**CLAIMS**

1. A pharmaceutical composition for oral administration comprising a granule particle said granule particle comprising:

(a) an inert substrate, and

(b) a mixture comprising *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, and at least one binder.

2. The pharmaceutical composition according to claim 1, wherein *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide is in a free form.

3. The pharmaceutical composition according to claims 1 or 2, wherein the (b) mixture optionally further comprises a surfactant.

4. The pharmaceutical composition according to anyone of claims 1-3, wherein the (b) mixture and optional surfactant, is layered onto the (a) inert substrate.

5. The pharmaceutical composition according to claim 4, wherein the (b) mixture and optional surfactant is layered onto the (a) inert substrate using a spray granulation method.

6. The pharmaceutical composition according to any one of claims 1-5, wherein the (a) inert substrate comprises a material which is selected from the group consisting of lactose, microcrystalline cellulose, mannitol, sucrose, starch, granulated hydrophilic fumed silica, or mixtures thereof, preferably the material, which is selected from the group consisting of lactose, mannitol, or mixtures thereof and most preferably the material is mannitol.

7. The pharmaceutical composition according to any one of claims 1-6, wherein the binder is independently selected from the group consisting of polyvinylpyrrolidone-vinyl acetate copolymer, polyvinyl pyrrolidone, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hypromellose, carboxymethyl cellulose, methyl cellulose, hydroxyethyl cellulose, carboxyethyl cellulose, carboxymethylhydroxyethyl cellulose, polyethylene glycol, polyvinylalcohol, shellac, polyvinyl alcohol-polyethylene glycol co-polymer, polyethylene–propylene glycol copolymer, or a mixture thereof, preferably the binder is polyvinylpyrrolidone-vinyl acetate copolymer.

8. The pharmaceutical composition according to any one of claims 1-7, wherein the surfactant is selected from the group consisting of sodium lauryl sulfate, potassium lauryl sulfate, ammonium lauryl sulfate, sodium lauryl ether sulfate, polysorbates, perfluorobutanesulfonate, dioctyl sulfosuccinate, or a mixture thereof, preferably the surfactant is sodium lauryl sulfate.

9. The pharmaceutical composition according to any one of claims 1-8, wherein the (b) mixture comprises *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, polyvinylpyrrolidone-vinyl acetate copolymer as a binder, and optionally sodium lauryl sulfate as a surfactant.

10. The pharmaceutical composition according to any one of claims 1-9, wherein the weight ratio between *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide or a pharmaceutically acceptable salt thereof, or a free form thereof, and the binder is about [3:1] , about [2:1] or about [1:1], or about [1:2] or about [1:3], preferably about [1:1] and more preferably about [2:1].

11. The pharmaceutical composition according to any one of claims 1-9, wherein the weight ratio of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide or a pharmaceutically acceptable salt thereof, or a free form thereof, the binder and the surfactant is [3 : 1 : 1], or about [3 : 1 : 0.5], or about [3 : 1 : 0.1], or about [2 : 1 : 1], or about [2 : 1 : 0.5], or about [2 : 1 : 0.1], or about [2 : 1 : 0.08], or about [2 : 1 : 0.05], or about [2 : 1 : 0.04], or about [2 : 1 : 0.03], or about [2 : 1 : 0.02], or about [1 : 1 : 0.5], or about [1 : 1 : 0.1], or about [1 : 1 : 0.07], or about [1 : 1 : 0.05], or about [1 : 1 : 0.04], or about [1 : 1 : 0.02], preferably, the ratio is about [2 : 1 : 1], or about [2 : 1 : 0.5], or about [2 : 1 : 0.1], or about [2 : 1 : 0.08], or about [2 : 1 : 0.05], or about [2 : 1 : 0.04], or about [2 : 1 : 0.03], or about [2 : 1 : 0.02], or about [1 : 1 : 0.5], or about [1 : 1 : 0.1], or about [1 : 1: 0.07], or about [1 : 1 : 0.05], or about [1 : 1 : 0.04], or about [1 : 1 : 0.02], or about [1:3:0.1], or about [1:3:0.2], or about [1:1.5:0.25]; more preferably, the ratio is about [2 : 1 : 1], or about [2 : 1 : 0.08], or about [2 : 1 : 0.5], or about [2 : 1 : 0.1], or about [2 : 1 : 0.05], or about [2 : 1 : 0.04], or about [2 : 1 : 0.03], or about [2 : 1 : 0.02].

12. The pharmaceutical composition according to any one of claims 1-11, wherein the binder (e.g. polyvinylpyrrolidone-vinyl acetate copolymer) is present in the (b) mixture in an amount of 25%w/w to about 100%w/w based on weight of *N*-(3-(6-amino-5-(2-(N-

methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, preferably about 50%w/w or about 100%w/w based on weight of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide or a pharmaceutically acceptable salt thereof, or a free form thereof.

13. The pharmaceutical composition according to any one of claims 1-12, wherein the (b) mixture further comprises a surfactant (e.g. Sodium lauryl sulfate) in an amount of 1%w/w to about 10%w/w based on weight of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, preferably about 4%w/w or about 5%w/w based on weight of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide or a pharmaceutically acceptable salt thereof, or a free form thereof.

14. The pharmaceutical composition according to any one of claims 1-13, wherein the particle size of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof is less than 1000 nm.

15. The pharmaceutical composition according to claim 14, wherein the particle size of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof is less than 500 nm.

16. The pharmaceutical composition according to claim 15, wherein the particle size of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof is less than 350 nm, preferably less than 250nm.

17. The pharmaceutical composition according to claim 14, wherein the particle size of *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof as measured by PCS is between about 100 nm to about 350 nm, preferably between about 110nm and about 180nm.

18. The pharmaceutical composition according to any one of claims 1-17 further comprising an external phase wherein the external phase comprises one or more pharmaceutically acceptable excipient.

19. The pharmaceutical composition according to claim 18, wherein the one or more pharmaceutically acceptable excipient is selected from a filler, a disintegrating agent, a lubricating agent, and a gliding agent.

20. The pharmaceutical composition according to claim 18 or 19 wherein the external phase comprises one or more filler selected from calcium carbonate, sodium carbonate, lactose (e.g. lactose SD), mannitol (e.g. mannitol DC), magnesium carbonate, kaolin, cellulose (e.g. microcrystalline cellulose, powdered cellulose), calcium phosphate, or sodium phosphate, or mixture thereof preferably mannitol or cellulose or mixture thereof.

21. The pharmaceutical composition according to any one of claims 18-20 wherein the external phase comprises one or more disintegrating agent selected from croscarmellose sodium, crospovidone, sodium starch glycolate, corn starch, or alginic acid, or mixture thereof.

22. The pharmaceutical composition according to any one of claims 18-21 wherein the external phase comprises one or more lubricating agent selected from magnesium stearate, sodium stearyl fumarate, stearic acid or talc or mixture thereof.

23. The pharmaceutical composition according to any one of claims 18-22 wherein the external phase comprises Mannitol and cellulose as fillers, sodium stearyl fumarate or magnesium stearate as lubricant, and croscamellose sodium or sodium carbonate as disintegrating agent.

24. The pharmaceutical composition according to any one of claims 18-23 wherein the external phase is present in a 20-50% w/w/ amount of to the total weight of the composition, preferably 40% w/w/ amount of to the total weight of the composition.

25. The pharmaceutical composition according to any one of claims 1-24, wherein the pharmaceutical composition is further formulated into a final dosage form, optionally in the presence of at least one pharmaceutically acceptable excipient, and wherein said final dosage form is a capsule, a tablet, a sachet, or a stickpack.

26. The pharmaceutical composition according to claim 25, wherein the final dosage form is a capsule or preferably a tablet.

27. The pharmaceutical composition according to claim 25 or 26, wherein the capsule is selected from hard shell capsule, hard gelatin capsule, soft shell capsule, soft gelatin capsule, plant-based shell capsule, or a mixture thereof and wherein a tablet is preferably a film coated tablet.

28. A final dosage form which is a capsule formulation comprising a pharmaceutical composition of any one of claims 1-25.

29. A final dosage form with is a tablet formulation comprising a pharmaceutical composition of any one of claims 1-25.

30. A final dosage form according to claim 29, wherein *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof is present in an amount of about 10%w/w to about 25%w/w, preferably about 19% or about 20% based on the total weight of the final dosage form.

31. A final dosage form according to claim 29 or 30, wherein a filler is present in an amount of about 20 to about 40%w/w based on the total weight of the final dosage form.

32. A final dosage form according to claim 29, 30 or 31, wherein a disintegrating agent is present in an amount of about 5%w/w to about 10%w/w, preferably about 5 or about 6% based on the total weight of the final dosage form.

33. A final dosage form according to any one of claims 29-32 wherein the inert substrate is present in an amount of about 20%w/w to about 40%w/w, preferably about 30% based on the total weight of final dosage form.

34. A final dosage form according to any one of claims 29-33 wherein the binder is present in an amount of about 5%w/w to about 25%w/w, preferably about 8 to about 12%w/w, based on the total weight of the final dosage form.

35. A final dosage form according to any one of claims 29-34 wherein a lubricant is present in an amount of about 0.1 to about 2%w/w, preferably about 0.5%w/w to about 1.5%w/w based on the total weight of the final dosage form.

36. A final dosage form according to any one of claims 29-35 wherein a surfactant is present in an amount of about 0.1%w/w to about 2.5%w/w, preferably about 0.2%w/w to about 0.8%w/w based on the total weight of the final dosage form.

37. A final dosage form according to any one of claims 29-36 comprising *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, in an amount of between about 0.5 mg to about 600 mg, e.g. about 5 mg to about 400 mg, e.g. about 10 mg to about 150 mg.

38. A final dosage form according to any one of claims 29-37 comprising *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, in an amount of about 0.5 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 50 mg, about 100 mg, about 150 mg, about 200 mg, about 250 mg, about 300 mg, about 350 mg, about 400 mg, about 450 mg, about 500 mg, or of about 600 mg, preferably in an amount of about 10mg, about 25mg, about 35mg, about 50 mg, about 75mg and about 100mg.

39. A process for preparing the pharmaceutical composition according to any one of claims 1-27, said process comprising the steps of:
    i) Mixing the (b) mixture comprising *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, at least one binder, and optionally a surfactant, in a liquid medium, and
    ii) Adding the said mixture (i) to the (a) inert substrate of the granule particles.

40. The process according to claim 39, wherein step (i) is performed in a wet milling chamber.

41. The process according to claim 39 or 40, wherein the liquid medium is an aqueous solution, e.g. purified water, preferably with a pH value between 5 and 8, and more preferably between 5 and 6.
42. The process according to any one of claims 39-41, wherein the mixture of step (i) is dispersed onto the (a) inert substrate.
43. The process according to any one of claims 39-42, wherein the process further comprises preparing the final dosage form by blending the mixture resulting from step (ii) with at least one pharmaceutically acceptable excipient.
44. The process according to claim 43, wherein the final dosage form is encapsulated or tableted.
45. The process according to claim 44, wherein the final dosage form is tableted and the resulting tablet is further film coated.
46. A process for preparing a suspension comprising mixing the (b) mixture comprising *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, at least one binder, and optionally a surfactant, with a liquid medium.
47. A suspension comprising *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, at least one binder, and optionally a surfactant, in a liquid medium.
48. The suspension according to claim 47 wherein the particle size of said suspension is less than 1000 nm, preferably less than 500nm, more preferably less than 350nm and most preferably less than 250nm.
49. The suspension according to claim 47 or 48, wherein the liquid medium is an aqueous solution, e.g. purified water, preferably with a pH value between 5 and 8, and more preferably between 5 and 6.
50. The suspension according to any one of claims 47 to 49, wherein *N*-(3-(6-amino-5-(2-(N-methylacrylamido)ethoxy)pyrimidin-4-yl)-5-fluoro-2-methylphenyl)-4-cyclopropyl-2-fluorobenzamide, or a pharmaceutically acceptable salt thereof, or a free form thereof, is present in an amount of about 10% to about 40% of the total weight of the suspension, preferably about 20% or about 25% of the total weight of the suspension.
51. The suspension according to claim 47 to 50, wherein the at least one binder is present in an amount of about 3% to about 15% of the total weight of the suspension.
52. The suspension according to claim 47 to 51, wherein the surfactant is present in an amount of about 0.05% to about 1% of the total weight of the suspension.

53. The pharmaceutical composition according to any one of claims 1-27 or the final dosage form according to claims 29-37, for use as a medicine.
54. Use of the pharmaceutical composition according to any one of claims 1-27, or the final dosage form according to claims 27-39 in the manufacture of a medicament for the treatment or prevention of a disease or disorder mediated by BTK or ameliorated by inhibition of BTK.
55. The use according to claim 54, wherein the disease or disorder mediated by BTK or ameliorated by the inhibition of BTK is selected from autoimmune disorders, inflammatory diseases, allergic diseases, airway diseases, such as asthma and chronic obstructive pulmonary disease (COPD), transplant rejection; diseases in which antibody production, antigen presentation, cytokine production or lymphoid organogenesis are abnormal or are undesirable; including rheumatoid arthritis, systemic onset juvenile idiopathic arthritis (SOJIA), gout, pemphigus vulgaris, idiopathic thrombocytopenic purpura, systemic lupus erythematosus, multiple sclerosis, myasthenia gravis, Sjögren‘s syndrome, autoimmune hemolytic anemia, anti-neutrophil cytoplasmic antibodies (ANCA)-associated vasculitides, cryoglobulinemia, thrombotic thrombocytopenic purpura, chronic urticaria (chronic spontaneous urticaria, inducible urticaria), chronic allergy (atopic dermatitis, contact dermatitis, allergic rhinitis), atherosclerosis, type 1 diabetes, type 2 diabetes, inflammatory bowel disease, ulcerative colitis, morbus Crohn, pancreatitis, glomerolunephritis, Goodpasture's syndrome, Hashimoto’s thyroiditis, Grave’s disease, antibody-mediated transplant rejection (AMR), graft versus host disease, B cell-mediated hyperacute, acute and chronic transplant rejection; thromboembolic disorders, myocardial infarct, angina pectoris, stroke, ischemic disorders, pulmonary embolism; cancers of haematopoietic origin including but not limited to multiple myeloma; a leukaemia; acute myelogenous leukemia; chronic myelogenous leukemia; lymphocytic leukemia; myeloid leukemia; non-Hodgkin lymphoma; lymphomas; polycythemia vera; essential thrombocythemia; myelofibrosis with myeloid metaplasia; and Waldenstroem disease. Preferably,the disease or disorder mediated by BTK or ameliorated by the inhibition of BTK is selected from rheumatoid arthritis; chronic urticaria, preferably chronic spontaneous urticaria; Sjögren‘s syndrome, multiple sclerosis or asthma.