

Summary

In one aspect of the present disclosure, there is provided 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, 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 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 about 120 mg/mL, histidine buffer at a concentration of about 10 mM, NaCl at a concentration of about 150 mM, and PS-80 at a concentration of about 0.05% (w/v), the pharmaceutical formulation having a pH between about 5.0 to about 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

SEQ ID NO: 1 and the amino acid sequence of HCVR given by SEQ ID NO: 2.

Preferably, the pharmaceutical formulation comprises an anti-CGRP antibody with 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. More preferably, the pharmaceutical formulation comprises an anti-CGRP antibody with 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.

In an alternative embodiment, the present invention provides a pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of about 50 mg/mL to about 150 mg/mL, histidine buffer at a concentration of about 5 mM to about 20 mM, sodium chloride at a concentration of about 50 mM to about 200 mM, 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 SEQ ID NO: 1 and the amino acid sequence of HCVR given by SEQ ID NO: 2.

Preferably, the pharmaceutical formulation comprises an anti-CGRP antibody with 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. More preferably, the pharmaceutical formulation comprises an anti-CGRP antibody with 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.

In an alternative embodiment, the present invention provides a pharmaceutical formulation comprising an anti-CGRP antibody at a concentration of about 100 mg/mL to about 160 mg/mL, histidine buffer at a concentration of about 5 mM to about 20 mM,

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 about 10 mM to about 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 about 125 mM to about 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 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 about 50 mg/mL, about 100 mg/mL, about 120mg/mL, and about 150 mg/mL, the concentration of histidine buffer is about 10mM, the concentration of NaCl is about 150mM, and the concentration of PS-80 is about 0.05%, the pharmaceutical formulation having a pH between about 5.5 to about 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 about 120 mg/mL, histidine buffer at a concentration of about 10 mM, NaCl at a concentration of about 150 mM, and PS-80 at a concentration of about 0.05% (w/v), the pharmaceutical formulation having a pH between about 5.0 to about 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.