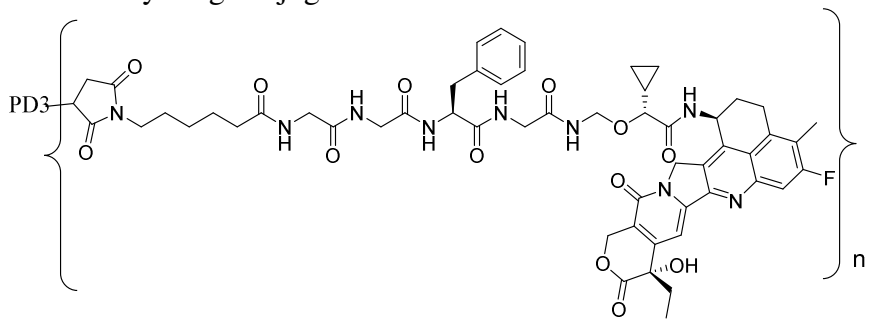


CLAIMS

1. A pharmaceutical composition, comprising:

(a) an antibody drug conjugate at a protein concentration of 1 mg/mL to 100 mg/mL, wherein the antibody drug conjugate has a structure shown below:



wherein:

PD3 is an anti-TROP2 antibody comprising a heavy chain set forth in SEQ ID NO: 1 and a light chain set forth in SEQ ID NO: 2;

n is 1 to 10;

(b) 0.01 mg/mL to 1.0 mg/mL polysorbate 80,

(c) 25 mg/mL to 80 mg/mL saccharide,

(d) 6 mg/mL to 15 mg/mL glycine, and

(e) 10 mM to 50 mM histidine-histidine hydrochloride buffer with a pH of 5.0 to 6.5.

2. The pharmaceutical composition according to claim 1, wherein the pH is of 5.5 to 6.5.

3. The pharmaceutical composition according to claim 1, wherein the pH is of 5.9 to 6.2.

4. The pharmaceutical composition according to claim 1, wherein n is 1 to 8.

5. The pharmaceutical composition according to claim 1, wherein the histidine-histidine hydrochloride buffer is at a concentration of 20 mM to 40 mM.

6. The pharmaceutical composition according to claim 1, wherein the polysorbate 80 is

at a concentration of 0.1 mg/mL to 0.3 mg/mL.

7. The pharmaceutical composition according to claim 1, wherein the saccharide is selected from the group consisting of sucrose and trehalose dihydrate.

8. The pharmaceutical composition according to claim 1, wherein the saccharide is sucrose.

9. The pharmaceutical composition according to claim 1, wherein the saccharide is at a concentration of 30 mg/mL to 50 mg/mL.

10. The pharmaceutical composition according to claim 1, wherein the glycine is at a concentration of 7 mg/mL to 11 mg/mL.

11. The pharmaceutical composition according to claim 1, wherein the antibody drug conjugate is at a protein concentration of 10 mg/mL to 30 mg/mL.

12. The pharmaceutical composition according to claim 1, comprising the following components:

- (a) the antibody drug conjugate at a protein concentration of 10 mg/mL to 30 mg/mL,
 - (b) 0.1 mg/mL to 0.3 mg/mL polysorbate 80,
 - (c) 30 mg/mL to 50 mg/mL sucrose,
 - (d) 7 mg/mL to 11 mg/mL glycine, and
 - (e) 20 mM to 40 mM histidine-histidine hydrochloride buffer,
- the composition having a pH of 5.5-6.5.

13. The pharmaceutical composition according to claim 1, comprising the following components:

- (a) the antibody drug conjugate at a protein concentration of 18 mg/mL to 22 mg/mL,
- (b) 0.2 mg/mL polysorbate 80,
- (c) 40 mg/mL sucrose,

(d) 9 mg/mL glycine, and
(e) 30 mM histidine-histidine hydrochloride buffer,
the composition having a pH of 5.9-6.2.

14. A lyophilized formulation comprising an antibody drug conjugate, wherein the lyophilized formulation is reconstituted to form the pharmaceutical composition according to any one of claims 1 to 13.

15. A method for preparing a lyophilized formulation comprising an antibody drug conjugate, comprising a step of lyophilizing the pharmaceutical composition according to any one of claims 1 to 13.

16. A lyophilized formulation comprising an antibody drug conjugate, wherein the lyophilized formulation is obtained by lyophilizing the pharmaceutical composition according to any one of claims 1 to 13.

17. A reconstituted solution comprising an antibody drug conjugate, wherein the reconstituted solution is prepared by reconstituting the lyophilized formulation according to claim 14 or 16.

18. An article of manufacture, comprising a container, wherein the container contains the pharmaceutical composition according to any one of claims 1 to 13, the lyophilized formulation according to claim 14 or 16, or the reconstituted solution according to claim 17.

19. Use of the pharmaceutical composition according to any one of claims 1 to 13, the lyophilized formulation according to claim 14 or 16, the reconstituted solution according to claim 17, or the article of manufacture according to claim 18 in preparing a medicament for the treatment of a tumor or cancer, wherein the tumor or the cancer is selected from the group consisting of head and neck squamous cell carcinoma, head and neck cancer, brain cancer, neuroglioma, glioblastoma multiforme, neuroblastoma,

central nervous system carcinoma, neuroendocrine tumor, throat cancer, pharyngeal squamous cell carcinoma, oral squamous cell carcinoma, nasopharyngeal cancer, esophageal cancer, thyroid cancer, malignant pleural mesothelioma, lung cancer, breast cancer, liver cancer, hepatobiliary cancer, pancreatic cancer, stomach cancer, gastrointestinal cancer, intestinal cancer, colon cancer, colorectal cancer, kidney cancer, clear cell renal cell carcinoma, ovarian cancer, endometrial cancer, cervical cancer, bladder cancer, prostate cancer, testicular cancer, skin cancer, melanoma, Krukenberg tumor, squamous cell carcinoma, Ewing's sarcoma, urothelium carcinoma, and Merkel cell carcinoma.

20. The use according to claim 19, wherein the lung cancer is selected from the group consisting of non-small cell lung cancer and small cell lung cancer.