

CLAIMS

1. A dry microparticle comprising an antibody molecule, a polymer, and cyclodextrin, wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL, wherein the cyclodextrin is a member of the β -cyclodextrin family, and wherein the antibody molecule /cyclodextrin ratio (w/w) is from 12:1 to 7:6.
2. An aqueous antibody molecule-containing emulsion comprising an antibody molecule, a polymer, and cyclodextrin, wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL, wherein the cyclodextrin is a member of the β -cyclodextrin family, and wherein the antibody molecule /cyclodextrin ratio (w/w) is from 12:1 to 7:6.
3. The dry microparticle according to claim 1 or the aqueous antibody molecule-containing emulsion according to claim 2, wherein the cyclodextrin is selected from the group consisting of HP β CD and SBE β CD.
4. The dry microparticle according to claim 1 or claim 3 or the aqueous antibody molecule-containing emulsion according to claim 2 or 3, wherein the antibody molecule is a complete antibody molecule having full length heavy and light chains, or an antigen-binding fragment thereof, for example selected from the group comprising Fab, modified Fab, Fab', modified Fab', F(ab')₂, Fv, Fab-Fv, Fab-dsFv, Fab-Fv-Fv, scFv, Bis-scFv fragment, Fab linked to one or two scFvs or dsscFvs, such as a BYbe® or a TRYbe®, diabody, tribody, triabody, tetrabody, minibody, single domain antibody, camelid antibody, Nanobody™ or VNAR fragment.
5. The dry microparticle according to any one of claims 1, 3, or 4 or the aqueous antibody molecule-containing emulsion according to any one of claims 2 to 4, which further comprises a buffering agent.
6. The dry microparticle or the aqueous antibody molecule-containing emulsion according to claim 5, wherein the buffering agent is selected from the group consisting of phosphate, acetate, citrate, arginine, TRIS, and histidine.
7. The dry microparticle according to any one of claims 1 or 3 to 6 or the aqueous antibody molecule-containing emulsion according to any one of claims 2 to 6, which further comprises a surfactant.
8. The dry microparticle or the aqueous antibody molecule-containing emulsion according to claim 7, wherein the surfactant is poloxamer 407.
9. The dry microparticle according to any one of claims 1 or 3 to 8 which comprises 10 to 30 % weight (w)/w of the antibody molecule, 50 to 80 % w/w of the polymer, the cyclodextrin in an antibody molecule /cyclodextrin ratio (w/w) of from 12:1 to 7:6 and optionally 0.2 to 4 % w/w of the buffering agent and/or 0.05 to 4.0 % w/w of the surfactant.

10. A method for producing the dry microparticle according to any one of claims 1 and 3 to 9, comprising the steps of:

- a) adding cyclodextrin to an aqueous antibody molecule-containing solution to obtain an aqueous phase,
- b) solubilising a polymer in a solvent, to obtain an organic phase,
- c) adding the aqueous phase of step a) to the organic phase of step b) to obtain an aqueous antibody molecule-containing emulsion, and then
- d) spray-drying, and optionally further freeze-drying, the resulting aqueous antibody molecule-containing emulsion to obtain the dry microparticle,

wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL, wherein the cyclodextrin is a member of the β -cyclodextrin family.

11. A method for stabilizing an antibody molecule in a dry microparticle comprising the steps of adding cyclodextrin and a solubilised polymer to an aqueous antibody molecule-containing solution to obtain an aqueous antibody molecule-containing emulsion and then spray-drying the resulting aqueous antibody molecule-containing emulsion, and optionally further freeze-drying it in order to obtain the stabilised antibody molecule in said dry microparticle, wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL, wherein the cyclodextrin is a member of the β -cyclodextrin family, and wherein the antibody molecule /cyclodextrin ratio (w/w) is from 12:1 to 7:6.

12. A process for obtaining the dry microparticle according to any one of claims 1 or 3 to 9, comprising the steps of:

- a. Adding cyclodextrin to an aqueous antibody molecule-containing solution to obtain a first composition,
- b. combining the first composition of step a. to a polymer, wherein said polymer is solubilized, to obtain a second composition,
- c. Homogenising the second composition of step b. to obtain a water-in-oil emulsion.
- d. Spray-drying the water-in-oil emulsion of step c. to obtain said dry microparticle
- e. Optionally freeze-drying the dry microparticle of step d. to obtain the final dry microparticle, wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL, wherein the cyclodextrin is a member of the β -cyclodextrin family.

13. A method for improving the antibody molecule-sustained release performance of a dry microparticle, said method comprising the steps of adding cyclodextrin and a solubilised polymer to an aqueous antibody molecule-containing solution to obtain an aqueous antibody molecule-containing emulsion and then spray-drying the resulting aqueous antibody molecule-containing

emulsion, and optionally further freeze-drying it, to obtain said dry microparticle with enhanced antibody molecule-sustained release performance, wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL, wherein the cyclodextrin is a member of the β -cyclodextrin family, and wherein the antibody molecule /cyclodextrin ratio (w/w) is from 12:1 to 7:6.

14. A pharmaceutical composition comprising one or more of the dry microparticles according to any one of claims 1 or 3 to 9.