

## **CLAIMS**

1. A composition comprising an antibody having a heavy chain amino acid sequence as shown in SEQ ID NO: 1 and a light chain amino acid sequence as shown in SEQ ID NO: 2, wherein the composition comprises:  $\leq 80\%$  acidic antibody variants.
2. A composition comprising an antibody having a heavy chain amino acid sequence as shown in SEQ ID NO: 1 and a light chain amino acid sequence as shown in SEQ ID NO: 2, wherein the composition comprises:  $\leq 80\%$  acidic antibody variants and  $\leq 20\%$  aggregated antibody variants.
3. A composition comprising an antibody having a heavy chain amino acid sequence as shown in SEQ ID NO: 1 and a light chain amino acid sequence as shown in SEQ ID NO: 2, wherein the composition comprises:  $\leq 25\%$  deamidated antibody variants at N31 of the light chain amino acid sequence; and  $\leq 20\%$  aggregated antibody variants.
4. A composition comprising an antibody having a heavy chain amino acid sequence as shown in SEQ ID NO: 1 and a light chain amino acid sequence as shown in SEQ ID NO: 2, wherein the composition comprises:  $\leq 25\%$  deamidated antibody variants at N31 of the light chain amino acid sequence;  $\leq 55\%$  oxidised antibody variants at M64 of the heavy chain amino acid sequence;  $\leq 3\%$  oxidised antibody variants at W52 of the heavy chain amino acid sequence; and  $\leq 20\%$  aggregated antibody variants.
5. A composition comprising an antibody having a heavy chain amino acid sequence as shown in SEQ ID NO: 1 and a light chain amino acid sequence as shown in SEQ ID NO: 2, wherein the composition comprises:  $\leq 25\%$  deamidated antibody variants at N31 of the light chain amino acid sequence;  $\leq 35\%$  deamidated antibody variants at N386 of the heavy chain amino acid sequence; and  $\leq 20\%$  aggregated antibody variants.
6. A composition comprising an antibody having a heavy chain amino acid sequence as shown in SEQ ID NO: 1 and a light chain amino acid sequence as shown in SEQ ID NO: 2, wherein the composition comprises:  $\leq 25\%$  deamidated antibody variants at N31 of the light chain amino acid sequence;  $\leq 35\%$  deamidated antibody variants at N386 of the heavy chain amino acid sequence;  $\leq 55\%$  oxidised antibody variants at M64 of the heavy chain amino acid sequence, M254 of the heavy chain amino acid sequence, M430 of the heavy chain amino acid sequence;  $\leq 3\%$  oxidised antibody variants at W52 of the heavy chain amino acid sequence; and  $\leq 20\%$  aggregated antibody variants.

7. A composition comprising a purified preparation of a monoclonal antibody and a buffering agent, wherein the composition is at a pH from 6.8 to 7.2, wherein the buffering agent is histidine, phosphate, or citrate or a salt thereof, wherein the purified preparation comprises the isoforms represented by acidic form peak 65, acidic form peak 78, acidic form peak 88, acidic form peak 92, the main peak and basic form peak 112 shown in Figure 1, wherein the antibody comprises a heavy chain having the amino acid sequence shown in SEQ ID NO: 1 and a light chain amino acid sequence having the amino acid sequence shown in SEQ ID NO: 2, and wherein the antibody is produced by a Chinese Hamster Ovary cell.

8. A composition comprising a purified preparation of a monoclonal antibody and a buffering agent, wherein the composition is at a pH from 6.8 to 7.2, wherein the buffering agent is phosphate or a salt thereof, wherein the purified preparation comprises the isoforms represented by acidic form peak 65, acidic form peak 78, acidic form peak 88, acidic form peak 92, the main peak and basic form peak 112 shown in Figure 1, wherein the antibody comprises a heavy chain amino acid sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain amino acid sequence having the amino acid sequence shown in SEQ ID NO: 2, and wherein the antibody is produced by a Chinese Hamster Ovary cell.

9. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2; and
- b) a main form of the antibody comprising greater than, or equal to, 50% of the protein in the composition as measured using capillary isoelectric focusing of the composition.

10. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence the amino acid sequence shown in SEQ ID NO: 2;

- b) a main form of the antibody comprising greater than, or equal to, 50% of the protein in the composition as measured using capillary isoelectric focusing of the composition; and
- c) acidic forms of the antibody comprising about 20% to about 45% of the protein in the composition as measured using capillary isoelectric focusing of the composition.

11. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2;
- b) a main form of the antibody comprising greater than, or equal to, 50% of the protein in the composition as measured using capillary isoelectric focusing of the composition; and
- c) a basic form of the antibody comprising about 1% to about 15% of the protein in the composition as measured using capillary isoelectric focusing of the composition.

12. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2;
- b) a main form of the antibody comprising greater than, or equal to, 50% of the protein in the composition as measured using capillary isoelectric focusing of the composition;
- c) acidic forms of the antibody comprising about 20% to about 45% of the protein in the composition as measured using capillary isoelectric focusing of the composition; and
- d) a basic form of the antibody comprising about 1% to about 15% of the protein in the composition as measured using capillary isoelectric focusing of the composition.

13. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence the amino acid sequence shown in SEQ ID NO: 2; and
- b) deamidated forms of the antibody comprising at least one selected from the group consisting of 35% or less of a heavy chain amino acid residue deamidated at asparagine 386 and 25% or less of a light chain amino acid residue deamidated at asparagine 31.

14. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2; and
- b) oxidized forms of the antibody comprising at least one selected from the group consisting of 3% or less of a heavy chain amino acid residue oxidized at tryptophan 52, 55% or less of a heavy chain amino acid residue oxidized at methionine 64, 50% or less of a heavy chain amino acid residue oxidized at methionine 254, 50% or less of a heavy chain amino acid residue oxidized at methionine 360, and 50% or less of a heavy chain amino acid residue oxidized at methionine 430.

15. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2;
- b) deamidated forms of the antibody comprising at least one selected from the group consisting of 35% or less of a heavy chain amino acid residue deamidated at asparagine 386 and 25% or less of a light chain amino acid residue deamidated at asparagine 31; and
- c) oxidized forms of the antibody comprising at least one selected from the group consisting of 3% or less of a heavy chain amino acid residue oxidized at tryptophan 52, 50% or less of a heavy chain amino acid residue oxidized at methionine 64, 50% or less of a heavy chain amino acid residue oxidized at methionine 254, 50% or less of a heavy chain amino acid residue oxidized at methionine 360, and 50% or less of a heavy chain amino acid residue oxidized at methionine 430.

16. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain variable region having the CDRH1 amino acid sequence shown in SEQ ID NO: 5, the CDRH2 amino acid sequence shown in SEQ ID NO: 6, and the CDRH3 amino acid sequence shown in SEQ ID NO: 7; and a light chain variable region having the CDRL1 amino acid sequence shown in SEQ ID NO: 8, the CDRL2 amino acid sequence shown in SEQ ID NO: 9, and the CDRL3 amino acid sequence shown in SEQ ID NO: 10; and

- b) 25% or less of deamidated forms of the antibody comprising a light chain amino acid residue deamidated at asparagine 31.

17. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain variable region having the CDRH1 amino acid sequence shown in SEQ ID NO: 5, the CDRH2 amino acid sequence shown in SEQ ID NO: 6, and the CDRH3 amino acid sequence shown in SEQ ID NO: 7; and a light chain variable region having the CDRL1 amino acid sequence shown in SEQ ID NO: 8, the CDRL2 amino acid sequence shown in SEQ ID NO: 9, and the CDRL3 amino acid sequence shown in SEQ ID NO: 10; and
- b) oxidized forms of the antibody comprising at least one selected from the group consisting of 3% or less of a heavy chain amino acid residue oxidized at tryptophan 52 and 50% or less of a heavy chain amino acid residue oxidized at methionine 64.

18. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain variable region having the CDRH1 amino acid sequence shown in SEQ ID NO: 5, the CDRH2 amino acid sequence shown in SEQ ID NO: 6, and the CDRH3 amino acid sequence shown in SEQ ID NO: 7; and a light chain variable region having the CDRL1 amino acid sequence shown in SEQ ID NO: 8, the CDRL2 amino acid sequence shown in SEQ ID NO: 9, and the CDRL3 amino acid sequence shown in SEQ ID NO: 10;
- b) oxidized forms of the antibody comprising at least one selected from the group consisting of 3% or less of a heavy chain amino acid residue oxidized at tryptophan 52 and 50% or less of a heavy chain amino acid residue oxidized at methionine 64; and
- c) 25% or less of deamidated forms of the antibody comprising a light chain amino acid residue deamidated at asparagine 31.

19. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain variable region sequence having the amino acid sequence shown in SEQ ID NO: 3 and a light chain variable region sequence having the amino acid sequence shown in SEQ ID NO: 4; and
- b) 25% or less of deamidated forms of the antibody comprising a light chain amino acid residue deamidated at asparagine 31.

20. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain variable region sequence having the amino acid sequence shown in SEQ ID NO: 3 and a light chain variable region sequence having the amino acid sequence shown in SEQ ID NO: 4; and
- b) oxidized forms of the antibody comprising at least one selected from the group consisting of 3% or less of a heavy chain amino acid residue oxidized at tryptophan 52, and 50% or less of a heavy chain amino acid residue oxidized at methionine 64.

21. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain variable region sequence having the amino acid sequence shown in SEQ ID NO: 3 and a light chain variable region sequence having the amino acid sequence shown in SEQ ID NO: 4;
- b) 25% or less of deamidated forms of the antibody comprising a light chain amino acid residue deamidated at asparagine 31; and
- c) oxidized forms of the antibody comprising at least one selected from the group consisting of 3% or less of a heavy chain amino acid residue oxidized at tryptophan 52, and 50% or less of a heavy chain amino acid residue oxidized at methionine 64.

22. A composition comprising a population of anti-IL-5 antibodies having

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2;
- b) a modified form of the antibody heavy chain amino acid sequence shown in SEQ ID NO: 1 comprising at least one amino acid residue modification selected from the group consisting of an amino terminal pyroglutamate residue at amino acid residue 1, a carboxy terminal glycine amino acid residue at amino acid residue 448, a deamidated asparagine residue at position 386, an oxidized tryptophan residue at position 52, an oxidized methionine residue at position 64, an oxidized methionine at position 254, an oxidized methionine at position 360 and an oxidized methionine residue at position 430; and
- c) a modified form of the antibody light chain amino acid sequence shown in SEQ ID NO: 2 comprising a deamidated asparagine residue at amino acid residue 31.

23. A composition comprising a population of anti-IL-5 antibodies having
- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2;
  - b) a modified form of the antibody heavy chain amino acid sequence shown in SEQ ID NO: 1 comprising at least one amino acid residue modification selected from the group consisting of a deamidated asparagine residue at position 386, an oxidized tryptophan residue at position 52, an oxidized methionine residue at position 64, an oxidized methionine at position 254, an oxidized methionine at position 254, an oxidized methionine at position 360 and an oxidized methionine residue at position 430; and
  - c) a modified form of the antibody light chain amino acid sequence shown in SEQ ID NO: 2 comprising a deamidated asparagine residue at amino acid residue 31.
24. A composition comprising a population of anti-IL-5 antibodies having
- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2;
  - b) a modified form of the antibody heavy chain amino acid sequence shown in SEQ ID NO: 1 comprising a deamidated asparagine residue at position 386; and
  - c) a modified form of the antibody light chain amino acid sequence shown in SEQ ID NO: 2 comprising a deamidated asparagine residue at amino acid residue 31.
25. A composition comprising a population of anti-IL-5 antibodies having
- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2; and
  - b) a modified form of the antibody heavy chain amino acid sequence shown in SEQ ID NO: 1 comprising at least one amino acid residue modification selected from the group consisting of an oxidized tryptophan residue at position 52, an oxidized methionine residue at position 64, an oxidized methionine at position 254, an oxidized methionine at position 360 and an oxidized methionine residue at position 430.
26. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence having the amino acid sequence shown in SEQ ID NO: 2; and
- b) a main form of the antibody comprising greater than, or equal to, 20% of the protein in the composition as measured using capillary isoelectric focusing of the composition.

27. A composition comprising

- a) an anti-IL-5 antibody comprising a heavy chain sequence having the amino acid sequence shown in SEQ ID NO: 1 and a light chain sequence the amino acid sequence shown in SEQ ID NO: 2;
- b) a main form of the antibody comprising greater than, or equal to, 20% of the protein in the composition as measured using capillary isoelectric focusing of the composition; and
- c) acidic forms of the antibody comprising up to about 80% of the protein in the composition as measured using capillary isoelectric focusing of the composition.

28. A composition according to any one of the preceding Claims wherein the antibody is at a concentration of between about 75 mg/ml to about 100 mg/ml.

29. A composition according to any one of the preceding Claims wherein the composition further comprises one or a combination of:

- (a) a buffering agent selected from the group consisting of sodium phosphate dibasic heptahydrate, phosphate, citrate, sodium phosphate, potassium phosphate, sodium citrate, and histidine, providing a pH of between 6.8 and 7.2; and/or
- (b) a sugar; and/or
- (c) polysorbate 80; and/or
- (d) EDTA.

30. A composition according to any one of the preceding Claims wherein the composition has at least 0.70 IL-5 specific antigen binding activity; and/or at least 70% FcRn binding activity, compared with a reference standard composition comprising SEQ ID NO: 1 and SEQ ID NO:2.

31. A composition according to any one of Claims 1- 30 for use in therapy.

32. A pharmaceutical composition comprising a composition according to any one of Claims 1-30 and a pharmaceutically acceptable carrier.

33. A composition according to any one of Claims 1-30 for use in the treatment of asthma, severe eosinophilic asthma, severe asthma, uncontrolled eosinophilic asthma, eosinophilic asthma, sub-eosinophilic asthma, chronic obstructive pulmonary disease, eosinophilic granulomatosis with polyangiitis, hypereosinophilic syndrome, nasal polyposis, bullous pemphigoid and eosinophilic esophagitis.

34. Use of the composition according to any one of Claims 1-30 in the manufacture of a medicament, for the treatment of a disease selected from the group consisting of asthma, severe eosinophilic asthma, severe asthma, uncontrolled eosinophilic asthma, eosinophilic asthma, sub-eosinophilic asthma, chronic obstructive pulmonary disease, eosinophilic granulomatosis with polyangiitis, hypereosinophilic syndrome, nasal polyposis, bullous pemphigoid and eosinophilic esophagitis.

35. The use of Claim 34, wherein the medicament is to be administered at a dose of 100 mg once every 4 weeks.