

WHAT IS CLAIMED IS:

1. A method of removing entrapped gas, pressure, or both gas and pressure from a pre-packed chromatography column that comprises a column tube having a column tube inlet and a column tube outlet and first and second flow distributors arranged within the column tube to form a chamber filled with a packing medium, the method comprising:
 - (a) obtaining a tubing and valve set comprising tubing and at least one valve configured to define at least two different fluid paths through the tubing;
 - (b) either:
 - (i) attaching tubing of the tubing and valve set to the column tube inlet and the column tube outlet and then sterilizing the connected pre-packed chromatography column and the tubing and valve set, or
 - (ii) sterilizing the pre-packed chromatography column and the tubing and valve set individually and then attaching the sterile tubing of the tubing and valve set to the sterile column tube inlet and the sterile column tube outlet in a manner that maintains sterility of both the column and the tubing and valve set;
 - (c) attaching the sterile tubing and valve set to a sterile or aseptic fluid source and to a fluid outlet; and
 - (d) pumping sterile or aseptic liquid from the sterile or aseptic fluid source along the tubing and valve set, wherein the at least one valve is in a first position, into the column tube inlet and out from the column tube outlet along a first flow path, thereby removing any entrapped gas, pressure, or both gas and pressure from the chamber, the tubing, and the at least one valve along the first flow path without breaching the sterility of the pre-packed chromatography column and the tubing and valve set.
2. The method of claim 1, comprising attaching tubing of the tubing and valve set to the column tube inlet and the column tube outlet and then sterilizing the connected pre-packed chromatography column and the tubing and valve set.

3. The method of claim 1, comprising sterilizing the pre-packed chromatography column and the tubing and valve set individually and then attaching the sterile tubing of the tubing and valve set to the sterile column tube inlet and the sterile column tube outlet.
4. The method of claim 3, wherein attaching the sterile tubing of the tubing and valve set to the sterile column tube inlet and the sterile column tube outlet in a sterile manner comprises using aseptic or sterile connectors or weldable tubing.
5. The method of any one of claims 1-4, wherein sterilizing comprises irradiation with gamma radiation.
6. The method of claim 5, wherein sterilizing comprises applying a gamma radiation dose of at least 8 kGy.
7. The method of any one of claims 1-6, wherein attaching tubing to the column tube inlet and the column tube outlet comprises connecting ends of the tubing to a connector fixed to the column tube inlet and to a connector fixed to the column tube outlet.
8. The method of claim 7, wherein the connectors are screwed into, clamped onto, or welded to the column tube inlet and to the column tube outlet.
9. The method of any one of claims 1-8, further comprising moving the at least one valve from the first position to a second position to direct the sterile or aseptic liquid along a second flow path.
10. The method of any one of claims 1-8, further comprising moving the at least one valve from the first position to a second position and pumping sterile or aseptic liquid from the sterile or aseptic liquid source into the column tube outlet, through the pre-packed column tube, and out of the column inlet.
11. The method of claim 10, further comprising pumping a volume of sterile or aseptic liquid equivalent to 0.1 or more volumes of the chamber.

12. The method of any one of claims 1-11, further comprising attaching the tubing to a sterile or aseptic filter and pumping sterile or aseptic liquid through the sterile or aseptic filter.
13. The method of claim 12, further comprising collecting the sterile or aseptic liquid pumped through the sterile or aseptic filter and testing one or more properties of the sterile or aseptic liquid.
14. The method of any one of claims 1-13, comprising venting pressure from the tubing and valve set with a vent filter.
15. The method of any one of claims 1-14, further comprising attaching tubing from the tubing and valve set to an expansion bag.
16. The method of any one of claims 1-15, wherein the column tube is pre-packed for a single use and is disposable.
17. The method of any one of claims 1-16, wherein the pre-packed chromatography column and tubing and valve set are connected to a chromatography system.
18. A system for aseptic purification of biomolecules, the system comprising:
 - a sterile pre-packed chromatography column comprising a column tube having a column tube inlet and a column tube outlet and first and second flow distributors arranged within the column tube to form a chamber filled with a packing medium;
 - a sterile tubing and valve set attached to the column tube inlet and the column tube outlet, wherein the tubing and valve set comprises tubing and at least one valve configured to define at least two different fluid paths fluidly connected to the column tube inlet and the column tube outlet; and
 - a pump configured to pump sterile or aseptic liquid from a sterile or aseptic fluid source along the sterile tubing and valve set, wherein the at least one valve comprises a first position that enables the sterile or aseptic liquid to flow into the column tube inlet and out of the column tube outlet along a first flow path to remove any entrapped gas,

pressure, or both gas and pressure from the chamber, the tubing, and the at least one valve along the first flow path.

19. The system of claim 18, wherein the sterile column is pre-packed with resin and the column, resin, and tubing have a sterility assurance level (SAL) of 10^{-3} or better.

20. The system of claim 18 or claim 19, further comprising a controller configured and arranged to control the pump and the position of the at least one valve.

21. The system of claim 20, wherein the controller comprises a processor and a memory storing instructions for execution by the processor for opening and closing the at least one valve.

22. The system of any one of claims 18-21, further comprising connectors at the column inlet and outlet configured to form sterile or aseptic connections and to permit fluid to flow through the chamber formed between the first and second flow distributors.

23. The system of claim 22, wherein the connectors are pre-installed to form sterile or aseptic connections with the tubing and valve set.

24. The system of any one of claims 18-23, further comprising a second pump fluidly attached to the tubing and valve set.

25. The system of any one of claims 18-24, further comprising a vent filter arranged in the tubing and valve set to enable venting gas, pressure, or gas and pressure from the pre-packed chromatography column and the tubing and valve set.

26. The system of claim 25, wherein the vent filter comprises a hydrophobic vent filter and a check valve.

27. The system of any one of claims 18-26, wherein the chromatography column tube is formed of one or more of stainless steel, glass, polypropylene (PP), polyethylene (PE), polyamides, acetals, or glass-filled or carbon-filled plastics or elastomeric components.
28. The system of any one of claims 18-27, wherein the chromatography packing medium is one of glass, plastic, cellulose, agarose, ceramic, or polymer, in the form of rough particles, fibers, membranes, or beads.
29. The system of any one of claims 18-28, wherein the chromatography column tube is pre-packed for a single use and is disposable.