What is claimed is:

1. An oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

2. The oxycodone hydrochloride composition of claim 1 when made by a process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level of less than 25 ppm by reacting an oxycodone base composition having an 8,14-dihydroxy-7,8-dihydrocodeinone compound with hydrochloric acid, whereby 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydroxycodeinone, and reducing 14-hydroxycodeinone to oxycodone.

3. The oxycodone hydrochloride composition of claim 1, having less than 15 ppm 14-hydroxycodeinone.

4. The oxycodone hydrochloride composition of claim 1, having less than 10 ppm 14-hydroxycodeinone.

5. The oxycodone hydrochloride composition of claim 1, having less than 5 ppm 14-hydroxycodeinone.

6. The oxycodone hydrochloride composition of claim 1, having a lower limit of 14-hydroxycodeinone of 5 ppm.

7. The oxycodone hydrochloride composition of claim 1, having a lower limit of 14-hydroxycodeinone of 0.25 ppm, 0.5 ppm, 1 ppm or 2 ppm.

8. The oxycodone hydrochloride composition according to any one of claims 1 to 7 wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone.

9. The oxycodone hydrochloride composition of claim 8 wherein the 14-hydroxycodeinone is derived solely from 8α,14-dihydroxy-7,8-dihydrocodeinone.

10. A pharmaceutical dosage form comprising an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, further containing conventional excipients.

11. The pharmaceutical dosage form of claim 10, wherein said oxycodone hydrochloride composition is prepared using a process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level of less than 25 ppm by reacting an oxycodone base composition having an 8,14-dihydroxy-7,8-dihydrocodeinone compound with hydrochloric acid, whereby 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydroxycodeinone, and reducing 14-hydroxycodeinone to oxycodone.

12. The pharmaceutical dosage form of claim 10, wherein the oxycodone hydrochloride composition has less than 15 ppm 14-hydroxycodeinone.

13. The pharmaceutical dosage form of claim 10, wherein the oxycodone hydrochloride composition has less than 10 ppm 14-hydroxycodeinone.

14. The pharmaceutical dosage form of claim 10, wherein the oxycodone hydrochloride composition has less than 5 ppm 14-hydroxycodeinone.

15. The pharmaceutical dosage form of claim 10, wherein a lower limit of 14-hydroxycodeinone in the oxycodone hydrochloride composition is 5 ppm.

16. The pharmaceutical dosage form of claim 10, having a lower limit of 14-hydroxycodeinone in the oxycodone hydrochloride composition of 0.25 ppm, 0.5 ppm, 1 ppm or 2 ppm.

17. The pharmaceutical dosage form of claim 10, wherein said dosage form comprises excipients to provide sustained release of the oxycodone hydrochloride.

18. The pharmaceutical dosage form of claim 17, wherein the excipients

comprise a sustained release material, and the sustained release material is incorporated into a matrix along with the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

19. The pharmaceutical dosage form of claim 10, wherein the dosage form is for oral administration and comprises from 10 mg to 320 mg of the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

20. The oral pharmaceutical dosage form of claim 19, wherein the dosage form is suitable for once daily dosing and comprises 10 mg of oxycodone hydrochloride, or about 20 mg oxycodone hydrochloride, or 30 mg oxycodone hydrochloride, or 40 mg oxycodone hydrochloride, or 60 mg oxycodone hydrochloride, or 80 mg oxycodone hydrochloride, or 100 mg oxycodone hydrochloride, or 120 mg oxycodone hydrochloride, or 160 mg oxycodone hydrochloride, or 320 mg oxycodone hydrochloride,

or

wherein the dosage form is suitable for twice daily dosing and comprises 5 mg of oxycodone hydrochloride, or 10 mg of oxycodone hydrochloride, or 15 mg of oxycodone hydrochloride, or 20 mg of oxycodone hydrochloride, or 30 mg of oxycodone hydrochloride, or 40 mg of oxycodone hydrochloride, or 50 mg of oxycodone hydrochloride, or 60 mg of oxycodone hydrochloride, or 80 mg of oxycodone hydrochloride, or 100 mg of oxycodone hydrochloride, or 160 mg of oxycodone hydrochloride.

21. The pharmaceutical dosage form of claim 19, in the form selected from the group consisting of tablets, troches, lozenges, powders, granules, hard capsules, soft capsules, microparticles, buccal tablets, solutions and suspensions.

22. The pharmaceutical dosage form of claim 19, which is a sustained release oral formulation.

23. The oral pharmaceutical dosage form of claim 22, which is in the form of a

coated tablet or a multiparticulate formulation.

24. A sustained release oral dosage form comprising particles, the particles comprising from 10 mg to 320 mg oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, said particles being film-coated with a material that permits release of the oxycodone hydrochloride at a sustained rate in an aqueous medium.

25. The sustained release oral dosage form of claim 24, wherein said oxycodone hydrochloride composition is prepared by a process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level of less than 25 ppm by reacting an oxycodone base composition having an 8,14-dihydroxy-7,8-dihydrocodeinone compound with hydrochloric acid, whereby 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydroxycodeinone, and reducing 14-hydroxycodeinone to oxycodone.

26. A pharmaceutical dosage form comprising (i) from 5 mg to 320 mg of oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone; and (ii) a sustained release material, wherein the sustained release material is film coated onto said oxycodone hydrochloride composition.

27. The pharmaceutical dosage form as claimed in claim 26, wherein said oxycodone hydrochloride composition is prepared by a process for preparing an oxycodone hydrochloride composition having a 14-hydroxycodeinone level of less than 25 ppm by reacting an oxycodone base composition having an 8,14-dihydroxy-7,8-dihydrocodeinone compound with hydrochloric acid, whereby 8,14-dihydroxy-7,8-dihydrocodeinone is converted to 14-hydroxycodeinone, and reducing 14-hydroxycodeinone to oxycodone.

28. The pharmaceutical dosage form as claimed in any one of claims 10 to 27 wherein at least a portion of the 14-hydroxycodeinone is derived from 8α,14-dihydroxy-7,8-dihydrocodeinone.

29. The pharmaceutical dosage form of claim 28 wherein the 14-

hydroxycodeinone is derived solely from 8α,14-dihydroxy-7,8-dihydrocodeinone.

30. A pharmaceutically acceptable package containing at least 1 kg of the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone as claimed in any one of claims 1 to 9 or the pharmaceutical dosage form as claimed in any one of claims 10 to 29.

31. The pharmaceutically acceptable package of claim 30, containing the oxycodone hydrochloride composition in an amount from 10 kg to 1000 kg, or from 10 kg to 500 kg, or from 20 kg to 100 kg, or from 20 kg to 50 kg.

32. The pharmaceutically acceptable package of claim 30, wherein the package is selected from the group of packages consisting of a corrugated box container, a drum, and a flexible intermediate bulk container.

33. The pharmaceutically acceptable package of claim 30, further comprising a liner between the package and the oxycodone hydrochloride composition.

34. The oxycodone hydrochloride composition according to any one of claims 1 to 9 for use in treating pain.

35. The pharmaceutical dosage form as claimed in any one of claims 10 to 29 for use in treating pain.

What is claimed is:

1. A composition comprising (i) an oxycodone salt and (ii) 14-hydroxycodeinone in an amount of less than 25 ppm.

2. The composition of claim 1, wherein at least a portion of the 14-hydroxycodeinone is derived from 8α, 14-dihydroxy-7,8-dihydrocodeinone.

3. The composition of claim 1, wherein the 14-hydroxycodeinone is solely derived from 8α, 14-dihydroxy-7,8-dihydrocodeinone.

4. The composition of any one of claims 1-3, wherein the oxycodone salt is oxycodone hydrochloride.

5. The composition of any one of claims 1-4, having less than about 15 ppm 14-hydroxycodeinone.

6. The composition of any one of claims 1-4, having less than about 10 ppm 14-hydroxycodeinone.

7. The composition of any one of claims 1-4, having less than about 5 ppm 14-hydroxycodeinone.

8. The composition of any one of claims 1-6, having a lower limit of 14-hydroxycodeinone of 5 ppm.

9. The composition of any one of claims 1-7, having a lower limit of 14-hydroxycodeinone of 0.25 ppm.

10. The composition of any one of claims 1-7, having a lower limit of 14-hydroxycodeinone of 0.5 ppm.

11. The composition of any one of claims 1-7, having a lower limit of 14-hydroxycodeinone of 1 ppm.

12. The composition of any one of claims 1-7, having a lower limit of 14-hydroxycodeinone of 2 ppm.

13. A pharmaceutical dosage form comprising (i) an oxycodone salt composition comprising an oxycodone salt, and less than 25 ppm 14-hydroxycodeinone, and (ii) at least one excipient.

14. The pharmaceutical dosage form of claim 13, wherein the oxycodone salt is oxycodone hydrochloride.

15. The pharmaceutical dosage form of any one of claims 13-14, wherein the oxycodone salt composition has less than about 15 ppm 14-hydroxycodeinone.

16. The pharmaceutical dosage form of any one of claims 13-14, wherein the oxycodone salt composition has less than about 10 ppm 14-hydroxycodeinone.

17. The pharmaceutical dosage form of any one of claims 13-14, wherein the oxycodone salt composition has less than about 5 ppm 14-hydroxycodeinone.

18. The pharmaceutical dosage form of any one of claims 13-16, wherein a lower limit of 14-hydroxycodeinone in the oxycodone salt composition is 5 ppm.

19. The pharmaceutical dosage form of any one of claims 13-17, having a lower limit of 14-hydroxycodeinone in the oxycodone salt composition of 0.25 ppm.

20. The pharmaceutical dosage form of any one of claims 13-17, having a lower limit of 14-hydroxycodeinone in the oxycodone salt composition of 0.5 ppm.

21. The pharmaceutical dosage form of any one of claims 13-17, having a lower limit of 14-hydroxycodeinone in the oxycodone salt composition of 1 ppm.

22. The pharmaceutical dosage form of any one of claims 13-17, having a lower limit of 14-hydroxycodeinone in the oxycodone salt composition of 2 ppm.

23. The pharmaceutical dosage form of any one of claims 13-22, wherein the at least one excipient provides sustained release of the oxycodone salt.

24. The pharmaceutical dosage form of any one of claims 13-22, wherein the at least one excipient comprises a sustained release material, and the sustained release material is incorporated into a matrix along with the oxycodone salt composition.

25. The pharmaceutical dosage form of any one of claims 13-22, wherein the dosage form is for oral administration and comprises from about 10 mg to about 320 mg of the oxycodone salt composition.

26. The pharmaceutical dosage form of claim 25, in the form selected from the group consisting of tablets, troches, lozenges, powders, granules, hard capsules, soft capsules, microparticles, buccal tablets, solutions and suspensions.

27. The pharmaceutical dosage form of any one of claims 25-26, which is a sustained release oral formulation.

28. The oral pharmaceutical dosage form of claim 27 which is in the form of a coated tablet or a multiparticulate formulation.

29. A sustained release oral dosage form comprising particles, the particles comprising from about 10 mg to about 320 mg the oxycodone salt composition of any one of claims 1-12, said particles being film-coated with a material that permits release of the oxycodone salt at a sustained rate in an aqueous medium.

30. A pharmaceutical dosage form comprising (i) from about 5 mg to about 320 mg of the oxycodone salt composition of any one of claims 1-12; and (ii) a sustained

release material, wherein the sustained release material is film coated onto said oxycodone salt composition.

31. A pharmaceutically acceptable package containing at least 1 kg of the composition of any one of claims 1-12 or the dosage form as claimed in any one of claims 13-30.

32. The pharmaceutically acceptable package of claim 31, containing the composition in an amount from about 10 kg to about 1000 kg.

33. The pharmaceutically acceptable package of claim 31, containing the composition in an amount from about 10 kg to about 500 kg.

34. The pharmaceutically acceptable package of claim 31, containing the composition in an amount from about 20 kg to about 100 kg.

35. The pharmaceutically acceptable package of claim 31, containing the composition in an amount from about 20 kg to about 50 kg.

36. The pharmaceutically acceptable package of any one of claims 31-35, wherein the package is selected from the group of packages consisting of a corrugated box container, a drum and a flexible intermediate bulk container.

37. The pharmaceutically acceptable package of any one of claims 31-36, further comprising a liner between the package and the composition.

38. The pharmaceutical dosage form of any one of claims 25 and 30, wherein the oxycodone salt is present in an amount of 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg, 100 mg, 120 mg, 160 mg or 320 mg.

39. The sustained release oral dosage form of claim 29, wherein the oxycodone salt is present in an amount of 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 80 mg, 100 mg, 120 mg, 160 mg or 320 mg.