CLAIMS

1. An oral composition comprising cyclosporin, a hydrogel forming polymer matrix, a surfactant and an oil phase being dispersed in the hydrogel forming polymer matrix, wherein the surfactant comprises or is a medium chain or long chain fatty acid mono- or di-glyceride or a combination thereof and does not comprise or is not a polyethyleneglycol ether or ester; wherein the hydrogel-forming polymer is in an amount of at least 25% by weight based upon the dry weight of the composition.

2. A composition of claim 1 wherein the oil phase comprises a solution of the cyclosporin.

3. A composition of claim 1 or claim 2, wherein the surfactant is present in an amount of more than 6 wt% of the dry weight of the composition.

4. A composition of any of claims 1 to 3, wherein the surfactant is non-ionic; and/or the surfactant comprises or is a long chain fatty acid mono- or di-glyceride or a combination thereof.

5. A composition of any of claims 1 to 3, wherein the surfactant is or comprises a surfactant selected from:

   glyceryl monocaprate, glyceryl dicaprate, glyceryl monocaprylate, glyceryl dicaprylate, glyceryl caprate, glyceryl monocaprylate/caprate, glyceryl caprylate/caprate glyceryl dicaprylate/caprate, glyceryl monooleate/dioleate, glyceryl monooleate, glyceryl dioleate, glyceryl monostearate, glyceryl distearate, glyceryl monopalmitostearate, glyceryl dipalmitostearate, glyceryl monobehenate, glyceryl dibehenate, glyceryl monolinoleate, glycerol monolinoleate, glyceryl dilinoleate, polyglyceryl dioleate, propylene glycol monoheptanoate, polyglycerol dioleate, and a combination thereof; optionally

   wherein the surfactant is selected from: glyceryl monocaprylate/caprate, glyceryl dicaprylate/caprate, glyceryl monooleate, glycerol monolinoleate, glyceryl dioleate, glyceryl monostearate, glyceryl distearate, glyceryl monopalmitostearate, glyceryl dipalmitostearate, glyceryl monobehenate, glyceryl dibehenate, glyceryl monolinoleate, glyceryl dilinoleate, polyglyceryl dioleate and a combination thereof.

6. A composition of any of claims 1 to 3, wherein the surfactant is or comprises a surfactant selected from: glyceryl caprylate/caprate (Capmul MCM), glyceryl monooleate/dioleate (Capmul GMO-50), glycerol monolinoleate (Maisine 35-1) and a combination thereof.

7. The composition of any preceding claim, wherein the oil phase is or comprises a liquid lipid and optionally wherein the liquid lipid is or comprises a glyceride composition,
   further optionally wherein the liquid lipid is or comprises a medium chain fatty acid triglyceride or a combination thereof, or the liquid lipid is or comprises a caprylic/capric triglyceride composition.

8. The composition of any preceding claim, wherein the composition further comprises a solvent, wherein the solvent is miscible with the oil phase and water, optionally wherein the solvent is selected from 2-(2-ethoxyethoxy)ethanol and a poly(ethylene glycol), particularly wherein the solvent is 2-(2-ethoxyethoxy)ethanol.

9. The composition of any preceding claim wherein the hydrogel forming polymer or hydrogel forming polymer matrix is or comprises a hydrocolloid selected from carrageenan, gelatin, agar and pectin, or a combination thereof; optionally selected from gelatin and agar or a combination thereof, more optionally the polymer of the a hydrogel forming polymer matrix is or comprises gelatin.

10. The composition of any preceding claim, wherein the hydrogel forming polymer or hydrogel forming polymer matrix further comprise a plasticiser, optionally a plasticiser selected from glycerin, a polyol for example sorbitol, polyethylene glycol and triethyl citrate or a mixture thereof, particularly sorbitol.

11. The composition of any preceding claim, wherein the composition is a solid composition and has the characteristics of a composition formed by mixing an aqueous phase premix with an oil phase premix to form a mixture, the aqueous phase premix comprising the hydrogel forming polymer matrix and the oil phase premix comprising the oil phase in which the cyclosporin is dissolved and the surfactant, optionally the mixture being in the form of an emulsion, and allowing the mixture to solidify, further optionally wherein the mixture is passed on through a single orifice nozzle before being allowed to solidify.

12. The composition of any preceding claim, wherein the composition is a solid composition and further comprises at least one coating, optionally wherein the at least one coating is an outer coating (a second coating).

13. The solid composition of claim 12 wherein the at least one coating is adapted to release the cyclosporin in at least the colon; and/or the at least one coating comprises a pH-independent coating e.g. ethylcellulose.

14. The solid composition of any of claims 12 to 13, wherein the composition comprises two coatings, a first coating and a second coating; optionally

. wherein the composition comprises a first coating which comprises or is a water-soluble cellulose ether, for example hydroxypropylmethyl cellulose, and a second coating as specified in any of claims 11 to 12.

15. The composition of any of claims 1 to 14, wherein the composition is a solid composition that is in the form of a minibead optionally having a size of from 0.5mm to 5mm.

16. A multiple mini bead formulation, comprising a unit dosage form comprising a multiplicity of mini beads of claim 15.

17. A colloidal composition comprising
a continuous phase comprising:
a hydrogel forming polymer matrix comprising gelatin in an amount of 300 to 700 mg/g;
a disperse phase comprising:
cyclosporin in an amount of up to 200 mg/g; and
a medium chain tri-glyceride in an amount of 20 to 200 mg/g;

and the composition further comprising:
solvent in an amount of 100 to 250 mg/g;
surfactant having an HLB of up to 8 in an amount of 80 to 200 mg/g; and
anionic surfactant in an amount of up to 50 mg/g.

18. A composition comprising cyclosporin A, wherein after oral administration of the composition to a human the mean concentration of cyclosporin A: the concentration of cyclosporin A metabolites in a faecal sample from the human is greater than 12:1.

19. The composition of claim 18, wherein the composition is or comprises a composition according to any of claims 1 to 17.

20. The composition of any preceding claim, wherein the composition releases less than 15% (for example 0 to 10%) of the cyclosporin A after 2 hours; releases 10% to 40% (for example 10% to 35%, or suitably 15% to 35%) of the cyclosporin A at 4 hours; and releases from about 30% to 70% (for example 40% to 70%) of the cyclosporin A between 4 hours and 12 hours; when measured in a two stage dissolution test using a USP Apparatus II with a paddle speed of 75 rpm and a dissolution medium temperature of 37°C; wherein for the first 2 hours of the dissolution test the dissolution medium is 750 ml of 0.1 N HCl, and at 2 hours 250 ml of 0.2M tribasic sodium phosphate containing 2% SDS is added to the dissolution medium and the pH is adjusted to pH 6.8.

21. A composition comprising cyclosporin A and a surfactant, wherein the surfactant comprises, or is a medium chain or long chain fatty acid mono- or di-glyceride or a combination thereof and does not comprise or is not a polyethyleneglycol ether or ester; and wherein the surfactant is present in an amount of at least 6% by weight of the composition; wherein the composition further comprises an oil phase as defined in any of claims 12 to 19.

22. The composition of claim 21, wherein the cyclosporin A is partially or completely dissolved in the composition.

23. The composition of any preceding claim, further comprising a P450 inhibitor or a PgP inhibitor, or a combination thereof.

24. A process for making a composition, the process comprising mixing an oil phase with an aqueous phase comprising a hydrogel forming polymer present in an amount of at least 25% by weight of the composition based upon the dry weight of the composition, wherein the oil phase has cyclosporin in solution and comprises a surfactant comprising or being a medium chain or long chain fatty acid mono- or di-glyceride or a combination thereof and not comprising or not being a polyethyleneglycol ether or ester.

25. The process of claim 24, wherein the oil phase and the aqueous phase are mixed in a oil phase to aqueous phase ratio of from 1:2 to 1:12; and/or mixing the oil phase with the aqueous phase forms an emulsion; and/or the process further comprises causing the emulsion to solidify.

26. A composition of any of claims 1 to 23 for use in treating a condition.

27. The composition for use of claim 26, wherein the condition is a condition of the gastrointestinal tract; optionally wherein the condition is selected from inflammatory bowel disease, irritable bowel syndrome, Crohn's disease, ulcerative colitis, celiac disease, graft vs host disease, gastrointestinal graft-versus-host disease, gastroenteritis, duodenitis, jejunitis, ileitis, peptic ulcer, pouchitis, Curling's ulcer, appendicitis, colitis, pseudomembraneous colitis, diverticulosis, diverticulitis, microscopic colitis, collagenous colitis, lymphocytic colitis, colorectal carcinoma, adenocarcinoma, myasthenia gravis, stomach ulcers, proctitis, mucositis, chemotherapy-associated enteritis, radiation-associated enteritis, short bowel disease, or chronic diarrhea, endometriosis, inflammatory disorders such as diversion colitis, ischemic colitis, infectious colitis, chemical colitis, fulminant colitis, autistic enterocolitis, interdeminate colitis, jejunoiletis, atypical colitis, fulminant colitis, autistic enterocolitis, interdeminate colitis, jejunoiletis, ileocolitis or granulomatous colitis, the prevention of rejection following bone marrow transplantation, psoriasis, atopic dermatitis, rheumatoid arthritis, nephrotic syndrome primary sclerosing cholangitis, familial adenomatous polyposis, or perianal Crohn's, including perianal fistulae.

28. A composition of any of claims 21 to 23 for use in the treatment of a condition affecting the colon selected from inflammatory bowel disease, irritable bowel disease, Crohn's disease, ulcerative colitis, colonic graft vs host disease, colitis, pseudomembraneous colitis, diverticulosis, diverticulitis, collagenous colitis and colorectal carcinoma wherein the composition is topically applied to the colon; optionally wherein the composition is administered rectally, for example as an enema or suppository.

29. A liquid composition comprising an aqueous phase, a surfactant and an oil phase in which cyclosporin is dissolved, wherein the oil phase comprises a liquid lipid and the surfactant comprises or is a medium chain or long chain fatty acid mono- or di-glyceride or a combination thereof and does not comprise or is not a polyethyleneglycol ether or ester, the aqueous phase comprises a hydrogel-forming polymer and the oil phase is dispersed in the aqueous phase; wherein the hydrogel-forming polymer is in an amount of at least 25% by weight based upon the dry weight of the composition.