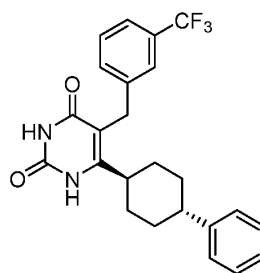


WHAT IS CLAIMED IS:

- 1 1. A composition comprising:
 2 Compound I, (E)-6-(4-Phenylcyclohexyl)-5-(3-trifluoromethylbenzyl)-1H-
 3 pyrimidine-2,4-dione:



- 4
 5 in an amount from 15.0 to 32.0% (w/w);
 6 a poly[(methyl methacrylate)-co-(methacrylic acid)] in an amount from 15.0 to 32.0%
 7 (w/w);
 8 a sustaining polymer in an amount from 10.0 to 32.0% (w/w);
 9 microcrystalline cellulose in an amount from 10.0 to 25.0% (w/w); and
 10 croscarmellose sodium (Ac-Di-Sol) in an amount from 5.0 to 11.0% (w/w).

- 1 2. The composition of claim 1, wherein
 2 Compound I is present in an amount from 20.0 to 28.0% (w/w);
 3 a poly[(methyl methacrylate)-co-(methacrylic acid)] in an amount from 20.0 to 28.0%
 4 (w/w); and
 5 a sustaining polymer in an amount from 10.0 to 28.0% (w/w).

- 1 3. The composition of claims 1 or 2, wherein the poly[(methyl
 2 methacrylate)-co-(methacrylic acid)] is Eudragit L100.

- 1 4. The composition of claims 1 to 3, wherein the sustaining polymer is
 2 hydroxypropyl methylcellulose acetate succinate (HPMCAS).

- 1 5. The composition of claims 1 to 4, wherein the sustaining polymer is
 2 hydroxypropyl methylcellulose acetate succinate high fine grade (HPMCAS-H).

- 1 6. The composition of any one of claims 3 to 5, comprising
 2 Compound I, in an amount from 22.0 to 28.0% (w/w);
 3 Eudragit L100 in an amount from 22.0 to 28.0% (w/w);

4 hydroxypropyl methylcellulose acetate succinate high fine grade in an amount from
5 13.0 to 28.0% (w/w);
6 microcrystalline cellulose (Avicel PH102) in an amount from 13.0 to 20.0% (w/w);
7 and
8 croscarmellose sodium (Ac-Di-Sol) in an amount from 5.0 to 11.0% (w/w).

1 7. The composition of any one of claims 1 to 6, further comprising
2 sodium lauryl sulfate in an amount from 0.5 to 5.0% (w/w).

1 8. The composition of any one of claims 1 to 7, further comprising
2 sodium lauryl sulfate in an amount from 1.25 to 1.75% (w/w).

1 9. The composition of any one of claims 1 to 8, further comprising
2 sodium lauryl sulfate in an amount from 1.3 to 1.5% (w/w).

1 10. The composition of any one of claims 1 to 9, comprising
2 Compound I, in an amount of about 22.8% (w/w);
3 Eudragit L100 in an amount of about 22.8% (w/w);
4 sodium lauryl sulfate in an amount of about 1.4% (w/w);
5 hydroxypropyl methylcellulose acetate succinate high fine grade in an amount of
6 about 23.0% (w/w);
7 microcrystalline cellulose (Avicel PH102) in an amount of about 19.4% (w/w);
8 croscarmellose sodium (Ac-Di-Sol) in an amount of about 10.0% (w/w); and
9 magnesium stearate in an amount of about 0.5% (w/w).

1 11. The composition of any one of claims 1 to 9, further comprising
2 colloidal silicon dioxide (Cab-O-Sil MP5) in an amount from 0.1 to 2.0% (w/w).

1 12. The composition of claim 11, wherein the colloidal silicon dioxide
2 (Cab-O-Sil MP5) is present in an amount from 0.50 to 1.5% (w/w).

1 13. The composition of any one of claims 1 to 9, 11 or 12, comprising
2 Compound I, in an amount of about 22.8% (w/w);
3 Eudragit L100 in an amount of about 22.8% (w/w);
4 sodium lauryl sulfate in an amount of about 1.4% (w/w);

5 hydroxypropyl methylcellulose acetate succinate high fine grade in an amount of
6 about 23.0% (w/w);
7 microcrystalline cellulose (Avicel PH102) in an amount of about 18.4% (w/w);
8 croscarmellose sodium (Ac-Di-Sol) in an amount of about 10.0% (w/w);
9 colloidal silicon dioxide (Cab-O-Sil MP5) in an amount of about 1.0% (w/w); and
10 magnesium stearate in an amount of about 0.5% (w/w).

1 14. The composition of claim 11 or 12, wherein the microcrystalline
2 cellulose (Avicel PH102) in an amount from 10.0 to 30.0% (w/w).

1 15. The composition of claim 14, wherein the microcrystalline cellulose
2 (Avicel PH102) in an amount from 13.0 to 20.0% (w/w).

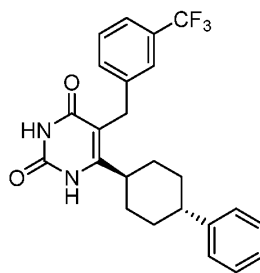
1 16. The composition of claims 14 or 15, wherein the weight ratio of
2 Compound I to the poly[(methyl methacrylate)-co-(methacrylic acid)] is about 1:1.

1 17. The composition of any one of claims 14 to 16, comprising
2 Compound I, in an amount of about 25.0% (w/w);
3 Eudragit L100 in an amount of about 25.0% (w/w);
4 hydroxypropyl methylcellulose acetate succinate high fine grade in an amount of
5 about 25.0% (w/w);
6 microcrystalline cellulose (Avicel PH102) in an amount of about 13.75% (w/w);
7 croscarmellose sodium (Ac-Di-Sol) in an amount of about 10.0% (w/w);
8 colloidal silicon dioxide (Cab-O-Sil MP5) in an amount of about 0.75% (w/w); and
9 magnesium stearate in an amount of about 0.5% (w/w).

1 18. The composition of any one of claims 14 to 16, comprising
2 Compound I, in an amount of about 22.9% (w/w);
3 Eudragit L100 in an amount of about 22.9% (w/w);
4 hydroxypropyl methylcellulose acetate succinate high fine grade in an amount of
5 about 22.9% (w/w);
6 microcrystalline cellulose (Avicel PH102) in an amount of about 19.8% (w/w);
7 croscarmellose sodium (Ac-Di-Sol) in an amount of about 10.0% (w/w);
8 colloidal silicon dioxide (Cab-O-Sil MP5) in an amount of about 1.0% (w/w); and
9 magnesium stearate in an amount of about 0.5% (w/w).

1 19. A method of preparing a composition of any one of claims 1 to 18,
2 comprising:

3 a) forming a mixture comprising a solvent, poly[(methyl methacrylate)-co-
4 (methacrylic acid)], and Compound I, (E)-6-(4-Phenylcyclohexyl)-5-(3-
5 trifluoromethylbenzyl)-1H-pyrimidine-2,4-dione:



6 ;
7 b) spray-drying the mixture to form an intermediate mixture;
8 c) blending a first intragranular mixture comprising the intermediate mixture, a
9 sustaining polymer, microcrystalline cellulose, and croscarmellose sodium;
10 d) roller compacting the first intragranular mixture to form a roller compacted
11 mixture; and
12 e) blending a first extragranular mixture comprising the roller compacted mixture
13 and croscarmellose sodium, thereby preparing the composition.

1 20. The method of claim 19, wherein the solvent comprises methanol and
2 dichloromethane.

1 21. The method of claims 19 or 20, wherein the poly[(methyl
2 methacrylate)-co-(methacrylic acid)] is Eudragit L100.

1 22. The method of any one of claims 19 to 21, wherein Compound I is a
2 crystalline anhydrate.

1 23. The method of any one of claims 19 to 22, wherein the sustaining
2 polymer is hydroxypropyl methylcellulose acetate succinate (HPMCAS).

1 24. The method of any one of claims 19 to 23, wherein the sustaining
2 polymer is hydroxypropyl methylcellulose acetate succinate high fine grade (HPMCAS-H).

1 25. The method of any one of claims 19 to 24, comprising

- 2 a) forming the mixture comprising the solvent, Eudragit L100, sodium lauryl
3 sulfate (SLS), and Compound I;
4 b) spray-drying the mixture to form the intermediate mixture;
5 c1) blending the first intragranular mixture comprising the intermediate mixture,
6 HPMCAS-H, microcrystalline cellulose, and croscarmellose sodium;
7 c2) blending a second intragranular mixture comprising the first intragranular
8 mixture and magnesium stearate;
9 d) roller compacting the second intragranular mixture to form a roller compacted
10 mixture;
11 e1) blending the first extragranular mixture comprising the roller compacted
12 mixture and croscarmellose sodium; and
13 e2) blending a second extragranular mixture comprising the first extragranular
14 mixture and magnesium stearate, thereby preparing the composition.

1 26. The method of any one of claims 19 to 25, wherein
2 the first intragranular mixture further comprises a first glidant; and
3 the first extragranular mixture further comprises a second glidant.

1 27. The method of claim 26, wherein the first glidant and second glidant
2 each comprise colloidal silicon dioxide.

1 28. The method of claim 27, comprising
2 a) forming the mixture comprising the solvent, Eudragit L100, sodium lauryl
3 sulfate (SLS), and Compound I;
4 b) spray-drying the mixture to form the intermediate mixture;
5 c1) blending the first intragranular mixture comprising the intermediate mixture,
6 HPMCAS-H, microcrystalline cellulose, croscarmellose sodium and colloidal
7 silicon dioxide;
8 c2) blending a second intragranular mixture comprising the first intragranular
9 mixture and magnesium stearate;
10 d) roller compacting the second intragranular mixture to form a roller compacted
11 mixture;
12 e1) blending the first extragranular mixture comprising the roller compacted
13 mixture, croscarmellose sodium and colloidal silicon dioxide; and

- 14 e2) blending a second extragranular mixture comprising the first extragranular
15 mixture and magnesium stearate, thereby preparing the composition.
- 1 29. The method of claim 27, comprising
- 2 a) forming the mixture comprising the solvent, poly[(methyl methacrylate)-co-
3 (methacrylic acid)], and Compound I;
- 4 b) spray-drying the mixture to form the intermediate mixture;
- 5 c1) blending the first intragranular mixture comprising the intermediate mixture,
6 HPMCAS-H, microcrystalline cellulose, croscarmellose sodium and colloidal
7 silicon dioxide;
- 8 c2) blending a second intragranular mixture comprising the first intragranular
9 mixture and magnesium stearate;
- 10 d) roller compacting the second intragranular mixture to form a roller compacted
11 mixture;
- 12 e1) blending the first extragranular mixture comprising the roller compacted
13 mixture, croscarmellose sodium and colloidal silicon dioxide; and
- 14 e2) blending a second extragranular mixture comprising the first extragranular
15 mixture and magnesium stearate, thereby preparing the composition.

1 30. A method of treating a disorder or condition through modulating a
2 glucocorticoid receptor, comprising administering to a subject in need of such treatment, a
3 therapeutically effective amount of a composition of any one of claims 1 to 18, thereby
4 treating the disorder or condition.

1 31. A method of treating a disorder or condition through antagonizing a
2 glucocorticoid receptor, comprising administering to a subject in need of such treatment, a
3 therapeutically effective amount of a composition of any one of claims 1 to 18, thereby
4 treating the disorder or condition.

1 32. A method of treating fatty liver disease, comprising administering to a
2 subject in need thereof, a therapeutically effective amount of a composition of any one of
3 claims 1 to 18, thereby treating fatty liver disease.

1 33. The method of claim 32, wherein the fatty liver disease is alcohol
2 related liver disease (ARLD) or nonalcoholic fatty liver disease (NAFLD).

- 1 34. The method of claims 33, wherein the alcohol related liver disease is
2 alcohol fatty liver disease (AFL), alcoholic steatohepatitis (ASH) or alcoholic cirrhosis.
- 1 35. The method of claims 33 or 34, wherein the nonalcoholic fatty liver
2 disease is nonalcoholic steatohepatitis (NASH) or nonalcoholic cirrhosis.
- 1 36. The method of claim 35, wherein the nonalcoholic fatty liver disease is
2 nonalcoholic steatohepatitis.
- 1 37. A method of treating antipsychotic induced weight gain, comprising
2 administering to a subject in need thereof, a therapeutically effective amount of a
3 composition of any one of claims 1 to 18, thereby treating antipsychotic induced weight gain.