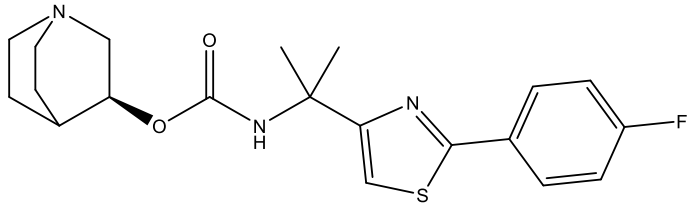
CLAIMS

We claim:

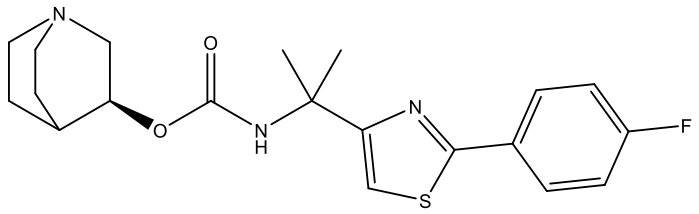
1. A process for the manufacture of an oral pharmaceutical composition comprising venglustat, (S)-quinuclidin-3-yl 2-(2-(4-fluorophenyl)thiazol-4-yl)propan-2-ylcarbamate:



in free base or pharmaceutically acceptable salt form, wherein the process comprises the steps of:

(a) sieving each ingredient;
(b) combining venglustat, in free base or pharmaceutically acceptable salt form, with a diluent/filler, and with sodium stearyl fumarate as a first lubricant, and optionally a glidant, any colors or flavors, or any other excipients, or a combination thereof;
(c) blending and/or milling and/or granulating the resulting mixture;
(d) optionally screening the resulting mixture;
(e) adding at least one other diluent or carrier to the mixture;
(f) blending and/or milling and/or granulating the resulting mixture;
(g) optionally screening the resulting mixture;
(h) adding magnesium stearate as a second lubricant and any additional excipients;
(i) blending and/or milling the resulting mixture;
(j) optionally granulating the resulting mixture;
(k) optionally screening the resulting mixture;
(l) compressing the resulting material to form a tablet;
(m) optionally applying one or more coatings to the tablet; and
(n) optionally packaging the resulting finished dosage form.

2. A process for the manufacture of an oral pharmaceutical composition comprising venglustat, (S)-quinuclidin-3-yl 2-(2-(4-fluorophenyl)thiazol-4-yl)propan-2-ylcarbamate:



in free base or pharmaceutically acceptable salt form, wherein the process comprises the steps of:

(a) sieving each ingredient;

(b) combining venglustat, in free base or pharmaceutically acceptable salt form, with a diluent/filler, and optionally with a glidant, any colors or flavors, or any other excipients, or a combination thereof;

(c) blending and/or milling and/or granulating the resulting mixture;

(d) optionally screening the resulting mixture;

(e) adding at least one other diluent or carrier to the mixture and adding a first portion of magnesium stearate as a lubricant to the mixture;

(f) blending and/or milling and/or granulating the resulting mixture;

(g) optionally screening the resulting mixture;

(h) adding the remaining portion of magnesium stearate as a lubricant and any additional excipients;

(i) blending and/or milling the resulting mixture;

(j) optionally granulating the resulting mixture;

(k) optionally screening the resulting mixture;

(l) encapsulating the resulting material;

(m) optionally applying one or more coatings to the capsule; and

(n) optionally packaging the resulting finished dosage form.

3. The process according to claim 1 or claim 2, wherein the venglustat is venglustat malate.

4. The process according to any one of claims 1 to 3, wherein steps (i), (j), and/or (k) are repeated for additional excipients added in step (h) before proceeding to steps (l), (m), or (n).

5. The process according to any one of claim 1, or any preceding claim dependent thereon, wherein magnesium stearate is added as the final excipient added before final mixing and compression to form the tablet.

6. The process according to any one of claims 1 to 5, wherein the diluent/filler is mannitol, and the disintegrant is crospovidone, and the binder is hydroxypropyl cellulose, and the glidant is silica.

7. The process according to claim 2, wherein the first portion comprises 15-50% by weight, or 20-30% by weight, of the total magnesium stearate lubricant added, and wherein the remaining portion comprises 50-85% by weight, or 70-80% by weight, of the total magnesium stearate lubricant added.

8. The process according to any one of claim 1, or any preceding claim dependent thereon, wherein the process comprises the following steps:

(a) sieving each of a first portion of mannitol, silica, venglustat malate, flavor, sodium stearyl fumarate, and optionally sucralose;

(b) combining the venglustat malate with the sieved mannitol, silica, flavor, sodium stearyl fumarate, and optionally sucralose, optionally wherein each ingredient is sieved sequentially into a common container to combine the ingredients;

(c) blending and/or milling and/or granulating the resulting mixture;

(e) sieving a second portion of mannitol, low-substituted hydroxypropyl cellulose, and crospovidone, and adding these sieved ingredients to the mixture from step (c);

(f) blending and/or milling and/or granulating the resulting mixture;

(h) sieving magnesium stearate and adding it to the mixture from step (f);

(i-j) blending and/or milling and/or granulating the resulting mixture;

(l) compressing the resulting material to form a tablet; and

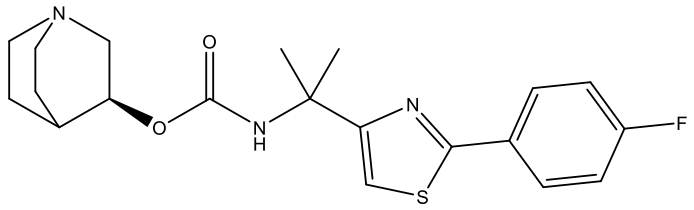
(n) optionally packaging the resulting finished dosage form.

9. The process according to claim 8, wherein sodium stearyl fumarate is combined in step (b) in an amount to provide 2-3% by weight of sodium stearyl fumarate in the tablet.

10. The process according to claim 8 or claim 9, wherein magnesium stearate is added in step (h) in an amount to provide from 0.1-1% by weight magnesium stearate in the tablet.

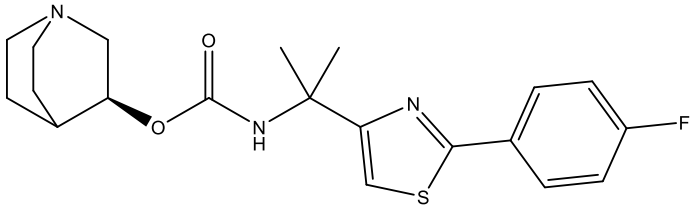
11. A composition prepared, or preparable, by the process as defined in any one of the preceding claims.

12. An oral pharmaceutical composition comprising venglustat, (S)-quinuclidin-3-yl 2-(2-(4-fluorophenyl)thiazol-4-yl)propan-2-ylcarbamate:



in free base or pharmaceutically acceptable salt form; wherein the oral pharmaceutical composition is in a finished dosage form of a tablet comprising or consisting of (a) venglustat malate in an amount from 9-11% by weight of venglustat free base equivalent; (b) from 65 to 70% by weight of mannitol; (c) from 2-3% by weight of sodium stearyl fumarate, and 0.1-1% magnesium stearate; (d) from 7-9% by weight of crospovidone; (e) from 4-6% by weight of low-substituted hydroxypropyl cellulose; (f) from 0.5-1.5% by weight of anhydrous colloidal silica; (g) from 0.5-3% by weight of flavor; and (h) from 0-2% by weight of sweetener.

13. An oral pharmaceutical composition comprising venglustat, (S)-quinuclidin-3-yl 2-(2-(4-fluorophenyl)thiazol-4-yl)propan-2-ylcarbamate:



in free base or pharmaceutically acceptable salt form; wherein the oral pharmaceutical composition is in a finished dosage form of a capsule comprising or consisting of (a) from 3% to 20% venglustat, by weight of venglustat measured as the free base equivalent (b) from 60-90% by weight of the diluent/filler cellulose, (c) from 0.5-6% by weight of the lubricant magnesium stearate, (d) from 2-15% by weight of the disintegrant croscarmellose sodium, (e) from 1-12% by weight of binder(s), (f) from 0-5% by weight of the glidant silica, (g) from 0-2% by weight of flavor(s), 0-2% by weight of sweetener(s), and/or 0-2% by weight of color(s), and (h) a capsule shell.

14. The composition according to claim 13, wherein the venglustat is venglustat malate.

15. The composition according to any one of claims 11 to 14, wherein said finished dosage form comprises from 2 to 30 mg of venglustat (measured as the equivalent amount of free base).

16. The composition according to any one of claims 11 to 15, wherein the composition: i) provides at least 80% dissolution within 15 minutes using FDA and/or EMEA immediate-release solid oral dosage form testing guidelines, such as in pH 1.2 in HCl, pH 4.5 in acetate buffer, or pH 6.8 in phosphate buffer dissolution medium, for example 85-100% dissolution.

17. The composition of any one of claims 11 to 16, wherein the composition is a chewable tablet having a chewing difficulty index selected from less than 0.6 Nm, or less than 0.5 Nm, or less than 0.4 Nm, or less than 0.2 Nm.

18. The composition of any one of claims 11 to 17 for use in the treatment or prevention of Gaucher disease type 2 or type 3, polycystic kidney disease, autosomal dominant polycystic kidney disease, Gaucher disease, Fabry disease, Alzheimer’s disease, Parkinson’s disease, Bardet-Biedl Syndrome, Joubert syndrome, GM2, or GM3.

19. The use of a composition of any one of claims 11 to 17 in the manufacture of a medicament for the treatment or prevention of Gaucher disease type 2 or type 3, polycystic kidney disease, autosomal dominant polycystic kidney disease, Gaucher disease, Fabry disease, Alzheimer’s disease, Parkinson’s disease, Bardet-Biedl Syndrome, Joubert syndrome, GM2, or GM3.