CLAIMS

1. A modified release pharmaceutical granulation comprising a plurality of coated granules, wherein,

the granules comprise a core and a modified release coating surrounding the core, wherein,

the modified release coating comprises:

from 50 wt% to 85 wt% of a matrix polymer; and

from 10 wt% to 20 wt% an antistatic agent;

wherein wt% is based on the total weight of the modified release coating;

the core comprises greater than 85 wt% of 4-((*L*-valyl)oxy)butanoic acid, wherein wt% is based on the total weight of the core; and

the modified release pharmaceutical granulation is characterized by an average particle size (D50) from 150 μm to 400 μm, wherein PSD is determined by sieve analysis.

2. The pharmaceutical granulation of claim 1, wherein the matrix polymer comprises ethylcellulose and hydroxypropyl cellulose.

3. The modified release pharmaceutical granulation of any one of claims 1 and 2, wherein the modified release coating comprises:

from 72 wt% to 92 wt% of the water-insoluble polymer; and

from 0.1 wt% to 10 wt% of the water-soluble polymer,

wherein wt% is based on the total weight of the modified release coating.

4. The modified release pharmaceutical granulation of any one of claims 1 to 3, wherein the antistatic agent comprises talc, magnesium stearate, or a combination thereof.

5. The modified release pharmaceutical granulation of any one of claims 1 to 4, wherein,

the core represents from 65 wt% to 85 wt% of the total weight of the coated granules; and

the modified release modified release coating represents from 15 wt% to 40 wt% of the total weight of the coated granules.

6. The modified release pharmaceutical granulation of any one of claims 1 to 5, wherein the modified release coating has a thickness from 5 μm to 30 μm.

7. The modified release pharmaceutical granulation of any one of claims 1 to 6, wherein the modified release pharmaceutical granulation has a water content less than 2 wt%, wherein wt% is based on the total weight of the modified release pharmaceutical granulation.

8. A pharmaceutical composition comprising:

(a) an immediate release component, wherein the immediate release component comprises: from 2 g to 8 g 4-((*L*-valyl)oxy)butanoic acid; and

(b) the modified release component, wherein the modified release component comprises: from 8 g to 16 g 4-((*L*-valyl)oxy)butanoic acid, and the modified release pharmaceutical granulation of any one of claims 1 to 7.

9. The pharmaceutical composition of claim 8, wherein the immediate release component comprises a plurality of immediate release microparticles.

10. The pharmaceutical composition of any one of claims 8 to 9, wherein the immediate release microparticles comprise greater than 90 wt% 4-((*L*-valyl)oxy)butanoic acid, wherein wt% is based on the total weight of the immediate release microparticles.

11. The pharmaceutical composition of any one of claims 8 to 9, wherein the immediate release microparticles have a volume mean diameter D(4.3) from 200 μm to 500 μm.

12. The pharmaceutical composition any one of claims 8 to 11, wherein the immediate release microparticles have an average particle diameter (D50) from 75 μm to 450 μm as determined by sieve analysis or by laser diffraction.

13. The pharmaceutical composition any one of claims 8 to 12, wherein,

the immediate release component comprises from 20 wt% to 40 wt% 4-((*L*-valyl)oxy)butanoic acid; and

the modified release component comprises form 60 wt% to 80 wt% 4-((*L*-valyl)oxy)butanoic acid

wherein wt% is based on the total weight of 4-((*L*-valyl)oxy)butanoic acid in the pharmaceutical composition.

14. The pharmaceutical composition any one of claims 8 to 13, wherein a weight ratio of 4-((*L*-valyl)oxy)butanoic acid in the immediate release component to 4-((*L*-valyl)oxy)butanoic acid in the modified release component is from 1:2 to 1:3.

15. The pharmaceutical composition any one of claims 8 to 14, wherein the immediate release component comprises a solution suitable for oral administration.

16. The pharmaceutical composition of claim 15, wherein the modified release component comprises the modified release granules suspended in the solution.

17. Use of the pharmaceutical granulation of any one of claims 1 to 7 or the pharmaceutical composition of any one of claims 8 to 16 for use in the manufacture of a medicament for the treatment of narcolepsy, excessive daytime sleepiness, cataplexy, excessive daytime sleepiness associated with narcolepsy, excessive daytime sleepiness associated with Parkinson's disease, excessive daytime sleepiness associated with multiple sclerosis, cataplexy associated with narcolepsy, fatigue, fatigue associated with Parkinson's diseases, fatigue associated with multiple sclerosis, or fibromyalgia.

18. Use of the pharmaceutical granulation of any one of claims 1 to 7 or the pharmaceutical composition of any one of claims 8 to 16 for use in the manufacture of a medicament for the treatment of a REM sleep behavior disorder, spasmodic dystonia, schizophrenia, insomnia, insomnia associated with schizophrenia, idiopathic hypersomnia, chronic fatigue syndrome, cluster headache, Alzheimer's disease, essential tremor, post-traumatic stress syndrome, insomnia associated with post-traumatic stress syndrome, or anxiety.

19. Use of the pharmaceutical granulation of any one of claims 1 to 7 or the pharmaceutical composition of any one of claims 8 to 16 for use in the manufacture of a medicament for the treatment of a sleep disorder associated with a bacterial infection.

20. Use of the pharmaceutical granulation of any one of claims 1 to 7 or the pharmaceutical composition of any one of claims 8 to 16 for use in the manufacture of a medicament for enhancing cognitive function.