Claims

1. A composition in the form of a plurality of particles of a weight-, number-, or volume-based mean diameter that is between 1 µm and 50 µm, which particles comprise:

(a) solid cores, wherein the cores comprise a biologically active agent and/or a pharmaceutically-acceptable excipient;

(b) one or more discrete layers surrounding said cores, said one or more layers each comprising at least one separate coating material; and

(c) an outer overcoating layer of a coating material, which overcoating layer surrounds, encloses and/or encapsulates said core and/or said previously-applied layers of coating material, and which final layer is of a thickness that is less than said previously-applied layers,

wherein the thickness of the outer overcoating layer is no more than about 1/1000 of the volume-based mean diameter of the core, including any discrete layers of coating material.

2. A composition as claimed in Claim 1, wherein the carrier/excipient material is a sugar or a sugar alcohol and/or is a pH modifying agent.

3. A composition as claimed in Claim 1, wherein the cores consist essentially of biologically active agent.

4. A composition as claimed in any one of Claims 1 to 3, wherein the biologically active agent is selected from an analgesic, an anaesthetic, an anti-ADHD agent, an anorectics agent, an antiaddictives agent, an antibacterial agent, an antimicrobial agent, an antifungal agent, an antiviral agent, an antiparasitic agent, an antiprotozoal agent, an anthelminic, an ectoparasiticide, a vaccine, an anticancer agent, an antimetabolite, an alkylating agent, an antineoplastic agent, a topoisomerase, an immunomodulator, an immunostimulant, an immunosuppressant, an anabolic steroid, an anticoagulant agent, an antiplatelets agent, an anticonvulsant agent, an antidementia agent, an antidepressant agent, an antidote, an antihyperlipidemic agent, an antigout agent, an antimalarial, an antimigraine agent, an anti-inflammatory agent, an antiparkinson agent, an antipruritic agent, an antipsoriatic agent, an antiemetic, an anti-obesity agent, an anthelmintic, an anti-arrhythmic agent, an antiasthma agent, an antibiotic, an anticoagulant, an antidepressant, an antidiabetic agent, an antiepileptic, an antifibrinolytic agent, an antihemorrhagic agent, an antihistamine, an antitussive, an antihypertensive agent, an antimuscarinic agent, an antimycobacterial agent, an antioxidant agent, an antipsychotic agent, an antipyretic, an antirheumatic agent, an antiarrhythmic agent, an anxiolytic agent, an aphrodisiac, a cardiac glycoside, a cardiac

stimulant, an entheogen, an entactogen, an euphoriant, an orexigenic, an antithyroid agent, an anxiolytic sedative, a hypnotic, a neuroleptic, an astringent, a bacteriostatic agent, a beta blocker, a calcium channel blocker, an ACE inhibitor, an angiotensin II receptor antagonist, a renin inhibitor, a beta-adrenoceptor blocking agent, a blood product, a blood substitute, a bronchodilator, a cardiac inotropic agent, a chemotherapeutic, a coagulant, a corticosteroid, a cough suppressant, a diuretic, a deliriant, an expectorant, a fertility agent, a sex hormone, a mood stabilizer, a mucolytic, a neuroprotective, a nootropic, a neurotoxin, a dopaminergic, an antiparkinsonian agent, a free radical scavenging agent, a growth factor, a fibrate, a bile acid sequestrants, a cicatrizant, a glucocorticoid, a mineralcorticoid, a haemostatic, a hallucinogen, a hypothalamic-pituitary hormone, an immunological agent, a laxative agent, a antidiarrhoeals agent, a lipid regulating agent, a muscle relaxant, a parasympathomimetic, a parathyroid calcitonin, a serenic, a statin, a stimulant, a wakefulness-promoting agent, a decongestant, a dietary mineral, a biphosphonate, a cough medicine, an ophthamological, an ontological, a H1 antagonist, a H2 antagonist, a proton pump inhibitor, a prostaglandin, a radio-pharmaceutical, a hormone, a sedative, an anti-allergic agent, an appetite stimulant, an anoretic, a steroid, a sympathomimetic, a trombolytic, a thyroid agent, a vasodilator, a xanthine, an erectile dysfunction improvement agent, a gastrointestinal agent, a histamine receptor antagonist, a keratolytic, an antianginal agent, a non-steroidal antiinflammatory agent, a COX-2 inhibitor, a leukotriene inhibitor, a macrolide, a NSAID, a nutritional agent, an opioid analgesic, an opioid antagonist, a potassium channel activator, a protease inhibitor, an antiosteoporosis agent, a cognition enhancer, an antiurinary incontinence agent, a nutritional oil, an antibenign prostate hypertrophy agent, an essential fatty acid, a non-essential fatty acid, a cytokine, a peptidomimetic, a peptide, a protein, a radiopharmaceutical, a senotherapeutic, a toxoid, a serum, an antibody, a nucleoside, a nucleotide, a vitamin, a portion of genetic material, a nucleic acid, or a mixture of any of these.

5. A composition as claimed in any one of the preceding claims, wherein, not including the final overcoating, more than one discrete layers of coating material is applied to the core sequentially.

6. A composition as claimed in Claim 5, wherein between 3 and 10 discrete layers of coating material are applied.

7. A composition as claimed in any one of the preceding claims, wherein, not including the overcoating layer, the total thickness of the discrete layers of coating material is between 0.5 nm and 2 µm.

8. A composition as claimed in any one of the preceding claims, wherein the maximum thickness of an individual discrete layer of coating material is about 1 hundredth of the weight-, number-, or volume-based mean diameter of the core, including any other previously-applied discrete layers of coating material that are located between said individual discrete layer and the outer surface of the core.

9. A composition as claimed in any one of the preceding claims, wherein the thickness of the overcoating layer is no more than a factor of about 0.7 of the thickness of the widest previously-applied discrete coating.

10. A composition as claimed in Claim 9, wherein, for particles up to 20 μm, the thickness of the overcoating layer is between 0.3 nm to 10 nm.

11. A composition as claimed in any one of the preceding claims, wherein the thickness of the outer overcoating layer is no more than a factor of about 0.7 of the thickness of the last discrete layer of coating material that is applied.

12. A composition as claimed in any one of the preceding claims, wherein the thickness of the outer overcoating layer is no more than a factor of about 0.7 of the average thickness of all the previously-applied discrete layers.

13. A composition as claimed in any one of the preceding claims, wherein the overcoating layer gives rise to particles that are essentially free of abrasions, pinholes, breaks, gaps, cracks and/or voids through which active ingredient, if present, is potentially exposed.

14. A composition as claimed in any one of the preceding claims, wherein the coating materials of the one or more discrete layers and/or overcoating layer comprise one or more inorganic materials.

15. A composition as claimed in Claim 14, wherein the coating materials comprise one or more metal-containing, or metalloid-containing, compounds.

16. A composition as claimed in Claim 15, wherein the compounds comprise a hydroxide and/or an oxide.

17. A composition as claimed in Claim 15 or Claim 16, wherein the compounds comprise aluminium oxide, titanium dioxide and/or zinc oxide.

18. A composition as claimed in any one of the preceding claims, wherein the coating material of the overcoating layer comprises aluminium oxide.

19. A composition as defined in any one of the preceding claims for use in medicine or in veterinary practice.

20. A pharmaceutical or veterinary formulation comprising a composition as defined in any one of Claims 1 to 18 and a pharmaceutically-acceptable or a veterinarily-acceptable adjuvant, diluent or carrier.

21. A formulation as claimed in Claim 20 in the form of a sterile injectable and/or infusible dosage form.

22. A formulation as claimed in Claim 21 in the form of a liquid, a sol or a gel, administrable *via* a surgical administration apparatus that forms a depot formulation.

23. A process for the preparation of a composition as defined in any one of Claims 1 to 18, which comprises applying layers of coating materials to cores, and/or previously-coated cores, by atomic layer deposition.

24. A process as claimed in Claim 23, wherein:
(i) solid cores are coated with a first discrete layer of coating material;
(ii) the coated cores from step (i) are then subjected to a deagglomeration process step;
(iii) the deagglomerated coated cores from step (ii) are then coated with a second discrete layer of coating material;
(iv) repeating steps (ii) and (iii) to obtain the required number of discrete layers;
(v) subjecting the coated particles from step (iv) to a final deagglomeration process step; and
(vi) application of the final overcoating layer of coating material to the deagglomerated coated particles from step (v).

25. A process as claimed in Claim 24, wherein the deagglomeration step that takes place between applications of coatings comprises sieving.

26. A process as claimed in Claim 25, wherein the sieving comprises sonic sifting.

27. A process as claimed in any one of Claims 23 to 26, wherein the particles are subjected to a final vortexing step after application of the overcoating layer.

28. A process as for the preparation of a formulation as defined in any one of Claims 20 to 22, which comprises admixing a composition as defined in any one of Claims 1 to 18 with the relevant pharmaceutically-acceptable or a veterinarily-acceptable adjuvant, diluent or carrier.

29. A process as claimed in any one of Claims 23 to 28, which process comprises an further step of resuspending separated particles in a solvent, with or without the presence of one or more pharmaceutically acceptable excipients.