CLAIMS

1. Use of an isolation layer to accelerate drug release in the intestine of a subject from a delayed release drug formulation for oral administration to said subject, said formulation comprising:

a core comprising said drug;

said isolation layer coating said core; and

an outer coating for providing intestinal release of said drug, said outer coating comprising an outer layer and an inner layer,

wherein the outer layer comprises a pH dependently soluble polymeric material which has a pH threshold at about pH 5 or above,

wherein the inner layer comprises a soluble polymeric material which is soluble in intestinal fluid or gastrointestinal fluid, said soluble polymeric material being selected from the group consisting of a polycarboxylic acid polymer that is at least partially neutralised, and a non-ionic polymer, provided that, where said soluble polymeric material is a non-ionic polymer, said inner layer comprises at least one additive selected from a buffer agent and a base, and

wherein intestinal release of said drug from said formulation is accelerated compared to an equivalent formulation without said isolation layer.

2. Use as claimed in Claim 1, wherein drug release is accelerated in the colon of said subject.

3. Use as claimed in Claim 1 or Claim 2, wherein lag time (T_{lag}) *in vitro* in Krebs buffer at pH 7.4 after 2 h at 0.1M HCl is reduced by at least 10%, preferably by at least 20%, more preferably by at least 30% and most preferably by at least 40%.

4. Use as claimed in any of the preceding claims, wherein lag time (T_{lag}) *in vitro* in Krebs buffer at pH 7.4 after 2 h at 0.1M HCl is reduced by at least 10 minutes, preferably by at least 20 minutes, more preferably by at least 30 minutes, and most preferably by at least 45 minutes.

5. Use as claimed in Claim 1, wherein drug release is accelerated in the small intestine of said subject.

6. Use as claimed in Claim 1, wherein drug release is accelerated in the proximal small intestine of said subject.

7. Use as claimed in any of the preceding claims, wherein said isolation layer is present in a coating amount from about 1 mg polymer/cm^2 to about 5 mg polymer/cm^2, preferably from about 2 mg polymer/cm^2 to about 4 mg polymer/cm^2, more preferably from about 2.5 mg polymer/cm^2 to about 3.5 mg polymer/cm^2, and most preferably of about 3 mg polymer/cm^2.

8. Use as claimed in any of the preceding claims, wherein said isolation layer has a thickness from about 5 μm to about 100 μm, preferably from about 10 μm to about 60 μm, and most preferably from about 20 μm to about 40 μm.

9. Use as claimed in any of the preceding claims, wherein said isolation layer comprises at least one non-ionic polymer.

10. Use as claimed in any of the preceding claims, wherein said isolation layer comprises at least one polymer selected from the group consisting of methylcellulose (MC); hydroxypropyl cellulose (HPC); hydroxypropyl methylcellulose (HPMC); poly(ethylene oxide)-graft-polyvinyl alcohol; polyvinylpyrollidone (PVP); and polyvinyl alcohol (PVA).

11. Use as claimed in any of the preceding claims, wherein said isolation layer comprises HPMC.

12. Use as claimed in any of the preceding claims, wherein said isolation layer comprises PVA.

13. Use as claimed in Claim 11 or Claim 12, wherein said non-ionic polymer is present in the isolation layer as the sole film-forming polymeric material.

14. Use as claimed in any of the preceding claims, wherein said core is acidic.

15. Use as claimed in any of the preceding claims, wherein said drug, or any other component in the core, comprises at least one acidic group.

16. Use as claimed in any of the preceding claims, wherein said drug is an anti-inflammatory agent.

17. Use as claimed in any of the preceding claims, wherein said drug is 5ASA.

18. Use as claimed in any of the preceding claims, wherein said soluble polymeric material of said inner layer is said polycarboxylic acid polymer that is at least partially neutralised.

19. Use as claimed in Claim 18, wherein at least 10%, preferably at least 25%, more preferably at least 50%, and most preferably at least 90%, of the carboxylic acid groups of said polycarboxylic acid polymer are in the form carboxylate anions.

20. Use as claimed in Claim 18 or Claim 19, wherein said polycarboxylic acid polymer is fully neutralised.

21. Use as claimed in any of Claims 18 to 20, wherein said pH dependently soluble polymeric material of said outer layer is based on the same polycarboxylic acid polymer as said soluble polymeric material of said inner layer, said the soluble polymeric material of said inner layer having a higher degree of neutralisation than said pH dependently soluble polymeric material of said outer layer.

22. Use as claimed in any of Claims 18 to 21, wherein said polycarboxylic acid polymer of said soluble polymeric material of said inner layer is selected from polymethacrylates; cellulose acetate phthalate (CAP); polyvinyl acetate phthalate (PVAP); hydroxypropyl methylcellulose phthalate (HPMCP); hydroxypropyl methylcellulose acetate succinate (HPMC-AS); cellulose acetate trimellitate (CAT); xanthan gum; alginates; and shellac.

23. Use as claimed in any of Claims 18 to 22, wherein said soluble polymeric material of said inner layer is an at least partially neutralised co-polymer of (meth)acrylic acid and a (meth)acrylic acid C_{1-4} alkyl ester.

24. Use as claimed in any of Claims 18 to 23, wherein said soluble polymeric material of said inner layer is a fully neutralised co-polymer of (meth)acrylic acid and (meth)acrylic acid methyl ester.

25. Use as claimed in any of Claims 18 to 24, wherein said inner layer comprises at least one additive selected from a buffer agent and a base.

26. Use as claimed in any of Claims 1 to 17, wherein said soluble polymeric material of said inner layer is said non-ionic polymer.

27. Use as claimed in Claim 26, wherein said non-ionic polymer of said inner layer is selected from HPMC; PVA; MC; HPC; poly(ethylene oxide)-graft-polyvinyl alcohol; and PVP.

28. Use as claimed in any of the preceding claims, wherein the inner layer comprises at least one buffer agent and at least one base.

29. Use as claimed in any of the preceding claims, wherein the buffer agent is selected from the group consisting of a carboxylic acid having from 1 to 16 carbon atoms, an alkali metal salt, an alkali earth metal salt, an ammonium salt and a soluble metal salt.

30. Use as claimed in any of the preceding claims, wherein the buffer agent is a phosphate salt.

31. Use as claimed in any of the preceding claims, wherein the buffer agent is potassium dihydrogen phosphate.

32. Use as claimed in any of the preceding claims, wherein the buffer agent is present in the inner layer a total amount from about 0.1 wt % to about 50 wt % based on the dry weight of the soluble polymeric material of the inner layer.

33. Use as claimed in any of the preceding claims, wherein the buffer agent is present in the inner layer in a total amount from about 0.1 wt % to about 20 wt % based on the dry weight of the at least partially neutralised polycarboxylic acid of the inner layer.

34. Use as claimed in any of Claims 1 to 32, wherein the buffer agent is present in the inner layer in a total amount from about 10 wt % to about 30 wt % based on the dry weight of the non-ionic polymer of the inner layer.

35. Use as claimed in any of the preceding claims, wherein the base is selected from the group consisting of hydroxide bases, alkali metal bicarbonates, alkali metal carbonates, alkali metal phosphates, alkali metal citrates, or physiologically tolerated amines.

36. Use as claimed in any of the preceding claims, wherein the base is a hydroxide base.

37. Use as claimed in any of the preceding claims, wherein the base is sodium hydroxide.

38. Use as claimed in any of the preceding claims, wherein the pH dependently soluble polymeric material of the outer layer is a blend of at least two different polymers having a pH threshold of about pH 5 and above.

39. Use as claimed in Claim 38, wherein the polymers in the blend are different polymethacrylate polymers.

40. Use as claimed in Claim 38 or Claim 39, wherein there are two different polymers in the blend in a ratio from about 40:60 to about 60:40, and preferably about 50:50.

41. Use as claimed in any of the preceding claims, wherein said pH dependently soluble polymeric material is present in the outer layer as the sole film forming polymeric material.

42. Use as claimed in any of Claims 1 to 40, wherein said pH dependently soluble polymeric material is present in the outer layer in admixture with a digestible polymeric material which is susceptible to attack by colonic bacteria.

43. Use as claimed in Claim 42, wherein said digestible polymeric material and said pH dependently soluble polymeric material are present in the outer layer in a ratio of up to about 60:40.

44. Use as claimed in Claim 42 or Claim 43, wherein said digestible polymeric material and said pH dependently soluble polymeric material are present in the outer layer in a ratio from about 25:75 to about 35:65, preferably about 30:70.

45. Use as claimed in Claim 42 or Claim 43, wherein said digestible polymeric material and said pH dependently soluble polymeric material are present in the outer layer in a ratio from about 40:60 to about 60:40, preferably about 50:50.

46. A method of accelerating drug release in the intestine of a subject from a delayed release drug formulation for oral administration to said subject, said formulation comprising:

a core comprising said drug; and

an outer coating for providing intestinal release of said drug, said outer coating comprising an outer layer and an inner layer,

wherein the outer layer comprises a pH dependently soluble polymeric material which has a pH threshold at about pH 5 or above, and

wherein the inner layer comprises a soluble polymeric material which is soluble in intestinal fluid or gastrointestinal fluid, said soluble polymeric material being selected from the group consisting of a polycarboxylic acid polymer that is at least partially neutralised, and a non-ionic polymer, provided that, where said soluble polymeric material is a non-ionic polymer, said inner layer comprises at least one additive selected from a buffer agent and a base,

said method comprising providing an isolation layer between said core and said outer coating,

wherein intestinal release of said drug from said formulation is accelerated compared to an equivalent formulation without said isolation layer.

47. A method as claimed in Claim 46, wherein the formulation is as defined in any of Claims 2 to 45.