

**APPARATUS AND METHOD FOR CRYOGRANULATING A
PHARMACEUTICAL COMPOSITION**

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ABSTRACT

Cryogranulation systems with improved dispenser assemblies are provided for use in manufacturing frozen pellets of pharmaceutical substances in a fluid medium.

10 Methods of cryogranulating the pharmaceutical substance in the fluid medium are also provided. In particular embodiments, the dispenser assembly is used with suspensions or slurries of pharmaceutical compositions including biodegradable substances, such as proteins, peptides, and nucleic acids. In certain embodiments, the pharmaceutical
15 substance can be adsorbed to any pharmaceutically acceptable carrier particles suitable for making pharmaceutical powders. In one embodiment, the pharmaceutical carrier can be, for example, diketopiperazine-based microparticles. The dispenser assembly improves the physical characteristics of the cryopellets formed and minimizes product loss during processing.

20 Figure 1