

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, and wherein the cyclodextrin is a member of the β -cyclodextrin family.

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, and wherein the cyclodextrin is a member of the β -cyclodextrin family.

3. The dry microparticle according to claim 1 or the aqueous antibody molecule-containing emulsion according to claim 2, wherein the cyclodextrin is a member of the β -cyclodextrin family, preferably selected from the group consisting of HP β CD and SBE β CD or a member of the α -cyclodextrin family.

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, wherein the antibody molecule /cyclodextrin ratio (w/w) is from 12:1 to 7:6.

~~6. The dry microparticle according to any one of claims 1 or 3 to 5 or the aqueous antibody molecule-containing emulsion according to any one of claims 2 to 5, wherein the polymer is selected from the group consisting of PLGA, PLA, PEG-PLGA or PCL.~~

~~7.6.~~ The dry microparticle according to any one of claims 1 or 3 to ~~6-5~~ or the aqueous antibody molecule-containing emulsion according to any one of claims 2 to ~~65~~, which further comprises a buffering agent.

~~8.7.~~ The dry microparticle or the aqueous antibody molecule-containing emulsion according to claim ~~76~~, wherein the buffering agent is selected from the group consisting of phosphate, acetate, citrate, arginine, TRIS, and histidine.

~~9.8.~~ The dry microparticle according to any one of claims 1 or 3 to ~~8-7~~ or the aqueous antibody molecule-containing emulsion according to any one of claims 2 to ~~87~~, which further comprises a surfactant.

~~10-9.~~ The dry microparticle or the aqueous antibody molecule-containing emulsion according to claim ~~98~~, wherein the surfactant is poloxamer 407.

~~11-10.~~ The dry microparticle according to any one of claims 1 or 3 to ~~10-9~~ which comprises ~~about~~ 10 to 30 % weight (w)/w of the antibody molecule, ~~about~~ 50 to 80 % w/w of the polymer, the cyclodextrin in an antibody molecule /cyclodextrin ratio (w/w) of from ~~or from about~~ 12:1 to ~~or to about~~ 7:6 and optionally ~~about~~ 0.2 to 4 % w/w of the buffering agent and/or ~~about~~ 0.05 to 4.0 % w/w of the surfactant.

~~12. A dry microparticle which is obtained by spray drying, or by spray drying followed by freeze-drying, the aqueous antibody molecule-containing emulsion according to any one of claims 2 to 10.~~

~~13-11.~~ A method for producing the dry microparticle according to any one of claims 1 and 3 to ~~11-10~~, 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.

~~14-12.~~ 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.

~~15-13.~~ A process for obtaining the dry microparticle according to any one of claims 1 or 3 to ~~14-12~~, 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 \$\beta\$ -cyclodextrin family.](#)

~~16-14.~~ 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 \$\beta\$ -cyclodextrin family.](#)

~~17-15.~~ A pharmaceutical composition comprising one or more of the dry microparticles according to any one of claims 1 or 3 to [1210](#).