Claims

1. A solid phase dispersion formulation, comprising Edaravone, Soluplus and optionally TPGS 1000.

2. A method of preparing the solid phase dispersion formulation of claim 1, comprising a step of:

Dispersing Edaravone or a pharmaceutically acceptable salt thereof as an active ingredient in Soluplus and, optionally, TPGS 1000.

3. A method of claim 2, further comprising a step selected from: melting ice bath agitation, thin film cooling, liquid nitrogen, spray congealing, hot-melt extrusion, Meltrex^{TM}, 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.

4. 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.

5. The micelle-based formulation of claim 4, 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.

6. The micelle-based formulation of claim 4, further comprising a surfactant, a solid adsorbent, an acidifying agent and/or an anti-oxidant.

7. The micelle-based formulation of claim 4, comprising Edaravone, Soluplus, TPGS 1000 and PBS.

8. A method of preparing the micelle-based formulation of any one of claims 4 to 7, 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.

9. A method of protecting Edaravone as a therapeutic agent, comprising entrapping the therapeutic agent within the micelle-based formulation of any one of claims 4 to 7.

10. The solid phase dispersion formulation of claim 1, or the micelle-based formulation of any one of claims 4 to 7, 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.

11. The solid phase dispersion formulation of claim 1, or the micelle-based formulation of any one of claims 4 to 7, 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,

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, or

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.

12. Use of the solid phase dispersion formulation of claim 1, or the micelle-based formulation of any one of claims 4 to 7 in manufacture of a medicament for treatment of an oxidative stress-related disease selected from Alzheimer's disease, ALS, Parkinson's disease, ischemic heart disease, cerebral infarction/stroke, COPD, HIV/AIDS and diabetes.

13. The solid phase dispersion formulation of claim 1, comprising Edaravone and Soluplus in a ratio of 1:1 to 1:16 by mass.

14. The solid phase dispersion formulation of claim 13, comprising Edaravone and Soluplus in a ratio of 1:5 by mass.

15. An oral pharmaceutical composition, comprising Edaravone or a pharmaceutically acceptable salt thereof, and Soluplus.