CLAIMS

What is claimed is:

1. A pharmaceutical composition for oral administration comprising: N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide (Lazertinib) or a pharmaceutically acceptable salt, hydrate, or solvate thereof as an active ingredient; and a combination of (i) a cellulose derivative and (ii) a sugar or polyol as diluents, wherein the cellulose derivative and the sugar or polyol are present in the pharmaceutical composition in a weight ratio of 1:0.10 to 1:0.40.

2. The pharmaceutical composition of claim 1, wherein the cellulose derivative and the sugar or polyol are present in the pharmaceutical composition in a weight ratio of 1:0.15 to 1:0.40.

3. The pharmaceutical composition of claim 1, wherein the cellulose derivative and the sugar or polyol are present in the pharmaceutical composition in a weight ratio of 1:0.20 to 1:0.30.

4. The pharmaceutical composition of claim 1, wherein the cellulose derivative and the sugar or polyol are present in the pharmaceutical composition in a weight ratio of 1:0.20 to 1:0.25.

5. The pharmaceutical composition of any one of the preceding claims, wherein the cellulose derivative is microcrystalline cellulose.

6. The pharmaceutical composition of any one of the preceding claims, wherein the sugar or polyol is mannitol.

7. The pharmaceutical composition of claim 1, further comprising: croscarmellose sodium as a disintegrating agent.

8. The pharmaceutical composition of claim 7, wherein the croscarmellose sodium is present in a range of 2 to 3 wt%, with respect to the total weight of the composition.

9. The pharmaceutical composition of claim 1, further comprising: magnesium stearate as a lubricant.

10. The pharmaceutical composition of claim 1, further comprising croscarmellose sodium as a disintegrating agent, and magnesium stearate as a lubricant.

11. The pharmaceutical composition of any preceding claim, wherein the active ingredient is N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide mesylate.

12. The pharmaceutical composition of claim 11, wherein N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide mesylate is a crystalline form having a PXRD pattern with peaks at 5.614, 12.394, 14.086, 17.143, 18.020, 19.104, 21.585, 22.131, and 22.487°2θ ± 0.2°2θ.

13. The pharmaceutical composition of claim 11, wherein N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide mesylate is a crystalline form having a differential scanning calorimeter (DSC) thermogram with an endothermic peak at 210 to 230 °C.

14. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises 15-40 wt% of N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide mesylate; 55-80 wt% of the combination of microcrystalline cellulose and mannitol; 2-3 wt% of croscarmellose sodium; and 0.5 to 2 wt% of magnesium stearate.

15. The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises 17-38 wt% of N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide mesylate; 60 to 77 wt% of the combination of microcrystalline cellulose and mannitol; 2.5-3 wt% of croscarmellose sodium; and 0.75-1.25 wt% of magnesium stearate.

16. The pharmaceutical formulation according to any preceding claim, further comprising colloidal silicon dioxide.

17. The pharmaceutical formulation according to claim 16, wherein the colloidal silicon dioxide is hydrophobic colloidal silicone dioxide.

18. The pharmaceutical formulation according to claim 16 or claim 17, wherein the colloidal silicone dioxide is present in an amount of about 0.50 wt%, based on the total weight of the pharmaceutical formulation.

19. The pharmaceutical composition of claim 15, wherein N-(5-(4-(4-((dimethylamino)methyl)-3-phenyl-lH-pyrazol-l-yl)pirimidine-2-ylamino)-4-methoxy-2-morpholinophenyl)acrylamide mesylate is a crystalline form having a differential scanning calorimeter (DSC) thermogram with an endothermic peak at 217±2 °C.

20. The pharmaceutical formulation according to any preceding claim, wherein the active ingredient is present in the pharmaceutical formulation in a weight ratio of 1:1.5 to 1:4 relative to the combination of diluents.

21. The pharmaceutical formulation according to any preceding claim, wherein the active ingredient is present in the pharmaceutical formulation in a weight ratio of 1:1.8 to 1:3.9 relative to the combination of diluents.

22. The pharmaceutical formulation according to any preceding claim, wherein the active ingredient is present in an amount of 15-35 wt%, relative to the total weight of the pharmaceutical formulation.

23. The pharmaceutical formulation according to any preceding claim, wherein the active ingredient is present in an amount of 18-35 wt%, relative to the total weight of the pharmaceutical formulation.

24. The pharmaceutical formulation according to any preceding claim, wherein the active ingredient is present in an amount of about 20 wt%, relative to the total weight of the pharmaceutical formulation.

25. The pharmaceutical formulation according to any one of claims 1-23, wherein the active ingredient is present in an amount of about 25 wt%, relative to the total weight of the pharmaceutical formulation.