Claims

1. A method for the separation of host cell proteins, antibody fragments and low molecular weight substances from solutions containing antibodies, said method comprising:
contacting a solution containing antibodies with a hydrophobic chromatography material for a period of time whereby the antibodies stay in solution and host cell proteins, antibody fragments and low molecular weight substances are adsorbed by the hydrophobic chromatography material,
wherein said hydrophobic chromatography material is a particulate material consisting of polystyrene or poly(ethyl)styrene, which is cross-linked with copolymer of divinylbenzene and ethyleneglycol methacrylate in a ratio of 98:2 up to 10:90% by weight.

2. The method of claim 1, wherein said solution containing antibodies is an aqueous solution having a pH value in the range of 2-11 and a conductivity in the range of 1-150 mS/cm.

3. The method of claim 1, wherein said solution containing antibodies is an aqueous solution, and said aqueous solution is passed through at a flow rate in the range of 150-1000 cm/min.

4. The method of claim 1, wherein the separation is processed after a Protein A affinity binding step.

5. The method of claim 1, further comprising contacting the solution with an ion exchange resin.

6. The method of claim 1, wherein said particulate material has mean particle diameters in the range of 10 µm to 600 µm.

7. The method according to claim 6, wherein said hydrophobic chromatography material has pore sizes in the range of 4-500 nm.

8. The method of claim 1, wherein said hydrophobic chromatography material has pore sizes in the range of 4-500 nm.

9. The method of claim 1, further comprising contacting said solution with an ion exchange resin, specific for the separation of Protein A, resulting in a depletion of up to <10 ng host cell proteins and removal of leached Protein A.

10. The method according to claim 9, wherein said hydrophobic chromatography material is hydrophobic polymer beads.

11. The method of claim 1, wherein said solution containing antibodies is an aqueous solution having a pH value in the range of 5-9 and a conductivity in the range of 2-50 mS/cm.

12. The method of claim 1, wherein said solution containing antibodies is an aqueous solution, and said aqueous solution is passed through at a flow rate in the range of 300-900 cm/min.

13. The method of claim 1, wherein said particulate material has mean particle diameters in the range of 20 µm to 150 µm.

14. The method of claim 1, wherein said particulate material has mean particle diameters in the range of 20 µm to 63 µm.

15. The method of claim 1, wherein said hydrophobic chromatography material has pore sizes in the range of 10-30 nm.

16. The method of claim 1, wherein said hydrophobic chromatography material has pore sizes in the range of 13 nm to 25 nm.

17. The method of claim 1, wherein said hydrophobic chromatography material is rigid hydrophobic porous polymer beads having mean particle diameters in the range of 10 µm to 600 µm with pore sizes in the range of 4-500 nm.

18. A method for the separation of host cell proteins, antibody fragments and low molecular weight substances from solutions containing antibodies, said method comprising:
contacting a solution containing antibodies with a hydrophobic chromatography material for a period of time whereby the antibodies stay in solution and host cell proteins, antibody fragments and low molecular weight substances are adsorbed by the hydrophobic chromatography material,
wherein said hydrophobic chromatography material is poly(ethyl)styrene crosslinked with divinylbenzene or poly(ethyl)styrene crosslinked with divinylbenzene and ethylene glycol dimethylacrylate.

19. A method for the separation of host cell proteins, antibody fragments and low molecular weight substances from solutions containing antibodies, said method comprising:
contacting a solution containing antibodies with a hydrophobic chromatography material for a period of time whereby the antibodies stay in solution and host cell proteins, antibody fragments and low molecular weight substances are adsorbed by the hydrophobic chromatography material,
wherein said hydrophobic chromatography material is hydrophobic polymer beads consisting of cross-linked vinylbenzene, poly(ethyl)styrene-divinylbenzene, or polystyrene-divinylbenzene ethyleneglycol-dimethylacrylate resin.