

a1. providing a cell culture supernatant containing the antibody;

b1. processing the cell culture supernatant through an affinity chromatography resin to obtain an affinity chromatography pool containing the antibody;

c1. inactivating viruses in the affinity chromatography pool to obtain a virus inactivated solution;

d1. treating the virus inactivated solution with an activated carbon material to obtain an activated carbon material pool; and

e1. processing the activated carbon material pool through a cation exchange material to obtain a cation exchange material pool.

[2] A method for purifying an antibody from a composition containing one or more impurities, comprising the steps of:

a2. providing a cell culture supernatant containing the antibody;

b2. processing the cell culture supernatant through an affinity chromatography resin to obtain an affinity chromatography pool containing the antibody;

c2. inactivating viruses in the affinity chromatography pool to obtain a virus inactivated solution;

d2. processing the virus inactivated solution through a depth filter to obtain a depth filtration pool;

Claims

[Claim 1]

A method for purifying an antibody from a composition containing one or more impurities, comprising the steps of:

a1. providing a cell culture supernatant containing the antibody;

b1. processing the cell culture supernatant through a Protein A affinity chromatography resin to obtain an affinity chromatography pool containing the antibody;

c1. inactivating viruses in the affinity chromatography pool to obtain a virus inactivated solution;

d1. treating the virus inactivated solution with an activated carbon material to obtain an activated carbon material pool; and

e1. processing the activated carbon material pool through a cation exchange material in flow-through (F/T) mode to obtain a cation exchange material pool,

wherein the solution to be loaded on the activated carbon material, and an equilibration buffer and a wash buffer for the activated carbon material each have a pH of 4.5 to 7.5 or an electrical conductivity of 2 to 10 mS/cm, or both.

[Claim 2]

A method for purifying an antibody from a composition containing one or more impurities, comprising the steps of:

a2. providing a cell culture supernatant containing the antibody;

b2. processing the cell culture supernatant through a Protein A affinity chromatography resin to obtain an affinity chromatography pool containing the antibody;

c2. inactivating viruses in the affinity chromatography pool to obtain a virus inactivated solution;

d2. processing the virus inactivated solution through a depth filter to obtain a depth filtration pool;

e2. treating the depth filtration pool with an activated carbon material to obtain an activated carbon material pool; and

f2. processing the activated carbon material pool through a cation exchange material in flow-through (F/T) mode to obtain a cation exchange material pool,

wherein the solution to be loaded on the activated carbon material, and an equilibration buffer and a wash buffer for the activated carbon material each have a pH of 4.5 to 7.5 or an electrical conductivity of 2 to 10 mS/cm, or both.

[Claim 3]

The method according to claim 1 or 2, wherein the affinity chromatography resin is a protein A resin.

[Claim 4]

The method according to any one of claims 1 to 3, wherein the virus inactivation is a treatment with at least one selected from the group consisting of an acid, a surfactant, a chemical substance, a nucleic acid cross-linking agent, ultraviolet rays, gamma rays and heat.

[Claim 5]

The method according to claim 4, wherein the virus inactivation comprises lowering pH of the affinity chromatography pool to 3 to 4.

[Claim 6]

The method according to claim 5, wherein the affinity chromatography pool is incubated for 60 to 120 minutes during the virus inactivation, and/or the affinity chromatography pool is incubated at 15 to 30°C during the virus inactivation.

[Claim 7]

The method according to any one of claims 1 to 6, wherein the solution to be loaded on the activated carbon material, and an equilibration buffer and a wash buffer for the activated carbon material each have a pH of 4.5 to 7.5, for example each have a pH of 4.5 to 5.5.

[Claim 8]

The method according to any one of claims 1 to 7, wherein the solution to be loaded on the activated carbon material, and an equilibration buffer and a wash buffer for the activated carbon material each have an electrical conductivity of 2 to 10 mS/cm, for example an electrical conductivity of 2 to 5 mS/cm.

[Claim 9]

The method according to any one of claims 1 to 8, wherein the treatment with an activated carbon material is carried out by use of a filter containing the activated carbon material.

[Claim 10]

The method according to any one of claims 1 to 9, wherein the activated carbon material pool is loaded on the cation exchange material in an amount exceeding the binding capacity of the cation exchange material.

[Claim 11]

The method according to claim 10, wherein the activated carbon material pool is loaded on the cation exchange material at a loading density of 500 to 2000 g/L, for example a loading density of 1000 to 1500 g/L.

[Claim 12]

The method according to any one of claims 1 to 11, wherein the cation exchange material is a resin, a monolith column or a membrane, for example the cation

exchange material has a functional group, which is sulfopropyl, sulfoethyl, sulfoisobutyl or carboxyl.

[Claim 13]

The method according to any one of claims 1 to 12, wherein the solution to be loaded on the cation exchange material has a pH of 4 to 6, for example a pH of 4.5 to 5.5.

[Claim 14]

The method according to any one of claims 1 to 13, wherein the solution to be loaded on the cation exchange material has an electrical conductivity of 3 to 7 mS/cm, for example an electrical conductivity of 3 to 5 mS/cm.

[Claim 15]

The method according to any one of claims 1 to 14, wherein the cation exchange material pool is further processed through hydrophobic interaction chromatography to obtain a pool solution, for example the hydrophobic interaction chromatography is performed in a flow-through mode, for example the hydrophobic interaction chromatography is performed by use of a resin or a membrane, for example the hydrophobic interaction chromatography resin or membrane has a phenyl group, a benzyl group or a hexyl group.

[Claim 16]

The method according to any one of claims 1 to 9, wherein the activated carbon material pool is processed through hydrophobic interaction chromatography to obtain

a pool solution, which is further processed through a cation exchange material to obtain a pool solution, for example the hydrophobic interaction chromatography is performed in a flow-through mode, for example the hydrophobic interaction chromatography is performed by use of a resin or a membrane, for example the hydrophobic interaction chromatography resin or membrane has a phenyl group, a benzyl group or a hexyl group.

[Claim 17]

The method according to claim 16, wherein the hydrophobic interaction chromatography pool is loaded on the cation exchange material in an amount exceeding the binding capacity of the cation exchange material, for example the hydrophobic interaction chromatography pool is loaded on the cation exchange material at a loading density of 500 to 2000 g/L, for example the hydrophobic interaction chromatography pool is loaded on the cation exchange material at a loading density of 1000 to 1500 g/L.

[Claim 18]

The method according to claim 16 or 17, wherein the cation exchange material is a resin, a monolith column or a membrane, for example the cation exchange material has a functional group, which is sulfopropyl, sulfoethyl, sulfoisobutyl or carboxyl.

[Claim 19]

The method according to any one of claims 16 to 18, wherein the solution to be loaded on the cation exchange material has a pH of 4 to 6, for example a pH of 4.5 to 5.5.

[Claim 20]

The method according to any one of claims 16 to 19, wherein the solution to be loaded on the cation exchange material has an electrical conductivity of 3 to 7 mS/cm, for example an electrical conductivity of 3 to 5 mS/cm.

[Claim 21]

The method according to any one of claims 1 to 20, wherein at least one of the impurities is selected from the group consisting of host cell-derived proteins (host cell proteins; HCPs), phospholipase B-like 2 (PLBL2), viruses, virus-like particles, high-molecular weight species (HMWS), low-molecular weight species (LMWS), culture medium components, leached protein A and/or DNA.

[Claim 22]

The method according to any one of claims 1 to 21, wherein the steps are carried out continuously.