Claims

1. A lipid-based drug delivery system comprising Edaravone or its pharmaceutically acceptable salt thereof as an active ingredient, and a lipid, wherein the lipid is a triglyceride, including a long chain triglyceride (LCT), a medium chain triglyceride (MCT) and a short chain triglyceride (SCT), wherein the long-chain triglyceride is selected from the group consisting of hydrogenated soybean oil, hydrogenated vegetable oil, corn oil, olive oil, soybean oil, peanut oil, and sesame oil, and the medium chain triglyceride is selected from the group consisting of caprylic/capric triglyceride derived from coconut oil or palm seed oil.

2. The lipid-based drug delivery system of claim 1, wherein the lipid is selected from one or more of Caproyl 90, Capmul MCM and Caproyl™ PGMC.

3. The lipid-based drug delivery system of claim 1, further comprising a water-soluble organic solvent, a surfactant, a co-surfactant, a polymer solubilizer, a phospholipid, an acidulant, a buffering agent, a stabilizer, an anti-oxidant, a preservative, and/or a solid adsorbent.

4. The lipid-based drug delivery system of claim 3, wherein the water-soluble organic solvent is selected from PEG 200-10,000 (e.g., PEG 300, PEG 400, PEG 1,000 and PEG 6,000), polyvinyl caprolactam (PCL), polyvinyl acetate (PVA) or a copolymer thereof, a water-soluble form of vitamin E and ethanol; the surfactant is selected from Cremophor RH 40, Labrasol, TPGS 1000, Tween 20, Cremophor E1 and Tween 80; the co-surfactant is selected from PEG 300, PEG 400, propylene glycol, glycerol, ethanol, Transcutol HP and Transcutol P; and the polymer solubilizer is selected from Soluplus, Chitosan, poly(vinyl pyrrolidone) (PVP), PVP/VA, HPC, HPMC, HPMCAS, eudragit E100, and a cationic copolymer based on dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate.

5. The lipid-based drug delivery system of claim 1, further comprising Capryol™ PGMC, Cremophor® RH 40, Labrasol, TPGS 1000, Transcutol P and/or Aerosil 200, in addition to Edaravone.

6. The lipid-based drug delivery system of claim 1, further comprising a polymer carrier selected from Soluplus, hydroxypropyl methyl cellulose (HPMC), polyethylene glycol (PEG), Chitosan, PVP, PVP/VA, HPC, hydroxypropylmethylcellulose acetate (HPMCAS), eudragit E100, a cationic copolymer based on dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate.

7. The lipid-based drug delivery system of claim 1, which is selected from a lipid solution, a lipid suspension, surfactant or polymer-lipid mixed micelles, a self-micro emulsifying drug delivery system (SMEDDS), and a nanoemulsion formulation.

8. The lipid-based drug delivery system of claim 7, wherein SMEDDS is solid, and further comprises a solid absorbent.

9. The lipid-based drug delivery system of claim 8, wherein the solid absorbent is Aerosil 200.

10. The lipid-based drug delivery system of claim 7, wherein the nanoemulsion formulation further comprises water/buffering agent.

11. A method of preparing the lipid-based drug delivery system of any one of claims 1-10, comprising a step of:

Dissolving Edaravone or its pharmaceutically acceptable salt thereof as an active ingredient into a lipid, a surfactant, or a mixture of lipid and surfactant.

12. A solid phase dispersion formulation, comprising Edaravone or its

pharmaceutically acceptable salt thereof as an active ingredient, and a polymer carrier, wherein the polymer carrier is selected from Soluplus, hydroxypropyl methyl cellulose (HPMC), polyethylene glycol (PEG), Chitosan, PVP, PVP/VA, HPC, hydroxypropylmethylcellulose acetate (HPMCAS), eudragit E100, a cationic copolymer based on dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate.

13. The solid phase dispersion formulation of claim 12, further comprising a surfactant.

14. The solid phase dispersion formulation of claim 13, wherein the surfactant includes an anionic, cationic, or amphoteric surfactant, selected from the group consisting of sodium dodecanesulfonate, sodium dodecyl sulfate (SDS), sodium lauryl sulfate (SLS), polyoxyethylene sorbitan long-chain fatty acid esters, Vitamin E-TPGS, bile salts, sodium deoxycholate, sodium glycocholate, polyoxyethylene polyoxypropylene glycols and combinations thereof.

15. The solid phase dispersion formulation of claim 13, wherein the surfactant is TPGS 1000.

16. The solid phase dispersion formulation of claim 12, comprising Edaravone, Soluplus and optionally TPGS 1000.

17. A method of preparing the solid phase dispersion formulation of any one of claims 12-16, comprising a step of:

Dispersing Edaravone or a pharmaceutically acceptable salt thereof as an active ingredient in a polymer carrier and, optionally, a surfactant.

18. A method of claim 17, further comprising a step selected from: melting ice bath agitation, thin film cooling, liquid nitrogen, spray

congealing, hot-melt extrusion, Meltrex™, melt agglomeration or solvent evaporation (oven drying, vacuum drying, rotary evaporation, heating on hot plate, spray drying, freeze drying, supercritical anti-solvent, co-precipitation, electrostatic spinning, spray freeze drying, ultra-rapid freezing, fluid-bed coating) and solvent melting.

19. A micelle-based formulation, comprising Edaravone or its pharmaceutically acceptable salt thereof as an active ingredient, a polymer carrier and water/a buffering agent, wherein an effective amount of Edaravone is included in the micelles.

20. The micelle-based formulation of claim 19, wherein the polymer carrier is selected from Soluplus, hydroxypropyl methyl cellulose (HPMC), polyethylene glycol (PEG), Chitosan, PVP, PVP/VA, HPC, hydroxypropylmethylcellulose acetate (HPMCAS), eudragit E100, a cationic copolymer based on dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate.

21. The micelle-based formulation of claim 19, further comprising a surfactant, a solid adsorbent, an acidifying agent and/or an anti-oxidant.

22. The micelle-based formulation of claim 19, comprising Edaravone, Soluplus, TPGS 1000 and PBS.

23. A method of preparing the micelle-based formulation of any one of claims 19-22, comprising steps of:

Dissolving Edaravone or its pharmaceutically acceptable salt thereof as an active ingredient, a polymer carrier and optionally a surfactant in ethanol,

Removing the organic solvent by rotary evaporation,

Drying in vacuo after formation of film, then adding a buffer for hydration, and,

Sonicating.

24. A method of protecting Edaravone as a therapeutic agent, comprising entrapping the therapeutic agent within the micelle-based formulation of any one of claims 19-22.

25. The lipid-based drug delivery system of any one of claims 1-10, the solid phase dispersion formulation of any one of claims 12-16, or the micelle-based formulation of any one of claims 19-22, wherein content of Edaravone is 0.001-1000 mg/ml, or 0.1-100 mg/ml, or 10-20 mg/ml in a liquid formulation, and dose of Edaravone is 0.001-1000 mg/unit, or 0.1-100 mg/unit, or 10-20 mg/unit in a solid formulation.

26. The lipid-based drug delivery system of any one of claims 1-10, the solid phase dispersion formulation of any one of claims 12-16, or the micelle-based formulation of any one of claims 19-22, formulated as a solid dosage form selected from a tablet, a capsule, powders or strips (strip), by oral, parenteral, inhalation, topical or transdermal, intranasal, ocular, ear, rectal, vaginal route.

27. The lipid-based drug delivery system of any one of claims 1-10, the solid phase dispersion formulation of any one of claims 12-16, or the micelle-based formulation of any one of claims 19-22, formulated as a liquid dosage form selected from a solution, a suspension, an emulsion, a co-solvent-based system, an aerosol by oral, parenteral, inhalation, topical or transdermal, intranasal, intraocular, ear, rectal, vaginal route.

28. The lipid-based drug delivery system of any one of claims 1-10, the solid phase dispersion formulation of any one of claims 12-16, or the micelle-based formulation of any one of claims 19-22, formulated as a semi-solid dosage form selected from ointment, cream, gel, paste, by topical or transdermal route, for a topical or systemic administration purpose.

29. Use of the lipid-based drug delivery system of any one of claims 1-10, the solid phase dispersion formulation of any one of claims 12-16, or the micelle-based formulation of any one of claims 19-22 in manufacture of a medicament for treatment of an oxidative stress-related disease.

30. Use of claim 29, wherein the oxidative stress-related disease is selected from Alzheimer's disease, ALS, Parkinson's disease, ischemic heart disease, cerebral infarction/stroke, COPD, HIV/AIDS and diabetes.