

WHAT IS CLAIMED IS:

1. An anti-human PD-1 antibody formulation, comprising:
 - a) about 5 mg/mL to about 200 mg/mL of an anti-human PD-1 antibody, or
5 antigen binding fragment thereof;
 - b) about 5 mM to about 20 mM buffer;
 - c) a stabilizer selected from the group consisting of:
 - i) about 6% to about 8% weight/volume (w/v) sucrose, trehalose or (2-
10 hydroxypropyl)- β -cyclodextrin;
 - ii) about 3% to about 5% w/v mannitol, sorbitol, L-arginine, a
pharmaceutically acceptable salt of L-arginine, L-proline, or a
pharmaceutically acceptable salt of L-proline; and
 - iii) about 1.8 to about 2.2% w/v glycine, or a pharmaceutically acceptable
salt thereof;
 - d) about 0.01 % to about 0.10% non-ionic surfactant; and
 - e) about 1 mM to about 20 mM anti-oxidant.
2. The anti-human PD-1 antibody formulation of claim 1, wherein the
formulation has a pH between 5.0 and 6.0.
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3. The anti-human PD-1 antibody formulation of any one of claims 1-2, wherein
the stabilizer is selected from the group consisting of:
 - i) about 6% to about 8% weight/volume (w/v) sucrose, trehalose or (2-
25 hydroxypropyl)- β -cyclodextrin;
 - ii) about 3 % to about 5% mannitol, sorbitol, or L-proline, or a
pharmaceutically acceptable salt of L-proline; and
 - iii) about 1.8 to about 2.2% w/v glycine, or a pharmaceutically acceptable
salt thereof.
- 30 4. The anti-human PD-1 antibody formulation of any one of claims 1-3, wherein
the buffer is a histidine buffer, the stabilizer is sucrose, the non-ionic surfactant is polysorbate 80
and the anti-oxidant is L-methionine, or a pharmaceutically acceptable salt thereof, the formulation
comprising:
 - a) about 25 mg/mL to about 200 mg/mL of an anti-human PD-1 antibody, or
35 antigen binding fragment thereof;
 - b) about 5 mM to about 20 mM histidine buffer;
 - c) about 6% to about 8% w/v sucrose;
 - d) about 0.01 % to about 0.04% w/v polysorbate 80; and

e) about 1 mM to about 20 mM L-methionine, or a pharmaceutically acceptable salt thereof.

5 5. The anti-human PD-1 antibody formulation of any one of claims 1-4, wherein the concentration of the anti-human PD-1 antibody or antigen binding fragment thereof is from about 75 mg/mL to about 200 mg/mL.

10 6. The anti-human PD-1 antibody formulation of claim 1, wherein the buffer is a histidine buffer, the stabilizer is sucrose, the non-ionic surfactant is polysorbate 80 and the anti-oxidant is L-methionine, or a pharmaceutically acceptable salt thereof, the formulation comprising:

- a) about 75 to about 200 mg/mL of an anti-human PD-1 antibody, or antigen binding fragment thereof;
- b) 8 mM to about 12 mM histidine buffer;
- c) about 5 mM to about 10 mM L-methionine, or a pharmaceutically acceptable salt thereof;
- d) about 6% to about 8% w/v sucrose; and
- e) 0.01 % to about 0.04% w/v polysorbate 80.

20 7. The anti-human PD-1 antibody formulation of claim 6, comprising:

- a) about 125 to about 200 mg/mL of an anti-human PD-1 antibody, or antigen binding fragment thereof;
- b) about 10 mM histidine buffer;
- c) about 10 mM L-methionine, or a pharmaceutically acceptable salt thereof;
- d) about 7 w/v sucrose; and
- e) about 0.02 % to w/v polysorbate 80.

 8. The anti-human PD-1 antibody formulation of claim 7, wherein the antioxidant is L-methionine HCl.

30 9. The anti-human PD-1 antibody formulation of any one of claims 6-8, further comprising from about 1.25% to about 2.5% w/v L-arginine, or a pharmaceutically acceptable salt thereof.

35 10. The anti-human PD-1 antibody formulation of any of claims 1-9 that is a reconstituted solution from a lyophilized formulation.

 11. The anti-human PD-1 antibody formulation of any of claims 1-10, wherein the anti-human PD-1 antibody or antigen binding fragment thereof comprises three light chain

CDRs comprising CDRL1 of SEQ ID NO:1, CDRL2 of SEQ ID NO:2 and CDRL3 of SEQ ID NO:3 and three heavy chain CDRs of CDRH1 of SEQ ID NO:6, CDRH2 of SEQ ID NO:7 and CDRH3 of SEQ ID NO:8.

5 12. The anti-human PD-1 antibody formulation of any of claims 1-11, wherein the anti-human PD-1 antibody or antigen binding fragment thereof comprises a V_L region which comprises the amino acid sequence set forth in SEQ ID NO:4, and a V_H region which comprises the amino acid sequence set forth in SEQ ID NO:9.

10 13. The anti-human PD-1 antibody formulation of any of claims 1-12, wherein the formulation comprises a light chain comprising or consisting of a sequence of amino acids as set forth in SEQ ID NO:5 and a heavy chain comprising or consisting of a sequence of amino acids as set forth in SEQ ID NO: 10.

15 14. The anti-human PD-1 antibody formulation of any of claims 1-13, wherein the formulation comprises an anti-human PD-1 antibody that is pembrolizumab.

 15. Use of the anti-human PD-1 antibody formulation of any one of claims 1-14 in the manufacture of a medicament for treating chronic infection in a human patient in need thereof.
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 16. Use of the anti-human PD-1 antibody formulation of any one of claims 1-14 in the manufacture of a medicament for treating cancer in a human patient in need thereof.

 17. The use of claim 15 or 16, wherein the anti-human PD-1 antibody formulation
25 is to be administered by subcutaneous administration.

 18. The anti-human PD-1 antibody formulation of any one of claims 1-14 for use as a medicament.