TITLE OF THE INVENTION

APPARATUS AND METHOD OF MICROWAVE VACUUM DRYING STERILE PRODUCTS

FIELD OF THE DISCLOSURE

The present disclosure relates to apparatuses and methods for microwave vacuum-drying of organic materials, including biologically-active materials such as vaccines, antibiotics, proteins, and microorganism cultures.

BACKGROUND OF THE DISCLOSURE

Microwave vacuum-drying is a drying method that can be employed to dehydrate pharmaceutical biologic materials such as vaccines and antibodies. Microwave vacuum-drying, also called microwave vacuum dehydration, is a rapid drying method that can yield products with improved quality compared to air-dried and freeze-dried products. Because the drying is done under reduced pressure, the boiling point of water and the oxygen content of the atmosphere are lowered, so that components sensitive to oxidation and thermal degradation can be retained to a higher degree than by air-drying. The drying process is also much faster than air-drying and freeze-drying.

However, microwave vacuum-drying of pharmaceutical biologic materials at a large scale, while also complying with current Good Manufacturing Practice (cGMP) regulations, is difficult. Microwave vacuum-drying machines are currently made to address food safety concerns and are not designed to be used in a more stringently controlled GMP environment for drying pharmaceutical products. Using a microwave vacuum drying in cGMP conditions must be able to minimize particle generation during the drying process, allow drying to occur in a controlled and reproducible manner, as well as allow cleaning and sterilization of the drying chamber according to cGMP regulations.

SUMMARY OF THE DISCLOSURE

In the disclosure, a microwave vacuum dryer includes a loading chamber and a first vacuum pump in communication with the loading chamber, a first door separating the loading chamber from an external environment, a drying chamber adjacent the loading chamber, a second vacuum pump in communication with the drying chamber, and a condenser in communication with the drying chamber, a second door separating the loading chamber and the

drying chamber, an unloading chamber adjacent the drying chamber and a third vacuum pump in communication with the unloading chamber, a third door separating the drying chamber from the unloading chamber, a fourth door separating the unloading chamber from the external environment, and a microwave chamber having a plurality of magnetrons, the microwave chamber positioned on a different plane from the loading and unloading chambers and adjacent the drying chamber.

In one aspect of the disclosure, there is provided a microwave vacuum dryer comprising: a loading chamber and a first vacuum pump in communication with the loading chamber; a first door separating the loading chamber from an external environment; a drying chamber adjacent the loading chamber, a second vacuum pump in communication with the drying chamber, and a condenser in communication with the drying chamber; a second door separating the loading chamber and the drying chamber; an unloading chamber adjacent the drying chamber and a third vacuum pump in communication with the unloading chamber; a third door separating the drying chamber from the unloading chamber; a fourth door separating the unloading chamber from the external environment; and a microwave chamber having a plurality of magnetrons, the microwave chamber positioned on a different plane from the loading and unloading chambers and adjacent the drying chamber, wherein each of the unloading, drying and loading chambers comprises an outer gasket to act as a microwave seal when one of the doors to the chamber is closed, and an inner gasket adjacent the outer gasket, the inner gasket to provide a sterile boundary when one of the doors to the chamber is closed.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the microwave chamber is positioned underneath the drying chamber.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the drying chamber has at least two walls and a floor that define two inner parallel edges, the two edges comprising removable tray guidance rails.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the loading chamber, the drying chamber and the unloading chamber are each aligned along a central axis.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the first door and the fourth door are manually operable.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the second door and the third door are automatically operable and allow for simultaneous movement of the second and third doors.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the plurality of magnetrons is arranged in an array along a length of the drying chamber between the second and third doors.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the array of magnetrons is arranged in banks.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the banks comprise six banks of magnetrons.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein each of the six banks of magnetrons includes three individual magnetrons.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein each of the plurality of magnetrons has a predetermined power setting based on a location along the length of the drying chamber.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the drying chamber comprises a plurality of ports for monitoring the drying

of containers of frozen solution. In some examples, the plurality of ports comprise a thermal imaging or fiber optic probe.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein at least one of the unloading, drying and loading chambers comprises an outer gasket to act as a microwave seal when one of the doors to the chamber is closed, and an inner gasket adjacent the outer gasket, the inner gasket to provide a sterile boundary when one of the doors to the chamber is closed.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein each of the unloading, drying and loading chambers comprises an outer gasket to act as a microwave seal when one of the doors to the chamber is closed, and an inner gasket adjacent the outer gasket, the inner gasket to provide a sterile boundary when one of the doors to the chamber is closed.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, further comprising a tray unloader housed within the unloading chamber, and a tray loader housed within the loading chamber.

In another example of the disclosure is a microwave vacuum dryer in accordance with the foregoing, wherein the unloading chamber comprises a closeable valve for partially backfilling the unloading chamber with an inert gas, and a stoppering mechanism to close partially-stoppered containers.

In the disclosure, a method of drying a product comprises providing a microwave vacuum dryer having a loading chamber and a first vacuum pump in communication with the loading chamber, a first door separating the loading chamber from an external environment, a drying chamber adjacent the loading chamber, a second vacuum pump in communication with the drying chamber, and a condenser in vapor communication with the drying chamber, a second door separating the loading chamber and the drying chamber, an unloading chamber adjacent the drying chamber and a third vacuum pump in communication with the unloading chamber, a third door separating the drying chamber from the unloading chamber, a fourth door separating the unloading chamber from the external environment, a microwave chamber having a plurality of magnetrons, the microwave chamber positioned on a different plane from the loading and unloading chambers and adjacent the drying chamber, evacuating air from the drying chamber using the second vacuum pump, and activating at least one of the plurality of magnetrons to generate a microwave field within the drying chamber. The product may include but not limited to a pharmaceutical product that reflects GMP requirements.

In another aspect of the disclosure, there is provided a method of drying a product, comprising: providing a microwave vacuum dryer having a loading chamber and a first vacuum pump in communication with the loading chamber, a first door separating the loading chamber from an external environment, a drying chamber adjacent the loading chamber, a second vacuum pump in communication with the drying chamber, and a condenser in vapor communication with the drying chamber, a second door separating the loading chamber and the drying chamber, an unloading chamber adjacent the drying chamber and a third vacuum pump in communication with the unloading chamber, a third door separating the drying chamber from the unloading chamber, a fourth door separating the unloading chamber from the external environment, and a microwave chamber having a plurality of magnetrons, the microwave chamber positioned on a different plane from the loading and unloading chambers and adjacent the drying chamber, wherein each of the unloading, drying and loading chambers comprises an outer gasket to act as a microwave seal when one of the doors to the chamber is closed, and an inner gasket adjacent the outer gasket, the inner gasket to provide a sterile boundary when one of the doors to the chamber is closed; evacuating air from the drying chamber using the second vacuum pump; and activating at least one of the plurality of magnetrons to generate a microwave field within the drying chamber.

WHAT IS CLAIMED:

1. A microwave vacuum dryer comprising:

a loading chamber and a first vacuum pump in communication with the loading chamber;

a first door separating the loading chamber from an external environment;

a drying chamber adjacent the loading chamber, a second vacuum pump in communication with the drying chamber, and a condenser in communication with the drying chamber;

a second door separating the loading chamber and the drying chamber;

an unloading chamber adjacent the drying chamber and a third vacuum pump in communication with the unloading chamber;

a third door separating the drying chamber from the unloading chamber;

a fourth door separating the unloading chamber from the external environment; and

a microwave chamber having a plurality of magnetrons, the microwave chamber positioned on a different plane from the loading and unloading chambers and adjacent the drying chamber,

wherein each of the unloading, drying and loading chambers comprises an outer gasket to act as a microwave seal when one of the doors to the chamber is closed, and an inner gasket adjacent the outer gasket, the inner gasket to provide a sterile boundary when one of the doors to the chamber is closed.

2. The microwave vacuum dryer of claim 1, wherein the microwave chamber is positioned underneath the drying chamber.

3. The microwave vacuum dryer of claim 1, wherein the drying chamber has at least two walls and a floor that define two inner parallel edges, the two edges comprising removable tray guidance rails.

4. The microwave vacuum dryer of claim 1, wherein the loading chamber, the drying chamber and the unloading chamber are each aligned along a central axis.

5. The microwave vacuum dryer of claim 1, wherein the first door and the fourth door are manually operable.

6. The microwave vacuum dryer of claim 1, wherein the second door and the third door are automatically operable and allow for simultaneous movement of the second and third doors.

7. The microwave vacuum dryer of claim 1, wherein the plurality of magnetrons is arranged in an array along a length of the drying chamber between the second and third doors.

8. The microwave vacuum dryer of claim 7, wherein the array of magnetrons is arranged in banks.

9. The microwave vacuum dryer of claim 8, wherein the banks comprise six banks of magnetrons.

10. The microwave vacuum dryer of claim 9, wherein each of the six banks of magnetrons includes three individual magnetrons.

11. The microwave vacuum dryer of claim 7, wherein each of the plurality of magnetrons has a predetermined power setting based on a location along the length of the drying chamber.

12. The microwave vacuum dryer of claim 1, wherein the drying chamber comprises a plurality of ports for monitoring the drying of containers of frozen solution.

13. The microwave vacuum dryer of claim 1, further comprising a tray unloader housed within the unloading chamber, and a tray loader housed within the loading chamber.

14. The microwave vacuum dryer of claim 1, wherein the unloading chamber comprises a closeable valve for partially backfilling the unloading chamber with an inert gas, and a stoppering mechanism to close partially-stoppered containers.

15. A method of drying a product, comprising:

providing a microwave vacuum dryer having

a loading chamber and a first vacuum pump in communication with the loading chamber,

a first door separating the loading chamber from an external environment,

a drying chamber adjacent the loading chamber, a second vacuum pump in communication with the drying chamber, and a condenser in vapor communication with the drying chamber,

a second door separating the loading chamber and the drying chamber,

an unloading chamber adjacent the drying chamber and a third vacuum pump in communication with the unloading chamber,

a third door separating the drying chamber from the unloading chamber,

a fourth door separating the unloading chamber from the external environment, and

a microwave chamber having a plurality of magnetrons, the microwave chamber positioned on a different plane from the loading and unloading chambers and adjacent the drying chamber,

wherein each of the unloading, drying and loading chambers comprises an outer gasket to act as a microwave seal when one of the doors to the chamber is closed, and an inner gasket adjacent the outer gasket, the inner gasket to provide a sterile boundary when one of the doors to the chamber is closed;

evacuating air from the drying chamber using the second vacuum pump; and

activating at least one of the plurality of magnetrons to generate a microwave field within the drying chamber.

16. The method of claim 15, further comprising the step of recirculating water adjacent to the drying chamber to remove excess microwaves from the drying chamber.

17. The method of claim 15, further comprising the steps of opening the first door, loading a first tray holding one or more containers having frozen solution into the loading chamber, closing the first door, and evacuating air from the loading chamber to equilibrate the environment of the loading chamber with the environment of the drying chamber.

18. The method of claim 17, further comprising the steps of opening the second door, advancing the first tray of containers into the drying chamber using a tray loader housed within the loading chamber, and closing the second door.

19. The method of claim 18, further comprising the steps of loading an additional tray into the loading chamber, closing the first door, and evacuating air from the loading chamber to equilibrate the environment of the loading chamber with the environment of the drying chamber.

20. The method of claim 19, wherein the additional tray holds one or more containers having frozen solution, or wherein the additional tray is empty.

21. The method of claim 19, further comprising the steps of pushing the additional tray into the drying chamber using a tray loader housed within the loading chamber, thereby pushing the first tray further into the drying chamber with the additional tray.

22. The method of claim 21, further comprising repeating the step of loading additional trays into the loading chamber and pushing the tray ahead of it through the drying chamber, until the drying chamber is filled with trays.

23. The method of claim 22, wherein the plurality of magnetrons is arranged in an array along a length of the drying chamber between the second and third doors, and wherein the

magnetrons in different parts of the array are activated at different power levels before the first tray of containers is pushed into the drying chamber.

24. The method of claim 22, wherein the plurality of magnetrons is arranged in an array along a length of the drying chamber between the second and third doors, and wherein the plurality of magnetrons are activated to one or more predetermined power levels, and wherein the plurality of magnetrons is activated after the drying chamber is filled with trays.

25. The method of claim 22, further comprising the step of opening the third door, and advancing the first tray into the unloading chamber using a tray unloader housed within the unloading chamber.

26. The method of claim 25, further comprising the step of advancing all of the trays from the drying chamber to the unloading chamber in a sequential manner.

27. The method of claim 25, further comprising the step of removing the first tray from the unloading chamber.

28. The method of claim 15, wherein the drying chamber has at least two walls and a floor that define two inner parallel edges, the two edges comprising removable tray guidance rails.

29. The method of claim 15, further comprising the steps of operating the microwave vacuum dryer in a semi-continuous mode by performing the following steps sequentially: (i) evacuating air from the drying chamber with the second vacuum pump, (ii) recirculating water in a water chamber above the drying chamber, (iii) generating the microwave field within the drying chamber, (iv) loading a first tray of containers having frozen solution into the loading chamber and closing the first door, (v) evacuating air from the loading chamber to equilibrate the environment of the loading chamber with the environment of the drying chamber, and (vi) drying the frozen solution in the containers of the first tray within the drying chamber.

30. The method of claim 15, further comprising the steps of operating the microwave vacuum dryer in a batch mode by performing the following steps sequentially: (i) evacuating air from the drying chamber with the second vacuum pump, (ii) loading a plurality of trays of containers containing frozen solution into the drying chamber via the loading chamber, (iii) recirculating water in a water chamber above the drying chamber, (iv) generating the microwave field within the drying chamber, and (v) drying the frozen solution in the containers within the drying chamber.

31. The method of claim 15, wherein the unloading chamber comprises a closeable valve for partially backfilling the unloading chamber with an inert gas, and a stoppering mechanism to close partially-stoppered containers.