Claims

1. A solid pharmaceutical composition for delivering by oral administration a pharmaceutically active binding polypeptide to a region of the intestinal tract comprising a compressed core, wherein the compressed core comprises a pharmaceutically active binding polypeptide and wherein the compressed core is coated with a pH sensitive enteric coating.

2. Use of a solid pharmaceutical composition in the manufacture of a medicament for treating 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 a pharmaceutically active binding polypeptide and wherein the compressed core is coated with a pH sensitive enteric coating.

3. Use of a solid pharmaceutical composition in the manufacture of a medicament for treating 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

and wherein the compressed core is coated with a pH sensitive enteric coating.

4. Use of a solid pharmaceutical composition in the manufacture of a medicament for treating 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,

(i) 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,

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

and wherein the compressed core is coated with a pH sensitive enteric coating.

5. The pharmaceutical composition or use according to any one of claims 1 to 4 wherein the pH sensitive enteric coating releases pharmaceutically active binding polypeptide when exposed to a region of the intestinal tract.

6. The use according to any one of claims 3 and 4 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.

7. The use according to any one of claims 3 and 4 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.

8. The pharmaceutical composition or use according to any one of claims 1 to 7 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.

9. The pharmaceutical composition or use according to any one of claims 1 to 7 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.

10. The pharmaceutical composition or use according to any one of claims 1 to 9 wherein the pharmaceutically active binding polypeptide is present at about 50%-60% by weight relative to the weight of the core.

11. The pharmaceutical composition or use according to any one of claims 1 to 10 wherein the pH sensitive enteric coating has a thickness of 10-300um.

12. The pharmaceutical composition or use according to any one of claims 1 to 11 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.

13. The pharmaceutical composition or use according to claim 12 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.

14. The pharmaceutical composition or use according to any one of claims 12 to 13 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.

15. The pharmaceutical composition or use according to any one of claims 1 to 14 wherein the molecular weight of the pharmaceutically active binding polypeptide is 5-200kD.

16. The pharmaceutical composition or use according to any one of claims 1 to 15 wherein the pharmaceutically active binding polypeptide has an aqueous solubility of greater than 10 mg/mL, such as greater than 30 mg/mL.

17. The pharmaceutical composition or use according to any one of claims 1 to 16 wherein the pharmaceutically active binding polypeptide is an immunoglobulin.

18. The pharmaceutical composition or use according to claim 17 wherein the pharmaceutically active binding polypeptide is a VH or VHH.

19. The pharmaceutical composition or use according to any one of claims 1 to 18 wherein when assayed in the Pharmacopeial Enteric Coating Test, the pharmaceutical composition releases less than 10% by weight of the pharmaceutically active binding polypeptide after 2 hours.

20. The pharmaceutical composition or use according to any one of claims 1 to 18 wherein when assayed in the Pharmacopeial Dissolution Test, the pharmaceutical composition releases:
(i) 10-40% by weight of the pharmaceutically active binding polypeptide after 30 minutes,
(ii) 30-60% by weight of the pharmaceutically active binding polypeptide after 60 minutes and
(iii) 60% by weight or greater of the pharmaceutically active binding polypeptide after 120 minutes.

21. The pharmaceutical composition or use according to any one of claims 1 to 18 wherein when assayed in the Dynamic Dissolution Test:

the start of release of the pharmaceutical composition occurs between 90 to 210 minutes,

the pharmaceutical composition releases:

(i) 10-30% by weight of the pharmaceutically active binding polypeptide after 60 minutes from start of release,

(ii) 40-70% by weight of the pharmaceutically active binding polypeptide after 120 minutes from start of release and

(iii) 60% by weight or greater of the pharmaceutically active binding polypeptide after 180 minutes from start of release.