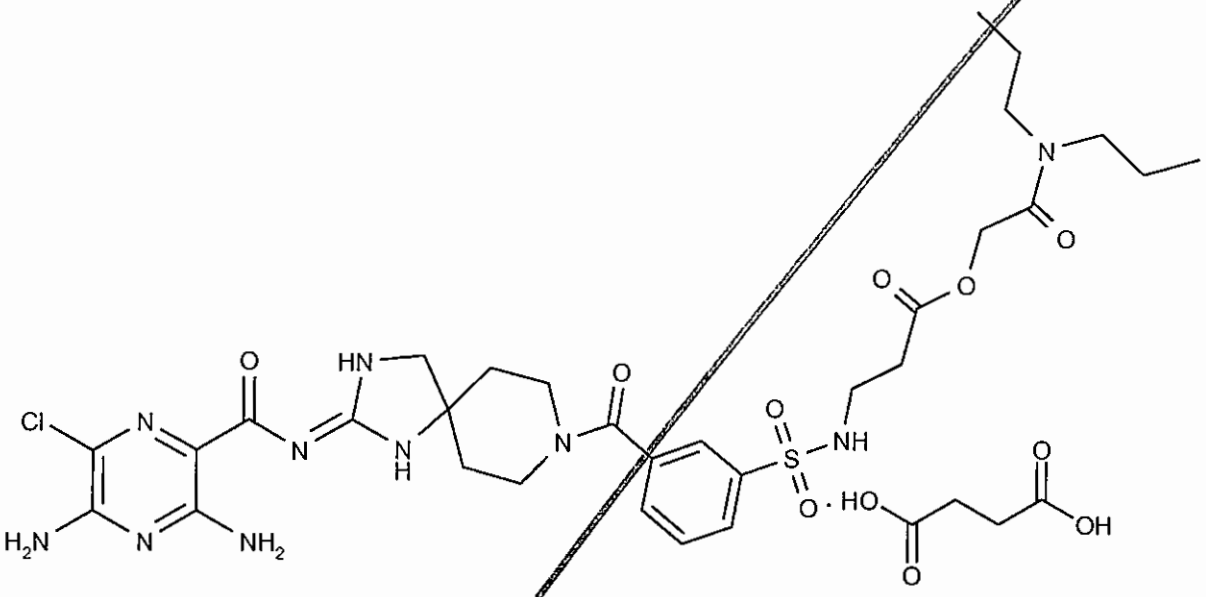
Claims

1. A crystalline form of 3-(3-{2-[(E)-3,5-Diamino-6-chloro-pyrazine-2-carbonylimino]-1,3,8-triaza-spiro[4.5]decane-8-carbonyl}-benzenesulfonylamino)-propionic acid dipropylcarbamoylmethyl ester succinate of formula



comprising Form C.

2. The crystalline form according to claim 1 consisting essentially of Form C.

3. The crystalline form according to claim 1 or 2, wherein said Form C is in substantially pure form.

4. The crystalline form according to any one of claims 1 to 3, characterized by an x-ray powder diffraction pattern comprising four or more 2-theta values selected from the group of 7.0°±0.2, 10.6°±0.2, 14.3°±0.2,18.2°±0.2, 18.6°±0.2, 19.2°±0.2, 21.2°±0.2, 21.8°±0.2, 24.7°±0.2, 29.0°±0.2 and 31.5°±0.2 at a temperature of 21-26°C °C.

5. The crystalline form according to any one of claims 1 to 3, characterized by an x-ray powder diffraction pattern comprising six or more 2-theta values selected from the group of 7.0°±0.2, 10.6°±0.2, 14.3°±0.2,18.2°±0.2, 18.6°±0.2, 19.2°±0.2, 21.2°±0.2, 21.8°±0.2, 24.7°±0.2, 29.0°±0.2 and 31.5°±0.2 at a temperature of 21-26°C °C.

6. A crystalline form according to claim 1, wherein the x-ray powder diffraction spectrum is substantially the same as the x-ray powder diffraction spectrum shown in Figure 7.

7. A crystalline form according to claim 1, wherein the differential scanning calorimetry thermogram is substantially the same as that shown in Figure 8.

8. A pharmaceutical composition comprising the crystalline form according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier or diluent.

9. A pharmaceutical composition according to claim 8 in combination with one or more additional active ingredients.

10. A pharmaceutical composition according to claim 8 or 9, which is in inhalable form.

11. A crystalline form according to any one of claims 1 to 7 for use in the treatment of respiratory diseases, such as cystic fibrosis, primary ciliary dyskinesia, chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, respiratory tract infections (acute and chronic; viral and bacterial) and lung carcinoma.

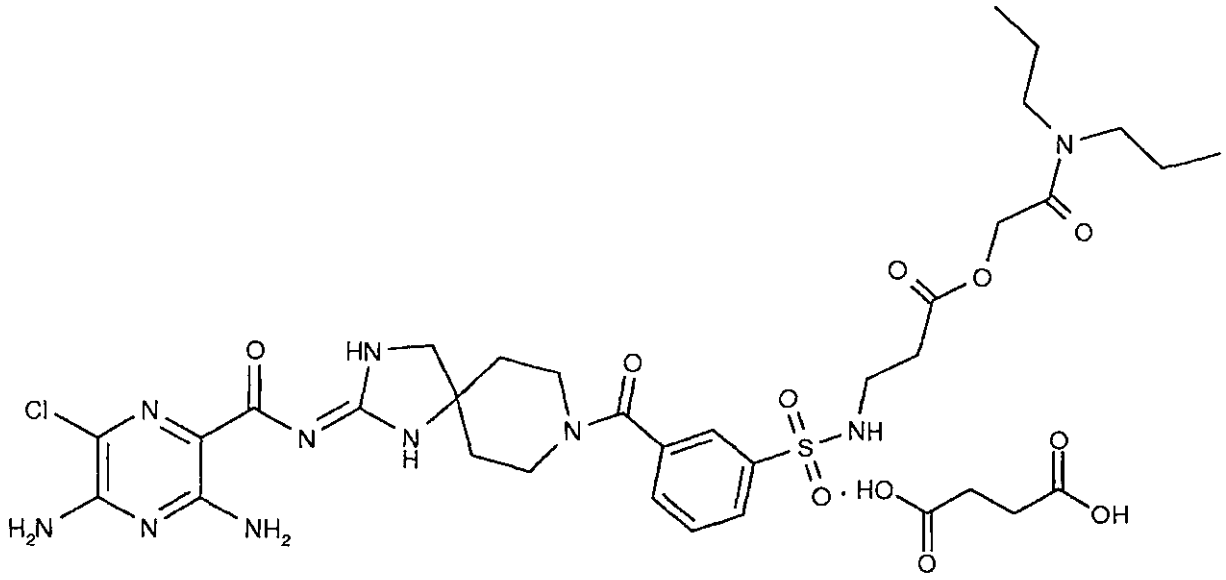
12. Use of a crystalline form according to any one of claims 1 to 7 in the manufacture of a medicament for the treatment of respiratory diseases, such as cystic fibrosis, primary ciliary dyskinesia, chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, respiratory tract infections (acute and chronic; viral and bacterial) and lung carcinoma.

13. A method of treating respiratory diseases, such as cystic fibrosis, primary ciliary dyskinesia, chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, respiratory tract infections (acute and chronic; viral and bacterial) and lung carcinoma comprising administering to a patient in need thereof an effective amount of a crystalline form according to any of claims 1 to 7.

14. An inhalation device that contains and is adapted to deliver a crystalline form according to any one of claims 1 to 7 by pulmonary administration.

Claims

1. A crystalline form of 3-(3-{2-[(E)-3,5-Diamino-6-chloro-pyrazine-2-carbonylimino]-1,3,8-triaza-spiro[4.5]decane-8-carbonyl}-benzenesulfonylamino)-propionic acid dipropylcarbamoylmethyl ester succinate of formula



comprising Form C, wherein said Form C is in substantially pure form, being **characterized by** an x-ray powder diffraction pattern comprising four or more 2-theta values selected from the group of 7.0°±0.2, 10.6°±0.2, 14.3*±0.2,18.2*±0.2, 18.6°±0.2, 19.2°±0.2, 21.2°±0.2, 21.8°±0.2, 24.7°±0.2, 29.0°±0.2 and 31.5°±0.2 at a temperature of 21-26°C °C.

2. The crystalline form according to claim 1, **characterized by** an x-ray powder diffraction pattern comprising six or more 2-theta values selected from the group of 7.0°±0.2, 10.6°±0.2, 14.3°±0.2,18.2°±0.2, 18.6°±0.2, 19.2°±0.2, 21.2°±0.2, 21.8°±0.2, 24.7-±0.2, 29.0°±0.2 and 31.5°±0.2 at a temperature of 21-26°C °C.

3. A crystalline form according to claim 1, wherein the x-ray powder diffraction spectrum is substantially the same as the x-ray powder diffraction spectrum shown in Figure 7.

4. A crystalline form according to claim 1, wherein the differential scanning calorimetry thermogram is substantially the same as that shown in Figure 8.

5. A pharmaceutical composition comprising the crystalline form according to any one of claims 1 to 4 and a pharmaceutically acceptable carrier or diluent.

6. A pharmaceutical composition according to claim 5 in combination with one or more additional active ingredients.

7. A pharmaceutical composition according to claim 5 or 6, which is in inhalable form.

8. A crystalline form according to any one of claims 1 to 4 for use in the treatment of respiratory diseases, such as cystic fibrosis, primary ciliary dyskinesia, chronic bronchitis, chronic obstructive pulmonary disease (COPD), asthma, respiratory tract infections (acute and chronic; viral and bacterial) and lung carcinoma.

9. Use of a crystalline form according to any one of claims 1 to 4 in the manufacture of a medicament for the treatment of respiratory diseases, such as cystic fibrosis, primary ciliary dyskinesia, chronic bronchitis, chronic obstructive

pulmonary disease (COPD), asthma, respiratory tract infections (acute and chronic; viral and bacterial) and lung carcinoma.

10. An inhalation device that contains and is adapted to deliver a crystalline form according to any one of claims 1 to 4 by pulmonary administration.