CLAIMS

1. A method of producing a delayed release drug formulation for oral administration to deliver a drug to the colon, the method comprising:

forming a core comprising a drug;

combining a first aqueous preparation of an enzymatically degradable starch which is degradable by colonic bacterial enzymes; a second aqueous preparation of a film-forming enteric acrylate polymer having a pH threshold of pH 6 or above; and an organic anti-tack agent selected from glyceryl monostearate and stearic acid, to form an outer layer coating preparation; and

coating the core with the outer layer coating preparation to form an outer layer coated core;

in which the proportion of the enzymatically degradable starch to the film-forming enteric acrylate polymer in the outer coating preparation is in a range from 10:90 to 50:50; and

in which the outer layer coating preparation comprises no more than 5% v/v organic solvent.

2. A method according to Claim 1, in which the second aqueous preparation is formed by suspending the enteric polymer in water under stirring to form a suspension, and partially neutralising the suspension with a base.

3. A method according to Claim 2, in which the base is added to the suspension in an amount sufficient to neutralise from 10% to 30%, preferably from 15% to 20%, of the carboxylic acid groups in the enteric polymer.

4. A method according to Claim 2 or 3, in which the suspension is partially neutralised using aqueous ammonia.

5. A method according to Claim 4, in which the aqueous ammonia has a concentration from 0.5 N to 2 N, preferably 1 N.

6. A method according to any preceding claim, in which the organic anti-tack agent is in the form of an aqueous dispersion.

7. A method according to Claim 6, in which the aqueous dispersion comprises a surfactant.

8. A method according to Claim 7, in which the surfactant is non-ionic.

9. A method according to Claim 7 or 8, in which the surfactant is hydrophilic.

10. A method according to any preceding claim, in which the core is pre-coated with either an isolation layer comprising a film-forming non-ionic polymer that is soluble in gastrointestinal fluid; or an inner layer comprising a polymeric material which is soluble in intestinal or gastrointestinal fluid, the 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 the polymeric material is a non-ionic polymer, the inner layer comprises at least one additive selected from a buffer agent and a base; or both the isolation layer and the inner layer.

11. A method according to Claim 10, in which the inner layer comprises a buffer agent and a base.

12. A delayed release drug formulation for oral administration to deliver a drug to the colon, the formulation produced according to a method according to any preceding claim, comprising:

a core comprising a drug, and

an outer coating layer for the core, the outer coating layer comprising a mixture of an enzymatically degradable starch which is degradable by colonic bacterial enzymes, a film-forming enteric acrylate polymer having a pH threshold at pH 6 or above, and an organic anti-tack agent selected from glyceryl monostearate and stearic acid;

in which the outer coating layer comprises no more than 5000 ppm residual free organic solvent;

and

in which the proportion of the enzymatically degradable starch to the film-forming enteric acrylate polymer in the outer coating preparation is in a range from 10:90 to 50:50.

13. A delayed release drug formulation according to Claim 12, in which the outer coating layer comprises at least 10% by weight of at least one plasticiser based on the weight of the film-forming enteric polymer.

14. A delayed release drug formulation according to Claim 12 or 13 comprising an inner layer located between the core and the outer coating layer, in which the inner layer comprises a film-forming non-ionic polymer that is soluble in gastrointestinal fluid, a buffer agent, and a base.

15. A delayed release drug formulation according to Claim 12, 13 or 14 comprising an isolation layer located on the surface of the core, the isolation layer comprising a film-forming non-ionic polymer that is soluble in gastrointestinal fluid.

16. A delayed release drug formulation for oral administration to deliver a drug to the colon, the formulation comprising:

a core comprising a drug, and

an outer coating layer for the core, the outer coating layer comprising a mixture of an enzymatically degradable starch which is degradable by colonic bacterial enzymes, a film-forming enteric acrylate polymer having a pH threshold at pH 6 or above, and an organic anti-tack agent selected from glyceryl monostearate and stearic acid;

in which the outer coating layer comprises at least 50% by weight of at least one plasticiser based on the weight of the film-forming enteric acrylate polymer.