

[0005] Antibodies to human interleukin-33 (hIL-33) are one example of therapeutically relevant macromolecules that require proper formulation.

[0006] Although anti-hIL-33 antibodies are known in the art (see, e.g., WO 2014/164959), there remains a need for pharmaceutical formulations comprising anti-hIL-33 antibodies that are sufficiently stable and suitable for administration to patients.

SUMMARY

[0007] Stable liquid pharmaceutical formulations comprising an anti-IL-33 antibody and one or more excipients, as well as kits comprising such formulations and uses thereof, are provided.

[0008] In one aspect, a stable liquid pharmaceutical formulation comprising: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33); (ii) a buffer; (iii) an amino acid; (iv) a thermal stabilizer; and (v) an organic cosolvent is provided. In another aspect, the present disclosure refers to a stable liquid pharmaceutical formulation comprising: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33), wherein the antibody comprises a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO: 2 and a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO: 10, wherein the antibody is present at a concentration of from 1 mg/ml to 200 mg/ml; (ii) 5 mM to 15 mM acetate; (iii) 60 mM to 80 mM arginine hydrochloride; (iv) sucrose at a concentration of from 3% w/v to 7% w/v; and (v) 0.06% w/v to 0.1% w/v polysorbate 20 or polysorbate 80; wherein the formulation has a pH of from 5 to 5.6. In yet another aspect, the present disclosure refers to a stable liquid pharmaceutical formulation comprising: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33) at a concentration of from 15 ± 1.5 mg/ml to 150 ± 15 mg/ml, wherein the antibody comprises a HCVR comprising the amino acid sequence of SEQ ID NO: 2 and a LCVR comprising the amino acid sequence of SEQ ID NO: 10; (ii) $10 \text{ mM} \pm 2 \text{ mM}$ acetate; (iii) $70 \text{ mM} \pm 14 \text{ mM}$ arginine hydrochloride; (iv) $5\% \text{ w/v} \pm 1\% \text{ w/v}$ sucrose; and (v) $0.08\% \pm 0.016\% \text{ w/v}$ polysorbate 80, wherein the formulation has a pH of from 5.1 to 5.5. In some examples, the buffer is acetate or histidine at a concentration of from 1 mM to 40 mM. In some examples, the buffer is acetate or histidine at a concentration of from 1 mM to 20 mM. In some examples, the amino acid is arginine or glutamic acid at a concentration of from 30 mM to 110 mM. In some examples, the thermal stabilizer is sucrose at a concentration of from 1% w/v to 20% w/v. In some cases, the thermal stabilizer is sucrose at a concentration of from 1% w/v to 10 % w/v. In some cases, the organic cosolvent is a surfactant at a concentration of from 0.01% w/v to 0.15% w/v. In some examples, the surfactant is polysorbate 80. In some examples, the antibody is present at a concentration of from 1 mg/ml to 200 mg/ml. In some cases, the antibody is present at a concentration of from 15 mg/ml to 150 mg/ml.

[0009] In various examples of the formulations, the antibody comprises the complementarity determining regions (HCDR1-HCDR2-HCDR3) of a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO: 2, and the complementarity determining regions (LCDR1-LCDR2-LCDR3) of a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO: 10. In some cases, the antibody comprises HCDR1-HCDR2-HCDR3 regions comprising the amino acid sequences of SEQ ID NOs: 4-6-8, respectively, and LCDR1-LCDR2-LCDR3 regions comprising the amino acid sequences of SEQ ID NOs: 12-14-16, respectively. In some examples, the antibody comprises a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO: 2, and a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO: 10. In some examples, the antibody has a human IgG heavy chain constant region. In some examples, the heavy chain constant region is of isotype IgG1. In some examples, the heavy chain constant region is of isotype IgG4. In some examples, the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 18 and a light chain comprising the amino acid sequence of SEQ ID NO: 20.

[0010] In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 15 mg/ml to about 150 mg/mL of the human antibody that specifically binds to hIL-33; (ii) about 5 mM to about 15 mM acetate; (iii) about 60 mM to about 80 mM arginine hydrochloride; (iv) about 3% w/v to about 7% w/v sucrose; and (v) about 0.06% w/v to about 0.1% w/v polysorbate 80. In some cases, the formulation has a pH of from about 5 to about 5.6.

[0011] In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 15 mg/ml $\pm$ 1.5 mg/ml of the antibody; (ii) about 10 mM $\pm$ 2 mM acetate; (iii) about 70 mM $\pm$ 14 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 1% w/v sucrose; and (iv) about 0.08% $\pm$ 0.016% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 75 mg/ml $\pm$ 5 mg/ml of the antibody; (ii) about 10 mM $\pm$ 2 mM acetate; (iii) about 70 mM $\pm$ 14 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 1% w/v sucrose; and (iv) about 0.08% $\pm$ 0.016% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 150 mg/ml $\pm$ 15 mg/ml of the antibody; (ii) about 10 mM $\pm$ 2 mM acetate; (iii) about 70 mM $\pm$ 14 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 1% w/v sucrose; and (iv) about 0.08% $\pm$ 0.016% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 15 mg/ml $\pm$ 1.5 mg/ml of the antibody; (ii) about 10 mM $\pm$ 1 mM acetate; (iii) about 70 mM $\pm$ 7 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 0.5% w/v sucrose; and (iv) about 0.08% $\pm$ 0.008% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 75 mg/ml $\pm$ 5 mg/ml of the antibody; (ii) about 10 mM $\pm$ 1 mM acetate; (iii) about 70 mM $\pm$ 7 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 0.5% w/v sucrose; and (iv) about 0.08% $\pm$ 0.008% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 150 mg/ml $\pm$ 15 mg/ml of the antibody; (ii) about 10 mM $\pm$ 1 mM acetate; (iii) about 70 mM $\pm$ 7 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 0.5% w/v sucrose; and (iv) about 0.08% $\pm$ 0.008% w/v polysorbate 80. In some cases, the pH of the formulation is from 5.2 to 5.4. In some examples, the pH of the formulation is about 5.3. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 15 mg/ml $\pm$ 1.5 mg/ml of the antibody; (ii) about 10 mM $\pm$ 2 mM acetate; (iii) about 70 mM $\pm$ 14 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 1% w/v sucrose; and (iv) about 0.08% $\pm$ 0.04% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 75 mg/ml $\pm$ 8 mg/ml of the antibody; (ii) about 10 mM $\pm$ 2 mM acetate; (iii) about 70 mM $\pm$ 14 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 1% w/v sucrose; and (iv) about 0.08% $\pm$ 0.04% w/v polysorbate 80. In some examples, the stable liquid pharmaceutical formulation comprises: (i) about 150 mg/ml $\pm$ 15 mg/ml of the antibody; (ii) about 10 mM $\pm$ 2 mM acetate; (iii) about 70 mM $\pm$ 14 mM arginine hydrochloride (iv) about 5% w/v $\pm$ 1% w/v sucrose; and (iv) about 0.08% $\pm$ 0.04% w/v polysorbate 80. In some cases, the pH of the formulation is from 5.2 to 5.4. In some examples, the pH of the formulation is about 5.3.

[0012] In some examples, the stable liquid pharmaceutical formulation comprises: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33) at a concentration of from 15 ± 1.5 mg/ml to 150 ± 15 mg/ml, wherein the antibody comprises a HCVR comprising HCDR1, HCDR2, and HCDR3 regions comprising the amino acid sequences of SEQ ID NOs: 4, 6, and 8, respectively, and LCDR1, LCDR2, and LCDR3 regions comprising the amino acid sequences of SEQ ID NOs: 12, 14, and 16, respectively; (ii) $10 \text{ mM} \pm 2 \text{ mM}$ acetate; (iii) $70 \text{ mM} \pm 14 \text{ mM}$ arginine hydrochloride; (iv) $5\% \text{ w/v} \pm 1\% \text{ w/v}$ sucrose; and (iv) about $0.08\% \pm 0.016\% \text{ w/v}$ polysorbate 80, wherein the formulation has a pH of from 5.1 to 5.5. In some examples, the stable liquid pharmaceutical formulation comprises: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33) at a concentration of from 15 ± 1.5 mg/ml to 150 ± 15 mg/ml, wherein the antibody comprises a HCVR comprising HCDR1, HCDR2, and HCDR3 regions comprising the amino acid sequences of SEQ ID NOs: 4, 6, and 8, respectively, and LCDR1, LCDR2, and LCDR3 regions comprising the amino acid sequences of SEQ ID NOs: 12, 14, and 16, respectively; (ii) $10 \text{ mM} \pm 1 \text{ mM}$ acetate; (iii) $70 \text{ mM} \pm 7 \text{ mM}$ arginine hydrochloride; (iv) $5\% \text{ w/v} \pm 0.5\% \text{ w/v}$ sucrose; and (iv) about $0.08\% \pm 0.008\% \text{ w/v}$ polysorbate 80, wherein the formulation has a pH of from 5.1 to 5.5. In some cases, the antibody comprises a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO: 2, and a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO: 10. In some examples, the antibody has a human IgG heavy chain constant region. In some examples, the heavy chain constant region is of isotype IgG1. In some examples, the heavy chain constant region is of isotype IgG4.

[0013] In some examples, the stable liquid pharmaceutical formulation comprises: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33) at a concentration of from 15 ± 1.5 mg/ml to 150 ± 15 mg/ml, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 18 and a light chain comprising the amino acid sequence of SEQ ID NO: 20; (ii) $10 \text{ mM} \pm 2 \text{ mM}$ acetate; (iii) $70 \text{ mM} \pm 14 \text{ mM}$ arginine hydrochloride; (iv) $5\% \text{ w/v} \pm 1\% \text{ w/v}$ sucrose; and (iv) about $0.08\% \pm 0.016\% \text{ w/v}$ polysorbate 80, wherein the formulation has a pH of from 5.1 to 5.5. In some examples, the stable liquid pharmaceutical formulation comprises: (i) a human antibody that specifically binds to human interleukin-33 (hIL-33) at a concentration of from 15 ± 1.5 mg/ml to 150 ± 15 mg/ml, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 18 and a light chain comprising the amino acid sequence of SEQ ID NO: 20; (ii) $10 \text{ mM} \pm 1 \text{ mM}$ acetate; (iii) $70 \text{ mM} \pm 7 \text{ mM}$ arginine hydrochloride; (iv) $5\% \text{ w/v} \pm 0.5\% \text{ w/v}$ sucrose; and (iv) about $0.08\% \pm 0.008\% \text{ w/v}$ polysorbate 80, wherein the formulation has a pH of from 5.1 to 5.5.

[0014] In some examples, the stable liquid pharmaceutical formulation contains at least 90% of the native form of the antibody after two months of storage at 5°C , as determined by size

exclusion-ultra performance liquid chromatography (SE-UPLC). In some cases, the formulation contains at least 95% of the native form of the antibody after two months of storage at 5°C, as determined by SE-UPLC. In some cases, the formulation contains at least 99% of the native form of the antibody after two months of storage at 5°C, as determined by SE-UPLC.

[0015] In some cases, the formulation contains at least 95% of the native form of the antibody after nine months of storage at -20°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation contains at least 97.5% of the native form of the antibody after nine months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation contains at least 99% of the native form of the antibody after nine months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation contains at least 95% of the native form of the antibody after 12 months of storage at -20°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation contains at least 97.5% of the native form of the antibody after 12 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation contains at least 99% of the native form of the antibody after 12 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation contains at least 95% of the native form of the antibody after 18 months of storage at -20°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation contains at least 97.5% of the native form of the antibody after 18 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation contains at least 99% of the native form of the antibody after 18 months of storage at -20°C, as determined by SE-UPLC.

[0016] In some cases, the formulation contains at least 95% of the native form of the antibody after nine months of storage at 2-8°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation contains at least 97.5% of the native form of the antibody after nine months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation contains at least 99% of the native form of the antibody after nine months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation contains at least 95% of the native form of the antibody after 12 months of storage at 2-8°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation contains at least 97.5% of the native form of the antibody after 12 months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation contains at least 99% of the native form of the antibody after 12 months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation contains at least 95% of the native form of the antibody after 18 months of storage at 2-8°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation contains at least 97.5% of the native form of the antibody after 18 months of storage at 2-8°C, as determined by SE-UPLC.

In some cases, the formulation contains at least 99% of the native form of the antibody after 18 months of storage at 2-8°C, as determined by SE-UPLC.

[0017] In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% high molecular weight (HMW) species after two months of storage at 5°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after two months of storage at 5°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 0.6% HMW species after two months of storage at 5°C, as determined by SE-UPLC.

[0018] In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% HMW species after nine months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after nine months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 0.5% HMW species after nine months of storage at -20°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% HMW species after 12 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after 12 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 0.5% HMW species after 12 months of storage at -20°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% HMW species after 18 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after 18 months of storage at -20°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 0.5% HMW species after 18 months of storage at -20°C, as determined by SE-UPLC.

[0019] In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% HMW species after nine months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after nine months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 0.7% HMW species after nine months of storage at 2-8°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% HMW species after 12 months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after 12 months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 0.7% HMW species after 12 months of storage at 2-8°C, as determined by SE-UPLC. In some examples, the stable liquid pharmaceutical formulation comprises no more than 2% HMW species after 18 months of storage at 2-8°C, as determined by SE-UPLC. In some cases, the formulation comprises no more than 1% HMW species after 18 months of storage at 2-8°C, as determined by SE-UPLC.

In some cases, the formulation comprises no more than 0.7% HMW species after 18 months of storage at 2-8°C, as determined by SE-UPLC.

[0020] In some examples, the pharmaceutical formulation exhibits a viscosity of less than about 15 cPoise, less than about 12 cPoise, or less than about 10 cPoise, when measured at 20°C.

[0021] In some examples, the stable liquid pharmaceutical formulation is contained in a glass vial, a syringe, or a large volume device or bolus injector. In some examples, the syringe comprises a fluorocarbon-coated plunger. In some examples, the syringe is a low tungsten syringe. In some examples, the syringe contains up to 2500 ppb tungsten. In some examples, the syringe contains about 250-750 ppb tungsten. In some examples, the syringe is a prefilled syringe. In some examples, the syringe is a prefilled staked needle syringe.

[0022] In another aspect, a pen or autoinjector delivery device containing a stable liquid pharmaceutical formulation, in any of the examples discussed above or herein, is provided. In some cases, the delivery device is a disposable pen delivery device. In some cases, the delivery device is a reusable pen delivery device.

[0023] In another aspect, a container containing a stable liquid pharmaceutical formulation, in any of the examples discussed above or herein, is provided.

[0024] In another aspect, a safety system delivery device containing a stable liquid pharmaceutical formulation, in any of the examples discussed above or herein, is provided. In some examples, the safety system delivery device includes a safety sleeve configured to extend by manual operation. In some examples, the safety system delivery device includes a safety sleeve configured to automatically extend following injection of the stable liquid pharmaceutical formulation.

[0025] In another aspect, a kit comprising (i) a container containing the stable liquid pharmaceutical formulation as discussed above or herein, and (ii) labeling for use of the pharmaceutical formulation is provided. In some examples, the labeling recites subcutaneous administration of the pharmaceutical formulation. In some examples, the labeling recites intravenous administration of the pharmaceutical formulation.

[0026] In another aspect, the present disclosure provides a unit dosage form comprising a stable liquid pharmaceutical formulation as discussed above or herein, wherein the anti-IL-33 antibody is present in an amount of from 1 mg to 500 mg. In some cases, the anti-IL-33 antibody is present in an amount of about 150 mg. In some cases, the anti-IL-33 antibody is present in an amount of about 300 mg. In some examples of the unit dosage form, the formulation is contained in a syringe. In some cases, the syringe is a prefilled syringe.

[0027] In various examples, any of the features or components of examples discussed above or herein may be combined, and such combinations are encompassed within the scope of the present disclosure. Any specific value discussed above or herein may be combined with another related value discussed above or herein to recite a range with the values representing the upper and lower ends of the range, and such ranges are encompassed within the scope of the present disclosure. Each of the values discussed above or herein may be expressed with a variation of 1%, 5%, 10% or 20%. For example, a concentration of 10 mM may be expressed as 10 mM $\pm$ 0.1 mM (1% variation), 10 mM $\pm$ 0.5 mM (5% variation), 10 mM $\pm$ 1 mM (10% variation) or 10 mM $\pm$ 2 mM (20% variation).

[0028] Other examples will become apparent from a review of the detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Figure 1 shows the pH-dependent viscosity of 150 mg/mL of an anti-IL-33 antibody (mAb1).

[0030] Figure 2 shows the viscosity of 150 mg/mL of an anti-IL-33 antibody (mAb1) with different concentrations of viscosity modifiers.

[0031] Figure 3 shows the effect of various viscosity modifiers on the stability of an anti-IL-33 antibody (mAb1) incubated at 37°C for 34 days. For clarity, the points at the far right side of Fig. 3 are ordered, from top to bottom: F13, F4, F12, F3, F2, F7, F1, F5, F8, F6 and F9.

[0032] Figure 4A illustrates the impact of the formulation parameters on the viscosity of an anti-IL-33 antibody (mAb1).

[0033] Figure 4B illustrates the impact of the formulation parameters on the formation of high-molecular weight (HMW) variants of an anti-IL-33 antibody (mAb1).

DETAILED DESCRIPTION

[0034] Before the present invention is described, it is to be understood that this invention is not limited to particular methods and experimental conditions described, as such methods and conditions may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[0035] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. As used herein, the term "about," when used in reference to a particular recited numerical value or range of values, means that the value may vary from the recited value by no more than 1%. For

What is claimed is:

1. A stable liquid pharmaceutical formulation comprising:
 - (i) a human antibody that specifically binds to human interleukin-33 (hIL-33), wherein the antibody comprises a heavy chain variable region (HCVR) comprising the amino acid sequence of SEQ ID NO: 2 and a light chain variable region (LCVR) comprising the amino acid sequence of SEQ ID NO: 10, wherein the antibody is present at a concentration of from 1 mg/ml to 200 mg/ml;
 - (ii) 5 mM to 15 mM acetate;
 - (iii) 60 mM to 80 mM arginine hydrochloride;
 - (iv) sucrose at a concentration of from 3% w/v to 7% w/v; and
 - (v) 0.06% w/v to 0.1% w/v polysorbate 20 or polysorbate 80;wherein the formulation has a pH of from 5 to 5.6.
2. The stable liquid pharmaceutical formulation of claim 1, wherein:
the antibody is present at a concentration of from 15 mg/ml to 150 mg/ml; or
the antibody is present at a concentration of 15 mg/ml $\pm$ 1.5 mg/ml; or
the antibody is present at a concentration of 75 mg/ml $\pm$ 5 mg/ml; or
the antibody is present at a concentration of 150 mg/ml $\pm$ 15 mg/ml.
3. The stable liquid pharmaceutical formulation of claim 1 or 2, wherein the antibody has a human IgG heavy chain constant region.
4. The stable liquid pharmaceutical formulation of claim 3, wherein the heavy chain constant region is of isotype IgG1.
5. The stable liquid pharmaceutical formulation of claim 3, wherein the heavy chain constant region is of isotype IgG4.
6. The stable liquid pharmaceutical formulation of claim 1 or 2, wherein the antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 18 and a light chain comprising the amino acid sequence of SEQ ID NO: 20.

7. The stable liquid pharmaceutical formulation of any one of claims 1-6 comprising: (i) 15 mg/ml to 150 mg/mL of the human antibody that specifically binds to hIL-33; (ii) 5 mM to 15 mM acetate; (iii) 60 mM to 80 mM arginine hydrochloride; (iv) 3% w/v to 7% w/v sucrose; and (v) 0.06% w/v to 0.1% w/v polysorbate 80.

8. The stable liquid pharmaceutical formulation of any one of claims 1-7, comprising: (i) 15 mg/ml $\pm$ 1.5 mg/ml of the antibody; (ii) 10 mM $\pm$ 2 mM acetate; (iii) 70 mM $\pm$ 14 mM arginine hydrochloride; (iv) 5% w/v $\pm$ 1% w/v sucrose; and (v) 0.08% $\pm$ 0.016% w/v polysorbate 80.

9. The stable liquid pharmaceutical formulation of any one of claims 1-7, comprising: (i) 75 mg/ml $\pm$ 5 mg/ml of the antibody; (ii) 10 mM $\pm$ 2 mM acetate; (iii) 70 mM $\pm$ 14 mM arginine hydrochloride; (iv) 5% w/v $\pm$ 1% w/v sucrose; and (v) 0.08% $\pm$ 0.016% w/v polysorbate 80.

10. The stable liquid pharmaceutical formulation of any one of claims 1-7, comprising: (i) 150 mg/ml $\pm$ 15 mg/ml of the antibody; (ii) 10 mM $\pm$ 2 mM acetate; (iii) 70 mM $\pm$ 14 mM arginine hydrochloride; (iv) 5% w/v $\pm$ 1% w/v sucrose; and (v) 0.08% $\pm$ 0.016% w/v polysorbate 80.

11. The stable liquid pharmaceutical formulation of any one of claims 1-10, wherein:

the pH of the formulation is from 5.2 to 5.4; or
the pH of the formulation is 5.3.

12. A stable liquid pharmaceutical formulation comprising:

(i) a human antibody that specifically binds to human interleukin-33 (hIL-33) at a concentration of from 15 $\pm$ 1.5 mg/ml to 150 $\pm$ 15 mg/ml, wherein the antibody comprises a HCVR comprising the amino acid sequence of SEQ ID NO: 2 and a LCVR comprising the amino acid sequence of SEQ ID NO: 10;

(ii) 10 mM $\pm$ 2 mM acetate;

(iii) 70 mM $\pm$ 14 mM arginine hydrochloride;

(iv) 5% w/v $\pm$ 1% w/v sucrose; and

(v) 0.08% $\pm$ 0.016% w/v polysorbate 80,

wherein the formulation has a pH of from 5.1 to 5.5.

13. The stable liquid pharmaceutical formulation of claim 12, wherein the antibody has a human IgG heavy chain constant region.

14. The stable liquid pharmaceutical formulation of claim 13, wherein the heavy chain constant region is of isotype IgG1.

15. The stable liquid pharmaceutical formulation of claim 13, wherein the heavy chain constant region is of isotype IgG4.

16. The stable liquid pharmaceutical formulation of any one of claims 1-15, wherein:

at least 90% of the native form of the antibody is recovered after two months of storage at 5°C, as determined by size exclusion-ultra performance liquid chromatography (SE-UPLC); or

at least 95% of the native form of the antibody is recovered after nine months of storage at -20°C, as determined by SE-UPLC; or

at least 95% of the native form of the antibody is recovered after nine months of storage at 2-8°C, as determined by SE-UPLC; or

the formulation comprises no more than 2% high molecular weight (HMW) species after two months of storage at 5°C, as determined by SE-UPLC; or

the formulation comprises no more than 2% HMW species after nine months of storage at -20°C, as determined by SE-UPLC; or

the formulation comprises no more than 2% HMW species after nine months of storage at 2-8°C, as determined by SE-UPLC.

17. The stable liquid pharmaceutical formulation of any one of claims 1-16, wherein the formulation exhibits a viscosity of less than 15 cPoise, when measured at 20°C.

18. The stable liquid pharmaceutical formulation of any one of claims 1-17 contained in a glass vial, a syringe, a pen delivery device, an autoinjector delivery device, a large volume device, or a bolus injector.

19. The stable liquid pharmaceutical formulation of claim 18 contained in a syringe.

20. The stable liquid pharmaceutical formulation of claim 19, wherein the syringe (i) comprises a fluorocarbon-coated plunger, (ii) is a low tungsten syringe, (iii) is a prefilled syringe, or (iv) is a prefilled staked needle syringe.

21. The stable liquid pharmaceutical formulation of claim 18 contained in a pen delivery device.

22. The stable liquid pharmaceutical formulation of claim 21, wherein the pen delivery device (i) is a disposable pen delivery device, or (ii) is a reusable pen delivery device.

23. The stable liquid pharmaceutical formulation of claim 18 contained in an autoinjector delivery device.

24. A pen or autoinjector delivery device containing a stable liquid pharmaceutical formulation of any one of claims 1-17.

25. The delivery device of claim 24 that is a disposable pen delivery device.

26. The delivery device of claim 24 that is a reusable pen delivery device.

27. A container containing a stable liquid pharmaceutical formulation of any one of claims 1-17.

28. A kit comprising (i) a container containing the stable liquid pharmaceutical formulation of any one of claims 1-17, and (ii) labeling for use of the pharmaceutical formulation.

29. The kit of claim 28, wherein:
the labeling recites subcutaneous administration of the pharmaceutical formulation;
or
the labeling recites intravenous administration of the pharmaceutical formulation.

30. A unit dosage form comprising a stable liquid pharmaceutical formulation of any one of claims 1-17, wherein the anti-IL-33 antibody is present in an amount of from 1 mg to 500 mg.

31. The unit dosage form of claim 30, wherein:
the anti-IL-33 antibody is present in an amount of 150 mg; or
the anti-IL-33 antibody is present in an amount of 300 mg.

32. The unit dosage form of claim 30 or 31, wherein the formulation is contained in a syringe.

33. The unit dosage form of claim 32, wherein the syringe is a prefilled syringe.

34. A safety system delivery device containing a stable liquid pharmaceutical formulation of any one of claims 1-17.

35. The safety system delivery device of claim 34, including a safety sleeve configured to extend by manual operation.

36. The safety system delivery device of claim 35, including a safety sleeve configured to automatically extend following injection of the stable liquid pharmaceutical formulation.