Claims

1. Use of a solid pharmaceutical composition in the manufacture of a medicament to treat a disease of the intestinal tract by oral administration to a region of the intestinal tract, the solid pharmaceutical composition comprising a compressed core, wherein the compressed core comprises:

(i) a pharmaceutically active binding polypeptide wherein the pharmaceutically active binding polypeptide is present at 40-75% by weight relative to the weight of the core,

(ii) one or more compression aids,

(iii) one or more disintegrants

wherein the compressed core is coated with a pH sensitive enteric coating and wherein the pharmaceutically active binding polypeptide is a domain antibody.

2. Use of a solid pharmaceutical composition in the manufacture of a medicament to treat a disease of the intestinal tract by oral administration to a region of the intestinal tract, the solid pharmaceutical composition comprising a compressed core, wherein the compressed core comprises:

(i) a pharmaceutically active binding polypeptide wherein the pharmaceutically active binding polypeptide is present at 40-75% by weight relative to the weight of the core,

(ii) one or more compression aids wherein the one or more compression aids is present at 20-55% by weight relative to the weight of the core,

(iii) one or more disintegrants wherein the one or more disintegrants is present at 2-6% by weight relative to the weight of the core;

wherein the compressed core is coated with a pH sensitive enteric coating and wherein the pharmaceutically active binding polypeptide is a domain antibody.

3. The use according to any one of claims 1 to 2 wherein the pH sensitive enteric coating releases pharmaceutically active binding polypeptide when exposed to a region of the intestinal tract.

4. The use according to any one of claims 1 and 2 wherein the one or more compression aids is selected from the list consisting of synthetic polymers such as crospovidone, saccharides such as sucrose, glucose, lactose and fructose, sugar alcohols such as mannitol, xylitol, maltitol, erythritol, sorbitol, water-soluble polysaccharides such as celluloses such as crystalline cellulose, microcrystalline cellulose, powdered cellulose,

hydroxypropylcellulose and methyl cellulose, starches, synthetic polymers such as polyvinylpyrrolidone, sodium starch glycolate, crospovidone and inorganic compounds such as calcium carbonate.

5. The use according to any one of claims 1 and 2 wherein the one or more disintegrants is selected from the list consisting of carboxymethyl cellulose, sodium carboxymethyl cellulose, croscarmellose sodium, cellulose such as low substitution degree hydroxypropylcellulose, starch such as sodium carboxymethyl starch, hydroxypropyl starch, rice starch, wheat starch, potato starch, maize starch, partly pregelatinized starch.

6. The use according to any one of claims 1 to 5 comprising one or more lubricants wherein the one or more lubricants is selected from the list consisting of glyceryl behenate, a stearic acid salt such as calcium stearate; magnesium stearate; zinc stearate, mineral oil, polyethylene glycol, sodium lauryl sulfate, sodium stearyl fumarate, starch such as corn starch; potato starch; pregelatinized starch; tapioca starch; wheat starch, stearic acid, talc, vegetable oil and zinc stearate.

7. The use according to any one of claims 1 to 5 comprising one or more lubricants wherein the one or more lubricants is present at 0.1-2%, such as about 1% by weight relative to the weight of the core.

8. The use according to any one of claims 1 to 7 wherein the pharmaceutically active binding polypeptide is present at 50%-60% by weight relative to the weight of the core.

9. The use according to any one of claims 1 to 10 wherein the pH sensitive enteric coating has a thickness of 10-300 µm.

10. The use according to any one of claims 1 to 9 wherein the pH sensitive enteric coating comprises or consists of a pH sensitive enteric polymer coat optionally together with one or more of a plasticiser, an anti-tacking agent and a surfactant.

11. The use according to claim 10 wherein the pH sensitive enteric polymer coat comprises one or more of: methyl acrylate-methacrylic acid copolymers, cellulose acetate succinate, hydroxy propyl methyl cellulose phthalate, hydroxy propyl methyl cellulose acetate succinate (hypromellose acetate succinate), polyvinyl acetate phthalate (PVAP), methyl methacrylate-methacrylic acid copolymers, sodium alginate and stearic acid.

12. The use according to any one of claims 10 to 11 wherein the pH sensitive enteric polymer coat does not dissolve until after 2 hours or longer exposure to a pH between 0.5 and 3.5.

13. The use according to any one of claims 1 to 12 wherein the pharmaceutically active binding polypeptide has an aqueous solubility of greater than 10 mg/mL, such as greater than 30 mg/mL.

14. The use according to any one of claims 1 to 13 wherein the pharmaceutically active binding polypeptide is a VH or VHH.