

Claims

1. A method of purifying a recombinant polypeptide from Host Cell Proteins (HCP), the method comprising: (a) applying a solution comprising the recombinant polypeptide and HCP to a superantigen chromatography solid support, (b) washing the superantigen chromatography solid support with a wash buffer comprising greater than about 50 mM caprylate and greater than about 0.5 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support.
2. The method according to claim 1, wherein the caprylate is sodium caprylate.
3. The method according to claim 1, wherein the wash buffer comprises about 75 mM to about 300 mM caprylate.
4. The method according to any one of claims 1 to 3, wherein the wash buffer comprises about 0.75 M to about 1.5 M arginine.
5. The method according to any one of claims 1 to 4, wherein the wash buffer further comprises about 0.5 M to about 1 M lysine.
6. The method according to any preceding claim, wherein the eluted recombinant polypeptide contains less than about 2% fragmented recombinant polypeptide.
7. The method according to any one of the preceding claims, wherein the HCP is derived from a mammalian cell.
8. The method according to any one of the preceding claims, wherein the HCP is phospholipase B-Like 2 protein.
9. The method according to any one of claims 1 to 7, wherein the HCP is cathepsin L.
10. The method according to claim 9, wherein the purification of the recombinant polypeptide from cathepsin L is measured by a reduced cathepsin L activity in the eluate of step (c).
11. The method according to any one of the preceding claims, wherein the pH of the wash buffer is between pH 7 to pH 9; or pH 7.5 to pH 8.5.

12. The method according to any one of the preceding claims, wherein the recombinant polypeptide is a monoclonal antibody (mAb).
13. The method according to claim 12, wherein the mAb is an IgG1, or an IgG4.
14. The method according to any one of the preceding claims, wherein the wash buffer does not contain sodium chloride.
15. The method according to any one of the preceding claims, wherein the superantigen is selected from the group consisting of Protein A, Protein G, and Protein L.
16. The method according to any one of the preceding claims, wherein after step (c) the amount of HCP is less than about 200 ng HCP/mg product.
17. A method of purifying a recombinant polypeptide from Host Cell Proteins (HCP), the method comprising: (a) applying a solution comprising the recombinant polypeptide and HCP to a superantigen chromatography solid support; (b1) washing the superantigen chromatography solid support with a wash buffer comprising greater than about 50mM caprylate; (b2) washing the superantigen chromatography solid support with a wash buffer comprising greater than about 0.5 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support.
18. A method of purifying a recombinant polypeptide from Host Cell Proteins (HCP), the method comprising: (a) applying a solution comprising the recombinant polypeptide and HCP to a superantigen chromatography solid support; (b1) washing the superantigen chromatography solid support with a wash buffer comprising greater than about 0.5 M arginine; (b2) washing the superantigen chromatography solid support with a wash buffer comprising greater than about 50mM caprylate; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support.
19. A method of purifying a recombinant polypeptide from phospholipase B-Like 2 protein, the method comprising: (a) applying a solution comprising the recombinant polypeptide and HCP to a superantigen chromatography solid support, (b) washing the superantigen chromatography solid support with a wash buffer comprising about 100 mM caprylate and about 1.1 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support.

20. A method of purifying a recombinant polypeptide from cathepsin L, the method comprising: (a) applying a solution comprising the recombinant polypeptide and HCP to a superantigen chromatography solid support, (b) washing the superantigen chromatography solid support with a wash buffer comprising about 150 mM caprylate and about 1.1 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support.

21. A method of purifying a recombinant polypeptide from Host Cell Proteins (HCP), the method comprising: (a) applying a solution comprising the recombinant polypeptide and HCP to a superantigen chromatography solid support; (b) washing the superantigen chromatography solid support with a wash buffer comprising caprylate at a concentration greater than about 250 mM; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support.