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:

(a) comprises no yellow, no brown, no black, and no red color;

(b) is not melted, not shrunken, and comprises no density variation; and/or

(c) comprises a glass transition temperature above 25ºC.

3. The lyophilized cake of claim 1 or 2, comprising about 3% to about 7% water by weight or about 5% to about 8% water by weight.

4. The lyophilized cake of any one of claims 1-3, 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.

5. The lyophilized cake of any one of claims 1-4, wherein an increase in the amount of aggregated protein in said lyophilized cake stored for about 18 months or about 24 months at room temperature is less than 2%.

6. The lyophilized cake of any one of claims 1-5, wherein said aggregated protein is detected by size exclusion chromatography or electrophoresis.

7. The lyophilized cake of any one of claims 1-6, wherein said buffer comprises histidine, optionally wherein said histidine is present at 0.34% to about 2.04% by weight.

8. The lyophilized cake of any one of claims 1-7, wherein said stabilizer is:

(a) selected from the group consisting of a polyol, a sugar, an amino acid, a salt, and combinations thereof, optionally 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;

(b) present at about 19% to about 83% by weight;

(c) comprises sucrose, optionally wherein the sucrose is present at about 15% to about 71% by weight; and/or

(d) comprises trehalose, optionally wherein the trehalose is present at about 15% to about 70% by weight.

9. The lyophilized cake of claim 8(c), wherein said stabilizer further comprises:

(a) arginine, optionally wherein said arginine is present at about 4% to about 20% by weight; or

(b) mannitol, optionally wherein said mannitol is present at 8% to about 23% by weight.

10. The lyophilized cake of claim 8(d), wherein said stabilizer further comprises:

(a) arginine, optionally wherein said arginine is present at about 0.8% to about 15% arginine by weight; or

(b) sorbitol, optionally wherein said sorbitol is present at about 1.3% to about 23% sorbitol by weight.

11. The lyophilized cake of any one of claims 1-10, further comprising a surfactant, optionally wherein:

(a) 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; or

(b) said surfactant is present at about 0.02% to about 1% by weight.

12. The lyophilized cake of any one of claims 1-11, wherein said protein is present from about 6% to about 64% by weight, from about 6% to about 19% by weight, or from about 33% to about 64% by weight.

13. The lyophilized cake of any one of claims 1-12, wherein said protein is an antigen-binding protein, optionally wherein said antigen-binding protein is selected from the group consisting of antibody, antibody fragment, and receptor-Fc-fusion protein.

14. The lyophilized cake of any one of claims 1-13, wherein said vial comprises type I borosilicate glass and is closed with a polytetrafluorethylene coated butyl rubber stopper.

15. 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.

16. The lyophilized cake of claim 15, 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.

17. The lyophilized cake of claim 15 or 16, wherein said stabilizer:

(a) is selected from the group consisting of a non-reducing sugar, a sugar alcohol, an amino acid, and a combination thereof, optionally 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;or

(b) comprises sucrose or trehalose.

18. The lyophilized cake of claim 17(b) further comprising arginine, mannitol or sorbitol, optionally wherein:

(a) the ratio of sucrose to arginine is about 3.2:1 to about 3.4:1 by weight;

(b) the ratio of sucrose to mannitol is about 1.8:1 to about 2:1 by weight;

(c) the ratio of trehalose to arginine is about 3.2:1 to about 3.4:1 by weight; or

(d) the ratio of trehalose to sorbitol is about 1:1 to about 2:1 by weight.

19. The lyophilized cake of any one of claims 15-18, 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.

20. The lyophilized cake of any one of claims 15-19, wherein said protein is selected from the group consisting of an antibody, an antibody fragment, and a receptor-Fc-fusion protein.

21. The lyophilized cake of any one of claims 15-20, further comprising a buffer, optionally wherein said buffer is selected from the group consisting of citrate, phosphate, histidine, succinate, carbonate, acetate, and a combination thereof.

22. The lyophilized cake of any one of claims 15-21, wherein said discoloration is selected from the group consisting of red, yellow, brown, black, and a combination thereof.

23. The lyophilized cake of any one of claims 15-22, wherein said container is a vial or a syringe, optionally wherein said vial comprises type I borosilicate glass and a polytetrafluoroethylene coated butyl rubber stopper.

24. 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.