CLAIMS

1. A formulation comprising a melt-processed solid dispersion product comprising
   (a) an active agent having at least one moiety selected from hydrogen bond donor moieties and proton donor moieties,
   (b) a pharmaceutically acceptable polyvinyllactam polyvinylacetate poly(alkylene glycol) graft copolymer, and
   (c) a pharmaceutically acceptable pH modifier;
   wherein the active agent is selected from pharmaceutically active agents, cosmetically active agents and nutritional supplements, and is a compound with a solubility in water at 25°C and pH 7.0 of 0.01 g/100 ml or less.

2. The formulation of claim 1, wherein the active agent has at least one hydrogen bond donor moiety.

3. The formulation of claim 2, wherein the hydrogen bond donor moiety is selected from primary amino, secondary amino, hydroxy, carbamoyl, thiocarbamoyl, sulfamoyl, sulfinamoyl and ureido.

4. The formulation of claim 1, wherein the active agent has at least one proton donor moiety.

5. The formulation of claim 4, wherein the proton donor moiety is selected from organic acid moieties and CH-acidic moieties.

6. The formulation of any one of claims 1-5, wherein the active agent is non-ionic.

7. The formulation of claim 1, wherein the active agent is selected from (*RS*)-2-(4-(2-methylpropyl)phenyl)propanoic acid, 2-{4-[(4-chlorophenyl)carbonyl]phenoxy}-2-methylpropanoic acid and (2*S*)-2-(6-methoxynaphthalen-2-yl) propanoic acid.

8. The formulation of any one of claims 1-7, wherein the graft copolymer comprises
   (i) 10 to 50 wt% poly(alkylene glycol) moieties,
   (ii) 30 to 80 wt% N-vinyllactam moieties, and
   (iii) 10 to 50 wt% vinyl acetate moieties.

9. The formulation of claim 8, wherein the N-vinyllactam moieties are N-vinylcaprolactam moieties.

10. The formulation of any one of claims 1-9, wherein the pH modifier is an alkaline pH modifier.

11. The formulation of claim 10, wherein the alkaline pH modifier is selected from basic salts of organic acids and inorganic acids, basic amino acids, metal oxides and metal hydroxides.

12. The formulation of any one of claims 1-9, wherein the pH modifier is an acidic pH modifier.

13. The formulation of claim 12, wherein the acidic pH modifier is selected from mono-, di- and polybasic carboxylic acids, mono-, di- and poly-sulfonic acids, and acidic salts thereof.

14. The formulation of any one of claims 1-13, comprising 0.5 to 20 wt% of the pH modifier relative to the weight of the solid dispersion product.

15. The formulation of any one of claims 1-14, wherein the sum of components (a), (b) and (c) makes up at least 80% of the solid dispersion product.

16. A method for producing the formulation of any one of claims 1-15 comprising a solid dispersion product, wherein the active agent having at least one hydrogen bond donor moiety or proton donor moiety, the pharmaceutically acceptable pH modifier and the pharmaceutically acceptable polyvinyllactam polyvinylacetate poly(alkylene glycol) graft copolymer are intimately blended so as to obtain the solid dispersion product.

17. The method of claim 16, comprising the steps of

(a) blending the active agent, the pH modifier and the graft copolymer;

(b) heating the blend to obtain a homogeneous melt;

(c) forcing the thus obtained melt through one or more nozzles; and

(d) allowing the melt to solidify to obtain a solid dispersion product.

18. The method of claim 17, wherein step (b) is carried out in an extruder and the blend is subjected to a mixing action in a mixing section of the extruder.

19. Use of a pharmaceutically acceptable pH modifier for increasing the dispersion rate of a solid dispersion product in an aqueous medium relative to the dispersion rate of a comparative product in the aqueous medium and
for increasing the release rate of an active agent from the solid dispersion product into the aqueous medium relative to the release rate of the active agent from the comparative product into the aqueous medium;
wherein the active agent has at least one moiety selected from a hydrogen bond donor moieties and proton donor moieties, is selected from pharmaceutically active agents, cosmetically active agents and nutritional supplements, and is a compound with a solubility in water at 25°C and pH 7.0 of 0.01 g/100 ml or less;
the solid dispersion product comprises
(a) the active agent,
(b) a pharmaceutically acceptable polyvinyllactam polyvinylacetate poly(alkylene glycol) graft copolymer, and
(c) the pharmaceutically acceptable pH modifier; and
the comparative product differs from the solid dispersion product in lacking the pharmaceutically acceptable pH modifier.

CLAIMS

1. Use of a pharmaceutically acceptable pH modifier for increasing the dispersion rate of a solid dispersion product in an aqueous medium

wherein the solid dispersion product comprises

(a) an active agent having at least one of a hydrogen bond donor moiety and a proton donor moiety,
(b) a pharmaceutically acceptable polyvinyllactam polyvinylacetate poly(alkyleneglycol) graft copolymer, and
(c) a pharmaceutically acceptable pH modifier;

wherein the active agent is selected from the group consisting of pharmaceutically active agents, cosmetically active agents and nutritional supplements, and is a compound with a solubility in water at 25°C and pH 7.0 of 0.01 g/100 ml or less.

2. Use of a pharmaceutically acceptable pH modifier for increasing the release rate of an active agent from a solid dispersion product in an aqueous medium

wherein the solid dispersion product comprises

(a) an active agent having at least one of a hydrogen bond donor moiety and a proton donor moiety,
(b) a pharmaceutically acceptable polyvinyllactam polyvinylacetate poly(alkyleneglycol) graft copolymer, and
(c) a pharmaceutically acceptable pH modifier;

wherein the active agent is selected from the group consisting of pharmaceutically active agents, cosmetically active agents and nutritional supplements, and is a compound with a solubility in water at 25°C and pH 7.0 of 0.01 g/100 ml or less.

3. The use of either claims 1 or 2, wherein the hydrogen bond donor moiety is selected from primary amino, secondary amino, hydroxy, carbamoyl, thiocarbamoyl, sulfamoyl, sulfinamoyl and ureido.

4. The use of either claims 1 to 3, wherein the proton donor moiety is selected from organic acid moieties and CH-acidic moieties.

5. The use of either claims 1 to 4, wherein the active agent is non-ionic.

6. The use of either claims 1 to 5, wherein the active agent is selected from (RS)-2-(4-(2-methylpropyl)phenyl)propanoic acid, 2-{4-[(4-chlorophenyl)carbonyl]phenoxy}-2-methylpropanoic acid and (2*S*)-2-(6-methoxynaphthalen-2-yl) propanoic acid.

7. The use of either claims 1 to 6, wherein the graft copolymer comprises

   (i) from 10 to 50 wt% poly(alkylene glycol) moieties,
   (ii) from 30 to 80 wt% N-vinyllactam moieties, and
   (iii) from 10 to 50 wt% vinyl acetate moieties.

8. The use of claim 7, wherein the N-vinyllactam moieties are N-vinylcaprolactam moieties.

9. The use of either claims 1 to 8, wherein the pH modifier is an alkaline pH modifier.

10. The use of claim 9, wherein the alkaline pH modifier is selected from basic salts of organic acids and inorganic acids, basic amino acids, metal oxides and metal hydroxides.

11. The use of either claims 1 to 8, wherein the pH modifier is an acidic pH modifier.

12. The use of claim 11, wherein the acidic pH modifier is selected from mono-,di- and polybasic carboxylic acids, mono-, di- and poly-sulfonic acids, and acidic salts thereof.

13. The use of either claims 1 to 12, comprising 0.5 to 20 wt% of the pH modifier relative to the weight of the solid dispersion product.

14. The use of either claims 1 to 13, wherein the sum of components (a), (b) and (c) makes up at least 80% of the solid dispersion product.