CLAIMS

1. A continuous process for preparing a tablet comprising Compound 1 (3-(6-(1-(2,2-difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxamido)-3-methylpyridin-2-yl)benzoic acid) Form I and a solid dispersion comprising substantially amorphous Compound 2 (N-(5-hydroxy-2,4-ditert-butyl-phenyl)-4-oxo-1H-quinoline-3-carboxamide) comprising the steps of:

a) mixing Compound 1 Form I, a solid dispersion comprising substantially amorphous Compound 2, a filler, and a disintegrant in a blender to form a blend;

b) preparing a granulation solution with water, a binder, and a surfactant;

c) feeding the blend from step a) into a continuous twin screw granulator while adding the granulation solution from step b) to produce granules;

d) drying the granules from step c) and milling them;

e) blending the milled granules from step d) with a filler, disintegrant, and lubricant to form a blend; and

f) compressing the blend from step e) into a tablet;

wherein at least one of the above steps comprises process analytical technology.

2. The process of claim 1, wherein step a) comprises process analytical technology, wherein the process analytical technology is NIR spectroscopy for monitoring blend uniformity.

3. The process of claim 1 or claim 2, wherein step b) comprises process analytical technology.

4. The process of any of claims 1-3, wherein step c) comprises process analytical technology.

5. The process of any of claims 1-4, wherein step d) comprises process analytical technology, wherein the process analytical technology is NIR spectroscopy for monitoring granule uniformity and/or for monitoring moisture content, or wherein the process analytical technology is laser diffraction for monitoring particle size distribution.

6. The process of any of claims 1-5, wherein step e) comprises process analytical technology, wherein the process analytical technology is NIR spectroscopy for monitoring blend uniformity.

7. The process of any of claims 1-6, wherein step e) comprises process analytical technology, wherein the process analytical technology is NIR spectroscopy for monitoring moisture content.

8. The process of any of claims 1-7, wherein step f) comprises process analytical technology, wherein the process analytical technology is Raman spectroscopy for monitoring active pharmaceutical ingredient solid form identity.

9. The process of any of claims 1-8, wherein step f) comprises process analytical technology, where the process analytical technology is a tablet tester for monitoring the weight of the tablet.

10. The process of any of claims 1-9, wherein step f) comprises process analytical technology, wherein the process analytical technology is a tablet tester for monitoring thickness of the tablet.

11. The process of any of claims 1-10, wherein step f) comprises process analytical technology, wherein the process analytical technology is a tablet tester for monitoring hardness of the tablet.

12. The process of any of claims 1-11, wherein the process comprises coating the tablet, and monitoring the coating thickness by Raman spectroscopic techniques.

13. The process of any of claims 1-12, wherein the process analytical technology comprises at least one of laser diffraction, a tablet tester, NIR and Raman spectroscopic techniques to monitor defined standards.

14. The process of claim 13, wherein the defined standard is selected from blend uniformity, granule uniformity, moisture, particle size distribution, active pharmaceutical ingredient solid form identity, active pharmaceutical ingredient concentration, weight, thickness, hardness, and coating thickness.

15. The process of claim 13 or 14, wherein the defined standard is monitored for real time release testing (RTRT).

16. The process of any one of claims 1-15, wherein Form I is characterised as a crystal form having a monoclinic crystal system, a $P2_1/n$ space group, and the following unit cell dimensions:

a = 4.9626 (7) Å

b = 12.299 (2) Å β = 93.938 (9)°

c = 33.075 (4) Å. and/or

wherein Form I is **characterized by** one or more peaks at 15.4 ± 0.2 degrees, 16.3 ± 0.2 degrees, and 14.5 ± 0.2 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

17. The process of claim 16, **characterized in that** Compound 1 Form I is **characterized by** one or more peaks, within one or more 2θ value ranges, selected from 15.2 to 15.6 degrees, 16.1 to 16.5 degrees, and 14.3 to 14.7 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

18. The process of claim 17, **characterized in that** Compound 1 Form I is **characterized by** a peak having a 2θ value at 15.2 to 15.6 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

19. The process of claim 18, **characterized in that** Compound 1 Form I is **characterized by** a peak having a 2θ value at 15.4 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

20. The process of claim 17, **characterized in that** Compound 1 Form I is **characterized by** a peak having a 2θ value at 16.1 to 16.5 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

21. The process of claim 20, **characterized in that** Compound 1 Form I is **characterized by** a peak having a 2θ value at 16.3 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

22. The process of claim 17, **characterized in that** Compound 1 Form I is **characterized by** a peak having a 2θ value at 14.3 to 14.7 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

23. The process of claim 22, **characterized in that** Compound 1 Form I is **characterized by** a peak having a 2θ value at 14.5 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

24. The process of claim 17, **characterized in that** Compound 1 Form I is further **characterized by** a peak having a 2θ value at 17.6 to 18.0 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

25. The process of claim 17, **characterized in that** Compound 1 Form I is further **characterized by** a peak having a 2θ value at 7.6 to 8.0 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

26. The process of any one of claims 1-15, **characterized in that** Compound 1 Form I is **characterized by** at least one peak having a 2θ value, ± 0.2 degrees, selected from 14.41 degrees; 14.64 degrees; 15.23 degrees; 16.11 degrees; 17.67 degrees; 19.32 degrees; 21.67 degrees; 23.40 degrees; 23.99 degrees; 26.10 degrees; and 28.54 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

27. The process of any one of claims 1-15, **characterized in that** Compound 1 Form I is **characterized by** at least one peak having a 2θ value, ± 0.2 degrees, selected from 7.83 degrees; 14.51 degrees; 14.78 degrees; 15.39 degrees; 16.26 degrees; 16.62 degrees; 17.81 degrees; 21.59 degrees; 23.32 degrees; 24.93 degrees; and 25.99 degrees in an X-ray powder diffraction obtained using Cu K alpha radiation.

28. The process of any one of claims 1-15, **characterized in that** Compound 1 Form I is **characterized by** the diffraction pattern of Figure 1.

29. The process of any one of claims 1-15, **characterized in that** Compound 1 Form I is **characterized by** the diffraction pattern of Figure 2.

30. The process of claim 16, **characterized in that** Compound 1 Form I is characterized as a monoclinic crystal system and a $P2_1/n$ space group, and has the following unit cell dimensions:

a = 4.9626 (7) Å

b = 12.299 (2) Å β = 93.938 (9)°

c = 33.075 (4) Å.

31. A tablet prepared by the process of any one of claims 1-30.

32. Use of the tablet of claim 31 in the manufacture of a medicament for the treatment of cystic fibrosis in a patient.

33. The use of claim 32, characterized in that the patient has a ΔF508 mutation in CFTR.

34. The use of claim 33, characterized in that the patient is homozygous for the ΔF508 mutation in CFTR.

35. The tablet of claim 31 for use in the treatment of cystic fibrosis.