CLAIMS

1. A pharmaceutical composition in a solid oral dosage form, comprising:

i) a combination of the two active pharmaceutical ingredients, dexketoprofen as a salt with organic or inorganic bases and tramadol as a salt with organic or inorganic acids, wherein:

- the organic or inorganic base is selected from the group consisting of trometamol, trimethylamine, dimethylamine, ethylamine, trimethylamine, diethylamine, L-lysine, L-arginine, diethanolamine, sodium hydroxide,
- the organic or inorganic acid is selected from the group consisting of hydrochloric, hydrobromic, phosphoric, sulfuric, methanesulfonic, benzenesulfonic, toluenesulfonic, acetic, propionic, malic, maleic, succinic, citric, L-tartaric, lactic, malonic, aspartic, glutamic;

ii) a filler which is microcrystalline cellulose;

iii) a binder selected from the group consisting of maize starch, maize starch pre-gelatinized and hypromellose, or mixtures thereof;

iv) a pharmaceutically acceptable excipient,

wherein all the components of the composition are in physical contact.

2. A pharmaceutical composition according to claim 1, wherein the two active ingredients form a homogeneous mixture in which said active ingredients are intimately mixed.

3. A pharmaceutical composition according to claim 1, wherein the organic base is trometamol and the inorganic acid is hydrochloric acid.

4. A pharmaceutical composition according to claim 1, wherein said pharmaceutical excipient is selected from disintegrant, lubricant and glidant.

5. A pharmaceutical composition according to claims 1-4, containing a mixture of the two active ingredients in a weight ratio of dexketoprofen to tramadol from 2:1 to 1:10, equivalent to a weight ratio of dexketoprofen trometamol to tramadol

hydrochloride from 2.59:1 to 1:7.7.

6. A pharmaceutical composition according to claim 5, containing a mixture of the two active ingredients in a weight ratio of dexketoprofen to tramadol from 1:1 to 1:6, equivalent to a weight ratio of dexketoprofen trometamol to tramadol hydrochloride from 1.3:1 to 1:4.63.

7. A pharmaceutical composition according to claims 1-4 containing the two active ingredients, dexketoprofen and tramadol or salts thereof, in the following amounts for each oral dosage unit:

- dexketoprofen from 8 to 50 mg, equivalent to dexketoprofen trometamol from 11.8 to 73.8 mg;
- tramadol from 17.6 to 105.4 mg, equivalent to tramadol hydrochloride from 20 to 120 mg.

8. A pharmaceutical composition according to claim 7, containing the two active ingredients, dexketoprofen and tramadol or salts thereof, in the following amounts, for each oral dosage unit:

- dexketoprofen from 10 to 30 mg, equivalent to dexketoprofen trometamol from 14.8 to 44.29 mg;
- tramadol from 26.3 to 87.8 mg, equivalent to tramadol hydrochloride from 30 to 100 mg.

9. A pharmaceutical composition according to claims 1-8, containing the two active ingredients, dexketoprofen and tramadol or salts thereof, in the following specific amounts for each oral dosage unit:

- dexketoprofen 12.5 mg or 25 mg, equivalent to dexketoprofen trometamol 18.45 mg or 36.95 mg;
- tramadol 32.9 mg or 65.9 mg, equivalent to tramadol hydrochloride 37.5 mg or 75 mg.

10. A pharmaceutical composition according to claims 1-9, wherein microcrystalline

cellulose is in a concentration range from 45 to 75% by weight of the total amount.

11. A pharmaceutical composition according to claims 1-10, wherein the binder is selected from the group consisting of maize starch, maize starch pre-gelatinized and hypromellose or mixtures thereof, in amounts from 5% to 20%, preferably from 7% to 12% by the total weight of the composition.

12. A pharmaceutical composition according to claims 1-11, wherein the disintegrant is selected from croscarmellose sodium and sodium starch glycolate or mixtures thereof, in amounts from 4% to 14% by the total composition weight.

13. A pharmaceutical composition according to claims 1-12, wherein the dissolution of the two active ingredients, dexketoprofen and tramadol, occurs in a time range not higher than 15 minutes, preferably between 3 and 11 minutes.

14. A pharmaceutical composition according to claims 1 to 13, wherein the dissolution rate and the purity profile of the components remain unchanged during shelf-life of 18 months at (25 ± 2)°C and (60 ± 5)% relative humidity in aluminium - aluminium and PVC/PVDC packages.

15. A pharmaceutical composition according to claims 1-14, which is in the form of tablet for immediate release of the active principles.

16. A pharmaceutical composition according to claim 15, wherein said tablet comprises a hypromellose based outer film coating.

17. A pharmaceutical composition according to claim 15, comprising a polyvinyl alcohol based outer film coating.

18. A pharmaceutical composition according to claims 1-14, which is in the form of a capsule for the immediate-release of both active principles.

19. A pharmaceutical composition according to claims 1-18, for use in the treatment of acute pain related to the following conditions: headache, toothache, inflammations and migraine.

20. A method of manufacturing a pharmaceutical composition in accordance with claims 1 to 18, said method comprising fluid bed granulation and fluid bed drying of a mixture of active principles and excipients.

21. Use of a pharmaceutical composition according to claims 1-14 in the manufacture of a medicament for the treatment of acute pain related to the following conditions: headache, toothache, inflammations and migraine.