CLAIMS

1. An oral immediate release pharmaceutical composition comprising at least oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in about a 2:1 ratio (oxycodone or a pharmaceutically acceptable salt thereof: naloxone or a pharmaceutically acceptable salt thereof) by weight.

2. An oral immediate release pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable salt of oxycodone and wherein the pharmaceutically acceptable salt of naloxone are selected from the hydrochloride salts of oxycodone and naloxone.

3. An oral immediate release pharmaceutical composition of claim 2, wherein the composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents.

4. An oral immediate release pharmaceutical composition of any of claims 1,2 or 3, wherein the formulation comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 1 mg to about 160 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 0.5 mg to about 80 mg of naloxone hydrochloride.

5. An oral immediate release pharmaceutical composition of claim 4, wherein the formulation comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 2.5 mg to about 40 mg of oxycodone hydrochloride and an amount of naloxone or a

pharmaceutically acceptable salt thereof equivalent to about 1.25 mg to about 20 mg of naloxone hydrochloride.

6. An oral immediate release pharmaceutical composition of claim 5, wherein the formulation comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 2.5 mg to about 20 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 1.25 mg to about 10 mg of naloxone hydrochloride.

7. An oral immediate release pharmaceutical composition of claim 6, wherein the formulation comprises about 2.5 mg to about 20 mg of oxycodone hydrochloride and about 1.25 mg to about 10 mg of naloxone hydrochloride.

8. An oral immediate release pharmaceutical composition of claim 7, wherein the composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents.

9. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7 or 8, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, $\geq$ 75% of oxycodone or a pharmaceutically acceptable salt thereof by weight and $\geq$ 75 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 45 min.

10. An oral immediate release pharmaceutical composition of claim 9, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV

detection at 230 nm, ≥ 80% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥ 80 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 45 min.

11. An oral immediate release pharmaceutical composition of claim 9 or 10, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥ 80% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥ 80 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

12. An oral immediate release pharmaceutical composition of claim 11, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥ 90% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥ 90 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

13. An oral immediate release pharmaceutical composition of claim 12, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥ 95% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥ 95 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

14. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13,
wherein the composition is in the form of a tablet, of a capsule, of multiparticulates, of pellets, or of a liquid.

15. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 or 14, wherein the formulation comprises at least a diluents and optionally a disintegrant as pharmaceutically acceptable excipients.

16. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13 or 14, wherein the formulation comprises at least a disintegrant and optionally a diluents as pharmaceutically acceptable excipients.

17. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 or 16, wherein the formulation comprises about 2.5 mg to about 20 mg of oxycodone hydrochloride and about 1.25 mg to about 10 mg of naloxone hydrochloride in about a 2:1 ratio (oxycodone hydrochloride: naloxone hydrochloride) by weight, wherein the composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents, wherein the composition is in solid form, optionally in the from of a tablet, wherein the formulation comprises at least a a disintegrant and optionally a diluent as pharmaceutically acceptable excipients and wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, $\geq$ 80% of oxycodone hydrochloride by weight and $\geq$ 80 % of naloxone hydrochloride by weight at 45 min.

18. An oral immediate release pharmaceutical composition of claim 17, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, $\geq$ 95% of oxycodone hydrochloride by weight and $\geq$ 95 % of naloxone hydrochloride by weight at 15 min.

19. An oral immediate release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥90% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥90 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

20. An oral immediate release pharmaceutical composition according to claim 19, wherein the formulation releases *in vitro*, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥ 95% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥95 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

21. An oral immediate release pharmaceutical composition according to claim 19 or 20, wherein the pharmaceutical composition comprises an amounts of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 1 mg to 160 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 0.5 mg to about 80 mg of naloxone hydrochloride.

22. An oral immediate release pharmaceutical composition according to claim 19, 20 or 21, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in about a 2:1 ratio (oxycodone or a pharmaceutically

acceptable salt thereof, naloxone or a pharmaceutically acceptable salt thereof) by weight.

23. An oral immediate release pharmaceutical composition according to claim 19, 20, 21 or 22, wherein the pharmaceutical composition is in solid form.

24. An oral immediate release pharmaceutical composition according to claim 19, 20, 21, 22 or 23, wherein the pharmaceutical composition additionally comprises at least a disintegrant.

25. An oral immediate release pharmaceutical composition according to claim 19, 20, 21, 22, 23 or 24, wherein the pharmaceutical composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents.

26. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26 for use in titrating patients suffering from pain.

27. An oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26 for treating breakthrough pain in patients suffering from pain.

28. Use of an oral immediate release pharmaceutical composition of any of claims , 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26 in the manufacture of a medicament for titrating patients suffering from pain.

29. Use of an oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26 in the manufacture of a medicament treating breakthrough pain in patients suffering from pain.

30. Method of titrating a patient suffering from pain by administering an oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26.

31. Method of treating breakthrough pain in a patient suffering from pain by administering an oral immediate release pharmaceutical composition of any of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 or 26.

CLAIMS

1. An oral immediate release pharmaceutical composition comprising at least oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in about a 2:1 ratio (oxycodone or a pharmaceutically acceptable salt thereof: naloxone or a pharmaceutically acceptable salt thereof) by weight, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥75% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥75 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 45 min.

2. An oral immediate release pharmaceutical composition of claim 1, wherein the pharmaceutically acceptable salt of oxycodone and the pharmaceutically acceptable salt of naloxone are selected from the hydrochloride salts of oxycodone and naloxone.

3. An oral immediate release pharmaceutical composition of claim 2, wherein the composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents.

4. An oral immediate release pharmaceutical composition of any one of claims 1, 2 or wherein the formulation comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 1 mg to about 160 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 0.5 mg to about 80 mg of naloxone hydrochloride.

5. An oral immediate release pharmaceutical composition of claim 4, wherein the formulation comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 2.5 mg to about 40 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 1.25 mg to about 20 mg of naloxone hydrochloride.

6. An oral immediate release pharmaceutical composition of claim 5, wherein the formulation comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent

to about 2.5 mg to about 20 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 1.25 mg to about 10 mg of naloxone hydrochloride.

7. An oral immediate release pharmaceutical composition of claim 6, wherein the formulation comprises about 2.5 mg to about 20 mg of oxycodone hydrochloride and about 1.25 mg to about 10 mg of naloxone hydrochloride.

8. An oral immediate release pharmaceutical composition of claim 7, wherein the composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents.

9. An oral immediate release pharmaceutical composition of claim 1, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 rim, ≥80% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥80 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 45 min.

10. An oral immediate release pharmaceutical composition of claim 9, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥80% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥80 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

11. An oral immediate release pharmaceutical composition of claim 10, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥90% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥90 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

12. An oral immediate release pharmaceutical composition of claim 11, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥95% of oxycodone or a

pharmaceutically acceptable salt thereof by weight and ≥95 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

13. An oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12,
wherein the composition is in the form of a tablet, of a capsule, of multiparticulates, of pellets, or of a liquid.

14. An oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13,
wherein the formulation comprises at least a diluent and optionally a disintegrant as pharmaceutically acceptable excipients.

15. An oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 13,
wherein the formulation comprises at least a disintegrant and optionally a diluent as pharmaceutically acceptable excipients.

16. An oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 or 15,
wherein the formulation comprises about 2.5 mg to about 20 mg of oxycodone hydrochloride and about 1.25 mg to about 10 mg of naloxone hydrochloride in about a 2:1 ratio (oxycodone hydrochloride: naloxone hydrochloride) by weight, wherein the composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents, wherein the composition is in solid form, optionally in the form of a tablet, wherein the formulation comprises at least a disintegrant and optionally a diluent as pharmaceutically acceptable excipients and wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥80% of oxycodone hydrochloride by weight and ≥80 % of naloxone hydrochloride by weight at 45 min.

17. An oral immediate release pharmaceutical composition of claim 16, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in

0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥95% of oxycodone hydrochloride by weight and ≥95 % of naloxone hydrochloride by weight at 15 min.

18. An oral immediate release pharmaceutical composition comprising oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥ 90% of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥90% of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

19. An oral immediate release pharmaceutical composition according to claim 18, wherein the formulation releases in vitro, when measured using the Ph. Eur. Paddle Method at 100 rpm in 0.1 N hydrochloric acid at 37°C and using UV detection at 230 nm, ≥95 % of oxycodone or a pharmaceutically acceptable salt thereof by weight and ≥95 % of naloxone or a pharmaceutically acceptable salt thereof by weight at 15 min.

20. An oral immediate release pharmaceutical composition according to claim 18 or 19, wherein the pharmaceutical composition comprises an amount of oxycodone or a pharmaceutically acceptable salt thereof equivalent to about 1 mg to 160 mg of oxycodone hydrochloride and an amount of naloxone or a pharmaceutically acceptable salt thereof equivalent to about 0.5 mg to about 80 mg of naloxone hydrochloride.

21. An oral immediate release pharmaceutical composition according to claim 18, 19 or 20, wherein the pharmaceutical composition comprises oxycodone or a pharmaceutically acceptable salt thereof and naloxone or a pharmaceutically acceptable salt thereof in about a 2:1 ratio (oxycodone or a pharmaceutically acceptable salt thereof, naloxone or a pharmaceutically acceptable salt thereof) by weight.

22. An oral immediate release pharmaceutical composition according to claim 18, 19, 20 or 21, wherein the pharmaceutical composition is in solid form.

23. An oral immediate release pharmaceutical composition according to claim 18, 19, 20, 21 or 22, wherein the pharmaceutical composition comprises at least a disintegrant.

24. An oral immediate release pharmaceutical composition according to claim 18, 19, 20, 21, 22 or 23, wherein the pharmaceutical composition comprises oxycodone hydrochloride and naloxone hydrochloride as the sole pharmaceutically active agents.

25. An oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 or 24 for use in titrating patients suffering from pain.

26. An oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 or 24 for treating breakthrough pain in patients suffering from pain.

27. Use of an oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 or 24 in the manufacture of a medicament for titrating patients suffering from pain.

28. Use of an oral immediate release pharmaceutical composition of any one of claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 or 24 in the manufacture of a medicament for treating breakthrough pain in patients suffering from pain.