

CLAIMS

1. Co-crystal of Ketoprofen Lysine (Form 4) characterized by having an X ray diffraction pattern with characteristic peaks at 13.6; 16.0; 16.5; 17.3; 19.1; 19.4; 20.5; 21.8; 22.9; 23.5; 24.9; 25.9; 27.6° 2theta $\pm$ 0.20 degrees.
- 5 2. The co-crystal according to claim 1, characterized by having a X ray diffraction pattern as represented in Figure 2.
3. The co-crystal according to claim 1 or 2, wherein the molecular ratio between Ketoprofen and Lysine is 1:1.
4. The co-crystal according to any one of claims 1 to 3, characterized by an
10 endothermic peak at 158.8°C $\pm$ 2°C measured by DSC according to the method reported in the description.
5. The co-crystal according to any one of claims 1 to 4, characterized by a particle size distribution wherein D90 is lower than 220 μ m, preferably lower than 150 μ m, measured according to the method reported in the description.
- 15 6. A pharmaceutical composition comprising the co-crystal of Ketoprofen Lysine (Form 4) of any one of the preceding claims and at least a physiologically acceptable excipient.
7. The pharmaceutical composition according to claim 6, wherein said excipients are selected from the group consisting of: povidone, colloidal silica,
20 hydroxypropylmethylcellulose, eudragit EPO, sodium dodecyl sulfate, stearic acid, magnesium stearate, aspartame, mannitol, xylitol, talc, flavors.
8. The pharmaceutical composition of claims 6 or 7, wherein said pharmaceutical composition is in solid granulate form.

9. A pharmaceutical composition comprising the co-crystal of Ketoprofen Lysine (Form 4) according to any one of claims 1 to 5 in combination with at least another pharmaceutically active ingredient.
10. The co-crystal of Ketoprofen Lysine (Form 4) of any one of claims 1 to 5 and the
5 pharmaceutical composition of any one of claims 6 to 9 for use as a medicament.
11. The co-crystal and the pharmaceutical composition for use according to claim 10, wherein said use is in the treatment of pain and inflammation diseases.
12. The co-crystal and pharmaceutical composition for use according to claim 11, wherein said pain is selected from the group consisting of: acute pain, headache,
10 toothache, menstrual pain, muscle pain, osteoarticular pain.
13. The co-crystal and pharmaceutical composition for use according to claim 11, wherein said inflammation diseases is selected from the group consisting of rheumatitis disease.
14. A process for the preparation of the co-crystal of Ketoprofen Lysine (Form 4),
15 wherein said process comprises the following steps:
- a) preparing a non-saturated solution of Ketoprofen in a solvent selected from 2-methyl -1- propanol and ethyl acetate;
- b) mixing the non-saturated solution of Ketoprofen with solid lysine to provide an admixture.
- 20 15. The process according to claim 14, wherein the non-saturated solution of step a) has a concentration of Ketoprofen from 50 to 150 mg/ml, preferably from 70 to 120 mg/m, more preferably from 80 to 100 mg/ml.
16. The process according to claim 14 or 15 wherein the molar ratio Ketoprofen : Lysine is from 1.5:1 to 3.5:1, more preferably from 2:1 to 3:1.

17. The process according to any one of claims 14 to 16, wherein the admixture obtained at step b) has a water content from 0.3 to 1.5% (v/v), more preferably from 0.8% to 1.1 % (v/v).

18. The process according to any one of claims 14 to 17, wherein the solvent of step
5 a) is 2-methyl -1- propanol.