composition, wherein upon reconstitution of the lyophilized polypeptide composition with a diluent, the time for reconstituting the polypeptide lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same polypeptide lyophilized in the absence of TBA. In some examples, the amount of TBA in the liquid formulation is between about 0.5% to about 20% by volume. In some examples, the amount of TBA in the liquid formulation is selected from the group consisting of 0.5%, 1%, 2.5%, 5%, 7.5%, 10%, 12.5%, 15%, 17.5%, and 20% by volume. In other examples, the amount of TBA added to the liquid polypeptide composition to form the liquid polypeptide/TBA mixture is between about 1% to about 20% by volume, between about 1% to about 10% by volume, between about 1% to about 5% by volume, between about 5% to about 20% by volume, or between about 5% to about 10% by volume. In one example, the TBA is added to the liquid composition comprising the polypeptide immediately prior to freezing the liquid polypeptide/TBA mixture. In certain examples, the polypeptide is an antibody. In certain examples, the addition of TBA to the polypeptide formulation has no effect on the integrity or stability of the polypeptide. In some examples, the polypeptide is an antibody and the lyophilized polypeptide composition is produced by preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least about 360:1 prior to adding TBA to the liquid composition.

[19a] In one aspect, there is provided a method for reducing reconstitution time of a lyophilized antibody composition, the method comprising: (a) preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least 360:1, (b) adding tert-butyl alcohol (TBA) to the liquid composition to form a liquid antibody/TBA mixture, wherein the amount of TBA in the liquid antibody/TBA mixture is 5%-6% by volume, (c) freezing the liquid antibody/TBA mixture, (d) lyophilizing the liquid antibody/TBA mixture to form a lyophilized antibody composition, (e) reconstituting the lyophilized antibody composition with a diluent, wherein the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA.

[0020] In one example, the present disclosure provides a method for reducing the reconstitution time of a lyophilized antibody composition, wherein the method comprises preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least about 360:1, adding tert-butyl alcohol (TBA) to the liquid composition to form a liquid antibody/TBA mixture, wherein the amount of TBA in the liquid antibody/TBA mixture is between about 5%-20% by volume, freezing the liquid antibody/TBA mixture, lyophilizing the liquid antibody/TBA mixture to form a lyophilized antibody composition, and reconstituting the lyophilized antibody composition with a diluent, wherein the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA. In some examples, the amount of TBA added to the liquid antibody composition to form the liquid antibody/TBA mixture is selected from the group consisting of 5%, 7.5%, 10%, 12.5%, 15%, 17.5%, and 20% by volume. In some examples, the amount of TBA added to the liquid antibody composition to form the liquid antibody/TBA mixture is about 5%-6% by volume. In yet other examples, the amount of TBA added to

polypeptide or antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same polypeptide or antibody lyophilized in the absence of TBA. In some examples, the amount of TBA in the liquid polypeptide or antibody/TBA mixture is about 5%-6% by volume.

[0030] In another example, the present disclosure provides a method for reducing the reconstitution time of a lyophilized polypeptide or antibody composition, wherein the method comprises adding tert-butyl alcohol (TBA) to a liquid composition comprising the polypeptide or antibody and a sugar at a molar ratio of at least about 360:1 to form a liquid polypeptide or antibody/TBA mixture, wherein the amount of TBA in the liquid polypeptide or antibody/TBA mixture is about 5%-20% by volume, freezing the liquid polypeptide or antibody/TBA mixture, and lyophilizing the liquid polypeptide or antibody/TBA mixture to form a lyophilized polypeptide or antibody composition, wherein the lyophilized polypeptide or antibody composition is subsequently reconstituted with a diluent, wherein the time for reconstituting the polypeptide or antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same polypeptide or antibody lyophilized in the absence of TBA. In some examples, the amount of TBA in the liquid polypeptide or antibody/TBA mixture is about 5%-6% by volume.

[30a] In another aspect, there is provided a liquid antibody formulation suitable for lyophilization, wherein the formulation comprises the antibody, a sugar, a diluent, and TBA, wherein the amount of TBA in the liquid formulation is 5%-6% by volume, wherein the amount of sugar in the liquid formulation is at a molar ratio of sugar:antibody of at least 360:1, and wherein the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA.

[0031] The present disclosure provides liquid antibody formulations suitable for lyophilization. In some examples, the present disclosure provides liquid antibody formulations suitable for lyophilization, wherein the formulation comprises the antibody, a sugar, a diluent, and TBA, wherein the amount of TBA in the liquid formulation is between about 5%-20% by volume, wherein the amount of sugar in the liquid formulation is at a molar ratio of sugar:antibody of at least about 360:1, and wherein the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA. In some examples, the amount of TBA in the liquid formulation is selected from the group consisting of 5%, 7.5%, 10%, 12.5%, 15%, 17.5%, and 20% by volume. In other examples, the amount of TBA added to the liquid antibody composition to form the liquid antibody/TBA mixture is between about 5% to about 10% by volume. In some examples, the amount of TBA in the liquid formulation is about 5%-6% by volume. In one example, the TBA is added to the liquid composition comprising the antibody immediately prior to freezing the liquid antibody/TBA mixture. In some examples, the

sugar is sucrose or trehalose. In certain examples, the presence of TBA in the liquid antibody formulation has no effect on the integrity or stability of the antibody.

[31a] In another aspect, there is provided a lyophilized antibody composition, wherein the lyophilized antibody composition is produced by preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least 360:1, adding tert-butyl alcohol (TBA) to the liquid composition to form a liquid antibody/TBA mixture, wherein the amount of TBA in the liquid formulation is 5%-6% by volume, freezing the liquid antibody/TBA mixture, and lyophilizing the liquid antibody/TBA mixture to form a lyophilized antibody composition, wherein upon reconstitution of the lyophilized antibody composition with a diluent, the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA.

[0032] The present disclosure provides a lyophilized antibody composition, wherein the lyophilized antibody composition is produced by preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least about 360:1, adding tert-butyl alcohol (TBA) to the liquid composition to form a liquid antibody/TBA mixture, wherein the amount of TBA in the liquid antibody/TBA mixture is between about 5%-20% by volume, freezing the liquid antibody/TBA mixture, lyophilizing the liquid antibody/TBA mixture to form a lyophilized antibody composition, wherein upon reconstitution of the lyophilized antibody composition with a diluent, the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA. In some examples, the amount of TBA in the liquid formulation is selected from the group consisting of 5%, 7.5%, 10%, 12.5%, 15%, 17.5%, and 20% by volume. In other examples, the amount of TBA added to the liquid antibody composition to form the liquid antibody/TBA mixture is between about 5% to about 10% by volume. In some examples, the amount of TBA added to the liquid antibody composition to form the liquid antibody/TBA mixture is between about 5% to about 6% by volume. In one example, the TBA is added to the liquid composition comprising the antibody immediately prior to freezing the liquid antibody/TBA mixture. In some examples, the sugar is sucrose or trehalose. In certain examples, the addition of TBA to the liquid composition has no effect on the integrity or stability of the antibody in the liquid composition or in the lyophilized antibody composition.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Figure 1 sets forth data showing reconstitution times for a lyophilized antibody formulation containing 0%, 0.5%, 1%, 5%, and 20% (v/v) tert-butyl alcohol.

[0034] Figure 2 sets forth data showing reconstitution times for a 2.5 ml lyophilized antibody formulation containing 0%, 5%, and 10% (v/v) tert-butyl alcohol lyophilized in 6cc vials.

[0035] Figure 3 sets forth data showing reconstitution times for a 25 ml lyophilized antibody formulation containing 0%, 1%, 5%, 10%, and 20% (v/v) tert-butyl alcohol lyophilized in 50cc vials.

CLAIMS

What is claimed is:

1. A method for reducing reconstitution time of a lyophilized antibody composition, the method comprising: (a) preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least 360:1, (b) adding tert-butyl alcohol (TBA) to the liquid composition to form a liquid antibody/TBA mixture, wherein the amount of TBA in the liquid antibody/TBA mixture is 5%-6% by volume, (c) freezing the liquid antibody/TBA mixture, (d) lyophilizing the liquid antibody/TBA mixture to form a lyophilized antibody composition, (e) reconstituting the lyophilized antibody composition with a diluent, wherein the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA.
2. The method of claim 1, wherein the amount of TBA in the liquid antibody/TBA mixture is 5% by volume.
3. The method of claim 1, wherein the molar ratio of sugar:antibody is between 360:1 to 500:1.
4. The method of claim 1, wherein TBA is added to the liquid composition comprising the antibody immediately prior to freezing the liquid antibody/TBA mixture.
5. The method of claim 1, wherein the antibody is a full length antibody.
6. The method of claim 1, wherein the concentration of the antibody in the liquid composition comprising the antibody is between 10 mg/ml to 250 mg/ml, between 25 mg/ml to 250 mg/ml, 50 mg/ml to 250 mg/ml, 100 mg/ml to 250 mg/ml, 150 mg/mml to 250 mg/ml, 25 mg/ml to 100 mg/ml, 50 mg/ml to 100 mg/ml, 25 mg/ml to 125 mg/ml, or 50 mg/ml to 125 mg/ml.

7. The method of claim 1, wherein the amount of the antibody in the liquid composition comprising the antibody is between 150 mg-11 grams.

8. The method of claim 1, wherein the sugar is sucrose or trehalose.

9. The method of claim 1, wherein the liquid antibody/TBA mixture is lyophilized in a glass vial.

10. The method of claim 9, wherein the glass vial is a 6cc vial, a 10cc vial, a 15cc vial, a 20cc vial, a 25cc vial, a 50cc vial, or a 100 cc vial.

11. The method of claim 9, wherein the glass vial has a fill volume of 2.5 ml, 25 ml, 50 ml, or 100 ml.

12. The method of claim 1, wherein the time for reconstituting the lyophilized antibody composition which was lyophilized in the presence of TBA is reduced by 40-95% compared to the time for reconstituting the same amount of the same antibody composition lyophilized in the absence of TBA.

13. The method of claim 1, wherein the time for reconstituting the lyophilized antibody composition which was lyophilized in the presence of TBA is reduced by 50%, by 60%, by 70%, by 80%, by 90%, or by 95% compared to the time for reconstituting the same amount of the same antibody composition lyophilized in the absence of TBA.

14. The method of claim 1, wherein the time for reconstituting the lyophilized antibody composition which was lyophilized in the presence of TBA is reduced by 50-60%, by 60-70%, by 70-80%, by 80-90%, or by 90-95% compared to the time for reconstituting the same amount of the same antibody composition lyophilized in the absence of TBA.

15. The method of claim 1, wherein reconstituting the lyophilized antibody composition is performed under conditions in which the lyophilized antibody composition is under a vacuum.

16. The method of claim 15, wherein the vacuum is less than 100 Torr, less than 50 Torr, or between 100 mTorr and 50 Torr.

17. The method of claim 15, wherein the vacuum is 100 mTorr.

18. The method of claim 1, wherein reconstituting the lyophilized antibody compositing is performed using a shaker.

19. A liquid antibody formulation suitable for lyophilization, wherein the formulation comprises the antibody, a sugar, a diluent, and TBA, wherein the amount of TBA in the liquid formulation is 5%-6% by volume, wherein the amount of sugar in the liquid formulation is at a molar ratio of sugar:antibody of at least 360:1, and wherein the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA.

20. The liquid antibody formulation of claim 19, wherein the amount of TBA in the liquid composition is 5% by volume.

21. A lyophilized antibody composition, wherein the lyophilized antibody composition is produced by preparing a liquid composition comprising the antibody and a sugar at a molar ratio of sugar:antibody of at least 360:1, adding tert-butyl alcohol (TBA) to the liquid composition to form a liquid antibody/TBA mixture, wherein the amount of TBA in the liquid formulation is 5%-6% by volume, freezing the liquid antibody/TBA mixture, and lyophilizing the liquid antibody/TBA mixture to form a lyophilized antibody composition, wherein upon reconstitution of the lyophilized antibody composition with a diluent, the time for reconstituting the antibody lyophilized in the presence of TBA is less than the time for reconstituting the same amount of the same antibody lyophilized in the absence of TBA.

22. The lyophilized antibody composition of claim 21, wherein the amount of TBA in the liquid composition is 5% by volume.