What is Claimed:

1. A mixture of crystalline laquinimod sodium particles, wherein 10% or more of the total amount by volume of the laquinimod sodium particles have a size of greater than 40 microns.

2. The mixture of claim 1, wherein 50% or more of the total amount by volume of the laquinimod sodium particles have a size of greater than 15 microns.

3. The mixture of any of claim 1 or 2, having a tapped density of at least 0.6 g/mL.

4. The mixture of any of claims 1-3, having a bulk density of at least 0.4 g/mL.

5. The mixture of any of claims 1-4, having a tapped density of less than 0.8 g/mL.

6. The mixture of any of claims 1-5, comprising no more than 2 ppm of a heavy metal.

7. The mixture of claim 6, wherein the heavy metal is iron, nickel or chromium.

8. The mixture of claim 7, comprising no more than 2 ppm of iron.

9. The mixture of claim 7, comprising no more than 0.2 ppm of nickel.

10. The mixture of claim 7, comprising no more than 0.3 ppm of chromium.

11. A mixture of crystalline laquinimod sodium particles, having a tapped density of at least 0.6 g/mL.

12. The mixture of claim 11, having a bulk density of at least 0.4 g/mL.

13. The mixture of claim 11 or 12, having a tapped density of less than 0.8 g/mL.

14. The mixture of any of claims 11-13, comprising no more than 2 ppm of a heavy metal.

15. The mixture of claim 14, wherein the heavy metal is iron, nickel or chromium.

16. The mixture of claim 15, comprising no more than 2 ppm of iron.

17. The mixture of claim 15, comprising no more than 0.2 ppm of nickel.

18. The mixture of claim 15, comprising no more than 0.3 ppm of chromium.

19. A pharmaceutical composition comprising the mixture of any of claims 1-18 and a pharmaceutically acceptable carrier.

20. The pharmaceutical composition of claim 19 in the form of a tablet or capsule.

21. A composition comprising laquinimod sodium and no more than 2 ppm of a heavy metal calculated based on the total amount of laquinimod sodium in the composition.

22. The composition of claim 21, wherein the heavy metal is iron, nickel or chromium.

23. The composition of claim 22, wherein the iron content is no more than 2 ppm.

24. The composition of claim 22, wherein the nickel content is no more than 0.2 ppm.

25. The composition of claim 22, wherein the chromium content is no more than 0.3 ppm.

26. The composition of any of claim 21-25 in crystalline form.

27. The composition of any of claims 21-26 further comprising a pharmaceutically acceptable carrier.

28. The composition of claim 27 in the form of a tablet or capsule.

29. A process of recrystallization of laquinimod sodium comprising:

a) dissolving laquinimod sodium in water to form an aqueous solution;

b) filtering the aqueous solution to remove solid impurities;

c) concentrating the aqueous solution to form a concentrated solution;

d) adding a water-miscible anti-solvent to the concentrated solution to form laquinimod sodium crystals; and

e) isolating the laquinimod sodium crystals.

30. The process of claim 29 wherein step a) is performed

by heating the aqueous solution to a temperature of 40-80°C.

31. The process of any of claims 29-30 wherein the concentrated solution comprises 1-4 milliliters of water per gram of laquinimod sodium.

32. The process of claim 31 wherein the concentrated solution comprises 1-2 milliliters of water per gram of laquinimod sodium.

33. The process of any of claims 29-32 wherein the anti-solvent is one, or a mixture of more than one, of the group consisting of ethanol, isopropanol, and acetone.

34. The process of claim 33 wherein the anti-solvent is acetone.

35. The process of any of claims 29-34 wherein the anti-solvent is added in an amount between 3 and 15 milliliters per gram of laquinimod sodium.

36. The process of any of claims 29-35 wherein step c) is followed by cooling the solution to a temperature of below 10°C.

37. The process of any of claims 29-36 wherein step b) is followed by seeding the concentrated solution with laquinimod sodium.

38. Laquinimod sodium prepared by any one of claim 29-37.

39. A process for making a pharmaceutical composition comprising laquinimod sodium comprising:

a) obtaining a batch of laquinimod sodium;

b) determining whether insoluble matter is present in the batch of step a) by mixing a sample from the batch in deionized water at room temperature at a ratio of at least 110 mg of sample to 1.0 ml of water, and inspecting the resulting mixture for the presence of insoluble matter; and

c) mixing the batch of step a) with at least one pharmaceutically acceptable carrier if in step b) insoluble matter is determined to be present below a predetermined amount.

40. The process of claim 39, wherein if insoluble matter in the mixture of step b) is determined not to be present below a predetermined amount, the process further comprises:

d) dissolving the batch of step a) in water to form an aqueous solution;

e) filtering the aqueous solution of step d) to reduce the amount of insoluble matter to below the predetermined amount;

f) concentrating the aqueous solution of step e) to form a concentrated solution;

g) adding a water-miscible anti-solvent to the concentrated solution of step f) to form laquinimod sodium crystals; and

h) isolating the laquinimod sodium crystals of step g).

What is claimed is:

1. A mixture of crystalline laquinimod sodium particles wherein 10% or more of the total amount by volume of the laquinimod sodium particles have a size of greater than 40 microns, having a bulk density of at least 0.2 g/mL or a tapped density of at least 0.4 g/mL.

2. The mixture of claim 1, having a tapped density of at least 0.4 g/mL and a bulk density of at least 0.2 g/mL.

3. The mixture of claim 1, having a tapped density of at least 0.5 g/mL.

4. The mixture of claim 1, having a tapped density of less than 0.7 g/mL.

5. The mixture of claim 1, having a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

6. The mixture of claim 5, having a tapped density of at least 0.6 g/mL and less than 0.7 g/mL.

7. The mixture of claim 1, having a bulk density of at least 0.3 g/mL.

8. The mixture of claim 7, having a tapped density of at least 0.4 g/mL.

9. The mixture of claim 8, having a tapped density of at least 0.5 g/mL.

10. The mixture of claim 7, having a tapped density of less than 0.7 g/mL.

11. The mixture of claim 7, having a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

12. The mixture of claim 11, having a tapped density of at least 0.6 g/mL and less than 0.7 g/mL.

13. The mixture of claim 1, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm, the nickel is no more than 0.2 ppm and the chromium content is no than 0.3 ppm.

14. The mixture of claim 5, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm, the nickel content is no more than 0.2 ppm and the chromium content is no more than 0.3 ppm.

15. The mixture of claim 6, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm, the nickel content is no more than 0.2 ppm and the chromium content is no more than 0.3 ppm.

16. The mixture of claim 7, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm, the nickel content is no more than 0.2 ppm and the chromium content no more than 0.3 ppm.

17. The mixture of claim 11, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm,

the nickel content is no more than 0.2 ppm and the chromium content is no more than 0.3 ppm.

18. The mixture of claim 12, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm, the nickel content is no more than 0.2 ppm and the chromium content is no more than 0.3 ppm.

19. A pharmaceutical composition comprising the mixture of claim 1 and a pharmaceutically acceptable carrier.

20. The pharmaceutical composition of claim 19, wherein the mixture has a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

21. The pharmaceutical composition of claim 20, wherein the mixture has a tapped density of at least 0.6 g/mL and less than 0.7 g/mL.

22. The pharmaceutical composition of claim 19, wherein the mixture has a bulk density of at least 0.3 g/mL.

23. The pharmaceutical composition of claim 22, wherein the mixture has a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

24. The pharmaceutical composition of claim 23, wherein the mixture has a tapped density of at least 0.6 g/mL and less than 0.7 g/mL.

25. The pharmaceutical composition of claim 19 in the form of a tablet, capsule, pill, powder or granule.

26. The pharmaceutical composition of claim 25, wherein the

mixture has a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

27. The pharmaceutical composition of claim 26, wherein the mixture has a tapped density of at least 0.6 g/mL and less than 0.7 g/mL.

28. The pharmaceutical composition of claim 25, wherein the mixture has a bulk density of at least 0.3 g/mL.

29. The pharmaceutical composition of claim 28, wherein the mixture has a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

30. The pharmaceutical composition of claim 29, wherein the mixture has a tapped density of at least 0.6 g/mL and less than 0.7 g/mL.

31. A composition comprising a mixture of crystalline laquinimod sodium particles according to claim 1 and no more than 2 ppm of a heavy metal calculated based on total amount of laquinimod sodium in the composition, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm the nickel content is no more than 0.2 ppm and the chromium content is no more than 0.3 ppm.

32. The composition of claim 31 in crystalline, powder or granule form.

33. The composition of claim 31 further comprising a pharmaceutically acceptable carrier.

34. The composition of claim 31 in the form of a tablet, or capsule or pill.

35. The mixture of claim 2, having a tapped density of at least 0.5 g/mL and less than 0.7 g/mL.

36. The mixture of claim 35, comprising no more than 2 ppm of a heavy metal, wherein the heavy metal is iron, nickel, chromium or a mixture thereof, and the iron content is no more than 2 ppm, the nickel content is no more than 0.2 ppm and the chromium content is no more than 0.3 ppm.

37. The mixture of claim 35, wherein 50% or more of the total amount by volume of the laquinimod sodium particles have a size of greater than 15 microns.

38. The mixture of claim 1, wherein an amount of a polar impurity having an approximate retention time of 5.52 minutes when determined by isocratic reversed phase HPLC, using an ODS-3V column and a mobile phase comprised of a mixture of ammonium acetate buffer at pH 7.0 (80%) and acetonitrile (20%) is less than 0.01 of the total amount of laquinimod sodium as measured by ultraviolet absorption at 240 nm, or the impurity is not detectable.

39. The mixture of claim 1, wherein an amount of a polar impurity having an approximate retention time of 8.48 minutes when determined by isocratic reversed phase HPLC, using an ODS-3V column and a mobile phase comprised of a mixture of ammonium acetate buffer at pH 7.0 (80%) and acetonitrile (20%) is less than 0.01 of the total amount of laquinimod sodium as measured by ultraviolet absorption at 240 nm, or the impurity is not detectable.

40. The mixture of claim 1, wherein an amount of a polar impurity having an approximate retention time of 12.19 minutes when determined by isocratic reversed phase HPLC, using an ODS-

3V column and a mobile phase comprised of a mixture of ammonium acetate buffer at pH 7.0 (80%) and acetonitrile (20%) is less than 0.01 of the total amount of laquinimod sodium as measured by ultraviolet absorption at 240 nm, or the impurity is not detectable.

41. The pharmaceutical composition of claim 19, wherein the pharmaceutically acceptable carrier is mannitol.

42. The pharmaceutical composition of claim 33, wherein the pharmaceutically acceptable carrier is mannitol.

43. The pharmaceutical composition of claim 19, further comprising an alkaline-reacting component.

44. The pharmaceutical composition of claim 33, further comprising an alkaline-reacting component.