CLAIMS

1. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

an active pharmaceutical ingredient consisting of lurasidone or a pharmaceutically acceptable salt thereof; and

a biodegradable polymer,

wherein each polymer microsphere comprises a drug load of lurasidone of greater than or equal to 55% by weight of the polymer microsphere, and

wherein the polymer microspheres have a particle size of less than or equal to 25 μm (D_{50}).

2. The microsphere formulation of claim 5, wherein the pharmaceutically acceptable salt of lurasidone is lurasidone HC1.

3. The microsphere formulation of claim 5, wherein the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide).

4. The microsphere formulation of claim 5, wherein the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25.

5. The microsphere formulation of claim 1, wherein each polymer microsphere has a lurasidone drug load of from 55% to about 70% by weight of the polymer microsphere; and wherein the polymer microspheres have a particle size of from about 9 μm to 25 μm (D_{50}).

6. The microsphere formulation of claim 5, wherein the polymer microspheres have been irradiated.

7. A pharmaceutical composition comprising the microsphere formulation of claim 1.

8. The microsphere formulation of claim 1, characterized in that about 75% to 100% of the lurasidone is released over a period of about 30 days of injection into a subject, but not more than about 20% of the lurasidone has been released within about 24 hours of injection into the subject.

9. The microsphere formulation of claim 5, wherein the polymer microspheres have a particle size of between about 14 μm (D_{50}) and 25 μm (D_{50}).

10. The microsphere formulation of claim 5, wherein the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25, and wherein the biodegradable polymer has an inherent viscosity of about 0.14 dL/g to about 0.56 dL/g.

11. The microsphere formulation of claim 5, wherein:

the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25, and wherein the biodegradable polymer has an inherent viscosity of about 0.14 dL/g to about 0.21 dL/g.

12. The microsphere formulation of claim 5, wherein:

the biodegradable polymer comprises an acid terminated poly(D,L-lactide-co-glycolide) with lactide:glycolide of about 75: about 25, and wherein the biodegradable polymer has an inherent viscosity of about 0.14 dL/g to about 0.29 dL/g.

13. The microsphere formulation of claim 5, wherein the polymer microspheres have a particle size of from about 14 μm (D_{50}) to about 20 μm (D_{50}).

14. A pharmaceutical composition comprising the microsphere formulation of claim 5.

15. The microsphere formulation of claim 5, characterized in that about 75% to 100% of the lurasidone is released over a period of about 30 days of injection into a subject, but not more than about 20% of the lurasidone has been released within about 24 hours of injection into the subject.

16. A microsphere formulation, comprising:

polymer microspheres, each polymer microsphere comprising:

an active pharmaceutical ingredient consisting of lurasidone HCl; and

a biodegradable polymer comprising an acid terminated poly(D,L-lactide-co-glyycolide) ("PLGA") with lactide:glycolide of about 75: about 25 and an inherent viscosity of from about 0.14 dL/g to about 0.56 dL/g,

wherein each polymer microsphere has a lurasidone drug load of from about 55% to about 70% by weight of the polymer microsphere;

wherein the polymer microspheres have a particle size of about 14 μm (D_{50}) to about 25 μm (D_{50}); and

wherein the microsphere formulation is characterized in that about 75% to about 100% of the lurasidone is released over a period of about 30 days of injection into a subject, but not more than about 20% of the lurasidone has been released within about 24 hours of injection into the subject.

17. A pharmaceutical composition comprising the microsphere formulation of claim 17.

18. The microsphere formulation of claim 18, wherein the inherent viscosity of the PLGA is from about 0.14 dL/g to about 0.29 dL/g.

19. The microsphere formulation of claim 18, wherein the inherent viscosity of the PLGA is from about 0.14 dL/g to about 0.21 dL/g.