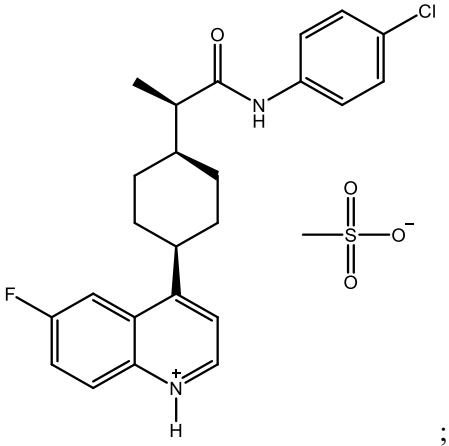
CLAIMS

WHAT IS CLAIMED IS:

1. A pharmaceutical composition suitable for oral administration comprising:

(a) an intra-granular phase comprising:

(i) a therapeutically effective amount of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide methane sulfonic acid salt present in an amount between 15% to 18% w/w of the composition having the structure:



;

(ii) crospovidone as a disintegrant present in an amount between 2.0% to 3.0% w/w of the composition; and,

(iii) magnesium stearate as a lubricant present in amount between 0.25% to 0.75% w/w of the composition;

(b) an extra-granular phase comprising:

(i) crospovidone as a disintegrant present in an amount of 2% to 3% w/w of the composition; and,

(ii) magnesium stearate as a lubricant present in an amount of 0.50% to 1.00% w/w of the composition;

wherein the ratio of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide methane sulfonic acid salt to total magnesium stearate is 8.0 to 40.0 by weight; and,

wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 25% by weight.

2. The pharmaceutical composition of claim 1 further comprising microcrystalline cellulose as a first diluent and lactose anhydrous as a second diluent present in a total amount between 50% to 80% w/w of the composition.

3. The pharmaceutical composition of claim 1 further comprising silicon dioxide as a glidant present in an amount of 1.0% to 3.0% w/w of the composition.

4. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide is less than 5% by weight.

5. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide is less than 3% by weight.

6. The pharmaceutical composition of claim 1, wherein the ratio of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*, 4*S*)-4-(6-fluoroquinolin-4-yl) cyclohexyl) propanamide methane sulfonic acid salt to total magnesium stearate is 23.0 to 40.0 by weight.

7. The pharmaceutical composition of claim 2, wherein the first diluent and the second diluent is present in a ratio ranging from 2:1 to 1:2 by weight.

8. The pharmaceutical composition of claim 2, wherein the first diluent is present in amount ranging from 25% to 40% w/w of the composition.

9. The pharmaceutical composition of claim 2, wherein the second diluent is present in amount ranging from 25% to 40% w/w of the composition.

10. The pharmaceutical composition of claim 3, wherein the silicon dioxide is present in an amount of 2.0% w/w of the composition.

11. The pharmaceutical composition of claim 1, wherein the intra-granular phase further comprises microcrystalline cellulose as a first diluent and lactose anhydrous as a second diluent present in a total amount between 75% to 80% w/w of the composition; and, silicon dioxide as a glidant present in an amount of 1.5% to 2.5% w/w of the composition.

12. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 10% by weight after 12 weeks at 40 °C and 75% relative humidity and has a particle size distribution characterized by a D90 has a value from 7 microns to 165 microns.

13. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 3% by weight after 24 weeks stored in a 200 cc high-density polyethylene bottle at 25 °C and 60% relative humidity.

14. The pharmaceutical composition of claim 1, wherein the composition has a particle size distribution characterized by a D90 has a value from 10 microns to 165 microns.

15. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 3% by weight after 6 months at 25 °C and 60% relative humidity with blister packaging.

16. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 3% by weight after 4 weeks at 25 °C and 60% relative humidity.

17. The pharmaceutical composition of claim 1, wherein salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 3% by weight after 4 weeks at 40 °C and 75% relative humidity.

18. The pharmaceutical composition of claim 1, wherein the composition is a blend and the salt disproportionation of (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide methane sulfonic acid to (*R*)-*N*-(4-chlorophenyl)-2-((1*S*,4*S*)-4-(6-fluoroquinolin-4-yl)cyclohexyl)propanamide is less than 3% by weight after 24 weeks at 25 °C and 60% closed relative humidity.

19. The pharmaceutical composition of claim 1, wherein the composition is selected from the group consisting of tablet, crushed tablet, capsule or sprinkled contents from a capsule, mini-tablets, and beads.

20. The pharmaceutical composition of claim 1 further comprising citric acid.