What is Claimed:

1. An amorphous 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof.

2. A dosage form comprising amorphous 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof.

3. A dosage form of claim 2 comprising 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid.

4. A dosage form of claim 2 or 3 comprising 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid, having a fasted state bioavailability that exceeds 130% of a hard-gelatin capsule comprising 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide.

5. A dosage form of any one of claims 1 to 4 comprising 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid, having a fed/fasted ratio of 0.8-1.5 for AUC and/or C_{max}.

6. The dosage form of any one of claims 3 to 5, wherein said at least one organic acid is selected from acetic acid, propionic acid, octanoic acid, decanoic acid, dodecanoic acid, glycolic acid, lactic acid, fumaric acid, succinic acid, adipic acid, pimelic acid, suberic acid, azelaic acid, malic acid, tartaric acid, citric acid, glutamic acid, aspartic acid, maleic acid, hydroxymaleic acid, methylmaleic acid, cyclohexanecarboxylic acid, adamantanecarboxylic acid, benzoic acid, salicylic acid, 4-aminosalicylic acid, phthalic acid, phenylacetic acid, mandelic acid, cinnamic acid, methane- or ethane-sulfonic acid, 2-hydroxyethanesulfonic acid, ethane-1,2-disulfonic acid, benzenesulfonic acid and ascorbic acid.

7. The dosage form of claims 3, 5, or 6, wherein the organic acid is citric acid.

8. The dosage form of claims 3, 5, or 6, wherein the organic acid is lactic acid.

9. The dosage form of claims 3, 5, or 6, wherein the organic acid is acetic acid.

10. The dosage form of any one of claims 3 to 9 further comprising a surfactant or an anionic polymer.

11. The dosage form of claims 10, wherein the surfactant or the anionic polymer is CYP3A4 or Pg-P inhibitor.

12. The dosage form of claim 10 or 11, wherein the surfactant is Poloxamer 407 and/or Vitamin E TPGS.

13. The dosage form of claim 10 or 11, wherein the polymer is Eudragid L100-55.

14. The dosage form of any one of claims 1 to 13, wherein the dosage form has water content of less than 10% w/w, preferably less than 5% w/w, particularly les than 2 % w/w.

15. The dosage form of any one of claims 1 to 14 further comprising excipients for solidifying the dosage form.

16. The dosage form of any one of claims 1 to 15, wherein the dosage form is solid.

17. The dosage form of claims 16, wherein the dosage form is a tablet.

18. The dosage form of claims 16, wherein the dosage form is a capsule.

19. A method for preparing amorphous 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof, comprising the step of adding at least one organic acid.

20. A method for preparing a dosage form comprising amorphous 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid, comprising the step of melt extruding 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and the at least one organic acid.

21. A method of claim 20, wherein 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid are mixed and melt extruded together.

22. A method of preparing a dosage form comprising 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid comprising the step of spray drying at least partly dissolved of 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and adding the at least one organic acid.

23. The method of claim 22, wherein the 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and the at least one organic acid together are in a solution or suspension for spray drying.

24. The method of any one of claims 20 to 23 further comprising a step of adding a surfactant or an anionic polymer.

25. The method of claim 24, wherein the surfactant or the anionic polymer is CYP3A4 or Pg-P inhibitor.

26. The method of claim 24 or 25, wherein the surfactant is Poloxamer 407 and/or Vitamin E TPGS.

27. The method of claim 24 or 25, wherein the polymer is Eudragid L100-55.

28. The method of any one of claims 20 to 27 comprising a further step of obtaining a solid dosage form.

29. The method of claim 28, wherein the solid dosage form is a tablet or a capsule.

30. Use of organic acid for increasing of bioavailability of nilotinib.

31. Use of organic acid for supressing the food effect associated with pharmaceutical composition comprising nilotinib or a pharmaceutically acceptable salt thereof.

32. A dosage form of any one of claims 1 to 20 for use as a medicine.

33. The dosage form of claim 32, wherein the medicine is stored under refrigeration at 2 to 8°C.

Claims

1. A dosage form comprising amorphous 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof, having a fed/fasted ratio of 0.8-1.5 for AUC and/or C_{max}.

2. A dosage form of claim 1 which has a fasted state bioavailability that exceeds 130% of a hard-gelatin capsule comprising 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide.

3. The dosage form of any one of claims 1 or 2, wherein said at least one organic acid is selected from acetic acid, propionic acid, octanoic acid, decanoic acid, dodecanoic acid, glycolic acid, lactic acid, fumaric acid, succinic acid, adipic acid, pimelic acid, suberic acid, azelaic acid, malic acid, tartaric acid, citric acid, glutamic acid, aspartic acid, maleic acid, hydroxylmaleic acid, methylmaleic acid, cyclohexanecarboxylic acid, adamantanecarboxylic acid, benzoic acid, salicylic acid, 4-aminosalicylic acid, phthalic acid, phenylacetic acid, mandelic acid, cinnamic acid, methane- or ethane-sulfonic acid, 2-hydroxyethanesulfonic acid, ethane-1,2-disulfonic acid, benzenesulfonic acid and ascorbic acid.

4. The dosage form of claims 3, wherein the organic acid is citric acid.

5. The dosage form of claims 3, wherein the organic acid is lactic acid.

6. The dosage form of claims 3, wherein the organic acid is acetic acid.

7. The dosage form of any one of claims 1 to 6 further comprising a surfactant or an anionic polymer.

8. The dosage form of claims 7, wherein the surfactant or the anionic polymer is a CYP3A4 or Pg-P inhibitor.

9. The dosage form of claim 7 or 8, wherein the surfactant is Poloxamer 407 and/or Vitamin E TPGS.

10. The dosage form of claim 7 or 8, wherein the polymer is Eudragit L100-55.

11. The dosage form of any one of claims 1 to 10, wherein the dosage form has water content of less than 10% w/w, preferably less than 5% w/w, particularly less than 2 % w/w.

12. The dosage form of any one of claims 1 to 11 further comprising excipients for solidifying the dosage form.

13. The dosage form of any one of claims 1 to 12, wherein the dosage form is solid.

14. The dosage form of claims 13, wherein the dosage form is a tablet.

15. The dosage form of claims 13, wherein the dosage form is a capsule.

16. A method for preparing a dosage form comprising amorphous 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid, comprising the step of melt extruding 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and the at least one organic acid, said dosage has a fed/fasted ratio of 0.8-1.5 for AUC and/or C_{max}.

17. A method of claim 16, wherein 4-Methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-N-[5-(4-methyl-1H-imidazol-1-yl)-3-(trifluoromethyl)phenyl] benzamide or a pharmaceutically acceptable salt thereof and at least one organic acid are mixed and melt extruded together.

18. The method of any one of claims 16 or 17 further comprising a step of adding a surfactant or an anionic polymer.

19. The method of claim 18, wherein the surfactant or the anionic polymer is a CYP3A4 or Pg-P inhibitor.

20. The method of claim 18 or 19, wherein the surfactant is Poloxamer 407 and/or Vitamin E TPGS.

21. The method of claim 18 or 19, wherein the polymer is Eudragit L100-55.

22. The method of any one of claims 16 to 21 comprising a further step of obtaining a solid dosage form.

23. The method of claim 22, wherein the solid dosage form is a tablet or a capsule.

24. The use of the dosage form of any one of claims 1 to 15 as a medicine.

25. The use of claim 24, wherein the medicine is stored under refrigeration at 2 to 8°C.