CLAIMS

1. A method for bulk manufacture of unit dosage forms, the method comprising:

rotating a drum around a rotational axis at a rotational speed, the drum having an outer surface with a plurality of cavities formed thereon;

chilling the outer surface of the drum to a target temperature;

dispensing a liquid formulation comprising a therapeutic or biotherapeutic agent into one or more of the plurality of cavities while rotating the drum about its rotational axis;

freezing the liquid formulation within the one or more of the plurality of cavities to form a frozen unit in the one or more of the plurality of cavities;

collecting the frozen units from the one or more of the plurality of cavities; and

drying the collected frozen units to form the unit dosage forms.

2. The method of claim 1, further comprising the step of selecting the target temperature for chilling the outer surface of the drum based on a rotational cycle of the drum, wherein the step of freezing the liquid formulation occurs within one rotational cycle of the drum after liquid formulation is dispensed.

3. The method of claim 1 or 2, wherein the target temperature of the outer surface of the drum ranges from between about -50 °C to about -150 °C.

4. The method of any one of claims 1-3, wherein chilling the outer surface of the drum further comprises delivering a cryogen into thermal contact with the outer surface.

5. The method of claim 4, wherein delivering the cryogen comprises injecting cryogen into an interior cavity of the drum.

6. The method of any one of claims 1-5, wherein the liquid formulation has a temperature of about 4° C to about 25° C during dispensing.

7. The method of claim 1, wherein the drying step further comprises drying the collected frozen units to a water activity level ranging from about 0.02 to about 0.1.

8. The method of any one of claims 1-7, wherein prior to dispensing the liquid formulation, the method further comprises characterizing the liquid formulation to determine a phase transition temperature of the liquid formulation, and wherein the target temperature of the outer surface of the drum is based on the phase transition temperature of the liquid formulation.

9. The method of claim 1, further comprising adjusting the rotational speed of the drum during the step of dispensing the liquid formulation.

10. A system for bulk manufacture of unit dosage forms, the system comprising:

a drum frame having a first support structure and a second support structure;

a drum coupled to the first support structure and the second support structure, the drum rotatable relative to the drum frame about a rotational axis, the drum having an outer surface with a plurality of cavities formed thereon;

a dispenser operable to dispense a liquid formulation comprising a therapeutic or biotherapeutic agent into one or more of the plurality of cavities on the outer surface of the drum;

a cryogenic component for chilling the outer surface of the drum to a target temperature capable of freezing the liquid formulation within the one or more of the plurality of cavities to form a frozen unit in the one or more of the plurality of cavities;

a collection tray positioned relative to the drum to collect the one or more frozen units from the one or more of the plurality of cavities; and

a dryer for drying the one or more frozen units to yield solid unit dosage forms.

11. The system of claim 10, wherein the plurality of cavities on the outer surface of the drum includes either a series of parallel grooves formed on the outer surface of the drum or a plurality of discrete pockets formed on the outer surface of the drum.

12. The system of claim 10 or 11, further comprising a drum sleeve separate from the drum, the drum sleeve encircling the drum and including the plurality of cavities formed thereon, wherein the drum sleeve is removable from the drum.

13. The system of any one of claims 10-12, the dispenser further comprising a plurality of nozzles each having an opening directed toward the outer surface of the drum and arranged to radially align with a corresponding cavity of the plurality of cavities during rotation of the drum.

14. The system of any one of claims 10-13, wherein the dispenser is supported by the first support structure and the second support structure of the drum frame, the dispenser further including an adjustment mechanism operable to facilitate a height adjustment of the dispenser relative to the outer surface of the drum.

15. The system of any one of claims 10-14, wherein the cryogenic component includes a delivery system for directing a cryogen into thermal contact with the outer surface of the drum.

16. The system of claim 15, wherein the drum includes a hollow interior chamber, and wherein the cryogenic component is injected into the hollow interior chamber to chill the outer surface of the drum.

17. The system of any one of claims 10-16, further comprising a cooling plate disposed within the drum frame, wherein the collection tray is seated on the cooling plate and the cooling plate is operable to chill the collection tray.

18. The system of any one of claims 10-17, further comprising a dislodging mechanism mounted within the drum frame, the dislodging mechanism operable for dislodging the one or more frozen units from the outer surface of the drum.

19. The system of claim 10, wherein the target temperature for chilling the outer surface of the drum is based on a rotational speed of the drum.

20. A liquid formulation for preparing solid unit dosage forms, the liquid formulation comprising:

a therapeutic or biotherapeutic agent, wherein said agent is homogeneously distributed throughout the liquid formulation;

a cryopreservative;

a lyopreservative; and

one or more excipients.