WHAT IS CLAIMED IS:

1. A process for preparing a quinolone compound comprising the step of reacting a des-chloro quinolone compound or a pharmaceutically acceptable salt or ester thereof with a chlorinating agent and an acid, wherein the molar ratio of the acid to des-chloro quinolone is from 0.007 to 0.02, wherein less than 0.40% of dimeric impurity on an area percent basis of the quinolone is produced, wherein the quinolone compound is 1-(6-amino-3,5-difluoropyridin-2-yl)-8-chloro-6-fluoro-7-(3-hydroxyazetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid or a pharmaceutically acceptable salt or ester thereof, the des-chloro quinolone compound is 1-(6-amino-3,5-difluoropyridin-2-yl)-6-fluoro-7-(3-hydroxy-azetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid or a pharmaceutically acceptable salt or ester thereof, and wherein the dimeric impurity is 1-amino-3-(azetidin-3-yloxy)-propan-2-ol-bis(*N*,*N*'-quinolone carboxylic acid), or a pharmaceutically acceptable salt or ester thereof.

2. A process according to claim 1 wherein the chlorinating agent is *N*-chlorosuccinimide.

3. A process according to any of claims 1 or 2 wherein the acid is selected from the group consisting of sulfuric acid, hydrochloric acid, hydrobromic acid, phosphoric acid, trifluoroacetic acid, triflic acid, methanesulfonic acid, *p*-toluenesulfonic acid, or perchloric acid, and mixtures thereof.

4. A process according to any of claims 1 to 3 wherein the acid is sulfuric acid.

5. A process according to any of claims 1 to 4 where the reaction is run at a temperature from 0 °C to 30 °C.

6. A process according to any of claims 1 to 5 wherein the reaction is run at a temperature from 15 °C to 25 °C.

7. A process according to any of claims 1 to 5 where the reaction is run at a temperature from 13 °C to 21 °C.

8. A process according to any of claims 1 to 7 wherein the chlorinating agent is *N*-chlorosuccinimide and the molar ratio of *N*-chlorosuccinimide to des-chloro quinolone is greater than 1.

9. A process according to any of claims 1 to 8 wherein the chlorinating agent is *N*-chlorosuccinimide and the molar ratio of *N*-chlorosuccinimide to des-chloro quinolone is from 1.05 to 1.2.

10. A process according to any of claims 1 to 8 wherein the chlorinating agent is *N*-chlorosuccinimide and the molar ratio of *N*-chlorosuccinimide to des-chloro quinolone is from 1.04 1.07.

11. A process according to any of claims 1 to 10 wherein the acid is sulfuric acid and the molar ratio of sulfuric acid to des-chloro quinolone is from 0.008 to 0.012.

12. A process according to any of claims 1 to 11 using an acetate ester as a solvent.

13. A process according to claim 12 wherein said acetate ester is selected from the group consisting of methyl acetate, ethyl acetate, and mixtures thereof.

14. A process according to claim 13 wherein said acetate ester is methyl acetate.

15. A process according to any of claims 1 to 14 comprising the further step of reacting the quinolone compound with a base.

16. A process according to claim 15 wherein the base is a hydroxide base.

17. A process according to claim 16 wherein the hydroxide base is selected from the group consisting of sodium hydroxide, potassium hydroxide, lithium hydroxide, barium hydroxide, and mixtures thereof.

18. A process according to claim 17 wherein the hydroxide base is potassium hydroxide.

19. A process according to any of claims 15 to 18 using a mixture of a C1-C6 alcohol and water as a solvent.

20. A process according to claim 19 wherein said C1-C6 alcohol is isopropanol.

21. A process according to any of claims 1-20 wherein said process is a commercial scale process.

22. A composition comprising the quinolone compound 1-(6-Amino-3,5-difluoropyridin-2-yl)-8-chloro-6-fluoro-7-(3-hydroxyazetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid or a salt or ester thereof having less than 0.40% of a dimeric impurity, wherein the dimeric impurity is 1-amino-3-(azetidin-3-yloxy)-propan-2-ol-bis(*N*,*N*'-quinolone carboxylic acid), or a pharmaceutically acceptable salt or ester thereof, made by the process of claim 1.

23. A composition according to claim 22 wherein said composition is a commercial scale composition.

24. A process or composition according to any of claims 1 to 23 wherein said dimeric impurity is less than 0.35%.

25. A process or composition according to any of claims 1 to 24 wherein said dimeric impurity is less than 0.30%.

26. A process or composition according to any of claims 1 to 25 wherein said dimeric impurity is less than 0.25%.

27. A process or composition according to any of claims 1 to 26 wherein said dimeric impurity is less than 0.20%.

28. A process or composition according to any of claims 1 to 27 wherein said dimeric impurity is less than 0.15%.

29. A process or composition according to any of claims 1 to 28 wherein said dimeric impurity is less than 0.10%.

30. A process or composition according to any of claims 1 to 29 wherein said dimeric impurity is less than 0.05%.

31. A process or composition according to any of claims 1 to 30 wherein said dimeric impurity is less than 0.04%.

32. A process or composition according to any of claims 1 to 31 wherein said dimeric impurity is less than 0.03%.

33. A process or composition according to any of claims 1 to 32 wherein said dimeric impurity is less than 0.02%.

34. A process or composition according to any of claims 1 to 33 wherein said dimeric impurity is less than 0.01%.

CLAIMS:

1. A process for preparing a quinolone compound comprising the step of reacting a des-chloro quinolone compound or a pharmaceutically acceptable salt or ester thereof with a chlorinating agent and an acid, wherein the molar ratio of the acid to des-chloro quinolone is from about 0.008 to about 0.012, wherein the quinolone compound is 1-(6-amino-3,5-difluoropyridin-2-yl)-8-chloro-6-fluoro-7-(3-hydroxyazetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid or a pharmaceutically acceptable salt or ester thereof, and the des-chloro quinolone compound is 1-(6-amino-3,5-difluoropyridin-2-yl)-6-fluoro-7-(3-hydroxy-azetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid or a pharmaceutically acceptable salt or ester thereof, wherein the ester is selected from the group consisting of lower alkyl groups such as methyl, ethyl, n-propyl, iso-propyl, n-butyl, iso-butyl, t-butyl, pentyl, hexyl, and heptyl; lower alkenyl groups such as vinyl, allyl, 1-propenyl, butenyl, pentenyl, hexenyl, and heptenyl; aralkyl groups such as benzyl; aryl groups such as phenyl and naphthyl; lower alkanoyloxy lower alkyl groups such as acetoxymethyl and pivaloyloxymethyl; lower alkoxycarbonyloxy lower alkyl groups such as methoxycarbonyloxymethyl and 1-ethoxycarbonyloxyethyl; lower alkoxymethyl groups such as methoxymethyl; lactonyl groups such as phthalidyl; di-lower alkylamino lower alkyl groups such as 1-dimethylaminoethyl; and (5-methyl-2-15 oxo-l,3-dioxole-4-yl)methyl.

2. A process according to claim 1 wherein the chlorinating agent is *N*-chlorosuccinimide.

3 A process according to any of claims 1 or 2 wherein the acid is selected from the group consisting of sulfuric acid, hydrochloric acid, hydrobromic acid, phosphoric acid, trifluoroacetic acid, triflic acid, methanesulfonic acid, *p*-toluenesulfonic acid, or perchloric acid, and mixtures thereof.

4. A process according to any of claims 1 to 3 wherein the acid is sulfuric acid.

5. A process according to any of claims 1 to 4 where the reaction is run at a temperature from about 0 °C to about 30 °C.

6. A process according to any of claims 1 to 5 wherein the reaction is run at a temperature from about 15 °C to about 25 °C.

7. A process according to any of claims 1 to 5 where the reaction is run at a temperature from about 13 °C to about 21 °C.

8. A process according to any of claims 1 to 7 wherein the chlorinating agent is *N*-chlorosuccinimide and the molar ratio of *N*-chlorosuccinimide to des-chloro quinolone is greater than about 1.

9. A process according to any of claims 1 to 8 wherein the chlorinating agent is *N*-chlorosuccinimide and the molar ratio of *N*-chlorosuccinimide to des-chloro quinolone is from about 1.05 to about 1.2.

10. A process according to any of claims 1 to 8 wherein the chlorinating agent is *N*-chlorosuccinimide and the molar ratio of *N*-chlorosuccinimide to des-chloro quinolone is from about 1.04 about 1.07.

11. A process according to any of claims 1 to 10 using an acetate ester as a solvent.

12. A process according to claim 11 wherein said acetate ester is selected from the group consisting of methyl acetate, ethyl acetate, and mixtures thereof.

13. A process according to claim 12 wherein said acetate ester is methyl acetate.

14. A process according to any of claims 1 to 13 comprising the further step of reacting the quinolone compound with a base.

15. A process according to claim 14 wherein the base is a hydroxide base.

16. A process according to claim 15 wherein the hydroxide base is selected from the group consisting of sodium hydroxide, potassium hydroxide, lithium hydroxide, barium hydroxide, and mixtures thereof.

17. A process according to claim 16 wherein the hydroxide base is potassium hydroxide.

18. A process according to any of claims 14 to 17 using a mixture of a C1-C6 alcohol and water as a solvent.

19. A process according to claim 18 wherein said C1-C6 alcohol is isopropanol.

20. A process according to any of claims 1-19 wherein said process is a commercial scale process.

21. A composition comprising the quinolone compound 1-(6-Amino-3,5-difluoropyridin-2-yl)-8-chloro-6-fluoro-7-(3-hydroxyazetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid or a pharmaceutically acceptable salt or ester thereof having less than about 0.40% of a dimeric impurity, wherein the dimeric impurity is 1-amino-3-(azetidin-3-yloxy)-propan-2-ol-bis(*N*,*N*'-quinolone carboxylic acid), or a pharmaceutically acceptable salt or ester thereof, made by the process of claim 1, wherein the ester is selected from the group consisting of lower alkyl groups such as methyl, ethyl, n-propyl, iso-propyl, n-butyl, iso-butyl, t-butyl, pentyl, hexyl, and heptyl; lower alkenyl groups such as vinyl, allyl, 1-propenyl, butenyl, pentenyl, hexenyl, and heptenyl; aralkyl groups such as benzyl; aryl groups such as phenyl and naphthyl; lower alkanoyloxy lower alkyl groups such as acetoxymethyl and pivaloyloxymethyl; lower alkoxycarbonyloxy lower alkyl groups such as methoxycarbonyloxymethyl and 1-ethoxycarbonyloxyethyl; lower alkoxymethyl groups such as methoxymethyl; lactonyl groups such as phthalidyl; di-lower alkylamino lower alkyl groups such as 1-dimethylaminoethyl; and (5-methyl-2-15 oxo-l,3-dioxole-4-yl)methyl.

22. A composition according to claim 21 wherein said composition is a commercial scale composition.

23. A process or composition according to any of claims 1 to 22 wherein said dimeric impurity is less than about 0.35%.

24. A process or composition according to any of claims 1 to 23 wherein said dimeric impurity is less than about 0.30%.

25. A process or composition according to any of claims 1 to 24 wherein said dimeric impurity is less than about 0.25%.

26. A process or composition according to any of claims 1 to 25 wherein said dimeric impurity is less than about 0.20%.

27. A process or composition according to any of claims 1 to 26 wherein said dimeric impurity is less than about 0.15%.

28. A process or composition according to any of claims 1 to 27 wherein said dimeric impurity is less than about 0.10%.

29. A process or composition according to any of claims 1 to 28 wherein said dimeric impurity is less than about 0.05%.

30. A process or composition according to any of claims 1 to 29 wherein said dimeric impurity is less than about 0.04%.

31. A process or composition according to any of claims 1 to 30 wherein said dimeric impurity is less than about 0.03%.

32. A process or composition according to any of claims 1 to 31 wherein said dimeric impurity is less than about 0.02%.

33. A process or composition according to any of claims 1 to 32 wherein said dimeric impurity is less than about 0.01%.