

STERILE CHROMATOGRAPHY RESIN AND USE THEREOF IN MANUFACTURING PROCESSES

Abstract

5 Provided herein are methods of reducing bioburden of (e.g., sterilizing) a
chromatography resin that include exposing a container including a composition
including a chromatography resin and at least one antioxidant agent and/or chelator to
a dose of gamma-irradiation sufficient to reduce the bioburden of the container and
the chromatography resin, where the at least one antioxidant agent and/or chelator are
present in an amount sufficient to ameliorate the loss of binding capacity of the
10 chromatography resin after/upon exposure to the dose of gamma-irradiation. Also
provided are reduced bioburden chromatography columns including the reduced
bioburden chromatography resin, compositions including a chromatography resin and
at least one chelator and/or antioxidant agent, methods of performing reduced
bioburden column chromatography using one of these reduced bioburden
15 chromatography columns, and integrated, closed, and continuous processes for
reduced bioburden manufacturing of a purified recombinant protein.

[Figure 14]