CLAIMS

1. A method for preparing a solid dosage form comprising i) an inert core unit; and ii) a drug coating comprising at least one antibody or functional fragment thereof as active agent, a buffer and at least one polymeric binder, deposited on the inert core unit by drug layering; the method comprising the steps of

    a) preparing an active agent coating liquid, comprising the at least one antibody or functional fragment thereof, the buffer and the at least one polymeric binder, as an aqueous solution or suspension;

    b) layering the inert core unit with the active agent coating liquid using spray coating;

    c) drying the wet drug layered inert core unit, simultaneously with step b), or after step b) has been completed, to give rise to a dried solid dosage form; and after step c),

    d) applying at least one additional coating in the form of a sustained release coating, by layering the solid dosage form of step c) with a sustained release coating liquid using spray coating, and then drying the wet layered solid dosage form using a fluidized bed or an oven; and after step d)

    e) applying at least one additional coating in the form of a delayed release coating, and wherein the solid dosage form is for oral administration.

2. Method according to claim 1, wherein the active agent coating liquid comprises 0.01-50 mg/ml of the at least one antibody or functional fragment thereof.

3. Method according any of the preceding claims, wherein the active agent coating liquid comprises:

    i) 0.5-5 wt.-% antibody or functional fragment thereof;

    ii) 1-20 wt.-% polymeric binder; and

    iii) 0-2 wt.-% anti-tacking agent.

4. The method according any of the preceding claims, wherein the spray coating is a fluidized-bed spray coating and wherein during the fluidized-bed spray coating the atomising air pressure at the spray nozzle is lower than 200 kPa.

5. Method according to any of the preceding claims, wherein at any time during steps a) and c) the temperature of the at least one antibody or functional fragment thereof is lower than the melting temperature (Tm) of the at least one antibody or functional fragment thereof.

6. Method according to any of the preceding claims, wherein the polymeric binder in the drug coating is selected from hydroxypropyl methylcellulose (HPMC), methylcellulose (MC), hydroxypropyl cellulose (HPC), macrogol poly(vinylalcohol) grafted copolymer, polyvinylpyrrolidone (PVP) and combinations thereof.

7. Method according to any of the preceding claims, wherein the drug coating is suitable for immediate release of the active agent and wherein the wet drug layered inert core unit is dried simultaneously with step b) using the inlet air flow of a fluidized bed, and wherein the inlet air has a temperature of up to 60 °C.

8. Method according to any of claims 1 to 5, wherein the polymeric binder in the drug coating comprises at least one sustained release polymeric binder, and wherein the wet drug layered inert core unit is dried after step b) has been completed, at a temperature of not higher than 65 °C.

9. Method according to claim 8, wherein the at least one sustained release polymeric binder (S) and the at least one antibody or functional fragment thereof (A) are present in the active agent coating liquid in a ratio S / A (w / w) of 0.5 to 100.

10. Method according to any of the preceding claims, wherein the sustained release coating liquid comprises 5-20 wt.-% sustained release polymer, relative to the total weight of the sustained release coating liquid, and wherein the solid dosage form after step d) comprises a polymer weight gain of 2.5-25 wt.-% relative to the solid dosage form before step d).

11. Method according to any of the preceding claims, wherein the at least one sustained release polymeric binder and/or the sustained release polymer is selected from the group consisting of poly(ethyl acrylate, methyl methacrylate) 2 : 1; poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1 : 2 : 0.1; poly(ethyl acrylate,

methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1 : 2 : 0.2; ethylcellulose; polyvinyl acetate; and combinations thereof.

12. Method according to any of the preceding claims, wherein the active agent coating liquid and/or the sustained release coating liquid further comprise(s) an anti-tacking agent, a surfactant, a filler, a plasticizer and/or a coalescence agent.

13. Method according to claim 12, wherein the active agent coating liquid and/or the sustained release coating liquid comprise(s) 5-50 wt.-% anti-tacking agent, 10-30 wt.-% plasticizer, and/or 2-15 wt.-% coalescence enhancer, relative to the total weight of the polymeric binder solids in the active agent coating liquid and/or the polymer solids in the sustained release coating liquid, and/or 0.01-2 wt.% surfactant relative to the total weight of the active agent coating liquid and/or the sustained release coating liquid .

14. Method according to any of the preceding claims, wherein the at least one antibody or functional fragment thereof is selected from antibodies specific to tumor necrosis factor alpha (TNFα) and functional fragments thereof, antibodies specific to α4β7 integrin and functional fragments thereof, antibodies specific to CD3, CD4 or CD20 and functional fragments thereof, antibodies specific to interleukin 6 (IL-6), interleukin 12 (IL-12), interleukin 13 (IL-13), interleukin 23 (IL-23) or to their receptors and functional fragments thereof, antibodies specific to CXCL10/IP-10 and functional fragments thereof, and antibodies specific to p40 protein subunit and functional fragments thereof.

15. Method according to any one of the preceding claims, wherein the delayed release coating comprises at least one component selected from the group consisting of poly vinyl acetate phthalate, cellulose acetate trimellitate, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate, hydroxypropyl methylcellulose acetate succinate (HPMCAS), poly(methacrylic acid, ethyl acrylate) 1:1, poly(methacrylic acid, methyl methacrylate) 1:1, poly(methacrylic acid, methyl methacrylate) 1:2, chondroitin sulfate, pectin, guar gum, chitosan, inulin, lactulose, raffinose, stachyose, alginate, dextran, xanthan gum, locust bean gum, arabinogalactan, amylose, cyclodextrin, pullulan, carrageenan, scleroglucan, chitin, curdulan, levan, amylopectin, starch, resistant starch, azo compounds being degraded by azo bonds splitting bacteria, and combinations thereof.

16. Solid dosage form prepared by the method of any of claims 1 to 15.

17. Use of a solid dosage form according to claim 16 for the manufacturing of a medicament for the treatment of a patient suffering from a gastrointestinal disease.