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, wherein the polymer carrier is Soluplus.

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

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

7. A method of preparing the micelle-based formulation of any one of claims 4 to 6, comprising steps of:

Dissolving Edaravone or its pharmaceutically acceptable salt thereof

as an active ingredient, Soluplus 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.

8. 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 6.

9. The solid phase dispersion formulation of claim 1, wherein dose of Edaravone is 0.001-1000 mg/unit, or 0.1-100 mg/unit, or 10-20 mg/unit in a solid formulation.

10. The micelle-based formulation of any one of claims 4 to 6, 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.

11. The solid phase dispersion formulation of claim 1, 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.

12. The micelle-based formulation of any one of claims 4 to 6, 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.

13. Use of the solid phase dispersion formulation of claim 1, or the micelle-based formulation of any one of claims 4 to 6 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.

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

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

16. An oral pharmaceutical composition, comprising Edaravone or a pharmaceutically acceptable salt thereof, and Soluplus, in form of a solid dispersion or a micelle-based formulation.