CLAIMS

What is claimed is:

1. A fluid path system comprising:

a vial to contain a pharmaceutical product therein;

a dissolution fluid path having an output end in fluid communication with the vial and an input end attached to a pressure vessel to contain a dissolution medium;

a delivery fluid path having a first end hermetically attached to the vial to transport therefrom a mixture of dissolved pharmaceutical product and dissolution medium;

wherein the dissolution fluid path and delivery fluid path are tubular structures and the dissolution fluid path is positioned internal to or parallel to the delivery fluid path;

a receiving vessel connected to a second end of the delivery fluid path to receive the mixture;

a dissolution fluid path valve positioned between the pressure vessel and the dissolution fluid path to control flow of the dissolution medium;

a delivery fluid path valve to control flow of the mixture from the delivery fluid path to the receiving vessel;

a filter cartridge integrated within the delivery fluid path to remove at least one of an electron paramagnetic agent (EPA) and a processing agent from the hyperpolarized solution before entering the receiving vessel;

a sliding seal unit positioned between the pressure vessel and the vial to seal a cryogenically cooled chamber containing the vial therein from an ambient environment without contacting contents of the vial, and wherein said sliding seal is seal unit biscects the dissolution fluid path and delivery fluid path and is capable of traversing the length of said fluid paths.

2. The fluid path system of claim 1 further comprising a nozzle attached to the outlet end of the dissolution fluid path to modify a fluid flow of a dissolution medium into the vial.

3. The fluid path system of claim 2 wherein the nozzle is comprised of a formable polymer material

4. The fluid path system of claim 2 wherein the nozzle includes a nozzle diameter and a nozzle depth based on at least one of a composition of the dissolution medium to be added to the dissolution fluid path , a temperature of the dissolution medium to be added to the dissolution fluid path, a pressure of the dissolution medium to be added to the dissolution fluid path, and a quantity of the pharmaceutical product to be added to the vial.

5. The fluid path system of claim 1 wherein the pressure vessel is a syringe.

6. The fluid path system of claim 1 wherein the dissolution fluid path and the delivery fluid path are comprised of a material having a low thermal conductivity.

7. The fluid path system of claim 6 wherein the dissolution fluid path is formed of a material having a different thermal conductivity than the material from which the delivery fluid path is formed.

8. The fluid path system of claim 1 wherein the sliding seal unit comprises a material capable of forming a vacuum seal with a leak rate of less than or equal to 2.5 ml/hr .

9. The fluid path system of claim 8 wherein the material is teflon.

10. The fluid path system of claim 1 wherein the sliding seal unit exerts a force on the delivery fluid path less than or equal to 25 Newtons.

11. The fluid path system of claim 1 wherein the dissolution fluid path valve and the delivery fluid path valve are comprised of a single valve system that operates to restrict flow independently in the dissolution fluid path and the delivery fluid path.

12. The fluid path system of claim 1 further comprising a pharmaceutical product positioned within the vial wherein said pharmaceutical product comprises a material to enhance contrast in at least one of magnetic resonance (MR) imaging and nuclear magnetic resonance (NMR) spectroscopy.

13. The fluid path system of claim 1 further comprising a dissolution medium positioned within the pressure vessel wherein said dissolution medium comprises a base solution and a buffering agent.

14. The fluid path system of claim 1 wherein each of the vial, the dissolution fluid path, the delivery fluid path, and the receiving vessel are composed of sterile medical grade materials to form a sterile environment for the mixture.

15. A polarizer system to polarize a material to be used in magnetic resonance (MR) imaging, the system comprising:

a cryogenic cooling system to cool a material to be hyperpolarized to a cryogenic temperature;

a superconducting magnet positioned about the cryogenic cooling system to create a magnetic field and hyperpolarize the material; and

a fluid delivery system to dissolve and deliver the hyperpolarized material, the fluid delivery system comprising:

a vial to contain a pharmaceutical product therein;

a dissolution fluid path having an output end in fluid communication with the vial and an input end attached to a pressure vessel to contain a dissolution medium;

a delivery fluid path having a first end hermetically attached to the vial to transport therefrom a mixture of dissolved pharmaceutical product and dissolution medium;

wherein the dissolution fluid path and delivery fluid path are tubular structures and the dissolution fluid path is positioned internal to or parallel to the delivery fluid path;

a receiving vessel connected to a second end of the delivery fluid path to receive the mixture;

a dissolution fluid path valve positioned between the pressure vessel and the dissolution fluid path to control flow of the dissolution medium;

a delivery fluid path valve to control flow of the mixture from the delivery fluid path to the receiving vessel;

a filter cartridge integrated within the delivery fluid path to remove at least one of an electron paramagnetic agent (EPA) and a processing agent from the hyperpolarized solution before entering the receiving vessel;

a sliding seal unit positioned between the pressure vessel and the vial to seal a cryogenically cooled chamber containing the vial therein from an ambient environment without contacting contents of the vial, and wherein said sliding seal is seal unit biscects the dissolution fluid path and delivery fluid path and is capable of traversing the length of said fluid paths.

16. The polarizer system of claim 15 further comprising a nozzle attached to the outlet end of the dissolution fluid path to modify a fluid flow of a dissolution medium into the vial.

17. The polarizer system of claim 15 wherein the nozzle is comprised of a formable polymer material

18. The polarizer system of claim 17 wherein the nozzle includes a nozzle diameter and a nozzle depth based on at least one of a composition of the dissolution medium to be added to the dissolution fluid path , a temperature of the dissolution medium to be added to the dissolution fluid path, a pressure of the dissolution medium to be added to the dissolution fluid path, and a quantity of the pharmaceutical product to be added to the vial.

19. The polarizer system of claim 15 wherein the pressure vessel is a syringe.

20. The polarizer system of claim 15 wherein the dissolution fluid path and the delivery fluid path are comprised of a material having a low thermal conductivity.

21. The polarizer system of claim 20 wherein the dissolution fluid path is formed of a material having a different thermal conductivity than the material from which the delivery fluid path is formed.

22. The polarizer system of claim 15 wherein the sliding seal unit comprises a material capable of forming a vacuum seal with a leak rate of less than or equal to 2.5 ml/hr

23. The polarizer system of claim 22 wherein the material is teflon.

24. The polarizer system of claim 15 wherein the sliding seal unit exerts a force on the delivery fluid path less than or equal to 25 Newtons.

25. The polarizer systerm of claim 15 wherein the dissolution fluid path valve and the delivery fluid path valve are comprised of a single valve system that operates to restrict flow independently in the dissolution fluid path and the delivery fluid path.

26. The polarizer system of claim 15 further comprising a pharmaceutical product positioned within the vial wherein said pharmaceutical product comprises a material to enhance contrast in at least one of magnetic resonance (MR) imaging and nuclear magnetic resonance (NMR) spectroscopy.

27. A method of manufacturing a fluid path system comprising the steps of:

hermetically sealing a first end of a delivery fluid path to a vial, said delivery fluid path comprising a tubular structure and the vial containing a solid material to be hyperpolarized therein;

positioning a dissolution fluid path within the delivery fluid path, the dissolution fluid path comprising a tubular structure and having an output end in fluid communication with an interior volume of the vial;

connecting a syringe to an input end of the dissolution fluid path, the syringe having a dissolution medium therein; and

connecting a receiving vessel to a second end of the delivery fluid path to receive a hyperpolarized solution therein, wherein the hyperpolarized solution comprises a dissolution medium and dissolved hyperpolarized material.

28. The method of claim 27 further comprising the step of positioning a nozzle at the output end of the dissolution fluid path.

29. The method of claim 27 wherein the positioning of the nozzle further comprises forming the nozzle at the output end of the dissolution fluid path, the forming comprising the steps of:

heating a portion of the dissolution fluid path to a melting temperature;

positioning a needle within the dissolution fluid path having a diameter equal to a desired nozzle diameter; and

removing the needle from the dissolution fluid path after said dissolution fluid path has cooled to form a nozzle having a desired diameter and length.

30. The method of claim 27 wherein the positioning of the nozzle further comprises placing the nozzle a desired distance from the solid material, the desired distance determined by at least one of the nozzle diameter, a composition of the dissolution medium, a temperature of the dissolution medium, and a quantity of the solid material.

31. The method of claim 27 wherein the positioning of the nozzle further comprises mounting a nozzle at the output end of the dissolution fluid path.

32. The method of claim 27 further comprising:
attaching a valve to control a flow of the dissolution medium through the dissolution fluid path; and attaching a second valve to control a flow of the hyperpolarized solution through the delivery fluid path.

33. The method of claim 27 wherein the receiving vessel is at least partially pre-filled with dissolution medium to modify at least one of pH, temperature, and concentration of the hyperpolarized solution.

34. The method of claim 27 further comprising integrating a filter cartridge within the delivery fluid path to remove at least one of an electron paramagnetic agent (EPA) and a processing agent from the hyperpolarized solution.

CLAIMS

1. A fluid path system comprising:

a vial to contain a pharmaceutical product therein;

the pharmaceutical product positioned within the vial wherein said pharmaceutical product comprises a material to enhance contrast in at least one of magnetic resonance (MR) imaging and nuclear magnetic resonance (NMR) spectroscopy;

a dissolution fluid path having an output end in fluid communication with the vial and an input end attached to a pressure vessel to contain a dissolution medium used to dissolve said pharmaceutical product forming a mixture;

a dissolution medium positioned within the pressure vessel wherein said dissolution medium comprises a base solution and a buffering agent;

a delivery fluid path having a first end hermetically attached to the vial to transport therefrom a mixture of the dissolved pharmaceutical product and the dissolution medium;

wherein the dissolution fluid path and the delivery fluid path are tubular structures and the dissolution fluid path is positioned internal to or parallel to the delivery fluid path;

a receiving vessel connected to a second end of the delivery fluid path to receive the mixture;

a dissolution fluid path valve positioned between the pressure vessel and the dissolution fluid path to control flow of the dissolution medium;

a delivery fluid path valve to control flow of the mixture from the delivery fluid path to the receiving vessel;

a filter cartridge integrated within the delivery fluid path to remove at least one of an electron paramagnetic agent (EPA) and a processing agent from the mixture before entering the receiving vessel; and

a sliding seal unit positioned between the pressure vessel and the vial to seal a cryogenically cooled chamber containing the vial therein from an ambient environment without contacting contents of the vial, and wherein said sliding seal unit bisects the dissolution fluid path and the delivery fluid path and is capable of traversing the length of said fluid paths.

2. The fluid path system of claim 1 further comprising a nozzle attached to the output end of the dissolution fluid path to modify a fluid flow of the dissolution medium into the vial.

3. The fluid path system of claim 2 wherein the nozzle is comprised of a formable polymer material.

4. The fluid path system of claim 2 wherein the nozzle includes a nozzle diameter and a nozzle depth based on at least one of a composition of the dissolution medium to be added to the dissolution fluid path, a temperature of the dissolution medium to be added to the dissolution fluid path, a pressure of the dissolution medium to be added to the dissolution fluid path, and a quantity of the pharmaceutical product to be added to the vial.

5. The fluid path system of claim 1 wherein the pressure vessel is a syringe.

6. The fluid path system of claim 1 wherein the dissolution fluid path and the delivery fluid path are comprised of a material having a low thermal conductivity.

7. The fluid path system of claim 6 wherein the dissolution fluid path is formed of a material having a different thermal conductivity than the material from which the delivery fluid path is formed.

8. The fluid path system of claim 1 wherein the sliding seal unit comprises a material capable of forming a vacuum seal with a leak rate of less than or equal to 2.5 ml/hr.

9. The fluid path system of claim 8 wherein the material is teflon.

10. The fluid path system of claim 1 wherein the sliding seal unit exerts a force on the delivery fluid path less than or equal to 25 Newtons.

11. The fluid path system of claim 1 wherein the dissolution fluid path valve and the delivery fluid path valve are comprised of a single valve system that operates to restrict flow independently in the dissolution fluid path and the delivery fluid path.

12. The fluid path system of claim 1 wherein the pharmaceutical product comprises pyruvic acid.

13. The fluid path system of claim 1 wherein each of the vial, the dissolution fluid path, the delivery fluid path, and the receiving vessel are composed of sterile medical grade materials to form a sterile environment for the mixture.

14. A polarizer system to polarize a material to be used in magnetic resonance (MR) imaging, the system comprising:

a cryogenic cooling system to cool a material to be hyperpolarized to a cryogenic temperature;

a superconducting magnet positioned about the cryogenic cooling system to create a magnetic field and hyperpolarize the material; and

a fluid delivery system to dissolve and deliver the material, the fluid delivery system comprising:

a vial to contain a pharmaceutical product therein;

a pharmaceutical product positioned within the vial wherein said pharmaceutical product comprises a material to enhance contrast in at least one of magnetic resonance (MR) imaging and nuclear magnetic resonance (NMR) spectroscopy;

a dissolution fluid path having an output end in fluid communication with the vial and an input end attached to a pressure vessel to contain a dissolution medium used to dissolve said pharmaceutical product forming a mixture;

a dissolution medium positioned within the pressure vessel wherein said dissolution medium comprises a base solution and a buffering agent;

a delivery fluid path having a first end hermetically attached to the vial to transport therefrom a mixture of the dissolved pharmaceutical product and the dissolution medium;

wherein the dissolution fluid path and delivery fluid path are tubular structures and the dissolution fluid path is positioned internal to or parallel to the delivery fluid path;

a receiving vessel connected to a second end of the delivery fluid path to receive the mixture;

a dissolution fluid path valve positioned between the pressure vessel and the dissolution fluid path to control flow of the dissolution medium;

a delivery fluid path valve to control flow of the mixture from the delivery fluid path to the receiving vessel;

a filter cartridge integrated within the delivery fluid path to remove at least one of an electron paramagnetic agent (EPA) and a processing agent from the mixture before entering the receiving vessel; and

a sliding seal unit positioned between the pressure vessel and the vial to seal a cryogenically cooled chamber containing the vial therein from an ambient environment without contacting contents of the vial, and wherein said sliding seal unit bisects the dissolution fluid path and the delivery fluid path and is capable of traversing the length of said fluid paths.

15. The polarizer system of claim 14 further comprising a nozzle attached to the output end of the dissolution fluid path to modify a fluid flow of the dissolution medium into the vial.

16. The polarizer system of claim 14 wherein the nozzle is comprised of a formable polymer material.

17. The polarizer system of claim 16 wherein the nozzle includes a nozzle diameter and a nozzle depth based on at least one of a composition of the dissolution medium to be added to the dissolution fluid path, a temperature of the dissolution medium to be added to the dissolution fluid path, a pressure of the dissolution medium to be added to the dissolution fluid path, and a quantity of the pharmaceutical product to be added to the vial.

18. The polarizer system of claim 14 wherein the pressure vessel is a syringe.

19. The polarizer system of claim 14 wherein the dissolution fluid path and the delivery fluid path are comprised of a material having a low thermal conductivity.

20. The polarizer system of claim 19 wherein the dissolution fluid path is formed of a material having a different thermal conductivity than the material from which the delivery fluid path is formed.

21. The polarizer system of claim 14 wherein the sliding seal unit comprises a material capable of forming a vacuum seal with a leak rate of less than or equal to 2.5 ml/hr.

22. The polarizer system of claim 21 wherein the material is teflon.

23. The polarizer system of claim 14 wherein the sliding seal unit exerts a force on the delivery fluid path less than or equal to 25 Newtons.

24. The polarizer system of claim 14 wherein the dissolution fluid path valve and the delivery fluid path valve are comprised of a single valve system that operates to restrict flow independently in the dissolution fluid path and the delivery fluid path.

25. The polarizer system of claim 14 wherein the pharmaceutical product comprises pyruvic acid.