WHAT IS CLAIMED:

1. A compound of diclofenac-tramadol salt in 1:1 ratio.

2. The compound according to Claim 1, in a crystalline form.

3. The compound according to Claim 2, characterized by a powder X-ray diffraction pattern, having X-ray diffraction peaks at about 11.0°, 19.0°, 20.5° and 20.8° ± 0.2° 2θ.

4. A method for preparing the compound according to claim 1, comprising:

dissolving a diclofenac free acid in a first solvent to form a first solution,

dissolving tramadol in a second solvent to form a second solution,

mixing the first solution and the second solution to form a mixture, and

removing the first solvent and the second solvent from the mixture to form the pharmaceutically compound.

5. The method according to claim 4, wherein said solvents are removed by natural evaporation, vacuum condensation or drying under nitrogen.

6. The method according to claim 4, wherein the first solvent and the second solvent are selected from the group consisting of dichloromethane, ethyl acetate, methanol, ethanol, isopropyl alcohol, acetone, toluene, chloroform, dimethylformamide, dimethylacetamide, dimethylsulfoxide, methylene chloride, and acetonitrile.

7. A method for preparing the compound according to claim 1, comprising:

dissolving a diclofenac free acid and tramadol in a solvent or a solvent mixture, and

removing the solvent or the solvent mixture to form the compound.

8. The method according to claim 4, wherein said solvent or said solvent mixture is removed by natural evaporation, vacuum condensation, or drying under nitrogen.

9. The method according to claim 7, wherein said solvent or said solvent mixture is selected from the group consisting of dichloromethane, ethyl acetate, methanol, ethanol, isopropyl alcohol, acetone, toluene, chloroform, dimethylformamide, dimethylacetamide, dimethylsulfoxide, methylene chloride, acetonitrile, and a combination thereof.

10. A pharmaceutical formulation comprising the compound of claim 1 and a pharmaceutically acceptable carrier.

11. Use of an effective amount of the compound of Claim 1 for the manufacture of a medicament in treating moderate to moderately severe pain with pain intensity scale of 5-9.

12. The use of Claim 11 in treating moderately severe pain with pain intensity scale of 8-9.

13. The use of Claim 11 in treating postoperative pain after Cesarean, postoperative pain after non-Cesarean surgeries, cancer pain, osteoarthritis pain or rheumatoid arthritis pain.

14. The use of Claim 13 in treating postoperative pain after Cesarean, postoperative pain or after non-Cesarean surgeries by intramuscular injection.

15. The use of Claim 13 in treating cancer pain by oral administration.

16. The use of Claim 13 in treating osteoarthritis pain or rheumatoid arthritis pain by oral or topical administration.

Claims

1. A compound of diclofenac-tramadol salt in 1:1 molar ratio in a crystalline form, characterized by a powder X-ray diffraction pattern, having X-ray diffraction peaks at 11.0°, 19.0°, 20.5° and 20.8° ± 0.2° 2θ.

2. A method for preparing the compound according to claim 1, comprising:
dissolving a diclofenac free acid in a first solvent to form a first solution,
dissolving tramadol in a second solvent to form a second solution,
mixing the first solution and the second solution to form a mixture, removing the first solvent and the second solvent from the mixture to form an amorphous solid,
dissolving the amorphous solid in acetonitrile and heated to 75°C to form a clear solution,
cooling the clear solution to room temperature to generate a white precipitate,
collecting and drying the white precipitate to form the compound of claim 1.

3. The method according to claim 2, wherein said solvents are removed by natural evaporation, vacuum condensation, or drying under nitrogen.

4. The method according to claim 2, wherein the first solvent and the second solvent are selected from the group consisting of dichloromethane, ethyl acetate, methanol, ethanol, isopropyl alcohol, acetone, toluene, chloroform, dimethylformamide, dimethylacetamide, dimethylsulfoxide, methylene chloride, and acetonitrile.

5. A method for preparing the compound according to claim 1, comprising:
dissolving a diclofenac free acid and tramadol in a solvent or a solvent mixture,
removing the solvent or the solvent mixture to form an amorphous solid,
dissolving the amorphous solid in acetonitrile and heated to 75°C to form a clear solution,
cooling the clear solution to room temperature to generate a white precipitate,
collecting and drying the white precipitate to form the compound of claim 1.

6. The method according to claim 5, wherein said solvent or said solvent mixture is

removed by natural evaporation, vacuum condensation, or drying under nitrogen.

7. The method according to claim 6, wherein said solvent or said solvent mixture is selected from the group consisting of dichloromethane, ethyl acetate, methanol, ethanol, isopropyl alcohol, acetone, toluene, chloroform, dimethylformamide, dimethylacetamide, dimethylsulfoxide, methylene chloride, acetonitrile, and a combination thereof.

8. A pharmaceutical formulation comprising the compound of claim 1 and a pharmaceutically acceptable carrier.

9. Use of an effective amount of the compound of claim 1 for the manufacture of a medicament in treating moderate to moderately severe pain with pain intensity scale of 5-9.

10. The use of claim 9 in treating moderately severe pain with pain intensity scale of 8-9.

11. The use of claim 9 in treating postoperative pain after Cesarean, postoperative pain after non-Cesarean surgeries, cancer pain, osteoarthritis pain, or rheumatoid arthritis pain.

12. The use of claim 11 in treating postoperative pain after Cesarean or postoperative pain after non-Cesarean surgeries by intramuscular injection.

13. The use of claim 11 in treating cancer pain by oral administration.