CLAIMS

1. A pharmaceutical formulation comprising an antibody to IL-1β which comprises the sequence according to Sequence ID No.1 and 2, and a buffer system which formulation has a pH from 5.5 to 7.5.

2. The formulation of claim 1, wherein the pH is from 5.5 to 7.

3. The formulation of claim 1, wherein the pH is from 6.2 to 6.8.

4. The formulation of claim 1, wherein the buffer system is selected from a group consisting of citrate, histidine, sodium succinate, and sodium and/or potassium phosphate buffer system.

5. The formulation of claim 4, wherein the buffer system is histidine buffer system.

6. The formulation of claim 5, wherein said histidine is in an amount from 15 to 50 mM.

7. The formulation of claim 1 further comprises a stabilizer.

8. The formulation of claim 7, wherein the stabilizer is selected from a group consisting of sucrose, trehalose, mannitol, sorbitol and arginine hydrochloride.

9. The formulation of claim 8, wherein the stabilizer is sucrose or mannitol in an amount from 50-300 mM.

10. The formulation according to any of the preceding claims, further comprising one or more from the excipients selected from the group comprising bulking agent, salt, surfactant and preservative.

11. The formulation according to any of the preceding claims which is reconstituted from a lyophilizate.

12. A lyophilizate prepared from a formulation according to any of the preceding claims.

13. A method for preparing a formulation comprising:

(i) lyophilizing the formulation of any of claims 1 to 10;

(ii) reconstituting said lyophilizate with a reconstitution medium.

14. A formulation comprising 10 to 150 mg/ml ACZ885, 270mM sucrose, 30mM histidine and 0.06% polysorbate 80, wherein the pH of the formulation is 6.5.

15. A formulation comprising 10 to 150 mg/ml ACZ885, 270mM mannitol, 20mM histidine and 0.04% polysorbate 80, wherein the pH of the formulation is 6.5.

16. Use of the formulation according to any of the preceding claims for the treatment of IL-1 mediated diseases or medical conditions.

AMENDED CLAIMS
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1. A pharmaceutical formulation comprising an antibody to IL-1β which comprises the sequence according to Sequence ID No.1 and 2, and a buffer system which formulation has a pH from 5.5 to 7.5 and wherein the buffer system is selected from a group consisting of citrate, histidine, sodium succinate, and sodium and/or potassium phosphate buffer system.

2. The formulation of claim 1, wherein the pH is from 5.5 to 7.

3. The formulation of claim 1, wherein the pH is from 6.2 to 6.8.

4. The formulation of claim 3, wherein the buffer system is histidine buffer system.

5. The formulation of claim 4, wherein said histidine is in an amount from 15 to 50 mM.

6. The formulation of claim 1 further comprises a stabilizer.

7. The formulation of claim 6, wherein the stabilizer is selected from a group consisting of sucrose, trehalose, mannitol, sorbitol and arginine hydrochloride.

8. The formulation of claim 7, wherein the stabilizer is sucrose or mannitol in an amount from 50-300 mM.

9. The formulation according to any of the preceding claims, further comprising one or more from the excipients selected from the group comprising bulking agent, salt, surfactant and preservative.

10. The formulation according to any of the preceding claims which is reconstituted from a lyophilizate.

11. A lyophilizate prepared from a formulation according to any of the preceding claims.

12. A method for preparing a formulation comprising:

(i) lyophilizing the formulation of any of claims 1 to 9;

(ii) reconstituting said lyophilizate with a reconstitution medium.

13. A formulation comprising 10 to 150 mg/ml ACZ885, 270mM sucrose, 30mM histidine and 0.06% polysorbate 80, wherein the pH of the formulation is 6.5.

14. A formulation comprising 10 to 150 mg/ml ACZ885, 270mM mannitol, 20mM histidine and 0.04% polysorbate 80, wherein the pH of the formulation is 6.5.

What is claimed is:

1. A pharmaceutical formulation, comprising 50 to 150 mg/ml of an antibody to IL-1β which comprises amino acids 20 to 137 of SEQ ID NO:1 and amino acids 20 to 126 of SEQ ID NO:2, about 270 mM mannitol, a histidine buffer and about 0.04 to 0.06% polysorbate 80, wherein the pH of the formulation is 5.5 to 7.0, wherein the pharmaceutical formulation is in liquid form, and further wherein the formulation maintains at least about 70% activity following storage for 24 months at 25° C. as determined by a reporter gene assay.

2. The pharmaceutical formulation of claim 1, wherein the pH of the formulation is 6.2 to 6.8.

3. The pharmaceutical formulation of claim 2, wherein the pH of the formulation is 6.5.

4. The pharmaceutical formulation of claim 1, wherein the antibody is ACZ885 and the buffer is 20-30 mM histidine.

5. The pharmaceutical formulation of claim 2, wherein the antibody is ACZ885 and the buffer is 20-30 mM histidine.

6. The pharmaceutical formulation of claim 3, wherein the antibody is ACZ885 and the buffer is 20-30 mM histidine.

7. The pharmaceutical formulation of claim 4, wherein the concentration of the antibody is 150 mg/ml, the concentration of histidine is 20 mM, and the concentration of polysorbate 80 is 0.04% (m/v).

8. The pharmaceutical formulation of claim 5, wherein the concentration of the antibody is 150 mg/ml, the concentration of histidine is 20 mM, and the concentration of polysorbate 80 is 0.04% (m/v).

9. The pharmaceutical formulation of claim 6, wherein the concentration of the antibody is 150 mg/ml, the concentration of histidine is 20 mM, and the concentration of polysorbate 80 is 0.04% (m/v).