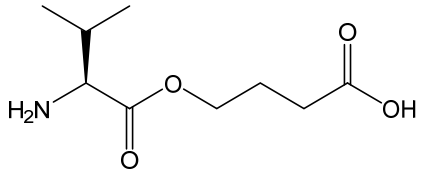
CLAIMS

1. Granules, wherein,

the granules comprise greater than 95 wt% of a compound of Formula (2a):



(2a)

or a pharmaceutically acceptable salt thereof;

from 0.1 wt% to 3.0 wt% of a binder; and

from 0.1 wt% to 2.0 wt% of an antistatic agent,

wherein wt% is based on the total weight of the granules; and

wherein the granules are characterized by:

a mean particle size (D50) from 150 μm to 500 μm, wherein the particle size distribution is determined by laser diffraction or by sieve analysis;

a friability value less than 2 wt%, wherein friability is determined using a sonic sifter; and

a bulk density from 0.5 g/mL to 1.20 g/mL, wherein bulk density is determined according to USP 616 Method I.

2. The granules of claim 1, wherein the granules comprise:

greater than 98.5 wt% of the compound of Formula (2a);

less than or equal to 0.5 wt% of the binder; and

less than or equal to 1.0 wt% of the antistatic agent,

wherein wt% is based on the total weight of the granules.

3. The granules of claim 1 or 2, wherein the granules comprise:

from 98 wt% to 99 wt% of the compound of Formula (2a);

from 0.25 wt% to 0.75 wt% of the binder; and

from 0.5 wt% to 1.5 wt% of the antistatic agent,

wherein wt% is based on the total weight of the granules.

4. The granules of any one of claims 1 to 3, wherein the granules are characterized by a sphericity from 0.90 to 1.00, wherein sphericity is determined by dynamic image analysis.

5. The granules of any one of claims 1 to 4, wherein

the granules are characterized by a particle size distribution D10 from 50 μm to 250 μm; and

a particle size distribution D90 from 400 μm to 750 μm,

wherein the particle size distribution is determined by laser diffraction or by sieve analysis.

6. The granules of any one of claims 1 to 5, wherein,
the binder comprises hydroxypropyl cellulose; and
the antistatic agent comprises hydrophilic fumed silica.

7. The granules of any one of claims 1 to 6, wherein the granules comprise a coating.

8. The granules of claim 7, wherein the coating comprises a controlled release coating.

9. A pharmaceutical composition comprising the granules of any one of claims 1 to 8.

10. The pharmaceutical composition of claim 8, wherein the pharmaceutical composition comprises an oral suspension.

11. The pharmaceutical composition of claim 9 or 10, wherein the pharmaceutical composition comprises an immediate release formulation.

12. The pharmaceutical composition of claim 9 or 10, wherein the pharmaceutical composition comprises a controlled release formulation.

13. Use of a granulation of any one of claims 1 to 8, or a pharmaceutical composition of any one of claims 9 to 12, in the manufacture of a medicament for the treatment of a disease selected from the group consisting of 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 in a patient with Parkinson’s disease, fatigue in a patient with multiple sclerosis, and fibromyalgia.