

GMP Grade Packed Column

50 mm i.d. x 100 mm bed height

Column handling on delivery

Open the outer box from the top. Carefully take out the inner column box and the side with the product label should face upwards. Open the top of the product box, remove the protection material (e.g., foam pads). Carefully hold the top side of the bag to take the column out. Be careful not to damage the tubing connections on the top.

Place the bagged column into a cold room on delivery.

General information of the column construction

All the column components that are in contact with fluids meet the regulatory requirements. e.g., FDA CFR 177, USP Class VI and animal origin free (or in compliance with the EMEA 410/01). Detailed information is available in the regulatory support file of GMP grade columns.

Column body (i.e., the tube): made of borosilicate glass.

End plunger: The main body, the flow distributor and the triclamp connector are made of polypropylene. The O-ring is of viton rubber. The triclamp gasket is made of EPDM. The supporting mesh is made of polyamide of 15 micrometre. They are inert to most aqueous buffers.

Connection: Both ends of the column have standard 1/2"-3/4" triclamp connector. The End Cap is made of polypropylene. The triclamp is made of nylon.

Holding frame: M8 stainless steel

Operating pressure: recommended rating is up to 3 bar (or 0.3 MPa, or 42 psi).

Operating temperature: 4°C to 30°C.

Inlet and outlet arrangement: The outlet of the column is located on the bottom plate and is sealed with a triclamp End Cap. The inlet of the column is located in the middle of the top plate and is connected to a soft sealing tubing to prevent the column from drying.

Column Packing and Storage

Each column is packed, tested, sanitised, and sealed inside a Class 7 cleanroom. The column is sanitised using 0.5 M NaOH and stored in 20% ethanol.

After labelling, the column is sealed inside 2 heat-sealed polyolefin bags in the clean room.

Instruction of Use

The column should be stored in a cold room after it is delivered. Handle the column with care to avoid any damage, as the column connections are vulnerable to strong forces.

Check the bioburden and endotoxin level of the column before use. If the level is too high, conduct the sanitisation-in-place step before use.

CAUTION: Be extremely careful during the tightening and loosening of the outlet triclamp. Hold the triclamp firmly under balanced force when unscrewing or screwing, as the triclamp connection to the column could be broken under a non-balanced force.

1. Remove the protection bags with care.
2. Place the column upwards to a suitable surface in a vertical position.
3. Hold the flexible sealing tubing upwards. Gently tap the lower and upper sides of the inlet tubing. It will allow air bubbles in the inlet tubing of the column (if any) to escape.
4. Gently remove the triclamp between the sealing tubing and the inlet. Gently squeeze the sealing tubing first, then disconnect it from the inlet. This procedure avoids sucking air into the inlet tubing.
5. Connect the inlet of the column to the chromatography instrument. Be careful not to trap air bubbles, for example, by running the instrument at very low flowrate during the connection period.
6. Keep running the pump at very low flowrate. Bend the outlet tubing (located at the bottom side of the column) upwards. Carefully remove the end cap and make connection to the outlet to avoid air getting into the bottom mesh of the column.
7. Check for the bioburden and endotoxin level. Alternatively, go to step 8.
8. Sanitisation-in-place (SIP) step. Run through 3 CV, i.e., 600 ml of 0.5 M NaOH and 4 CV, i.e., 800 ml of the equilibration buffer at a flowrate of 10 ml/min or less. The flowrate can be increased after 2 CV of the equilibration buffer is pumped through.
9. Now the column is ready for use.

Storage After Use

For the short-term storage, disconnect the outlet side of the column and seal it with a triclamp end cap. Then disconnect the inlet of the column and seal it with a triclamp end cap. Make sure the end caps are sanitised before use.

For long-term storage, follow the instructions below.

1. Flush the column with the storage liquid. If an organic solvent such as 20% ethanol is used, introduce it in a reduced flowrate such as 10 ml/min for at least 3 CV, i.e., 600 ml.
2. Disconnect the outlet of the column. Seal using a Triclamp end cap.
3. Disconnect the inlet of the column from the control instrument.
4. Connect one end of the sealing tubing to the inlet tubing of the control instrument. Hold the sealing tubing upwards. Run the pump slowly to fill the sealing tubing with the storage liquid. Then connect it to the inlet of the column. Avoid trapping air bubbles.
5. Disconnect the sealing tubing from the control instrument. Seal it using an end cap.
6. Place the column in a cold room.