CLAIMS

1. An injectable neurosteroid formulation comprising stable particle size nanoparticles having a D50 of less than 2000 nm, the nanoparticles comprising

a) a neurosteroid selected from ganaxolone and allopregnanolone

b) hydroxyethyl starch, wherein the (wt:wt) ratio of the neurosteroid to the hydroxyethyl starch is 4:1 to 0.5:1; and

c) an ionic surfactant selected from sodium cholate, sodium deoxycholate, and sodium cholesterol sulfate, and a mixture of any of the foregoing.

2. The injectable neurosteroid formulation of Claim 1, comprising nanoparticles having a D50 of less than 500 nm; wherein the formulation is an intravenous formulation; and the neurosteroid is ganaxolone.

3. The injectable neurosteroid formulation of Claim 2, wherein the formulation additionally comprises an antifoaming agent.

4. The injectable neurosteroid formulation of Claim 2, wherein the polymeric surface stabilizer is hydroxyethyl starch; and the surfactant is sodium deoxycholate.

5. The injectable neurosteroid formulation of Claim 2 additionally comprising a cryoprotectant, wherein the cryoprotectant is sucrose, dextrose, lactose, D-sorbitol, or a mixture of any of the foregoing.

6. The injectable neurosteroid formulation of Claim 2 additionally comprising one or more of the following

(a) 0.5% to 1.5% sodium chloride (weight percent);

(b) a buffer; and

(c) a preservative, wherein the preservative is benzyl alcohol, chlorbutanol, 2-ethoxyethanol, parabens, benzoic acid, sorbic acid, chlorhexidene, phenol, 3-cresol, thimerosal, a phenylmercurate salt, or a mixture of any of the foregoing.

7. The injectable neurosteroid formulation of Claim 1, wherein

the (wt:wt) ratio of the neurosteroid to the polymeric surface stabilizer is 4:1 to 1:1; and

the ionic surfactant is sodium deoxycholate and the ratio of neurosteroid to sodium deoxycholate (w:w) is 10:1.5 to 10:0.1.

8. The formulation of Claim 7, wherein the formulation is in the form of a lyophilized powder.

9. The formulation of Claim 2, wherein the formulation is an aqueous suspension and the neurosteroid concentration is 0.1 mg/mL to 300 mg/mL.

10. The injectable neurosteroid formulation of Claim 1, wherein the formulation is an aqueous ganaxolone formulation comprising

(a) nanoparticles having a D50 of less than 500 nm, the nanoparticles comprising ganaxolone, wherein the weight percent of the ganaxolone is 1 to 10%;

(b) hydroxyethyl starch, wherein the weight percent of the hydroxyethyl starch is 2 to 20%; and

(c) sodium deoxycholate, wherein the weight percent of the sodium deoxycholate is 0.1% to 2.0 %; and

(d) an antifoaming agent.

11. The injectable neurosteroid formulation of Claim 1 wherein the formulation is an aqueous formulation comprising

(a) nanoparticles having a D50 of less than 500 nm, the nanoparticles comprising ganaxolone, wherein the weight percent of the ganaxolone is 5%;

(b) hydroxyethyl starch 130/0.4, wherein the weight percent of the hydroxyethyl starch is 5% to 10%;

(c) sodium deoxycholate, wherein the weight percent of the sodium deoxycholate is 0.75%; and optionally

(d) simethicone, wherein the weight percent of simethicone is 0.009%.

12. A method for sterilizing the injectable neurosteroid nanoparticle formulation of Claim 2, comprising subjecting the formulation to ebeam radiation, wherein the method produces a

sterilized neurosteroid nanoparticle formulation containing a degradant concentration of not more than 0.2% w/w of neurosteroid.

13. The injectable ganaxolone formulation of Claim 2 for use in the treatment of a seizure disorder, stroke, or traumatic brain injury in a patient.

14. The injectable ganaxolone formulation of Claim 13, wherein the seizure disorder is status epilepticus, refractory status epilepticus, super refractory status epilepticus, or PCD19 female pediatric epilepsy.

15. The injectable ganaxolone formulation of Claim 13, wherein at least one additional active agent is an anticonvulsant or anesthetic/ sedative.