CLAIMS

1. A lyophilized formulation of an anti-tissue factor (TF) antibody-drug conjugate (ADC), the lyophilized formulation obtained by lyophilizing an aqueous formulation comprising 9 g/L to 11 g/L anti-TF ADC and pharmaceutically acceptable excipients comprising: from 28 mM to 34 mM histidine buffer having a pH of 5 to 7; from 84 to 92 mM sucrose; and from 158 to 172 mM mannitol; wherein the antibody comprises a VH region comprising an amino acid sequence of SEQ ID NO: 5 and a VL region comprising an amino acid sequence of SEQ ID NO: 45; a VH region comprising an amino acid sequence of SEQ ID NO: 33 and a VL region comprising an amino acid sequence of SEQ ID NO: 73; a VH region comprising an amino acid sequence of SEQ ID NO: 37 and a VL region comprising an amino acid sequence of SEQ ID NO: 77; or a VH region comprising an amino acid sequence of SEQ ID NO: 1 and a VL region comprising an amino acid sequence of SEQ ID NO: 41, and wherein the linker-drug is vcMMAE, vcMMAF or mcMMAF, wherein the formulation is free of surfactant.

2. The lyophilized formulation of claim 1, which is obtained by lyophilizing an aqueous formulation comprising 9 g/L to 11 g/L anti-TF ADC and pharmaceutically acceptable excipients comprising: 30 mM histidine buffer having a pH of 5 to 7; 88 mM sucrose; and 165 mM mannitol; wherein the antibody comprises a VH region comprising an amino acid sequence of SEQ ID NO: 5 and a VL region comprising an amino acid sequence of SEQ ID NO: 45; a VH region comprising an amino acid sequence of SEQ ID NO: 33 and a VL region comprising an amino acid sequence of SEQ ID NO: 73; a VH region comprising an amino acid sequence of SEQ ID NO: 37 and a VL region comprising an amino acid sequence of SEQ ID NO: 77; or a VH region comprising an amino acid sequence of SEQ ID NO: 1 and a VL region comprising an amino acid sequence of SEQ ID NO: 41, and wherein the linker-drug is vcMMAE, vcMMAF or mcMMAF.

3. The lyophilized formulation of claims 1 or 2, wherein the aqueous formulation comprises 10 g/L anti-TF ADC.

4. The lyophilized formulation of any one of the preceding claims, wherein the pH of the aqueous formulation is in a range from 5.5 to 6.5, such as 6.

5. The lyophilized formulation of any one of the preceding claims, wherein the average absolute number of drug moieties per antibody molecule is 1, 2, 3, 4, 5, 6, 7, or 8, such as 3, 4 or 5, preferably 4.

6. The lyophilized formulation of any one of the preceding claims, wherein the anti-TF antibody is a full-length antibody.

7. The lyophilized formulation of any one of the preceding claims, wherein the anti-TF antibody is a full length fully human monoclonal IgG1 antibody, optionally human IgG1κ.

8. The lyophilized formulation of any one of the preceding claims wherein the antibody comprises a VH region comprising an amino acid sequence of SEQ ID NO: 5 and a VL region comprising an amino acid sequence of SEQ ID NO: 45.

9. The lyophilized formulation of any one of the preceding claims wherein the anti-TF ADC is stable at 2-8 °C, such as at 5°C for pharmaceutical use for at least 6 months, such as for at least 9 months, such as for at least 15 months or preferably for at least 18 months, or even more preferred for at least 24 months, or most preferred for at least 36 months.

10. The lyophilized formulation of claim 9, wherein the formulation is stable when it has less than 3.0% aggregates, such as less than 2.0% aggregates when stored at 5°C for at least 6 months, such as for at least 9 months, such as for at least 15 months or preferably for at least 18 months, or even more preferred for at least 24 months, or most preferred for at least 36 months.

11. The lyophilized formulation of claim 9 or 10 wherein the stability is determined by size exclusion chromatography analysis.

12. The lyophilized formulation of any one of the preceding claims which lyophilized formulation contains less than 3.0 wt. % moisture, such as less than 2.0 wt. % moisture, such as less than 1 wt. % moisture, or less than 0.5 wt. % moisture.

13. The lyophilized formulation of any one of the preceding claims wherein the formulation is free of any inorganic salts.

14. An aqueous solution suitable for preparing a lyophilized formulation of an anti-TF ADC, wherein said aqueous solution does not contain a surfactant, said solution comprising 9 g/L to 11 g/L anti-TF ADC and pharmaceutically acceptable excipients comprising: from 28 mM to 34 mM histidine buffer having a pH of 5 to 7; from 84 to 92 mM sucrose; and from 158 to 172 mM mannitol; wherein the antibody comprises a VH region comprising an amino acid sequence of SEQ ID NO: 5 and a VL region

comprising an amino acid sequence of SEQ ID NO: 45; a VH region comprising an amino acid sequence of SEQ ID NO: 33 and a VL region comprising an amino acid sequence of SEQ ID NO: 73; a VH region comprising an amino acid sequence of SEQ ID NO: 37 and a VL region comprising an amino acid sequence of SEQ ID NO: 77; or a VH region comprising an amino acid sequence of SEQ ID NO: 1 and a VL region comprising an amino acid sequence of SEQ ID NO: 41, and wherein the linker-drug is vcMMAE, vcMMAF or mcMMAF.

15. An aqueous solution according to claim 14 wherein said pharmaceutically acceptable excipients comprises 30 mM histidine buffer having a pH of 5 to 7; 88 mM sucrose; and 165 mM mannitol.

16. A pharmaceutically acceptable liquid formulation obtained by reconstituting the lyophilized formulation of any one of claims 1-13 in a sterile aqueous diluent.

17. The liquid formulation of claim 16, comprising 9 to 11 mg/mL anti-TF ADC, 28 to 34 mM histidine, 84 to 92 mM sucrose and 158 to 172 mM mannitol.

18. A method for preparing a lyophilized formulation of any of claims 1-13 comprising the steps of:

a. cooling the aqueous solution of any of claims 14-15 at a rate of from 0.5°C/min to 1°C/min to a temperature of -40°C or less;
b. holding isothermally for at least 120 min;
c. warming to between -20°C and -15°C at a rate of from 0.5°C/min to 3°C/min;
d. holding isothermally for at least 180 min;
e. applying vacuum using a pressure between 50 mTorr and 200 mTorr at a temperature between -30°C and -10°C;
f. increasing the temperature to between 35°C and 50°C at a rate of from 0.5°C/min and 1°C/min and
g. holding isothermally for at least 10 hours.

19. A method of preparing an injectable solution of an anti-TF ADC, comprising the step of reconstituting the lyophilized formulation of any one of claims 1 to 13 in a sterile aqueous diluent.