

CLAIMS

1. A pharmaceutical product comprising:
 - a. a container having a headspace, wherein the oxygen content in the headspace is less than about 12%, and
 - b. a stable ready-to-use liquid pharmaceutical composition having a pH of 5.2 to 6.2 disposed within said container, said composition comprising:
 - i. 50 mg/ml to 175 mg/ml secukinumab; and
 - ii. 2.5 to 20 mM L-methionine.
2. The pharmaceutical product according to claim 1, wherein the concentration of methionine is about 2.5 mM, about 5 mM, about 10 mM or about 20 mM.
3. The pharmaceutical product according to any of the above claims, wherein the oxygen content in the headspace is less than about 10%, less than about 8%, or less than about 6%.
4. The pharmaceutical product according to any of the above claims, wherein the liquid pharmaceutical composition has a pH of about 5.8.
5. The pharmaceutical product according to any of the above claims, wherein the concentration of secukinumab is about 150 mg/ml.
6. A pharmaceutical product comprising
 - a. a container having a headspace, wherein the oxygen content in the headspace is less than about 6%; and
 - b. a stable ready-to-use liquid pharmaceutical composition disposed within said container, said composition comprising 50 mg/mL to 175 mg/mL secukinumab, 10 mM to 30 mM histidine pH 5.2-6.2, 200 mM to 225 mM trehalose, 0.01 % to 0.04 % polysorbate, and 2.5 mM to 20 mM methionine.
7. The pharmaceutical product according to claim 6, comprising about 150 mg/ml secukinumab and about 200 mM trehalose.

8. The pharmaceutical product according to any of the above claims, wherein the liquid composition maintains:
- a. at least about 86% purity by RP-HPLC upon storage at 2-8°C for 6 months, at least about 76% purity by RP-HPLC upon storage at 25°C/60% relative humidity (RH) for 6 months, and/or at least about 60% purity by RP-HPLC upon storage at 30°C/75% RH for 6 months;
 - b. at least about 77% purity by CEX upon storage at 2-8°C for 6 months, at least about 62% purity by CEX upon storage at 25°C/60% RH for 6 months, and/or at least about 50% purity by CEX upon storage at 30°C/75% RH for 6 months;
 - c. the liquid composition maintains at least about 98% purity by SEC upon storage at 2-8°C for 6 months, at least about 96% purity by SEC upon storage at 25°C/60% RH for 6 months, and/or at least about 94% purity by SEC upon storage at 30°C/75% RH for 6 months;
 - d. at least about 97% purity by CE-SDS (non-reducing conditions) upon storage at 2-8°C for 6 months, at least about 95% purity by CE-SDS (non-reducing conditions) upon storage at 25°C/60% RH for 6 months, and/or at least about 94% (preferably at least about 92%) purity by CE-SDS (non-reducing conditions) upon storage at 30°C/75% RH for 6 months;
 - e. less than about 0.57% impurity by SDS-PAGE (reducing conditions) upon storage at 2-8°C for 6 months, less than about 1.1% impurity by SDS-PAGE (reducing conditions) upon storage at 25°C/60% RH for 6 months, and/or less than about 1.9% impurity by SDS-PAGE (reducing conditions) upon storage at 30°C/75% RH for 6 months; and/or
 - f. at least about 88% relative biological activity by inhibition of IL-6 release from C-20/A4 chondrocytes upon storage at 2-8°C for 18 months, at least about 94% relative biological activity by inhibition of IL-6 release from C-20/A4 chondrocytes upon storage at 25°C/60% RH for 6 months, and/or at least about 85% relative biological activity by inhibition of IL-6 release from C-20/A4 chondrocytes upon storage at 30°C/75% RH for 6 months.
9. The pharmaceutical product according to according to any of the above claims, wherein the liquid composition maintains:
- a. at least about 84% purity by RP-HPLC upon storage at 2-8°C for 24 months;
 - b. at least about 73% purity by CEX upon storage at 2-8°C for 24 months;
 - c. at least about 97% purity by SEC upon storage at 2-8°C for 24 months;

- d. at least about 97% purity by CE-SDS (non-reducing conditions) upon storage at 2-8°C for 24 months; and/or
 - e. less than about 0.91% impurity by SDS-PAGE (reducing conditions) upon storage at 2-8°C for 24 months.
10. A process for reducing the oxidation of secukinumab, comprising:
 - a. preparing a stable ready-to-use liquid composition having a pH of 5.2 to 6.2 and comprising:
 - i. 50 mg/ml to 175 mg/ml secukinumab; and
 - ii. 2.5mM to 20 mM methionine;
 - b. disposing said liquid composition in a container having a headspace; and
 - c. adjusting the oxygen content in the headspace to less than or equal to about 12%.
 11. The process according to claim 10, wherein adjusting step c) is performed by purging the headspace using an inert gas selected from helium, nitrogen and argon.
 12. The process according to claim 10, wherein the concentration of methionine is about 2.5 mM, about 5 mM, about 10 mM or about 20 mM.
 13. The process according to claim 12, wherein the oxygen content in the headspace is adjusted to less than about 10%, less than about 8% or less than about 6%.
 14. The process according to claim 13, wherein the liquid composition has a pH of about 5.8.
 15. The process according to claim 14, wherein the concentration of secukinumab is about 150 mg/ml.
 16. A stable ready-to-use liquid pharmaceutical composition comprising, 50 mg/mL to 175 mg/mL secukinumab, 10 mM to 30 mM histidine pH 5.2-6.2, 200 mM to 225 mM trehalose, 0.01 % to 0.04 % polysorbate, and 2.5 mM to 20 mM methionine.
 17. The ready-to-use liquid pharmaceutical composition according to claim 16, wherein after 13 months storage at 25°C, aggregate formation as measured by AP-SEC is ≤ 3.5 %.
 18. The ready-to-use liquid pharmaceutical composition according to claim 16, wherein after 13 months storage at 25°C, degradation products by RP-HPLC are ≤ 39.4 %.

19. The ready-to-use liquid pharmaceutical composition according to claim 18, wherein the liquid composition maintains:
 - a. at least about 87.3% purity by RP-HPLC upon storage at 2-8°C for 24 months;
 - b. at least about 76.5% purity by CEX upon storage at 2-8°C for 24 months;
 - c. at least about 97.9% purity by SEC upon storage at 2-8°C for 24 months;
 - d. at least about 97.2% purity by CE-SDS (non-reducing conditions) upon storage at 2-8°C for 24 months; and/or
 - e. less than about 0.61% impurity by SDS-PAGE (reducing conditions) upon storage at 2-8°C for 24 months.
20. The ready-to-use liquid pharmaceutical composition according to claim 19, wherein after 13 months storage at 25°C, aggregate formation as measured by AP-SEC is ≤ 3.5 %.
21. The ready-to-use liquid pharmaceutical composition according to claim 19, wherein after 13 months storage at 25°C, degradation products by RP-HPLC are ≤ 39.4 %.
22. A stable ready-to-use liquid pharmaceutical composition comprising, about 150 mg/ml secukinumab, about 20 mM histidine pH 5.8, about 200 mM trehalose, about 0.02% polysorbate 80, and about 5 mM L-methionine.
23. The pharmaceutical product according to any one of claims 1-9, wherein the container is selected from the group consisting of a pen, a pre-filled syringe, an autoinjector and a vial.