CLAIMS

1. Chromatography media comprising:

porous silica particles having a median pore diameter of from 60 nm to 160 nm; a pore size distribution relative span of at least 1.0 up to 2.0; and a functionalized surface comprising an average of from greater than 1 to 3 linker molecules per square nanometer of surface area of said porous silica particles.

2. Chromatography media comprising:

porous silica particles having a median pore diameter of from 60 nm to 160 nm; a pore size distribution relative span of at least 1.0 up to 2.0; and a functionalized surface comprising a protein covalently bonded to surface portions of said porous silica particles, said protein having a molecular weight ranging from 10,000 to 100,000 D,

wherein said protein is covalently bonded to surface portions of said porous silica particles via an average of greater than 1 to 3 linker molecules per square nanometer of surface area of said porous silica particles.

3. Chromatography media comprising:

porous silica particles having an average BET surface area of from 20 m^2/g to 100 m^2/g; an average pore volume of at least 1 ml/g; a pore size distribution relative span of at least 1.0 up to 2.0; a functionalized surface comprising an average of from greater than 1 to 3 linker molecules per square nanometer of surface area of said porous silica particles; and a protein covalently bonded to at least some of said linker molecules, said protein having a molecular weight ranging from 10,000 to 100,000 D.

4. The chromatography media of any one of claims 1 to 3, wherein (i) at least 40% of the total pore volume is in pores having a diameter between 60 nm to 160 nm, preferably from 40% to 90% of the total pore volume, (ii) at least 20% of the total pore volume have pores in a diameter ranging from 100 nm to 160 nm, preferably from 20% to 60% of the total pore

volume, and (iii) at least 15% of the total pore volume have pores in a diameter ranging from 120 nm to 150 nm, preferably from 15% to 30% of the total pore volume.

5. The chromatography media of any one of claims 1 to 2 and 4, wherein said porous silica particles have an average BET surface area of greater than 10 m^2/g, preferably from 20 m^2/g to 200 m^2/g, more preferred from 25 m^2/g to 100 m^2/g.

6. The chromatography media of any one of claims 1 to 2 and 4 to 5, wherein said porous silica particles have an average pore volume of at least 1 ml/g.

7. The chromatography media of claim 6, wherein said porous silica particles have an average particle dimension of from 30 µm to 120 µm, preferably from 50 µm to 90 µm, more preferred of 70 µm.

8. The chromatography media of any one of claims 1 to 7, wherein said porous silica particles comprise silica, alumina, zirconia, or mixtures thereof, preferably comprise silica, and more preferred silica having at least 97% by weight SiO2 based upon a total weight of said porous silica particles.

9. The chromatography media of any one of claims 1 to 8, wherein said functionalized surface comprises a reaction product resulting from a reaction between (i) hydroxyl groups on said porous silica particles and (ii) a silane, preferably an epoxy silane, more preferred (3-glycidyloxypropyl) trimethoxysilane.

10. The chromatography media of any one of claims 1 and 4 to 9, wherein each of said linker molecules comprises a diol and/or wherein said functionalized surface comprises (i) a diol group and (ii) unreacted hydroxyl groups on said porous silica particles.

11. The chromatography media of claim 10, wherein said diol is present in an amount ranging from 30 to 150 µmol/g of said porous silica particles, preferably from 50 to 100 µmol/g of said porous silica particles.

12. The chromatography media of any one of claims 1 and 4 to 9, wherein each of said linker molecules comprises an aldehyde.

13. The chromatography media of any one of claims 1 and 4 to 9, wherein said functionalized surface comprises a protein covalently linked to surfaces of said porous silica particles via at least some of said linker molecules.

14. The chromatography media of any one of claims 2 to 9 and 13, wherein said functionalized surface comprises (i) said protein covalently linked to surface portions of said porous silica particles and (ii) unreacted hydroxyl groups on said porous silica particles.

15. The chromatography media of any one of claims 2 to 9 and 13 to 14, wherein said protein comprises Protein A, preferably a recombinant Protein A (rProA), wherein said protein preferably is present in an amount ranging from 5.7 to 9.8 mg/ml of said porous silica particles.

16. The chromatography media of any one of claims 1 to 15, wherein said chromatography media, when used in an affinity column, has a non-specific protein binding level of less than 20.0 ng/ml, preferably of less than 5.0 ng/ml, and/or has a dynamic binding capacity of at least 30 mg/ml, preferably from 30 to 90 mg/ml.

17. A method for making the chromatography media of any one of claims 1 to 16, said method comprising:
forming the porous silica particles; and
reacting surface portions of the porous silica particles with at least one reactant so as to form the functionalized surface.

18. The method of claim 17, wherein said forming step comprises forming porous silica particles via a particle-forming process selected from the group consisting of gelation, precipitation, aggregation, or combinations thereof, preferably via a gelation process.

19. The method of claim 17 or 18, wherein the at least one reactant comprises a silane, preferably an epoxy silane, more preferred (3-glycidyloxypropyl) trimethoxysilane.

20. The method of claim 19, further comprising:
converting at least one functional group on the silane to a hydroxyl group so as to form a diol, wherein preferably the functionalized surface comprises (i) a diol and (ii) unreacted hydroxyl groups on the porous silica particles.

21. The method of claim 20, wherein the diol is present on the surface in an amount ranging from 30 to 150 μmol/g of the porous silica particles, preferably from 50 to 100 μmol/g of the porous silica particles.

22. The method of claim 20 or 21, further comprising:
converting at least one diol to an aldehyde group, preferably further comprising reacting at least one aldehyde group with at least one free amino group on a protein to form an imine group and, optionally, reducing the imine group to an amine, and more preferred further comprising covalently bonding a protein to the functionalized surface via an imino or amino group.

23. The method of any one of claims 17 to 22, wherein the functionalized surface comprises a protein covalently linked to surfaces of the porous silica particles and preferably also comprises unreacted hydroxyl groups on the porous silica particles.

24. A chromatography device comprising:
a device housing; and

chromatography media positioned within said device housing, said chromatography media comprising the chromatography media of any one of claims 1 to 9 and 13 to 16.

25. The chromatography device of claim 24, wherein said device housing comprises a tubular housing member, and at least one separate and attachable tubular housing member end cap.

26. The chromatography device of claim 24 or 25, wherein said device housing comprises a polymeric material, a metal material, a glass material, a ceramic material, or a composite thereof, preferably a biodegradable polymeric material, or a metal material, preferably stainless steel.

27. The chromatography device of any one of claims 24 to 26, wherein said chromatography device comprises an affinity column, and/or wherein said chromatography device has a device back pressure of less than 5.0 bar when said chromatography media is run at a linear velocity of 1000 cm/h.

28. Chromatography media comprising:

porous silica particles having a median pore diameter of from 60 nm to 160 nm; a pore size distribution relative span of at least 1.0 up to 2.0; and a pore size distribution such that (i) at least 20% of the total pore volume have pores in a diameter ranging from 100 nm to 160 nm and (ii) at least 15% of the total pore volume have pores in a diameter ranging from 120 nm to 150 nm.

29. The chromatography media of claim 28, wherein the porous silica particles have a functionalized surface comprising an average of from greater than 1.3 to 2.0 linker molecules per square nanometer of surface area of said porous silica particles.

30. The chromatography media of claim 28 or 29, wherein (i) at least 40% of the total pore volume is in pores having a diameter between 60 nm to 160 nm, preferably from 40% to

90 % of the total pore volume, (ii) at least 20% to 60% of the total pore volume have pores in a diameter ranging from 100 nm to 160 nm, and (iii) at least 15% up to 30% of the total pore volume have pores in a diameter ranging from 120 nm to 150 nm.

31. The chromatography media of any one of claims 28 to 30, wherein said porous silica particles have a functionalized surface comprising a protein covalently bonded to surface portions of said porous silica particles, said protein having a molecular weight ranging from 10,000 to 100,000 D.