

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 ~~at least 75mM~~ to 300 mM caprylate and greater than 0.5 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support;
wherein the superantigen chromatography solid support is Protein A, Protein G, or Protein L.
2. The method according to claim 1, wherein the caprylate is sodium caprylate.
3. The method of claim 1 or 2, wherein the wash buffer comprises ~~at least 100 mM~~ to 300 mM sodium caprylate ~~and greater than 0.5 M arginine~~.
- ~~4. The method according to claim 1, wherein the wash buffer comprises 75 mM to 300 mM caprylate.~~
45. The method according to any one of claims 1 to 34, wherein the wash buffer comprises 0.75 M to 1.5 M arginine.
56. The method according to any one of claims 1 to 45, wherein the wash buffer further comprises 0.5 M to 1 M lysine.
67. The method according to any preceding claim, wherein the eluted recombinant polypeptide contains less than 2% fragmented recombinant polypeptide.
78. The method according to any one of the preceding claims, wherein the HCP is derived from a mammalian cell.
89. The method according to any one of the preceding claims, wherein the HCP is phospholipase B-Like 2 protein.
910. The method according to any one of claims 1 to 78, wherein the HCP is cathepsin L.

1011. The method according to claim 910, wherein the purification of the recombinant polypeptide from cathepsin L is measured by a reduced cathepsin L activity in the eluate of step (c).

1112. 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.

1213. The method according to any one of the preceding claims, wherein the recombinant polypeptide is a monoclonal antibody (mAb).

1314. The method according to claim 1213, wherein the mAb is an IgG1, or an IgG4.

1415. The method according to any one of the preceding claims, wherein the wash buffer does not contain sodium chloride.

1516. The method according to any one of the preceding claims, wherein after step (c) the amount of HCP is less than 200 ng HCP/mg product.

1617. 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 50mM~~ 75 mM to 300 mM caprylate; (b2) washing the superantigen chromatography solid support with a wash buffer comprising greater than 0.5 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support;

wherein the superantigen chromatography solid support is Protein A, Protein G, or Protein L.

1718. 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 0.5 M arginine; (b2) washing the superantigen chromatography solid support with a wash buffer comprising ~~greater than 50mM~~ 75 mM to 300 mM caprylate; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support;

wherein the superantigen chromatography solid support is Protein A, Protein G, or Protein L.

1819. The method according to claim 1, 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 100 mM caprylate and 1.1 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support;

wherein the superantigen chromatography solid support is Protein A, Protein G, or Protein L and wherein the HCP is phospholipase B-Like 2 protein.

1920. The method according to claim 1, 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 150 mM caprylate and 1.1 M arginine; and (c) eluting the recombinant polypeptide from the superantigen chromatography solid support;

wherein the superantigen chromatography solid support is Protein A, Protein G, or Protein L and wherein the HCP is cathepsin L.