CLAIMS

1. Crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate characterized by an X-ray diffraction pattern (XRPD) with peaks at 7.9, 18.3, 19.8, 23.8 and 25.5° 2-theta ± 0.2 degrees 2-theta.

2. The crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of claim 1 having a water content from 5.0% to 6.3% by weight, preferably from 5.0% to 5.5% by weight, more preferably from 5.0% to 5.3% by weight, measured by Karl Fischer method.

3. The crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of claim 1 or 2 characterized by an X-ray diffraction pattern (XRPD) with further peaks at 9.3, 15.5, 22.1, 22.3, 23.0 and 24.6° 2-theta ± 0.2 degrees 2-theta.

4. The crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of any one of the previous claims characterized by one or more of the following powder properties:
- particle size distribution of D(0.1) = 2 - 2.5 µm, D(0.5) = 6.5 - 8.5 µm, D(0.9) = 20 - 30 µm, measured by Malvern Mastersizer 3000 using Aero S accessory;
- bulk density from 0.17 to 0.20 g/ml, measured according to Ph. Eur. 2.9.34;
- tapped density from 0.19 g/ml to 0.28 g/ml, measured according to Ph. Eur. 2.9.34;
- compressibility index from 23 to 33;
- Hausner ratio lower than 1.50.

5. A composition comprising, consisting essentially of or consisting of the crystalline monohydrate according to any one of claims 1 to 4.

6. The composition of claim 5 with a content of (2S)-2-(4-{[4-hydroxy-4-(trifluoromethyl)-4,5-dihydro-1,3-thiazol-2-yl]amino}phenyl)propanoic acid lower than 0.5%, preferably lower than 0.2%, more preferably lower than 0.1% determined by HPLC method according to the description.

7. A process for the preparation of crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate comprising:

i) providing anhydrous sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate; and

ii) exposing it to an atmosphere having a Relative Humidity (R.H.) higher than 60% and lower than 80% by weight, at a temperature from 25°C to 40°C and at atmospheric pressure, preferably for a time from 12 to 72 hours, thus providing crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate.

8. The process of claim 7 wherein the atmosphere R.H. is from 65% to 75% by weight.

9. The process of claim 7 or 8 wherein the temperature is from 25°C to 30°C and, preferably, the time is from 24 to 72 hours.

10. The process of any one of claims 7 to 9 wherein the anhydrous sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of step i) is prepared according to the process of claim 11 or 12.

11. A process for the preparation of anhydrous sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate comprising:

- providing a solution of (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoic acid in a solvent selected among ethyl acetate, isobutyl acetate, propyl acetate and admixtures thereof, in which the concentration of the acid in the solution is from 0.08 to 0.12 Kg/l,
- adding to the solution a sodium base in a molar ratio compared to the acid from 0.9:1 to 0.95:1, thus providing an admixture,
- adding to the admixture an anti-solvent selected among toluene, m-xylene, p-xylene and admixtures thereof, the anti-solvent being in a volumetric ratio compared to the solvent from 0.4:1 to 0.6:1, thus precipitating anhydrous sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate.

12. The process of claim 11 wherein:

- the concentration of the (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoic acid in the solution is from 0.09 to 0.11 Kg/l;
- the solvent is isobutyl acetate;
- the sodium base is sodium hydroxide, preferably aqueous sodium hydroxide;
- the anti-solvent is toluene;
- the volumetric ratio of the anti-solvent compared to the solvent is around 0.5:1; and

- the precipitation is carried out by cooling at temperatures lower than 20°C, preferably lower than 10°C.

13. A pharmaceutical composition comprising a therapeutically effective amount of crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of any one of claims 1 to 4 and at least a pharmaceutically acceptable excipient.

14. Crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of any one of claims 1 to 4, for use as a medicament.

15. Use of the crystalline monohydrate sodium (2S)-2-(4-{[4-(trifluoromethyl)-1,3-thiazol-2-yl] amino} phenyl) propanoate of any one of claims 1 to 4, in the manufacture of a medicament for the prevention or treatment of an acute or chronic inflammatory-mediated disease, inflammatory and post-operative pain, interstitial cystitis (IC)/ bladder pain syndrome (BPS) and/or cancer.