WHAT IS CLAIMED IS:

1. A lyophilized cake comprising:

(a) a protein, wherein less than 0.5% of said protein is aggregated after 2 months at room temperature;

(b) a stabilizer;

(c) a buffer; and

(d) not less than 2% water by weight, and no more than 10% water by weight,

wherein the lyophilized cake is not collapsed and not discolored, and wherein said lyophilized cake is contained within a vial.

2. The lyophilized cake of claim 1, wherein said lyophilized cake comprises no yellow, no brown, no black, and no red color.

3. The lyophilized cake of claim 1 or claim 2, wherein said lyophilized cake is not melted, not shrunken, and comprises no density variation.

4. The lyophilized cake of any one of claims 1-3, wherein said lyophilized cake comprises a glass transition temperature above 25°C.

5. The lyophilized cake of any one of claims 1-4 comprising about 3% to about 7% water by weight or about 5% to about 8% water by weight.

6. The lyophilized cake of any one of claims 1-5 comprising about 3%, about 3.5%, about 4%, about 4.5%, about 5%, about 5.5%, about 6%, or about 6.5% water by weight.

7. The lyophilized cake of any one of claims 1-6, wherein the increase in the amount of aggregated protein in said lyophilized cake stored for about 18 months at room temperature is less than 2%.

8. The lyophilized cake of any one of claims 1-7, wherein the increase in the amount of aggregated protein in said lyophilized cake stored for about 24 months at room temperature is less than 2%.

9. The lyophilized cake of any one of claims 1-8, wherein said aggregated protein is detected by size exclusion chromatography or electrophoresis.

10. The lyophilized cake of any one of claims 1-9, wherein said buffer comprises histidine.

11. The lyophilized cake of claim 10, wherein said histidine is present at 0.34% to about 2.04% by weight.

12. The lyophilized cake of any one of claims 1-11, wherein said stabilizer is selected from the group consisting of a polyol, a sugar, an amino acid, a salt, and combinations thereof.

13. The lyophilized cake of claim 12, wherein (i) said polyol is selected from the group consisting of sorbitol, glycerol, mannitol, and a combination thereof; (ii) said sugar is selected from the group consisting of trehalose, sucrose, and a combination thereof; (iii) said amino acid is selected from the group consisting of arginine, alanine, proline, glycine, sodium chloride, and a combination thereof; and (iv) said salt is sodium chloride.

14. The lyophilized cake of any one of claims 1-13, wherein said stabilizer is present at about 19% to about 83% by weight.

15. The lyophilized cake of any one of claims 1-14, wherein said stabilizer comprises sucrose.

16. The lyophilized cake of claim 14, wherein said sucrose is present at about 15% to about 71% by weight.

17. The lyophilized cake of claim 15 or 16, wherein said stabilizer further comprises arginine.

18. The lyophilized cake of claim 17, wherein said arginine is present at about 4 % to about 20% by weight.

19. The lyophilized cake of claim 14 or 15, wherein said stabilizer further comprises mannitol.

20. The lyophilized cake of claim 19, wherein said mannitol is present at 8% to about 23% by weight.

21. The lyophilized cake of any one of claims 1-14, wherein said stabilizer comprises trehalose.

22. The lyophilized cake of claim 21, wherein said trehalose is present at about 15% to about 70% by weight.

23. The lyophilized cake of claim 21 or 22, wherein said stabilizer further comprises arginine.

24. The lyophilized cake of claim 23, wherein said arginine is present at about 0.8% to about 15% arginine by weight.

25. The lyophilized cake of claim 21 or 22, wherein said stabilizer further comprises sorbitol.

26. The lyophilized cake of claim 25, wherein said sorbitol is present at about 1.3% to about 23% sorbitol by weight.

27. The lyophilized cake of any one of claims 1-26 further comprising a surfactant.

28. The lyophilized cake of claim 27, wherein said surfactant is selected from the group consisting of polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, polyethylene glycol (PEG), PEG 3350, and a combination thereof.

29. The lyophilized cake of claim 27 or 28, wherein said surfactant is present at about 0.02% to about 1% by weight.

30. The lyophilized cake of any one of claims 1-29, wherein said protein is present at about 6% to about 64% by weight.

31. The lyophilized cake of claim 30 comprising from about 6% to about 19% protein by weight.

32. The lyophilized cake of claim 31 comprising from about 33% to about 64% protein by weight.

33. The lyophilized cake of any one of claims 1-32, wherein said protein is an antigen-binding protein.

34. The lyophilized cake of claim 33, wherein said antigen-binding protein is selected from the group consisting of antibody, antibody fragment, and receptor-Fc-fusion protein.

35. The lyophilized cake of any one of claims 1-34, wherein said vial comprises type I borosilicate glass and is closed with a polytetrafluorethylene coated butyl rubber stopper.

36. A lyophilized cake comprising:

(a) a protein, wherein less than 1% of said protein is degraded after one month at room temperature;

(b) a stabilizer at a ratio of about 0.2 parts stabilizer to 1 part protein by weight (0.2:1) to about 1.5 parts stabilizer to 1 part protein by weight (1.5:1); and

(c) water at a concentration no less than 3% by weight and no more than 10% by weight,

wherein said lyophilized cake is uniformly attached to the walls of a container and free of discoloration.

37. The lyophilized cake of claim 36, wherein the ratio of the stabilizer to protein by weight is selected from the group consisting of about 0.22:1, 0.44:1, 0.65:1, 0.87:1, 1.1:1, 1.3:1 by weight.

38. The lyophilized cake of claim 36 or 37, wherein said stabilizer is selected from the group consisting of a non-reducing sugar, a sugar alcohol, an amino acid, and a combination thereof.

39. The lyophilized cake of claim 37, wherein said non-reducing sugar comprises sucrose or trehalose; said sugar alcohol is selected from the group consisting of sorbitol, mannitol, and glycerol; and said amino acid is selected from the group consisting of arginine, alanine, proline, and glycine.

40. The lyophilized cake of any one of claims 35-38, wherein said stabilizer comprises sucrose.

41. The lyophilized cake of claim 39 further comprising arginine.

42. The lyophilized cake of claim 40, wherein the ratio of sucrose to arginine is about 3.2:1 to about 3.4:1 by weight.

43. The lyophilized cake of claim 39 further comprising mannitol.

44. The lyophilized cake of claim 42, wherein the ratio of sucrose to mannitol is about 1.8:1 to about 2:1 by weight.

45. The lyophilized cake of any one of claims 35-38, wherein said stabilizer comprises trehalose.

46. The lyophilized cake of claim 44 further comprising arginine.

47. The lyophilized cake of claim 40, wherein the ratio of trehalose to arginine is about 3.2:1 to about 3.4:1 by weight.

48. The lyophilized cake of claim 44 further comprising sorbitol.

49. The lyophilized cake of claim 42, wherein the ratio of trehalose to sorbitol is about 1:1 to about 2:1 by weight.

50. The lyophilized cake of any one of claims 35-48, wherein degraded protein comprises a dimer of said protein, a trimer of said protein, a tetramer of said protein, a higher order multimer of said protein, a chemically modified protein, and a combination thereof.

51. The lyophilized cake of any one of claims 35-49, wherein said protein is selected from the group consisting of an antibody, an antibody fragment, and a receptor-Fc-fusion protein.

52. The lyophilized cake of any one of claims 35-50 further comprising a buffer.

53. The lyophilized cake of claim 51, wherein said buffer is selected from the group consisting of citrate, phosphate, histidine, succinate, carbonate, acetate, and a combination thereof.

54. The lyophilized cake of claim 51 or 52, wherein said buffer comprises histidine.

55. The lyophilized cake of any one of claims 35-53, wherein said discoloration is selected from the group consisting of red, yellow, brown, black, and a combination thereof.

56. The lyophilized cake of any one of claims 35-53, wherein said container is a vial or a syringe.

57. The lyophilized cake of claim 55, wherein said vial comprises type I borosilicate glass and a polytetrafluoroethylene coated butyl rubber stopper.

58. A method of making a pharmaceutically acceptable lyophilized cake, said method comprising:

(a) a drying step that removes water from a sample comprising a protein, a stabilizer, and water to attain a pharmaceutically acceptable lyophilized cake comprising a moisture content between 2% and 10% by weight;

(b) heating said lyophilized cake at a temperature below the glass transition temperature of said pharmaceutically acceptable lyophilized cake; and

(c) storing said pharmaceutically acceptable lyophilized cake at room temperature, wherein said protein has less than 0.5% degradation after two months.

59. The method of claim 57, wherein said temperature below the glass transition temperature is determined by subjecting said sample after step (a) and before step (b) to differential scanning calorimetry.

60. The method of claim 57 or 58, wherein said temperature below the glass transition temperature is between about 25°C and about 90°C.

61. The method of any one of claims 57-59, wherein said temperature below the glass transition temperature is maintained for about 72 hours.

62. The method of any one of claims 57-60, wherein said protein is selected from the group consisting of antibody, antibody fragment, and receptor-Fc-fusion protein.

63. The method of any one of claims 57-61, wherein said protein is present in said sample at a concentration about 50 mg/mL to about 200 mg/mL.

64. The method of any one of claims 57-62, wherein said sample further comprises a buffer.

65. The method of any one of claims 63-80, wherein said buffer comprises histidine.

66. The method of any one of claims 57-64, wherein said stabilizer is selected from the group consisting of trehalose, sorbitol, glycerol, arginine, alanine, mannitol, sucrose, proline, NaCl, glycine, or a combination thereof.

67. The method of any one of claims 57-65, wherein said stabilizer comprises sucrose.

68. The method of claim 66, wherein said sucrose is present in said sample at a concentration of less than about 10% weight to volume (w/v).

69. The method of claim 67, wherein said sample further comprises 3% ± 0.1% arginine.

70. The method of claim 66, wherein said sucrose is present in said sample at a concentration of about 5% (w/v).

71. The method of claim 69, wherein said sample further comprises (i) about 1.3% ± 0.1% (w/v) alanine; (ii) about 1.5% ± 0.1% (w/v) arginine; (iii) about 1.34% ± 0.1% (w/v) glycerol; (iv) about 2.66% ± 0.1% (w/v) mannitol; or (v) about 2.66% ± 0.1% (w/v) sorbitol.

72. The method of any one of claims 57-66, wherein said stabilizer comprises (i) about 7.5% (w/v) sucrose and 2.3% ± 0.1% (w/v) arginine; (ii) about 12.5% (w/v) sucrose and 3.9% ± 0.1% (w/v) arginine; (iii) or about 15% (w/v) sucrose and 4.6% ± 0.1% (w/v) arginine.

73. The method of any one of claims 57-65, wherein said stabilizer comprises trehalose.

74. The method of claim 72, wherein said trehalose is present in said sample at a concentration of less than about 10% (w/v).

75. The method of claim 72, wherein said trehalose is present in said sample at a concentration of about 9.09% (w/v) trehalose, and said sample further comprises 0.48% (w/v) sorbitol; 0.24% (w/v) glycerol; 0.28% (w/v) arginine; or 0.24% (w/v) alanine.

76. The method of claim 72, wherein said trehalose is present in said sample at a concentration of about 8.33% (w/v) trehalose, and said sample further comprises 0.89% (w/v) sorbitol; 0.45% (w/v) glycerol; 0.51% (w/v) arginine; or 0.43% (w/v) alanine.

77. The method of claim 72, wherein said trehalose is present in said sample at a concentration of about 6.66% (w/v) trehalose, and said sample further comprises 0.1.77% (w/v) sorbitol; 0.9% (w/v) glycerol; 1.03% (w/v) arginine; or 0.87% (w/v) alanine.

78. The method of claim 72, wherein said trehalose is present in said sample at a concentration of about 5% (w/v) trehalose, and said sample further comprises 2.66% (w/v) sorbitol; 1.34% (w/v) glycerol; 1.54% (w/v) arginine; or 1.3% (w/v) alanine.

79. The method of any one of claims 57-78, wherein said moisture content is no less than 3% and no more than 8% by weight.

80. The method of claim 78, wherein said moisture content is about 3% by weight, about 3.5% by weight, about 4% by weight, about 4.5% by weight, about 5% by weight, about 5.5% by weight or about 6% by weight.

81. The method of any one of claims 57-80, wherein said pharmaceutically acceptable lyophilized cake is stored at room temperature for at least 18 months.

82. The method of claim 81, wherein said pharmaceutically acceptable lyophilized cake is stored at room temperature for at least 24 months.

83. The method of claim 82, wherein less than or equal to about 2% of said protein degrades during said at least 18 months.

84. The method of claim 83, wherein the degradation of said protein is determined by measuring the change in percent high molecular weight species by size exclusion chromatography.