

Summary

In one aspect of the present disclosure, there is provided a pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of 40 mg/mL to 160 mg/mL, histidine buffer at a concentration of 5 mM to 20 mM, NaCl at a concentration of 50 mM to 200mM, polysorbate-80 (PS-80) at a concentration of 0.03% (w/v) to 0.07% (w/v), and a pH at 5.0 to 6.5, wherein the anti-CGRP antibody comprises a light chain variable region (LCVR) and a heavy chain variable region (HCVR), the amino acid sequence of LCVR given by SEQ ID NO: 1 and the amino acid sequence of HCVR given by SEQ ID NO: 2.

In another aspect of the present disclosure, there is provided a pharmaceutical formulation as described herein for use in the treatment or prevention of at least one of migraine, episodic headache, chronic headache, chronic cluster headache, and episodic cluster headache.

In yet another aspect of the present disclosure, there is provided a use of a pharmaceutical composition as described herein for the preparation of a medicament for the treatment or prevention of at least one of migraine, episodic headache, chronic headache, chronic cluster headache, and episodic cluster headache.

In a further aspect of the present disclosure, there is provided a pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of 120 mg/mL, histidine buffer at a concentration of 10 mM, NaCl at a concentration of 150 mM, and polysorbate-80 (PS-80) at a concentration of 0.05% (w/v), the pharmaceutical formulation having a pH between 5.0 to 6.5, wherein the anti-CGRP antibody comprises two LC and a two HC, the amino acid sequence of each LC given by SEQ ID NO: 3, and the amino acid sequence of each HC given by SEQ ID NO: 4.

Description

Accordingly, the present invention provides a pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of about 40 mg/mL to about 160 mg/mL, histidine buffer at a concentration of about 5 mM to about 20 mM, sodium chloride (NaCl) at a concentration of about 50 mM to about 200mM, PS-80 at a concentration of about 0.03% (w/v) to about 0.07% (w/v), and a pH at about 5.0 to about 6.5, wherein the anti-CGRP antibody comprises a light chain variable region (LCVR) and a heavy chain variable region (HCVR), the amino acid sequence of LCVR given by

WE CLAIM:

1. A pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of 40 mg/mL to 160 mg/mL, histidine buffer at a concentration of 5 mM to 20 mM, NaCl at a concentration of 50 mM to 200mM, polysorbate-80 (PS-80) at a concentration of 0.03% (w/v) to 0.07% (w/v), and a pH at 5.0 to 6.5, wherein the anti-CGRP antibody comprises a light chain variable region (LCVR) and a heavy chain variable region (HCVR), the amino acid sequence of LCVR given by SEQ ID NO: 1 and the amino acid sequence of HCVR given by SEQ ID NO: 2.
2. The formulation of claim 1, wherein the anti-CGRP antibody comprises a light chain (LC) and a heavy chain (HC), the amino acid sequence of LC given by SEQ ID NO: 3 and the amino acid sequence of HC given by SEQ ID NO: 4.
3. The formulation of claim 1, wherein the anti-CGRP antibody comprises two LCs and two HCs, the amino acid sequence of each LC given by SEQ ID NO: 3 and the amino acid sequence of each HC given by SEQ ID NO: 4.
4. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is 50 mg/mL to 150 mg/mL.
5. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is 100 mg/mL to 160 mg/mL.
6. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is selected from the group consisting of about 40 mg/mL, about 50 mg/mL, about 100 mg/mL, about 120 mg/mL, and about 150 mg/mL.
7. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is about 50 mg/mL.
8. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is about 100 mg/mL.

9. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is about 120 mg/mL.
10. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is about 150 mg/mL.
- 5 11. The formulation of any one of claims 1 to 10, wherein the concentration of histidine buffer is 10 mM to 15 mM.
12. The formulation of claim 11, wherein the concentration of histidine buffer is about 10 mM.
13. The formulation of any one of claims 1 to 12, wherein the concentration of NaCl is 125 mM to 175 mM.
- 10 14. The formulation of claim 13, wherein the concentration of NaCl is about 150 mM.
15. The formulation of any one of claims 1 to 14, wherein the concentration of polysorbate-80 (PS-80) is about 0.05% (w/v).
- 15 16. The formulation of any one of claims 1 to 15, wherein the pH is about 5.8.
17. The formulation of any one of claims 1 to 3, wherein the concentration of anti-CGRP antibody is selected from the group consisting of 50 mg/mL, 100 mg/mL, 120mg/mL, and 150 mg/mL, the concentration of histidine buffer is about 10mM, the concentration of NaCl is 150mM, and the concentration of polysorbate-80 (PS-80) is 0.05%, the pharmaceutical formulation having a pH between 5.5 to 6.0.
- 20 18. The formulation of claim 17, where in the concentration of anti-CGRP antibody is about 100 mg/mL.
19. The formulation of claim 17, where in the concentration of anti-CGRP antibody is about 120 mg/mL.
- 25 20. The formulation of claim 17, where in the concentration of anti-CGRP antibody is about 150 mg/mL.
21. The formulation of claim 17, wherein the said formulation is suitable for subcutaneous injection.

22. A pharmaceutical formulation of any of claims 1 to 21 for use in the treatment or prevention of at least one of migraine, episodic headache, chronic headache, chronic cluster headache, and episodic cluster headache.
- 5 23. Use of a pharmaceutical composition according to any one of claims 1 to 21 for the preparation of a medicament for the treatment or prevention of at least one of migraine, episodic headache, chronic headache, chronic cluster headache, and episodic cluster headache.
24. The use of claim 23, wherein the anti-CGRP antibody is to be administered to a patient in a dose of 300 mg.
- 10 25. The use of claim 23, wherein the anti-CGRP antibody is to be administered to a patient in a dose of 240 mg.
26. The use of claim 23, wherein the anti-CGRP antibody is to be administered to a patient in a dose of 120 mg.
- 15 27. The use of any one of claims 24-26, wherein the dose is to be administered at monthly intervals.
28. The use of claim 25, wherein the 240 mg dose is to be followed by a monthly maintenance dose of 120 mg.
- 20 29. A pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of 120 mg/mL, histidine buffer at a concentration of 10 mM, NaCl at a concentration of 150 mM, and polysorbate-80 (PS-80) at a concentration of 0.05% (w/v), the pharmaceutical formulation having a pH between 5.0 to 6.5, wherein the anti-CGRP antibody comprises two LC and a two HC, the amino acid sequence of each LC given by SEQ ID NO: 3, and the amino acid sequence of each HC given by SEQ ID NO: 4.
- 25 30. The pharmaceutical formulation according to claim 29, wherein the pharmaceutical formulation has a pH of 5.8.