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 trometamol, lysine or arginine and tramadol hydrochloride or hydrobromide;
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 said pharmaceutical excipient is selected from disintegrant, lubricant and glidant.

4. A pharmaceutical composition according to claims 1-3, 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.

5. A pharmaceutical composition according to claim 4, 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.

6. A pharmaceutical composition according to claims 1-3 containing the two active ingredients 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.

7. A pharmaceutical composition according to claim 6, containing the two active ingredients 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.

8. A pharmaceutical composition according to claims 1-7, containing the two active ingredients 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.

9. A pharmaceutical composition according to claims 1-8, wherein microcrystalline cellulose is in a concentration range from 45 to 75% by weight of the total amount.

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

11. A pharmaceutical composition according to claims 1-10, further comprising a disintegrant, 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.

12. A pharmaceutical composition according to claims 1-11, 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.

13. A pharmaceutical composition according to claims 1 to 12, 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.

14. A pharmaceutical composition according to claims 1-13, which is in the form of tablet for immediate release of the active principles.

15. A pharmaceutical composition according to claim 14, wherein said tablet comprises a hypromellose based outer film coating.

16. A pharmaceutical composition according to claim 14, comprising a polyvinyl alcohol based outer film coating.

17. A pharmaceutical composition according to claims 1-13, which is in the form of a capsule for the immediate-release of both active principles.

18. A pharmaceutical composition according to claims 1-17, for use in the treatment of acute pain related to the following conditions: headache, toothache, inflammations and migraine.

19. A method of manufacturing a pharmaceutical composition in accordance with claims 1 to 17, said method comprising fluid bed granulation and fluid bed drying of a mixture of active principles and excipients.

20. Use of a pharmaceutical composition according to claims 1-13 in the manufacture of a medicament for the treatment of acute pain related to the following conditions: headache, toothache, inflammations and migraine.