CLAIMS

What is claimed is:

1. A process for purifying adalimumab from a fermentation harvest of cultured mammalian cells grown in culture expressing said adalimumab, said process comprising:

a) binding adalimumab from said fermentation harvest to a Protein A resin,

b) eluting the bound adalimumab at an elution pH of 3.2-4, and

c) incubating the eluted adalimumab at a pH of 3-4 for 0.5 to 2 hours.

2. The process of claim 1, wherein said eluting is at an elution pH of 3.2.

3. The process of claim 1, wherein said eluting is at an elution pH of 3.6.

4. The process of claim 1, wherein said eluting is at an elution pH of 3.8.

5. The process of claim 1, wherein said eluting is at an elution pH of 4.

6. The process of claim 1, further comprising after said incubating, subjecting adalimumab to one or more further chromatographic separations, wherein said one or more further chromatographic separations comprise an ion exchange chromatography, a hydrophobic interactive chromatography or a combination thereof.

7. The process of claim 1, further comprising subjecting adalimumab to an ion exchange chromatography after said incubating.

8. The process of claim 7, wherein said ion exchange chromatography is cation exchange chromatography.

9. The process of claim 7, wherein said ion exchange chromatography is anion exchange chromatography.

10. The process of claim 1, further comprising subjecting adalimumab to a hydrophobic interaction chromatography after said incubating.

11. The process of claim 1, further comprising determining the monomer level of adalimumab purified according to said process.

12. The process of claim 1, wherein the purified adalimumab is pharmaceutical grade.

13. The process of claim 1, wherein the purified adalimumab is pharmaceutical grade, said eluting is at an elution pH of 3.2, and the adalimumab monomer level after said incubating is 96.9%.

14. The process of claim 13, further comprising after said incubating, subjecting adalimumab to one or more further chromatographic separations, wherein said one or more further chromatographic separations comprise an ion exchange chromatography, a hydrophobic interactive chromatography or a combination thereof.

15. The process of claim 13, further comprising subjecting adalimumab to a hydrophobic interaction chromatography after said incubating.

16. The process of claim 1, wherein the purified adalimumab is pharmaceutical grade, said eluting is at an elution pH of 3.6, and the adalimumab monomer level after said incubating is 97%.

17. The process of claim 16, further comprising after said incubating, subjecting adalimumab to one or more further chromatographic separations, wherein said one or more further chromatographic separations comprise an ion exchange chromatography, a hydrophobic interactive chromatography or a combination thereof.

18. The process of claim 16, further comprising subjecting adalimumab to a hydrophobic interaction chromatography after said incubating.

19. The process of claim 1, wherein the purified adalimumab is pharmaceutical grade, said eluting is at an elution pH of 4, and the adalimumab monomer level after said incubating is 98.2%.

20. The process of claim 19, further comprising after said incubating, subjecting adalimumab to one or more further chromatographic separations, wherein said one or more further chromatographic separations comprise an ion exchange chromatography, a hydrophobic interactive chromatography or a combination thereof.

21. The process of claim 19, further comprising subjecting adalimumab to a hydrophobic interaction chromatography after said incubating.

22. The process of any one of claims 1-21. wherein said adalimumab from said fermentation harvest is bound to the Protein A resin at a binding capacity of no less than 32 g/L before said eluting.

23. The process of any one of claims 1-21, wherein said adalimumab from said fermentation harvest is bound to the Protein A resin at a binding capacity of 32 g/L before said eluting.

24. The process of any one of claims 1-21, wherein said adalimumab from said fermentation harvest is bound to the Protein A resin at maximal resin binding capacity before said eluting.

25. Adalimumab when purified according to a process of any one of claims 1 to 24.