Claims

1. A pharmaceutical composition comprising a labeling moiety-anti-human antibody Fab fragment conjugate, a buffering agent, a stabilizer and a nonionic surfactant and having a pH of 6.5 to 7.5, wherein

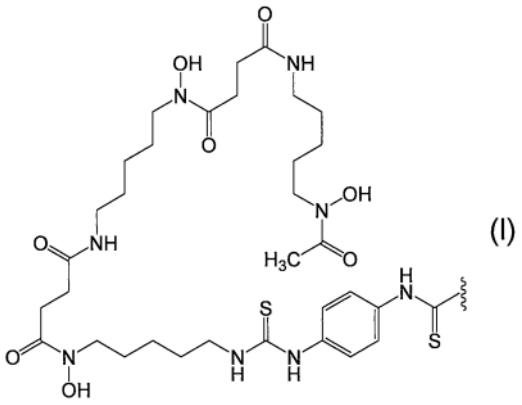
the anti-human antibody Fab fragment is one or more selected from the group consisting of the following (a) and (b):

(a) an anti-human CEACAM5 antibody Fab fragment comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 2 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 4; and

(b) an anti-human CEACAM5 antibody Fab fragment comprising a heavy chain fragment derived from a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 2 by the modification of glutamic acid at amino acid position 1 of SEQ ID NO: 2 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 4.,

the labeling moiety is a group represented by the following formula (I):

[Chemical Formula 1]



(I)

wherein the wavy line represents binding to the anti-human CEACAM5 antibody Fab fragment, where the anti-human CEACAM5 antibody Fab fragment is bound to the carbon atom of a labeling moiety terminal C(=S) group via an amino group in the anti-human CEACAM5 antibody Fab fragment,

the nonionic surfactant comprises Polysorbate 80,

the concentration of the nonionic surfactant is 0.02 to 0.2 w/v%,

the buffering agent comprises citric acid,

the concentration of the buffering agent is 10 to 30 mmol/L,

the stabilizer comprises sucrose or glycerin,

the concentration of the stabilizer is 5 to 30 w/v%.

2. A pharmaceutical composition comprising a labeling moiety-anti-human antibody Fab fragment conjugate, a buffering agent, a stabilizer and a nonionic surfactant and having a pH of 6.5 to 7.0, wherein

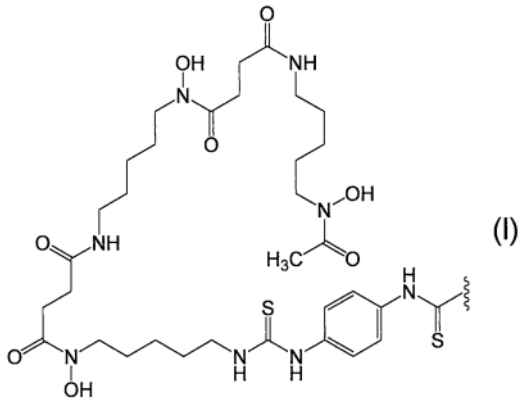
the anti-human antibody Fab fragment is one or more selected from the group consisting of the following (a) and (b):

(a) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 6 or SEQ ID NO: 8 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 10; and

(b) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment derived from a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 6 or SEQ ID NO: 8 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 6 or SEQ ID NO: 8 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 10,

the labeling moiety is a group represented by the following formula (I):

[Chemical Formula 2]



(I)

wherein the wavy line represents binding to the anti-human MUC1 antibody Fab fragment, where the anti-human MUC1 antibody Fab fragment is bound to the carbon atom of a labeling

moiety terminal C(=S) group via an amino group in the anti-human MUC1 antibody Fab fragment,

the nonionic surfactant comprises Polysorbate 80,

the concentration of the nonionic surfactant is 0.02 to 0.2 w/v%,

the buffering agent comprises citric acid,

the concentration of the buffering agent is 10 to 30 mmol/L,

the stabilizer comprises sucrose,

the concentration of the stabilizer is 5 to 30 w/v%.

3. The pharmaceutical composition according to claim 1, wherein

the stabilizer comprises sucrose, and

the range of pH is 6.5 to 7.0.

4. The pharmaceutical composition according to any one of claims 1 to 3, wherein

the concentration of the labeling moiety-anti-human antibody Fab fragment conjugate is 5 to 20 mg/mL,

the concentration of the nonionic surfactant is 0.04 to 0.1 w/v%, and

the concentration of the buffering agent is 15 to 25 mmol/L.

5. The pharmaceutical composition according to claim 4, wherein

the range of pH is 6.7.

6. The pharmaceutical composition according to claim 1 or 2, wherein

the concentration of the labeling moiety-anti-human antibody Fab fragment conjugate is 10 mg/mL,

the pH is 6.7,

the concentration of the nonionic surfactant is 0.05 w/v%,

the concentration of the buffering agent is 20 mmol/L,

the stabilizer comprises sucrose, and

the concentration of the stabilizer is 10 w/v%.

7. The pharmaceutical composition according to claim 1, wherein
the concentration of the labeling moiety-anti-human antibody Fab fragment conjugate is 10 mg/mL,
the pH is 6.7,
the concentration of the nonionic surfactant is 0.05 w/v%,
the concentration of the buffering agent is 20 mmol/L,
the stabilizer comprises glycerin, and
the concentration of the stabilizer is 30 w/v%.

8. The pharmaceutical composition according to any one of claims 1to 7, wherein the labeling moiety-anti-human antibody Fab fragment conjugate further comprises ^{89}Zr.

9. The pharmaceutical composition according to claim 8 for use in the diagnosis of colorectal cancer or a cancer resulting from the metastasis of colorectal cancer.

10. The pharmaceutical composition according to claim 8- for use in the diagnosis of breast cancer or a cancer resulting from the metastasis of breast cancer.

11. The pharmaceutical composition according to any one of claims 1 to 10, which is a liquid formulation, a frozen formulation or a lyophilized formulation.

12. A method for producing the pharmaceutical composition according to claim1, comprising the steps of:
(a) producing and adding the labeling moiety-anti-human antibody Fab fragment conjugate;
(b) adding citric acid at 10 to 30 mmol/L as a buffering agent;
(c) adding sucrose or glycerin at 5 to 30 w/v% as a stabilizer;
(d) adding Polysorbate 80 at 0.02 to 0.2 w/v% as a nonionic surfactant; and
(e) adjusting the pH to 6.5 to 7.5.

13. A method for producing the pharmaceutical composition according to claim 2, comprising the steps of:

(a) producing and adding the labeling moiety-anti-human antibody Fab fragment conjugate;
(b) adding citric acid at 10 to 30 mmol/L as a buffering agent;
(c) adding sucrose at 5 to 30 w/v% as a stabilizer;
(d) adding Polysorbate 80 at 0.02 to 0.2 w/v% as a nonionic surfactant; and
(e) adjusting the pH to 6.5 to 7.0.

14. A method for stably preserving a labeling moiety-anti-human antibody Fab fragment conjugate contained in the pharmaceutical composition according to claim 1, comprising the steps of:
(a) adding citric acid at 10 to 30 mmol/L as a buffering agent to a solution containing the labeling moiety-anti-human antibody Fab fragment conjugate;
(b) adding sucrose or glycerin at 5 to 30 w/v% as a stabilizer to the solution containing the labeling moiety-anti-human antibody Fab fragment conjugate;
(c) adding Polysorbate 80 at 0.02 to 0.2 w/v% as a nonionic surfactant to the solution containing the labeling moiety-anti-human antibody Fab fragment conjugate; and
(d) adjusting the pH of the solution containing the labeling moiety-anti-human antibody Fab fragment conjugate to 6.5 to 7.5.

15. A method for stably preserving a labeling moiety-anti-human antibody Fab fragment conjugate contained in the pharmaceutical composition according to claim 2, comprising the steps of:
(a) adding citric acid at 10 to 30 mmol/L as a buffering agent to a solution containing the labeling moiety-anti-human antibody Fab fragment conjugate;
(b) adding sucrose at 5 to 30 w/v% as a stabilizer to the solution containing the labeling moiety-anti-human antibody Fab fragment conjugate;
(c) adding Polysorbate 80 at 0.02 to 0.2 w/v% as a nonionic surfactant to the solution containing the labeling moiety-anti-human antibody Fab fragment conjugate; and
(d) adjusting the pH of the solution containing the labeling moiety-anti-human antibody Fab fragment conjugate to 6.5 to 7.0.