Claims

1. The use of a pharmaceutical composition suitable for administration to the lung, which composition comprises a plurality of amorphous nanoporous silica particles, in which one or more immunomodulatory imide drug is loaded into the pores of said particles, and wherein the silica particles have:

(a) a mass median aerodynamic diameter that is between about 0.1 µm and about 10 µm; and

(b) a geometric standard deviation that is less than about 4,

for the manufacture of a medicament for the treatment of an interstitial lung disease by pulmonary administration.

2. The use as claimed in Claim 1, wherein the loaded silica particles have a mass density that is less than about 0.4 g/cm^3.

3. The use as claimed in Claim 1 or Claim 2, wherein the mass median aerodynamic diameter is between about 3 µm and about 5 µm.

4. The use as claimed in any one of the preceding claims wherein the geometric standard deviation is between about 1 and about 1.5.

5. The use as claimed in any one of the preceding claims wherein the silica particles have a pore size that is between about 10 nm and about 20 nm.

6. The use as claimed in any one of the preceding claims wherein the silica particles have a pore volume that is between 0.2 and 3 cm^3/g.

7. The use as claimed in any one of the preceding claims wherein the silica particles have a surface area that is between about 150 and about 1200 m^2/g.

8. The use as claimed in any one of the preceding claims wherein the silica particles are essentially spherical.

9. The use as claimed in any one of the preceding claims wherein up to about 45% of the total weight of the loaded particles is immunomodulatory imide drug.

10. The use as claimed in any one of the preceding claims wherein the immunomodulatory imide drug is essentially amorphous.

11. The use as claimed in any one of the preceding claims wherein the silica particles consist essentially of a synthetic biodegradable amorphous mesoporous silica.

12. The use as claimed in any one of the preceding claims wherein the immunomodulatory imide drug is thalidomide.

13. A process for the production of a composition as defined in any one of the preceding claims, which process comprises:

(a) separating silica particles to obtain particles having a mass median aerodynamic diameter and a geometric standard deviation as defined in the relevant preceding claims; followed by

(b) loading the obtained particles with the immunomodulatory imide drug.

14. A process as claimed in Claim 13, wherein the silica particles are separated and classified into the desired particle size range using an air classifier.

15. A process as claimed in Claim 13 or Claim 14, wherein the silica particles are loaded with one or more immunomodulatory imide drug using a process of solvent evaporation.

16. A process as claimed in any one of Claims 13 to 15, wherein the silica particles are manufactured by reacting tetraethyl orthosilicate with a template made of micellar structures.

17. A process as claimed in any one of Claims 13 to 15, wherein the silica particles are manufactured by a sol-gel method comprising a condensation reaction of an aqueous suspension of silica nanoparticles with a non-miscible organic solution, oil, or liquid polymer, followed by gelation by means of change in pH and/or evaporation of the aqueous phase.

18. A pharmaceutical composition as defined in any one of Claims 1 to 12 and/or obtainable by way of a process as defined in any one of Claims 13 to 17.

19. A pharmaceutical formulation comprising a composition as defined in any one of the Claims 1 to 12 or 18 in admixture with one or more pharmaceutically-acceptable excipients.

20. The formulation as claimed in Claim 19, wherein the excipient is a hydrocarbon, a fluorocarbon and/or a hydrogen-containing fluorocarbon propellant.

21. A process for the production of a composition as defined in Claim 19 or Claim 20, which process comprising admixing the composition as defined in any one of the Claims 1 to 12 or 18 with the one or more pharmaceutically-acceptable excipients.

22. The use of a formulation as defined in Claim 19 or Claim 20 for the manufacture of a medicament for the treatment of an interstitial lung disease by pulmonary administration.

23. The use as defined in any one of Claims 1 to 12 or 22, wherein the interstitial lung disease is idiopathic pulmonary fibrosis.

24. The use as defined in any one of Claims 1 to 12 or 22, wherein the interstitial lung disease is sarcoidosis.