CLAIMS

1. A process for providing crystals of desired size distribution and morphology, the process comprising:

providing recrystallized columnar crystals having aspect ratios of larger than 1 and less than 20, the aspect ratio of a given columnar crystal being the ratio of a longest dimension along a lengthwise axis relative to a shortest dimension of a transverse plane perpendicular to the lengthwise axis; and

sizing the recrystallized columnar crystals to provide a collection of sized crystals having target dimensions, wherein the sizing includes segmenting at least a portion of the recrystallized columnar crystals along the respective lengthwise axes while retaining the dimensions of the transverse plane perpendicular to the lengthwise axis, wherein the crystals are crystals of fluticasone propionate.

2. The process of claim 1 wherein the recrystallized columnar crystals further meet one or more of the following criteria:

(i) 90% of the recrystallized columnar crystals by mass are no larger than 1200 microns;

(ii) 50% of the recrystallized columnar crystals by mass are less than 350 ± 180 microns;

(iii) no more than 10% of the recrystallized columnar crystals by mass are less than 50 microns; and

(iv) 75% or more of a total amount by volume of the recrystallized columnar crystals have an aspect ratio of 1-5.

3. The process of claim 1 wherein the recrystallized columnar crystals further meet one or more of the following criteria:

(i) 50% of the recrystallized columnar crystals by mass are in the range of 80 to 600 microns;

(ii) 75% of the recrystallized columnar crystals by mass are in the range of 50 to 800 microns; and

(iii) 90% of the recrystallized columnar crystals by mass are in the range of 20 to 1100 microns.

4. The process of claim 1 wherein the collection of the sized crystals meet one or more of the following target dimensions:

(i) 90% of the sized crystals by mass are no larger than 190 microns;

(ii) 50% of the sized crystals by mass are less than 90 ± 20 microns;

(iii) no more than 10% the sized crystals by mass are less than 30 microns;

(iv) 75% or more of a total amount by volume of the sized crystals have an aspect ratio of 1-3.

5. The process of claim 1 wherein the collection of the sized crystals meet one or more of the following target dimensions:

(i) 50% of the sized crystals by mass are in the range of 35 to 130 microns;

(ii) 75% of the sized crystals by mass are in the range of 30 to 145 microns; and

(iii) 90% of the sized crystals by mass are in the range of 25 to 170 microns.

6. The process of any one of claims 1-5 wherein the sizing comprises shortening the lengthwise axes of the recrystallized columnar crystals in a rotor/stator homogenizer to provide shortened crystals.

7. The process of claim 6 wherein the sizing further comprising sieving the shortened crystals to provide sieved crystals.

8. The process of claim 7 wherein the sieved crystals are rinsed one or more times with a rinsing liquid comprising a surfactant and one or more solvents selected from the group consisting of water, methanol, ethanol, and isopropanol.

9. The process of claim 8 wherein the rinsing liquid comprises 0.05-1% (w/w) of polysorbate 80.

~~10. The process of any one of claims 1-9 wherein the crystals are crystals of a pharmaceutically active ingredient (API).~~

~~11. The process of any one of claims 1-9 wherein the crystals are crystals of fluticasone propionate.~~

~~12~~10. The process of any one of claims ~~1-11~~1-9 wherein the sized crystals are further individually coated with a polymer membrane by a fluid bed coating equipment.

~~13~~11. The process of claim ~~12~~ 10 wherein the polymer membrane is formed of polyvinyl alcohol, polylactic acid (PLA), polylactic-co-glycolic acid (PLGA), polycaprolactone (PCL), poly(trimethylene carbonate) (pTMC) or a combination thereof.