Claims

1. A process for the preparation of composition in the form of a plurality of particles having a weight-, number-, and/or volume-based mean diameter that is between 10 nm and 700 µm, which particles comprise:

(a) solid cores; and

(b) two or more sequentially applied, discrete layers, each of which comprises at least one separate coating material, and which two or more layers together surround, enclose and/or encapsulate said cores,

which process comprises the sequential steps of:

(1) applying an initial layer of at least one coating material to said solid cores by way of a gas phase deposition technique;

(2) subjecting the coated particles to agitation to deagglomerate particle aggregates formed during step (1) by way of a sieving step;

(3) applying a further layer of at least one coating material to the deagglomerated particles; and

(4) optionally repeating steps (2) and (3) one or more times to increase the total thickness of the at least one coating material that enclose(s) said solid core,

wherein at least one of the sieving steps comprises a vibrational sieving technique, in which the vibrational sieving technique comprises supplying electrical power to a vibration motor coupled to a sieve.

2. The process as claimed in Claim 1, wherein the vibration motor is a piezoelectric vibrational motor or an eccentric rotating mass vibration motor.

3. The process as claimed in Claim 1 or Claim 2, wherein the vibration motor and sieve are suspended from a mount via a suspension means.

4. The process as claimed in Claim 3, wherein the suspension means comprises a spring or bellows.

5. the process as claimed in any one the preceding claims, wherein the vibrational sieving technique:

- further comprises controlling a vibration probe coupled to the sieve, and/or
- sieving coated particles with a throughput of at least 1 g/minute.

6. The process as claimed in any one the preceding claims, wherein sieve is formed from stainless steel.

7. The process as claimed in any one the preceding claims, wherein step (2) comprises discharging the coated particles from the gas phase deposition reactor prior to subjecting the coated particles to agitation, and step (3) comprises reintroducing the deagglomerated, coated particles from step (2) into the gas phase deposition reactor prior to applying a further layer of at least one coating material to the reintroduced particles.

8. The process as claimed in any one the preceding claims, wherein the cores:

- comprise, or consist essentially of, a biologically active agent; and/or
- comprise a pharmaceutically-acceptable excipient.

9. The process as claimed in Claim 8, wherein the carrier/excipient material is a sugar or a sugar alcohol and/or is a pH modifying agent.

10. The process as claimed in Claim 8 or Claim 9, wherein the biologically active agent is selected from an analgesic, an anaesthetic, an anti-ADHD agent, an anorectic agent, an antiaddictive 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 antiplatelet 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 antiasthma agent, an antibiotic, 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, a steroid, a sympathomimetic, a thrombolytic, 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.

11. The process as claimed in any one the preceding claims, wherein:

- the weight-, number-, or volume-, based mean diameter of the cores is between 1 μm and 50 μm;

- between 3 and 10 discrete layers of coating material are applied to the core sequentially and/or

- the total thickness of the discrete layers of coating material is between 0.5 nm and 2 μm and/or

- 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.

12. The process as claimed in any one of the preceding claims, wherein the coating materials:

- of the one or more of the discrete layers comprise one or more inorganic coating materials.

13. The process as claimed in Claim 12, wherein the coating materials comprise one or more metal-containing, or metalloid-containing, compounds.

14. The process as claimed in Claim 13, wherein the compounds comprise a hydroxide and/or an oxide.

15. The process as claimed in Claim 13 or Claim 14, wherein the one or more coating materials comprise silicon oxide, aluminium oxide, titanium dioxide, zinc sulphide and/or zinc oxide.

16. A process as claimed in Claim 15, wherein the one or more coating materials comprise a mixture of zinc oxide along with one or other or both of silicon dioxide and aluminium oxide.

17. The process as claimed in any one of the preceding claims, which comprises applying the separate layers of coating materials to cores, and/or previously-coated cores, by atomic layer deposition.

18. The process as claimed in any one of the preceding claims, which process comprises a further step of resuspending separated particles in a solvent, with or without the presence of one or more pharmaceutically acceptable excipients.

19. The process as claimed in Claim 8 or any claim dependent thereon, wherein the biologically-active agent is an anti-cancer agent.

20. The process as claimed in Claim 19, wherein the biologically-active agent is azacitidine.