

CLAIMS

1. A process for the preparation of pharmaceutical or veterinary composition in the form of a plurality of particles, which process comprises:

- 5 (a) loading a plurality of solid cores comprising a biologically-active agent into a stationary gas phase deposition reactor chamber; and
- (b) applying a gas phase deposition technique to surround, enclose and/or encapsulate said cores with one or more layers comprising one or more coating materials, each comprising one or more metal-containing or
10 metalloid-containing compounds; and
- (c) sequentially repeating step (b) above as required to form a plurality of particles having a weight-, number-, and/or volume-based mean diameter that is between about 10 nm and about 100 μm , each particle comprising a respective solid core and a coating surrounding, enclosing and/or
15 encapsulating said core,

which gas phase deposition technique comprises:

- (1) introducing a pulse of a first reactant gas into the stationary gas phase deposition reactor chamber and allowing the first reactant gas to contact said solid cores for a pre-determined period of soaking time;
- 20 (2) after step (1), evacuating and/or purging with an inert gas the stationary gas phase deposition reactor chamber;
- (3) introducing a pulse of a second reactant gas into the stationary gas phase deposition reactor chamber and allowing the second reactant gas to contact said solid cores for a pre-determined period of soaking time; and
- 25 (4) after step (3), evacuating and/or purging with an inert gas the stationary gas phase deposition reactor chamber,

wherein either the first reactant gas or the second reactant gas comprises a metal or metalloid-containing compound.

- 30 2. A process as claimed in Claim 1, wherein step (1), step (3) or both steps (1) and (3) comprise allowing the respective reactant gas to contact said solid cores for the respective pre-determined period of soaking time in the substantial absence of pumping that may result in flow of gases; and/or step (1), step (3) or both steps (1) and (3) comprise allowing the respective reactant gas to contact said solid cores for
35 the respective pre-determined period of soaking time in the substantial absence of mechanical agitation of the plurality of solid cores.

3. A process as claimed in any one of the preceding claims, wherein the pre-determined period of soaking time is from about 2 seconds to about 30 minutes.
4. A process as claimed in any one of the preceding claims, wherein step (1), step
5 (3) or both steps (1) and (3) comprise:
- o after said pre-determined period of soaking time, pumping the reactor for a pre-determined period of pumping time; and
 - o repeating, a pre-determined number of times, the steps of introducing a pulse
10 of the respective reactant gas, allowing the respective reactant gas to contact said solid cores for a pre-determined period of soaking time, and pumping the reactor for a pre-determined period of pumping time.
5. A process as claimed in any one of the preceding claims, wherein each repetition
15 of step (b) is carried out using the same, or different, first and second reactant gases to the previous iteration of step (b).
6. A process as claimed in any one of the preceding claims, wherein, between one or
20 more sequential pairs of step (b) iterations, the process comprises deagglomerating the coated solid cores.
7. A process as claimed in Claim 6, wherein, one or more instances of deagglomerating the coated solid cores comprises removing the coated solid cores from the stationary gas phase deposition reactor chamber, vibrational sieving or sonic sifting the coated solid cores and re-loading the coated solid cores into the stationary
25 gas phase deposition reactor chamber in order to repeat step (b).
8. A process as claimed in Claim 7, wherein vibrational sieving or sonic sifting of the coated solid cores is carried out using a sieve with a mesh size determined so that the ratio of the size of sieved or sifted particles to the sieve mesh size is about 1:>1,
30 preferably about 1:2, and optionally is about 1:4.
9. A process as claimed in any one of the preceding claims, wherein at least 200 mg of the solid cores are loaded into the stationary gas phase deposition reactor chamber for the gas phase deposition technique to be applied, optionally at least 1 g or at least
35 10 g and/or between 3 and 10 discrete layers of coating material are applied to the core sequentially.

10. A process as claimed in any one of the preceding claims, wherein, the total thickness of the discrete layers of coating material is between about 0.5 nm and about 2 μ m 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.

11. A process as claimed in any one of the preceding claims, wherein the coating materials of the one or more discrete layers comprise one or more inorganic coating materials.

12. A process as claimed in Claim 11, wherein the one or more metal-containing, or metalloid-containing, compounds comprise a hydroxide and/or an oxide.

13. A process as claimed in Claim 11 or Claim 12, wherein the one or more coating materials comprise silicon oxide, aluminium oxide, titanium dioxide, zinc sulphide and/or zinc oxide.

14. A process as claimed in Claim 13, 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.

15. A 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.

16. A process as claimed in any one of the preceding claims, wherein the cores comprise a pharmaceutically-acceptable excipient and/or the carrier/excipient material is a sugar or a sugar alcohol and/or is a pH modifying agent.

17. A process as claimed in any one of Claims 1 to 15, wherein the cores consist essentially of biologically active agent.

18. A process as claimed in any one of the preceding claims, 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 anthelmintic, 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
 5 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
 10 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
 15 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
 20 dopaminergic, 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
 25 wakefulness-promoting agent, a decongestant, a dietary mineral, a biphosphonate, a
 cough medicine, an ophthalmological, 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
 30 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
 35 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 19. A composition obtainable by way of a process as claimed in any one of the preceding claims.

20. A pharmaceutical or veterinary formulation comprising a composition as claimed in Claim 19 and a pharmaceutically-acceptable or a veterinarily-acceptable adjuvant, diluent or carrier.

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

15 22. A pharmaceutical or veterinary formulation as claimed in Claim 20 or Claim 21 in the form of a liquid, a sol or a gel, administrable *via* a surgical administration apparatus that forms a depot formulation.

20 23. A process for the preparation of a pharmaceutical or veterinary formulation as defined in any one of Claims 20 to 22, which comprises admixing a composition as defined in Claim 19 with the relevant pharmaceutically-acceptable or a veterinarily-acceptable adjuvant, diluent or carrier.