

SkillPak™ 5 mL INSTRUCTION MANUAL FOR TOYOPEARL®, TSKgel® AND Ca⁺⁺Pure-HA™ PROCESS MEDIA

INTRODUCTION

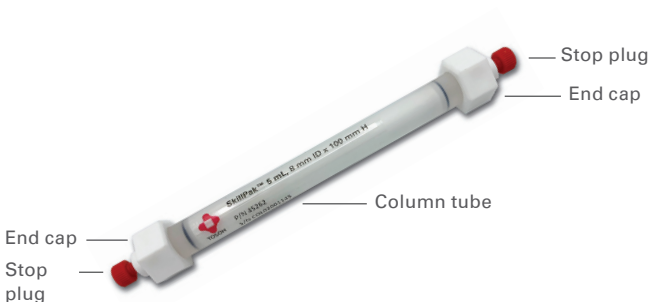
SkillPak 5 mL columns (8 mm ID × 10 cm) are designed for fast method development or resin screening and are pre-packed with TOYOPEARL, TSKgel or Ca⁺⁺Pure-HA process chromatography media for bio-separations. These columns are designed to be operated with commonly used low or medium pressure liquid chromatography systems.

SkillPak 5 mL columns are reproducibly packed and take into account the varying compressibility of each resin. This provides an accurate representation of conditions found in full scale columns.

PRODUCT DESCRIPTION

Hardware Materials

The hardware of SkillPak 5 mL columns is composed of bio-compatible polymers, mainly polypropylene. Table 1 lists properties and operation specifications of the SkillPak 5 mL columns.



INSTRUCTIONS FOR USE

Installation

SkillPak 5 mL columns are ready to use upon receipt. Connect the column to the instrument following the recommended flow direction as indicated on the column label. Connect inlet/outlet of column to instrument using 10-32 fitting. Finger-tight is recommended.

Equilibration

Before the first sample injection, the column should be equilibrated with at least 10 CV of the respective loading buffer. See Table 1 for standard flow rate and maximum operating pressure. Slowly increase flow until it reaches the desired running flow rate. Do not exceed the maximum flow rate.

Buffer composition and gradient design is dependent on the resin type and resin chemistry. Please refer to the TOYOPEARL, TSKgel or Ca⁺⁺Pure-HA product documentation for more information about recommended mobile phases.

 **Table 1.** Specifications of SkillPak 5 mL columns

| | |
|--------------------------------------|---|
| Column dimension | 8 mm ID × 10 cm bed height |
| Volume | 5 mL |
| Standard flow rate | 1.3 mL/min (150 cm/hr) |
| Maximum flow rate | 5 mL/min (600 cm/hr) for TOYOPEARL M and C grade resins; 2.5 mL/min (300 cm/hr) for TOYOPEARL S-grade, TSKgel, Ca ⁺⁺ Pure-HA and TOYOPEARL F grade resins, including TOYOPEARL AF-rProtein A HC-650F, TOYOPEARL AF-rProtein L-650F, and Ca ⁺⁺ Pure-HA |
| Maximum operating pressure | 0.3 MPa for TOYOPEARL resins, ≤ 0.4 MPa for TSKgel resins and Ca ⁺⁺ Pure-HA |
| Connections | Standard fittings (10-32 for 1/16 inch capillary) |
| Shipping buffer | 20% ethanol for TOYOPEARL and TSKgel, 20 mmol/L phosphate with 20% ethanol for Ca ⁺⁺ Pure-HA |
| Asymmetry factor (As) specifications | 0.8-1.4 for TOYOPEARL and TSKgel, 0.8-2.6 for Ca ⁺⁺ Pure-HA |

Column performance test

The chromatographic performance of a SkillPak 5 mL column should be tested initially and at regular intervals and is determined by the asymmetry factor. The specification can be found in Table 1.

For most of the TOYOPEARL S-grade, F-grade, M-grade, and TSKgel resins, the evaluation can be carried out as described below:

- Equilibrate columns with ≥ 10 CV of 150 mmol/L NaCl @ ≤ 300 cm/hr
- Decrease the flow rate to 150 cm/hr and inject 1% CV of 3 mol/L NaCl tracer
- Wash with 2 CV of 150 mmol/L NaCl @ 150 cm/hr

Note: the response can be detected using the conductivity meter.

For TOYOPEARL GigaCap series of resins, the evaluation can be carried out as described below:

- Equilibrate columns with ≥ 10 CV of 1 mol/L NaCl @ ≤ 300 cm/hr
- Decrease the flow rate to 150 cm/hr and inject 1% CV of 3 mol/L NaCl tracer
- Wash with 2 CV of 150 mmol/L NaCl @ 150 cm/hr

Note: the response can be detected using the conductivity meter.

For Ca⁺⁺Pure-HA media, the evaluation can be carried out as described below:

- Equilibrate columns with ≥ 10 CV of 0.2 mol/L sodium phosphate, pH 6.8 @ ≤ 300 cm/hr
- Decrease the flow rate to 150 cm/hr and inject 1% CV of 1% acetone tracer
- Inject 100 μ L of 1% acetone in 0.2 mol/L sodium phosphate, pH 6.8 @ 150 cm/hr

Note: the response can be detected using UV @ 280 nm.

Regeneration and storage conditions

SkillPak 5 mL columns can be washed/regenerated. The columns can also be returned to shipping buffer for later use. Please refer to the TOYOPEARL, TSKgel or Ca⁺⁺Pure-HA product documentation for more information about storage and cleaning solutions.

SkillPak 5 mL columns are reusable as long as the resin remains in acceptable condition, which will largely depend on the care taken, the cleaning performed and the tolerance of the resin to applied conditions. The columns are not designed to be repacked.

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