CLAIMS

1. Co-crystal of Ketoprofen Lysine Form 1 characterized by having an X ray diffraction pattern with characteristic peaks at 16.3; 17.5; 17.6; 17.7; 19.6; 19.7° 2theta ± 0.20 degrees and wherein the molecular ratio between Ketoprofen and Lysine is 1:1.

2. The co-crystal according to claim 1, characterized by having a X ray diffraction pattern as represented in Figure 4.

3. The co-crystal according to claim 1 or 2, wherein said co-crystal is selected from the group consisting of: (R)-2-(3-benzoylphenyl)-propionic acid D-Lysine, (R)-2-(3-benzoylphenyl)-propionic acid L-Lysine, (S)-2-(3-benzoylphenyl)-propionic acid D-Lysine and (S)-2-(3-benzoylphenyl)-propionic acid L-Lysine.

4. The co-crystal according to any one of claims 1 to 3 having a particle size distribution with a D90 lower than 300 µm, preferably lower than 250 µm, more preferably lower than 200 µm.

5. A pharmaceutical composition comprising the co-crystal of any one of the preceding claims and one or more physiologically acceptable excipients.

6. The pharmaceutical composition according to claim 5, wherein said excipients are selected from the group consisting of:
povidone, colloidal silica, hydroxypropylmethylcellulose, eudragit EPO, sodium dodecyl sulfate, stearic acid, magnesium stearate, aspartame, mannitol, xylitol, talc, flavors.

7. The pharmaceutical composition of claim 5 or 6, wherein said pharmaceutical composition is in solid granulate form.

8. A pharmaceutical composition comprising the co-crystal of Ketoprofen Lysine Form 1 according to any one of claims 1 to 4 in combination with one or more pharmaceutically active agents.

9. The co-crystal of Ketoprofen Lysine Form 1 and the pharmaceutical composition of any one of the preceding claims for use as a medicament.

10. Use of the co-crystal and the pharmaceutical composition of any one of claims 1 to 8, in the manufacture of a medicament for the treatment of pain and inflammation diseases.

11. The use according to claim 10, wherein said pain is selected from the group consisting of: acute pain, headache, toothache, menstrual pain, muscle pain, osteoarticular pain.

12. The use according to claim 10, wherein said inflammation diseases is selected from the group consisting of rheumatitis disease.

13. A process for the production of co-crystal of Ketoprofen Lysine Form 1 comprising the step of:

a) preparing a saturated solution of Ketoprofen wherein the solvent used for the saturated solution of Ketoprofen is selected form the group consisting of: alcohols, ethers, esters, amides, ketones, aromatic solvents, halogenated solvents and aprotic dipolar solvents,

b) mixing the saturated solution with Lysine,

wherein the equivalent ratio between Ketoprofen in the saturated solution and Lysine is from 10:1 to 1:1;

or

a_1) preparing a saturated solution of Lysine in water,

b_1) mixing the saturated solution with Ketoprofen,

wherein the equivalent ratio between saturated Lysine and Ketoprofen is 3:1 or higher, and

wherein said mixing step b) or b_1) is carried out a temperature from 15°C to 30°C, for 10 to 72 hours.

14. The process according to claim 13, wherein the equivalent ratio between saturated Ketoprofen and Lysine is 3:1 or higher.

15. The process according to claim 13, comprising the steps a) and b), wherein the equivalent ratio between Ketoprofen in the saturated solution and Lysine is from 3:1 to 1:1.

16. The process according to claim 13, comprising the steps a) and b), wherein the ratio between the amount of Lysine by weight (mg) and the volume (ml) of the saturated solution of Ketoprofen is comprised between 1 mg/ml and 90 mg/ml, preferably from 4 mg/ml to 70 mg/ml, more preferably from 5 mg/ml to 60 mg/ml.

17. The process according to any one of claims 13 to 16, wherein the solvent used for the saturated solution is selected from the groups of:

- alcohols, wherein said alcohols are selected from the group consisting of: ethanol, methanol, 1-butanol, 1-propanol, 2-butanol, 2-propanol, 1-pentanol and benzyl alcohol;
- ethers, wherein said ethers are selected from the group consisting of: 1,4-dioxane, tetrahydrofuran;
- esters, wherein said esters are selected from the group consisting of: ethyl acetate, methyl acetate, propyl acetate;
- amides, wherein said amides are selected from the group consisting of: N,N, dimethylacetamide, 1-methyl-2-pirrolidone;
- ketones, wherein said ketones are selected from the group consisting of: acetone, cyclopentanone, 4-Methyl-2-Pentanone.
- aromatic solvents, wherein said aromatic solvents are selected from the group consisting of: toluene, benzonitrile, p-xylene;
- halogenated solvents, wherein said halogenated solvents are selected from the group consisting of: dichloromethane, 1,2-dichloroethane and chloroform; or
- aprotic dipolar solvents, wherein said aprotic dipolar solvents are selected from the group consisting of: dimethylsulphoxide, acetonitrile, and their admixtures.

18. The process according to any one of claims 13 to 17, wherein said mixing step b) or b_1) is carried out at room temperature for 24 hours.