Claims:

1. A pharmaceutical composition comprising a co-crystal of (*rac*)-tramadol·HCl – celecoxib (1:1) and at least a solubility enhancer polymer.

2. The pharmaceutical composition according to claim 1 wherein the solubility enhancer polymer is selected from polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer or other hydrophilic polymers like copovidone, povidone, poloxamers, cyclodextrin, polyethylene glycol and lauroyl macrogol-32 glycerides EP, preferably selected from polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer or other hydrophilic polymers selected from copovidone, povidone, or poloxamers

3. The pharmaceutical composition according to any of claims 1 or 2 wherein the solubility enhancer polymer is polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer.

4. The pharmaceutical composition according to any of claims 1 or 2 wherein the solubility enhancer polymer is copolymer copovidone.

5. The pharmaceutical composition according to any of claims 1 to 4 wherein the content of solubility enhancer polymer used in the composition lies between 2-50 weight-%, preferably between 8-12 weight-% or approximately 8 weight-%.

6. The pharmaceutical composition according to any of claims 1 to 5 being in a form selected from tablet, powder capsules, or formulated by dry granulation, slurries and dry roller compaction, preferably being in form of a tablet, most preferably being in form of a tablet producible obtainable by a direct compression process.

7. A pharmaceutical composition according to claim 1 in form of a tablet comprising a co-crystal of (*rac*)-tramadol·HCl – celecoxib (1:1) and at least a solubility enhancer polymer obtainable by a direct compression process.

8. The pharmaceutical composition according to any of claims 1 to 7 comprising further at least a surfactant polymer.

9. The pharmaceutical composition according to claim 8 wherein the surfactant polymer is selected from microencapsulated polisorbate 80, microencapsulated polyoxyl 40 - hydrogenated castor oil and sodium lauryl sulphate.

10. The pharmaceutical composition according to any of claims 1 to 9 comprising at least one further pharmaceutically acceptable excipient like a filler, a disintegrant and/or a lubricant.

11. The pharmaceutical composition according to claim 10 wherein the filler is selected from sugars such as xylitol, sorbitol, isomalt, erythritol, sucrose, fructose, dextrose most preferable spray dried mannitol and lactose family or from insoluble fillers like calcium phosphate, calcium carbonate or microcrystalline celluloses like MCC 102 (90µm) and MCC 200 (200 µm) or other compounds such as silicified microcrystalline or compositions containing microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate and sodium stearyl fumarate, preferably are selected from sugars such as xylitol, sorbitol, isomalt, erythritol, sucrose, fructose, dextrose most preferable spray dried mannitol and lactose family or from microcrystalline cellulose, most preferably are selected from spray dried mannitol and microcrystalline cellulose.

12. The pharmaceutical composition according to claim 10 or 11 wherein the lubricant is selected from stearyl fumarate, magnesium stearate, talc, hydrophilic fumed silica, preferably are selected from stearyl fumarate and talc and/or

wherein the disintegrant is selected from crospovidone, croscarmelose sodium, sodium starch glycolate, pregelatinized starch, starch, polacrilin potassium, low-substituted hydroxypropyl cellulose (L-HPC), calcium carboxymethylcellulose, alginic acid, preferably is crospovidone.

13. The pharmaceutical composition according to any of claims 1 to 12, wherein the co-crystal of (*rac*)-tramadol·HCl and celecoxib (1:1) is characterized in that it shows a Powder X-Ray Diffraction pattern with peaks [2θ] at 7.1, 9.3, 10.2, 10.7, 13.6, 13.9, 14.1, 15.5, 16.1, 16.2, 16.8, 17.5, 18.0, 19.0, 19.5, 19.9, 20.5, 21.2, 21.3, 21.4, 21.8, 22.1, 22.6, 22.7, 23.6, 24.1, 24.4, 25.2, 26.1, 26.6, 26.8, 27.4, 27.9, 28.1, 29.1, 29.9, 30.1, 31.1, 31.3, 31.7, 32.5, 32.8, 34.4, 35.0, 35.8, 36.2 and 37.2[°], with the 2θ values being obtained using copper radiation ($Cu_{K\alpha1}$ 1.54060Å); and/or

wherein the co-crystal of (*rac*)-tramadol·HCl and celecoxib (1:1) is characterized in that it shows a Fourier Transform Infra Red pattern with absorption bands at 3481.6 (m), 3133.5 (m), 2923.0 (m), 2667.7 (m), 1596.0 (m), 1472.4 (m), 1458.0 (m), 1335.1 (m), 1288.7 (m), 1271.8 (m), 1168.7 (s), 1237.3 (m), 1168.7 (s), 1122.6 (s), 1100.9 (m), 1042.2 (m), 976.8 (m), 844.6 (m), 820.1 (m), 786.5 (m) 625.9 (m) cm^{-1}; and/or

characterized in that the co-crystal of (*rac*)-tramadol·HCl and celecoxib (1:1) has an orthorhombic unit cell with the following dimensions:

a = 11.0323(7) Å
b = 18.1095(12) Å
c = 17.3206(12) Å; and/or

characterized in that the endothermic sharp peak corresponding to the melting point of the co-crystal of (*rac*)-tramadol·HCl and celecoxib (1:1) has an onset at 164°C.

14. Process for the production of an oral pharmaceutical composition according to any of claims 1 to 13 comprising the steps of:
    (a) blending the co-crystal of (*rac*)-tramadol·HCl – celecoxib (1:1) with at least a solubility enhancer polymer and optionally one or more filler, disintegrant or surfactant polymer or any combination thereof;
    (b) optionally adding at least a lubricant;
    (c) directly compressing the blend from step (a) or the lubricated blend from step (b) into a tablet.

15. A pharmaceutical composition according to any one of claims 1 to 13 for the treatment of pain, preferably acute pain, chronic pain, neuropathic pain, nociceptive pain, mild and severe to moderate pain, hyperalgesia, pain related to central sensitization, allodynia or cancer pain, including diabetic neuropathy or diabetic peripheral neuropathy and osteoarthritis, fibromyalgia; rheumatoid arthritis, ankylosing spondylitis, frozen shoulder or sciatica.

Claims:

1. A pharmaceutical composition comprising a co-crystal of (rac)-tramadol.HCl-celecoxib (1:1) and at least a solubility enhancer polymer, wherein the solubility enhancer polymer is selected from polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft polymer, copovidone, povidone, polyethylene glycol, and lauroyl macrogel-32 glycerides EP.

2. The pharmaceutical composition according to claim 1 wherein the solubility enhancer polymer is polyvinyl caprolactam-polyvinyl acetate-polyethylene glycol graft copolymer.

3. The pharmaceutical composition according to claim 1 wherein the solubility enhancer polymer is copolymer copovidone.

4. The pharmaceutical composition according to claim 1 wherein the content of solubility enhancer polymer used in the composition lies between 2-50 weight-%.

5. The pharmaceutical composition according to claim 1 being in a form selected from tablet, powder capsules, or formulated by dry granulation, slurries and dry roller compaction.

6. A pharmaceutical composition according to claim 1 in form of a tablet comprising a co-crystal of (rac)-tramadol.HCl-celecoxib (1:1) and at least a solubility enhancer polymer obtainable by a direct compression process.

7. The pharmaceutical composition according to claim 1 further comprising at least a surfactant polymer.

8. The pharmaceutical composition according to claim 7 wherein the surfactant polymer is selected from microencapsulated polisorbate 80, microencapsulated polyoxyl 40-hydrogenated castor oil and sodium lauryl sulphate.

9. The pharmaceutical composition according to claim 1 comprising at least one further pharmaceutically acceptable excipient.

10. The pharmaceutical composition according to claim 9 wherein the pharmaceutically acceptable excipient is a filler selected from a sugar.

11. The pharmaceutical composition according to claim 9 wherein the pharmaceutically acceptable excipient is a lubricant selected from stearyl fumarate, magnesium stearate, talc, and hydrophilic fumed silica, and/or wherein the pharmaceutically acceptable excipient is a disintegrant selected from crospovidone, croscarmelose sodium, sodium starch glycolate, pregelatinized starch, starch, polacrilin potassium, low-substituted hydroxypropyl cellulose (L-HPC), calcium carboxymethylcellulose, and alginic acid.

12. The pharmaceutical composition according to claim 1, wherein the co-crystal of (rac)-tramadol.HCl and celecoxib (1:1) is characterized in that it shows a Powder X-Ray Diffraction pattern with peaks [2θ] at 7.1, 9.3, 10.2, 10.7, 13.6, 13.9, 14.1, 15.5, 16.1, 16.2, 16.8, 17.5, 18.0, 19.0, 19.5, 19.9, 20.5, 21.2, 21.3, 21.4, 21.8, 22.1, 22.6, 22.7, 23.6, 24.1, 24.4, 25.2, 26.1, 26.6, 26.8, 27.4, 27.9, 28.1, 29.1, 29.9, 30.1, 31.1, 31.3, 31.7, 32.5, 32.8, 34.4, 35.0, 35.8, 36.2 and 37.2[°], with the 2θ values being obtained using copper radiation ($Cu_{K\alpha1}$.1.54060 Å), and/or wherein the co-crystal of (rac)-tramadol.HCl and celecoxib (1:1) is

characterized in that it shows a Fourier Transform Infra Red pattern with absorption bands at 3481.6 (m), 3133.5 (m), 2923.0 (m), 2667.7 (m), 1596.0 (m), 1472.4 (m), 1458.0 (m), 1335.1 (m), 1288.7 (m), 1271.8 (m), 1168.7 (s), 1237.3 (m), 1168.7 (s), 1122.6 (s), 1100.9 (m), 1042.2 (m), 976.8 (m), 844.6 (m), 820.1 (m), 786.5 (m) 625.9 (m) cm^{-1}; and/or characterized in that the co-crystal of (rac)-tramadol.HCl and celecoxib (1:1) has an orthorhombic unit cell with the following dimensions:
a=11.0323(7) Å
b=18.1095(12) Å
c=17.3206(12) Å; and/or
characterized in that the endothermic sharp peak corresponding to the melting point of the co-crystal of (rac)-tramadol.HCl and celecoxib (1:1) has an onset at 164C°.

13. Process for the production of a pharmaceutical composition according to claim 1 comprising the steps of:

    (a) blending the co-crystal of (rac)-tramadol.HCl-celecoxib (1:1) with at least a solubility enhancer polymer according to claim 1 and optionally one or more filler, disintegrant or surfactant polymer or any combination thereof;

    (b) optionally adding at least a lubricant;

    (c) directly compressing the blend from step (a) or the lubricated blend from step (b) into a tablet; wherein said pharmaceutical composition is an oral pharmaceutical composition.

14. A pharmaceutical composition according to claim 1 for the treatment of pain.

15. The pharmaceutical composition according to claim 1, wherein the solubility enhancer polymer is selected from copovidone, povidone, polyethylene glycol and lauroyl macrogol-32 glycerides EP.

16. The pharmaceutical composition according to claim 1, wherein the solubility enhancer polymer is selected from copovidone and povidone.

17. The pharmaceutical composition according to claim 4 wherein the content of solubility enhancer polymer used in the composition lies between 8-12 weight-%.

18. The pharmaceutical composition according to claim 4 wherein the content of solubility enhancer polymer used in the composition is approximately 8 weight-%.

19. The pharmaceutical composition according to claim 5, wherein the composition is in the form of a tablet obtainable by a direct compression process.

20. The pharmaceutical composition according to claim 9, wherein the at least one further pharmaceutically acceptable excipient is selected from the group consisting of a filler, a disintegrant and/or a lubricant.

21. The pharmaceutical composition according to claim 9, wherein the pharmaceutically acceptable excipient is an insoluble filler selected from calcium phosphate, calcium carbonate or microcrystalline celluloses like MCC 102 (90 µm) and MCC 200 (200 µm) or

wherein the pharmaceutically acceptable excipient is selected from other compounds selected from silicified microcrystalline or compositions containing microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate and sodium stearyl fumarate.

22. The pharmaceutical composition according to claim 10, wherein the pharmaceutically acceptable excipient is a filler, wherein the filler is a sugar selected from xylitol, sorbitol, isomalt, erythritol, sucrose, fructose, or dextrose.

23. The pharmaceutical composition according to claim 10, wherein the pharmaceutically acceptable excipient is a filler selected from spray dried mannitol and microcrystalline cellulose.

24. The pharmaceutical composition according to claim 11, wherein the pharmaceutically acceptable excipient is a lubricant selected from stearyl fumarate and talc, and/or wherein the disintegrant is crospovidone.

25. The pharmaceutical composition according to claim 1 for the treatment of pain, wherein the pain is selected from acute pain, chronic pain, neuropathic pain, nociceptive pain, mild and severe to moderate pain, hyperalgesia, pain related to central sensitization, allodynia or cancer pain, including diabetic neuropathy or diabetic peripheral neuropathy and osteoarthritis, fibromyalgia; rheumatoid arthritis, ankylosing spondylitis, frozen shoulder or sciatica.