CLAIMS

1. An edaravone suspension for human oral administration, comprising:

water;

edaravone particles comprising edaravone dispersed in the water; and

a dispersant dispersing the edaravone particles in the water such that the dispersant maintains the edaravone particles in a solid particle state in the water, wherein a blending amount of the edaravone particles is in a range of 0.5% (w/v) to 36% (w/v), and the dispersant is at least one dispersant selected from the group consisting of polyvinyl alcohol, methylcellulose, hypromellose, sucrose fatty acid ester and polysorbate; ~~and~~

~~water~~.

~~2. The suspension according to claim 1, wherein the dispersant is a dispersant exhibiting a transmission scattering light intensity of 1% or more.~~

~~3. The suspension according to claim 1, wherein he dispersant is a dispersant exhibiting a contact angle of 80 degrees or less.~~

~~4. The suspension according to claim 1, wherein the dispersant is one or more selected from polyvinyl alcohol, methylcellulose, hypromellose, sucrose fatty acid ester and polysorbate.~~

~~5~~2. The edaravone suspension according to claim ~~4~~1, wherein the dispersant is one or two dispersants selected from the group consisting of polyvinyl alcohol, ~~and~~ methylcellulose, hypromellose, sucrose fatty acid ester and polysorbate.

~~6~~3. The edaravone suspension according to claim ~~4 or 5~~2, wherein the dispersant is one or two dispersants selected from the group consisting of polyvinyl alcohol and methylcellulose.

4. The edaravone suspension according to claim 2, wherein the dispersant is polyvinyl alcohol.

~~7~~5. The edaravone suspension according to ~~any one of claims 4 – 6~~claim 2, wherein the dispersant includes the polyvinyl alcohol, and the polyvinyl alcohol has a saponification degree in a range of 86.5 ~~–~~to 89.0, and a 4% aqueous solution ~~thereof~~ of the polyvinyl alcohol has a kinematic viscosity in a range of 3 mm^2/s ~~–~~to 55.7 mm^2/s at 20 °C.

~~8~~6. The edaravone suspension according to ~~any one of claims 1 – 7~~claim 1, wherein a blending amount of the dispersant is in a range of 0.001% (w/v) ~~–~~to 1.0% (w/v).

~~9~~7. The edaravone suspension according to ~~any one of claims 1 – 8~~claim 1, further comprising a thickening agent.

~~10~~8. The edaravone suspension according to claim ~~9~~7, wherein the thickening agent is one or two thickening agents selected from the group consisting of xanthan gum and tragacanth powder.

~~11~~9. The edaravone suspension according to claim ~~9 or 10~~7, wherein the thickening agent is xanthan gum.

~~12~~10. The edaravone suspension according to ~~any one of claims 9 – 11~~claim 7, wherein a blending amount of the thickening agent is in a range of 0.1% (w/v) ~~–~~to 1.2% (w/v).

~~13~~11. The edaravone suspension according to ~~any one of claims 1 – 12~~claim 1, wherein the edaravone particles in the suspension have a D50 particle size in a range of 10 μm ~~–~~to 100 μm and a D90 particle size in a range of 50 μm ~~–~~to 300 μm.

~~14~~12. The edaravone suspension according to ~~any one of claims 1 – 13~~claim 1, wherein a blending amount of the edaravone particles is in a range of 1~~0.06~~% (w/v) ~~–~~to 36% (w/v).

~~15~~13. The edaravone suspension according to ~~any one of claims 1 – 14~~claim 1, further comprising at least one ~~or more~~ additive~~s~~ selected from the group consisting of a sweetener, a stabilizer and a pH regulator.

~~16~~14. The edaravone suspension according to ~~any one of claims 1 – 15~~claim 1 having a viscosity in a range of 50 mPa・s ~~–~~to 1750 mPa・s.

~~17~~15. The edaravone suspension according to ~~any one of claims 1 – 16~~claim 1 having a density in a range of 1 g/mL ~~–~~to 1.5 g/mL.

~~18~~16. The edaravone suspension according to ~~any one of claims 1 – 17~~claim 1, wherein ~~when a dissolution test (test solution: First Solution; and paddle rotation speed: 50 rpm) is performed according to Japanese Pharmacopeia,~~ the suspension has an edaravone dissolution rate of 80% or more 30 minutes after starting a dissolution test according to Japanese Pharmacopeia ~~the test is 80% or more~~.

~~19. A kit for preparing an edaravone suspension for human oral administration, comprising:~~

~~(A) a solid composition containing edaravone particles; and~~

~~(B) a dispersant solution.~~

~~20~~17. An edaravone suspension, comprising:

water;

edaravone particles comprising edaravone dispersed in water; and

a dispersant dispersing the edaravone particles in the water such that the dispersant maintains the edaravone particles in a solid particle state in the water,

wherein a blending amount of the edaravone particles is in a range of 0.5% (w/v) to 36% (w/v), the dispersant is at least one dispersant selected from the group consisting of polyvinyl alcohol, methylcellulose, hypromellose, sucrose fatty acid ester and polysorbate, and ~~for human oral administration, wherein~~ when edaravone in the edaravone suspension is in a range of ~~the suspension containing~~ 90 ~~—~~to 120 mg ~~of edaravone is orally administered to a human~~, edaravone in a plasma exhibits a mean Cmax in a range of 500 ~~—~~to 2500 ng/mL and a mean $AUC_{0-\infty}$ in a range of 1000 ~~—~~to 2500 h*ng/mL when the edaravone suspension is orally administered to a human.

~~21~~18. An edaravone suspension, comprising:

water;

edaravone particles comprising edaravone dispersed in the water; and

a dispersant dispersing the edaravone particles in water such that the dispersant maintains the edaravone particles in a solid particle state in the water,

wherein a blending amount of the edaravone particles is in a range of 0.5% (w/v) to 36% (w/v), the dispersant is at least one dispersant selected from the group consisting of polyvinyl alcohol, methylcellulose, hypromellose, sucrose fatty acid ester and polysorbate, and ~~for human oral administration, wherein~~ when the edaravone in the edaravone suspension is in a range of 90 to 120 mg, and a crossover study is performed such that ~~in which~~ the edaravone suspension ~~containing 90 – 120 mg of edaravone~~ is orally administered to a human ~~is performed using~~and that an edaravone injection is used as a control drug product, a lower limit of a 90% confidence interval of a ratio of a Cmax geometric mean value with respect to the control drug product and a lower limit of a 90% confidence interval of a ratio of an $AUC_{0-\infty}$ geometric mean value with respect to the control drug product both exceed 0.8.

~~22~~19. ~~An~~ The edaravone suspension ~~for human oral administration~~according to claim 18, wherein when edaravone ~~a crossover study~~ in ~~which~~ the edaravone suspension is in a range of ~~containing~~ 90 ~~—~~to 120 mg and a crossover study is performed such that the ~~of~~ edaravone is orally administered to a human ~~is performed using~~and that an edaravone injection is used as a control drug product, a ratio of a Cmax geometric mean value with

respect to the control drug product and a ratio of an $AUC_{0-\infty}$ geometric mean value with respect to the control drug product are both in a range of 0.8 ~~—~~to 1.25.

~~23~~20. An ALS therapeutic agent, comprising:

a drug product comprising the edaravone suspension of claim 1,

wherein a dose of ~~a~~ the drug product per one oral administration is in a range of 1 ~~—~~to 20 mL, and the dose contains edaravone in a range of 50 ~~—~~to 210 mg ~~of edaravone~~.

21. The edaravone suspension according to claim 1, wherein the dispersant is one or two dispersants selected from the group consisting of polyvinyl alcohol, methylcellulose, hypromellose, sucrose fatty acid ester and polysorbate, and a blending amount of the dispersant is in a range of 0.001% (w/v) to 1.0% (w/v).

22. The edaravone suspension according to claim 1, wherein the dispersant is polyvinyl alcohol, and a blending amount of the dispersant is in a range of 0.001% (w/v) to 1.0% (w/v).

23. The edaravone suspension according to claim 4, further comprising a thickening agent.

24. The edaravone suspension according to claim 4, wherein the thickening agent is one or two thickening agents selected from the group consisting of xanthan gum and tragacanth powder.

25. The edaravone suspension according to claim 24, wherein a blending amount of the thickening agent is in a range of 0.1% (w/v) to 1.2% (w/v).