CLAIMS

1. A lyophilized formulation comprising: Compound 1 (2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide), or a stereisomer or mixture of stereisomers, pharmaceutically acceptable salt, tautomer, prodrug, solvate, hydrate, co-crystal, clathrate, or polymorph thereof, a buffer and a bulking agent.

2. The lyophilized formulation of claim 1, wherein Compound 1 comprises a solid form of 2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide.

3. The lyophilized formulation of claim 1, wherein Compound 1 comprises an amorphous form of 2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide.

4. The lyophilized formulation of claim 1, wherein Compound 1 is present in an amount from about 0.1 to about 2% based on the total weight of the lyophilized formulation.

5. The lyophilized formulation of claim 1, wherein Compound 1 is present from about 0.1 to about 1% based on the total weight of the lyophilized formulation.

6. The lyophilized formulation of claim 1, wherein Compound 1 is present in about 0.36% based on the total weight of the lyophilized formulation.

7. The lyophilized formulation of claim 1, wherein the buffer is a citrate buffer.

8. The lyophilized formulation of claim 7, wherein citrate buffer is present in an amount from about 5% to about 25% based on total weight of the lyophilized formulation.

9. The lyophilized formulation of claim 7, wherein citrate buffer comprises anhydrous citric acid and anhydrous sodium citrate.

10. The lyophilized formulation of claim 9, wherein anhydrous citric acid is present in an amount from about 2% to about 10% based on total weight of the lyophilized formulation.

11. The lyophilized formulation of claim 9, wherein anhydrous citric acid is present in an amount from about 5% to about 8% based on total weight of the lyophilized formulation.

12. The lyophilized formulation of claim 9, wherein anhydrous citric acid is present in an amount from about 6% to about 8% based on total weight of the lyophilized formulation.

13. The lyophilized formulation of claim 9, wherein anhydrous citric acid is present in an amount of about 6.41% based on total weight of the lyophilized formulation.

14. The lyophilized formulation of claim 9, wherein anhydrous sodium citrate is present in an amount from about 2% to about 15% based on total weight of the lyophilized formulation.

15. The lyophilized formulation of claim 9, wherein anhydrous sodium citrate is present in an amount from about 4% to about 10% based on total weight of the lyophilized formulation.

16. The lyophilized formulation of claim 14, wherein anhydrous sodium citrate is present in an amount of about 6.37% based on total weight of the lyophilized formulation.

17. The lyophilized formulation of claim 1, wherein the bulking agent is selected from mannitol, sulfobutylether-β-cyclodextrin, β-cyclodextrin, hydroxypropyl β-cyclodextrin and methylated β-cyclodextrin.

18. The lyophilized formulation of claim 1, wherein the bulking agent is hydroxypropyl β-cyclodextrin.

19. The lyophilized formulation of claim 1, wherein the bulking agent is present in an amount from about 70% to about 95% based on total weight of the lyophilized formulation.

20. The lyophilized formulation of claim 1, wherein the bulking agent is present in an amount from about 80% to about 90% based on total weight of the lyophilized formulation.

21. The lyophilized formulation of claim 18, wherein hydroxypropyl β-cyclodextrin is present in an amount from about 80% to about 90% based on total weight of the lyophilized formulation.

22. The lyophilized formulation of claim 18, wherein hydroxypropyl β-cyclodextrin is present in an amount of about 86.86% based on total weight of the lyophilized formulation.

23. The lyophilized formulation of claim 1, wherein Compound 1 is present from about 0.1 to about 1%, and the lyophilized formulation comprises anhydrous citric acid in an amount from about 6% to about 8%, anhydrous sodium citrate in an amount from about 4% to about 10% and the bulking agent in an amount from about 70% to about 95% based on total weight of the lyophilized formulation.

24. The lyophilized formulation of claim 1, wherein Compound 1 in about 0.36%, and the lyophilized formulation comprises anhydrous citric acid in about 6.41%, anhydrous sodium citrate in about 6.37% and hydroxypropyl β-cyclodextrin in about 86.86% based on total weight of the lyophilized formulation.

25. A reconstituted formulation obtainable from the lyophilized formulation of claim 1 comprising a diluent.

26. The reconstituted formulation of claim 25, wherein the diluent is water.

27. The reconstituted formulation of claim 25, wherein Compound 1 is present in an amount of about 0.1 to 1 mg/mL.

28. The reconstituted aqueous formulation of claim 26, wherein Compound 1 is present in an amount of about 0.5 mg/mL.

29. The reconstituted aqueous formulation of claim 26, wherein the formulation has a pH in a range from about 4 to about 5.

30. The reconstituted aqueous formulation of claim 26, wherein the formulation has a pH of about 4.3.

31. A process for preparing a lyophilized formulation, comprising: dissolving a bulking agent and 2-(4-chlorophenyl)-N-((2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolin-5-yl)methyl)-2,2-difluoroacetamide, or a stereisomer or mixture of stereisomers, pharmaceutically acceptable salt, tautomer, prodrug, solvate, hydrate, co-crystal, clathrate, or polymorph thereof in a buffer solution to produce a solution; and lyophilizing the resulting solution to produce a powder.