Claims

1.- A device (1, 30) for holding and monitoring an individual predetermined dose (4) of a product during a drying, freezing and/or lyophilization process, the device comprising:

- a mold (2) adapted for shaping the predetermined dose (4) of the product, having a receptacle part (3) for containing said predetermined dose (4) of the product in direct contact with the receptacle part,
- at least one sensor (5), contacting the mold or integrated in the mold, for measuring a physical characteristic of said predetermined dose and/or a physical quantity affecting said predetermined dose during said process, and
- a transmitter (6) for transmitting said measured physical characteristic and/or physical quantity in the form of a sensor signal to a control unit for controlling a heating and/or cooling element (8,12,13) in said process,
- a heater and/or cooler unit (8) for heating and/or cooling the predetermined dose (4) when contained in the receptacle part (3),

wherein said heater and/or cooler unit (8) comprises the heating element (13) and/or the cooling element (12) that are controllable by the control unit, the heater and/or cooler unit (8) being integrated in the device and in communication with the control unit for controlling said element,

for controlling heat transport to the individual predetermined dose (4).

2.- The device of claim 1, wherein said mold (2) is adapted for shaping the predetermined dose (4) such that said predetermined dose (4) of the product forms a tablet when said process has been carried out.

3.- The device of claim 2, wherein said mold (2) is adapted for shaping an orally disintegrating tablet, a muco-adhesive tablet or a multilayer tablet.

4.- The device of any one of the previous claims, wherein the mold (2) is adapted for providing easy removal of the individual predetermined dose (4).

5.- The device of any one of the previous claims, wherein said heater and/or cooler unit (8) comprises a Peltier element adapted for freezing and/or heating the predetermined dose (4) in the receptacle part (3).

6.- The device of any one of the previous claims, wherein said heater and/or cooler unit (8) comprises an absorber (9) for absorbing heat radiation.

7.- The device of any one of the previous claims, wherein said device comprises an ultrasonic vibration generator (31) positioned in contact with the mold or integrated in the mold (2), wherein said ultrasonic vibration generator is adapted for controlling nucleation of the product by ultrasonification when freezing the predetermined dose (4).

8.- The device of any one of the previous claims, comprising an insert element (32) for inserting into the predetermined dose (4) when contained in the receptacle part (3), said insert element (32) comprising at least one elongate structure (33).

9.- The device of any one of the previous claims, further comprising a control unit (26) for controlling ~~a~~ the heating and/or cooling element (8, 12, 13) during said drying, freezing and/or lyophilization said process, wherein the transmitter (6) and the control unit (26) are integrated in the mold (2).

10.- A system (10) for freezing, drying and/or freeze-drying at least one predetermined dose (4) of a product, the system comprising:

- at least one device (1) in accordance with any one of claims 1 to 8 wherein the system comprises a control unit (15) for receiving at least one sensor signal from the transmitter of said device (1) and for controlling said heating element (13) and/or said cooling element (14), in which said controlling takes said at least sensor signal into account, ~~or~~
- ~~at least one device (30) in accordance with claim 9,~~
- a cooling element (12) for freezing the at least one predetermined dose (4) of the product when contained in the at least one receptacle part (3) of the mold (2) of the at least one device (1) and/or a heating element (13) for heating the at least one predetermined dose (4) of the product when contained in the at least one receptacle part (3) of the mold (2) of the at least one device (1), and
- a vacuum chamber (14) for exposing the at least one predetermined dose (4) to a low pressure environment while heating the at least one predetermined

dose (4) using said heating device (13) to desiccate said at least one predetermined dose.

11.- The system of claim 10, wherein said system comprises a vacuum lock (16) for inserting the at least one predetermined dose (4) into and/or removing the at least one predetermined dose (4) from the vacuum chamber (14).

12.- The system of claim 11, wherein said cooling element (12) is integrated in the vacuum lock (16).

13.- The system of any one of claims 10 to 12, wherein said cooling element (12) comprises a tunnel freezer, and wherein said system is adapted for transporting the at least one device (1) containing the at least one predetermined dose (4) in a liquid state through the tunnel freezer such as to freeze the at least one predetermined dose (4).

14.- The system of any one of claims 10 to 13, wherein said vacuum chamber (14) is a cylindrical chamber, and wherein said vacuum lock (16) forms a segment of said cylindrical chamber or wherein said vacuum lock (16) is connected to a segment of the cylindrical chamber.

15.- The system of claim 14, comprising a stationary surface (18) or a rotatable surface (18), wherein said vacuum chamber (14) is adapted for rotating over said stationary surface (18) or wherein said rotatable surface (21) is adapted for rotating in or underneath the vacuum chamber, and wherein said system is adapted for loading the at least one device (1) in the vacuum chamber (14) by placing the at least one device (1) on the stationary surface (18) or on the rotatable surface (21) via said vacuum lock.

16.- The system of any one of claims 10 to 13, comprising a conveyance mechanism (22) for transporting a plurality of devices (1) in accordance with any of claims 1 to 9, said conveyance mechanism forming a loop such as to transport the plurality of devices (1) along a closed loop trajectory.

17.- A method (50) for freeze-drying a product in an individual predetermined dose (4), the method comprising:

- providing (51) the predetermined dose (4) contained in a receptacle part (3) of a mold (2) adapted for shaping the predetermined dose (4) of the product,
- freezing (52) the predetermined dose of the product contained in the receptacle part of the mold,
- heating (53) the frozen predetermined dose of the product in the receptacle part of the mold while exposing the predetermined dose to a low pressure environment to desiccate the predetermined dose,
- measuring (54) a physical characteristic of the predetermined dose and/or a physical quantity affecting the predetermined dose during the step of freezing (52) and/or during the step of heating (53) using a sensor (5) that contacts the mold or that is integrated in the mold, and
- controlling (55) at least one parameter of the freezing (52) and/or the heating (53), wherein said controlling takes the measured physical characteristic and/or physical quantity into account,
- wherein freezing (52) and/or heating (53) the predetermined dose of the product in the receptacle part of the mold ~~comprised~~ comprises using a heater and/or cooler unit (8) comprising a heating element (13) and/or a cooling element (12) being integrated in a device (1) comprising the mold (3), the heater and/or cooler unit (8) being in communication with a control unit for controlling said heating element (13) and/or a cooling element (12), for controlling heat transfer properties of the individual predetermined dose.