The SkillPak Chromatography Platform is a family of pre-packed chromatography columns designed to support the full downstream lifecycle—from early process development through pilot and commercial-scale manufacturing.

In the past, the SkillPak platform encompassed a well-established, non-GMP portfolio supporting both batch and continuous process development. For batch workflows, SkillPak pre-packed columns are available in 1 mL, 5 mL, 50 mL, and 200 mL formats and are widely used for resin screening, method development, process optimization, and scale down modeling.

In parallel, the SkillPak BIO series enables non-GMP multi-column chromatography (MCC) workflows, supporting continuous process development, optimization, and pilot-scale intensification.

Together, these formats provide a robust foundation for early-stage development using TOYOPEARL® resins, ensuring consistent chemistry and predictable performance across batch and continuous applications.

Extending the Platform into GMP Manufacturing

SkillPak 1k MAX is the first GMP-ready batch chromatography column in the SkillPak manufacturing platform. It is a pre-packed column containing approximately 1 liter of resin, supplied ready-to-use for regulated batch production, and represents the initial step in extending SkillPak from development into GMP manufacturing.

The SkillPak MAX platform is designed as a scalable batch manufacturing solution. While the 1-liter format is the first size being introduced, additional larger batch columns—including 3 L, 6 L, 14 L, 30 L, and 60 L formats—are planned as part of a defined product pipeline to support seamless scale-up from pilot to commercial manufacturing. The size designation reflects the approximate resin volume in each column.

In parallel, the upcoming SkillPak PRO platform extends the SkillPak family into GMP-ready continuous (multi-column) chromatography. PRO columns are purpose-built for continuous processing and will be available in 250 mL and 800 mL formats, optimized for multi-column capture workflows.

Across both batch (SkillPak MAX) and continuous (SkillPak PRO) platforms, the TOYOPEARL resin portfolio will be available throughout the SkillPak family, enabling consistent resin chemistry from early development through full-scale GMP manufacturing.

SkillPak 1k MAX Super A

SkillPak 1k MAX Super A is a GMP-ready, pre-packed chromatography column designed to support the transition from process development into regulated batch manufacturing using TOYOPEARL Super A resin which is a cutting-edge, next generation Protein A media. As part of the SkillPak Chromatography Platform, it provides a standardized, manufacturing-relevant column format with defined geometry, predictable pressure-flow behavior, and reproducible packed-bed quality.

Supplied in a ready-to-use configuration, SkillPak 1k MAX Super A eliminates the need for onsite packing and column qualification, helping to reduce implementation time, operational variability, and scale-up risk in pilot and manufacturing environments.

Key Benefits

- GMP-ready, pre-packed column for batch manufacturing
- Ready-to-use format eliminates packing and qualification
- ISTA-evaluated shipping robustness
- BPOG-aligned extractables support for regulatory confidence
- Short lead times enabled by vertical integration

Standard Column Configuration

SkillPak 1k MAX is supplied in a standardized, manufacturing-relevant column configuration designed to support predictable scale-up and straightforward integration into existing batch chromatography systems. The defined geometry and industry-standard 3/4-inch sanitary tri-clamp connections ensure compatibility with commonly used process equipment while maintaining consistent pressure-flow behavior across scales.

Table 1. Physical parameters of SkillPak 1k MAX columns

Parameter	Value
Actual internal diameter	8 cm
Bed height	20 cm
Volume at 20 cm bed height	1.005 L
Assembled hardware height	39.4 cm
Hardware outer diameter	18.8 cm

This geometry aligns with established SkillPak development formats and larger MAX columns, enabling consistent process translation without re optimization when entering GMP production.

Packing Quality and Performance Confidence

Each SkillPak 1k MAX column is packed under controlled, proprietary conditions to support uniform bed structure and consistent chromatographic performance. Packing quality is verified prior to release using defined performance criteria, with results documented on the Certificate of Analysis (CoA).

Table 2. SkillPak 1k MAX specifications and operating conditions

Specification	Value
Asymmetry factor (As)*	0.80–1.60
Reduced plate height (h)*	≤ 8.0
Microbial bioburden	≤ 100 CFU/mL
Endotoxin activity	≤ 10 EU/mL
Operating Condition	Value
Maximum column pressure drop (ΔP)	3 bar
Maximum recommended system pressure	4 bar
Maximum recommended flow rate	≤ 250 cm/hr
Operating temperature	4–30 °C
Storage temperature	2–8 °C or 4– 35 °C (resin dependent)

*Measured under defined test conditions.

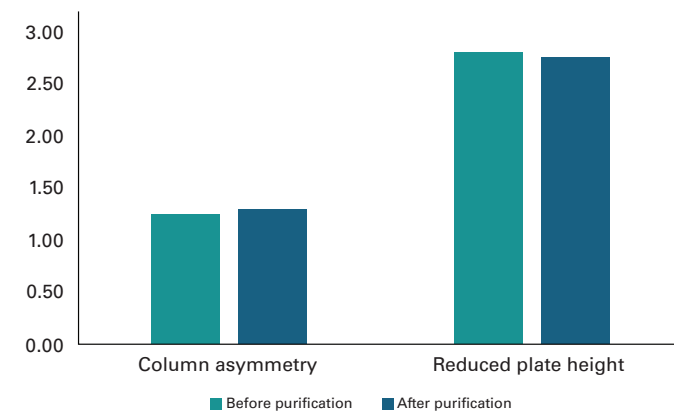
Packing quality and column robustness were evaluated on the SkillPak 1k MAX Super A column using a representative monoclonal antibody (mAb) capture process with trastuzumab as a model mAb as shown in **Table 3**. Column performance was assessed by measuring key efficiency parameters prior to use and after two purification cycles followed by cleaning-in-place (CIP).

Table 3. Process parameters for trastuzumab purification on SkillPak 1k MAX Super A

Parameter	Condition
Column	SkillPak 1k MAX Super A
Resin	TOYOPEARL Super A
Equilibration buffer	20 mmol/L sodium phosphate, 150 mmol/L NaCl, pH 7.4
Wash buffer	25 mmol/L sodium citrate, 150 mmol/L NaCl, pH 5.2
Elution buffer	25 mmol/L sodium citrate, pH 3.2
CIP solution	250 mmol/L NaOH
Load material	Trastuzumab feedstock (~9.43 g/L), 0.45 μm filtered
Load level	80% of TOYOPEARL Super A dynamic binding capacity
Linear velocity	240 cm/h
Residence time	5 minutes

The results as shown in **Figure 1**, demonstrate stable efficiency metrics across cycles, confirming preserved bed integrity, mechanical robustness, and reproducible chromatographic performance under representative operating conditions.

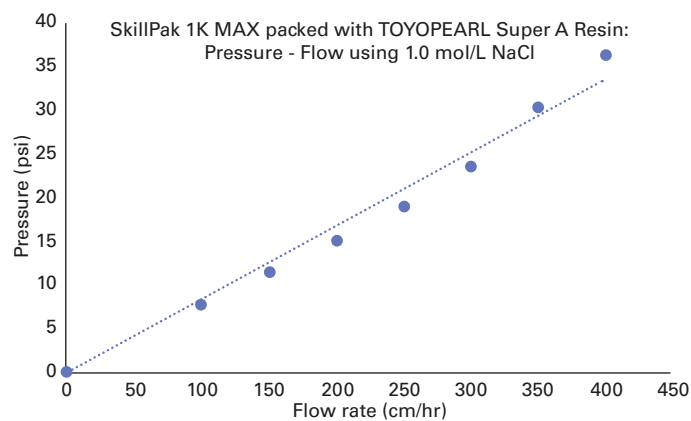
Figure 1. Demonstrated Packing Quality and Performance Stability



Pressure-flow Behavior and Operational Robustness

SkillPak 1k MAX is designed to deliver stable and predictable pressure-flow behavior, supporting reliable operation across pilot and manufacturing-scale batch workflows. As shown in **Figure 2**, the column exhibits a linear pressure-flow relationship over the tested operating range, indicating uniform bed packing and controlled pressure buildup during operation.

Figure 2. Pressure-flow data for SkillPak 1k MAX Super A



Key Design features include:

- Defined pressure rating suitable for batch chromatography operations
- Factory leak and pressure testing prior to shipment
- Uniform flow distribution to help minimize channeling and uneven bed utilization

A column stand (**Figure 3**) is available to support handling, installation and operational stability, particularly in GMP suites and pilot scale facilities, helping reduce installation risk and improve day-to-day usability.

Figure 3. SkillPak 1k MAX & Column stand



GMP Compliance and Regulatory Confidence

SkillPak 1k MAX is designed and manufactured to support use in regulated GMP environments, helping customers reduce qualification effort and accelerate deployment into clinical and manufacturing workflows.

Materials and design choices are made with regulatory expectations in mind, including:

- Wetted materials that meet USP Class VI requirements, supporting biocompatibility expectations
- Animal origin free materials, aligned with industry risk mitigation strategies
- Drop testing in flat, edge, and corner orientations to represent typical manual handling events
- Compression testing to simulate stacking conditions during storage and shipment

Table 4. Column Parts & Material of Construction

Part List	Material
Inlet/Outlet ports	Polyether ether ketone (PEEK)
Upper/Lower Adapters	Polypropylene (PP)
Column Body	Polypropylene (PP)
O-rings (internal)	Ethylene propylene diene monomer (EPDM)
Frits	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Sanitary Gaskets (for Shipping)	Platinum Cured Silicone
Sanitary Flanged End Caps (for Shipping)	Polypropylene (PP)
Tamperproof Sanitary Clamp and Ties (for Shipping)	Nylon
Tension Rod	Polyoxymethylene (POM)
Upper Retaining Ring	Polyoxymethylene (POM)
Skirt	Polypropylene (PP)
Bottom Retaining Ring (with Handles)	Polyoxymethylene (POM)
Top Cap	Polyoxymethylene (POM)
Screws/Bolts	Polyether ether ketone (PEEK)
Potting	Solvent resistant epoxy resin

Each column is supplied with a comprehensive Certificate of Analysis (CoA) documenting key quality and performance attributes. In addition, a Regulatory Support File (RSF) is available to support customer qualification, validation activities, and regulatory submissions.

Shipping Robustness and Product Integrity

Shipping robustness is assessed to ensure that the pre-packed SkillPak 1k MAX column maintains its packing quality and chromatographic performance throughout transport, enabling confident, ready-to-use deployment upon receipt.

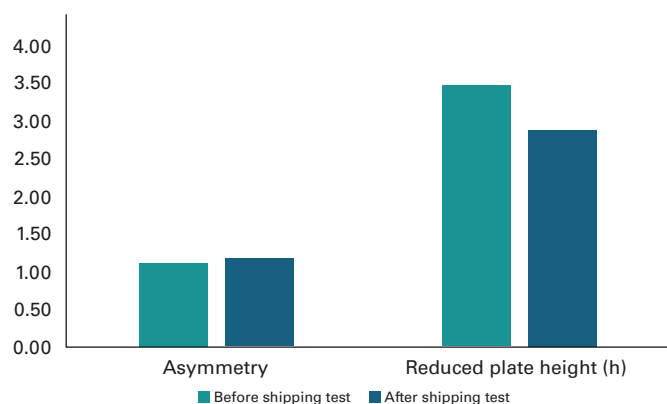
SkillPak 1k MAX packaging was evaluated using ISTA 3A shipping simulations designed to replicate real-world parcel distribution conditions encountered during routine global logistics.

The shipping assessment includes:

- Temperature and humidity conditioning to confirm performance stability across realistic environmental exposures
- Vibration testing simulating truck transport and conveyor handling to verify packed-bed stability during routine movement
- Drop testing in flat, edge, and corner orientations to represent typical manual handling events
- Compression testing to simulate stacking conditions during storage and shipment

Post-shipping acceptance is based on chromatography-relevant performance metrics: column asymmetry and reduced plate height. The results as shown in **Figure 4** demonstrate that packed-bed integrity and column efficiency are maintained following transport, supporting immediate, ready-to-use operation without additional handling or intervention and reduces operational uncertainty at receipt.

Figure 4. Column Performance Metrics Before and After ISTA 3A Shipping Evaluation



Seamless Scale-Up from Development to GMP Manufacturing

A seamless pathway from downstream process development to GMP manufacturing is enabled by the SkillPak platform, allowing purification processes to be advanced with confidence and consistency. Designed as a single, scalable column family, the platform supports smooth progression across development, pilot, and production scales while preserving process continuity. SkillPak 5 (5 mL) is used for early method development, SkillPak 50 (50 mL) supports scale-up and process verification, and SkillPak 1k MAX (~1 L) extends the same platform directly into production-scale, GMP batch chromatography. Through this integrated design, process changes are minimized, scale-up risk is reduced, and readiness for manufacturing is accelerated.

Platform scalability has been demonstrated using TOYOPEARL Super A in a representative monoclonal antibody capture application. The same purification approach was applied consistently across SkillPak development, scale-up, and GMP manufacturing formats, with operating conditions aligned to maintain comparable residence times across column sizes.

Table 5. Process Conditions

Parameter	Condition
Columns	SkillPak 5 Super A, 5 mL column, 8.0 × 10 cm
	SkillPak 50 Super A, 50 mL column, 2.5 × 10 cm
	SkillPak 1k MAX Super A, 1005mL column, 8.0 × 20 cm
Resin	TOYOPEARL Super A
Equilibration buffer	20 mmol/L sodium phosphate, 150 mmol/L NaCl, pH 7.4
Wash buffer	25 mmol/L sodium citrate, 150 mmol/L NaCl, pH 5.2
Elution buffer	25 mmol/L sodium citrate, pH 3.2
CIP solution	250 mmol/L NaOH
Load material	Trastuzumab feedstock (~9.43 g/L), 0.45 μm filtered
Load level	80% of TOYOPEARL Super A dynamic binding capacity
Linear velocity*	240 cm/h; 120 cm/h
Residence time	5 minutes

* Flow rates were adjusted to 120 cm/h for SkillPak 5 and SkillPak 50 to maintain identical residence times across the different column sizes.

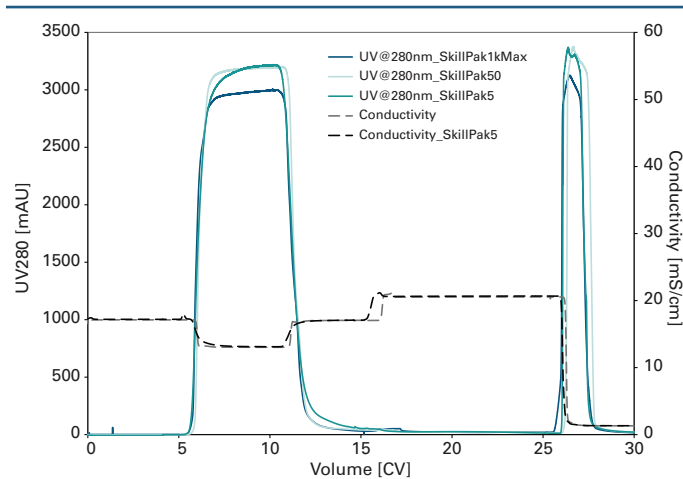
As a result, chromatographic performance and product quality were preserved while progressing from development to GMP manufacturing within a single, unified platform.

The consistent performance observed across scales confirms that processes developed on SkillPak 5 and SkillPak 50 can be transferred directly to SkillPak 1k MAX without fundamental re-optimization. By enabling predictable, straightforward scale-up, the SkillPak platform helps reduce development effort, simplify process transfer, and support a confident transition from development and pilot scale into GMP manufacturing.

Table 6. Key Results Summary

Parameter	SkillPak 5	SkillPak 50	SkillPak 1k MAX
Eluate concentration (mg/mL)	15.15	15.57	18.42
Recovery (%)	96.78	97.58	98.71
Monomer content (%)	94.11	93.10	94.74
HMW content (%)	4.63	5.59	3.99
LMW content (%)	1.32	1.32	1.26

Figure 5. Overlay of purification chromatograms across SkillPak 5, 50, and 1k MAX



Reliable Supply and a Defined Path to Scale

Reliable supply and manufacturing readiness are supported through end-to-end vertical integration of the SkillPak 1k MAX offering. Both resin manufacturing and column packing are performed within the Tosoh group under independently certified quality systems, providing customers with confidence in product consistency, quality oversight, and long-term supply continuity.

This integrated approach delivers clear customer benefits, including full lot traceability to support regulatory confidence, single-vendor accountability to simplify qualification and procurement, and typical lead times of approximately 3–4 weeks to enable faster implementation and more predictable manufacturing planning.

As the first GMP batch format within the SkillPak family, SkillPak 1k MAX establishes a strong and reliable foundation for customers transitioning from development-scale operations into regulated GMP production, while maintaining alignment with the broader SkillPak platform.

Ordering Information

Part #	Product Description
0045601	SkillPak 1k MAX Super A, 1005 mL column, 8.0 × 20 cm
0045600	SkillPak Column Stand (8-20 cm ID)

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