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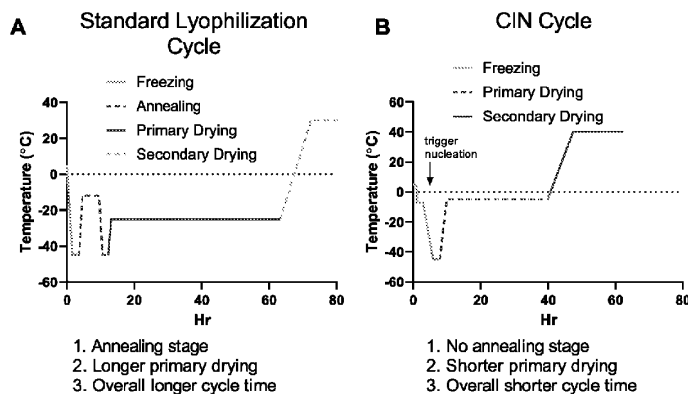
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(54) Title: CONTROLLED-ICE NUCLEATION LYOPHILIZATION PROCESS FOR BISPECIFIC MOLECULES

Fig. 1A-B



(57) **Abstract:** The disclosure provides a method of preparing a lyophilized bispecific molecule composition, the method comprising (a) inducing ice nucleation in a liquid protein composition having a concentration of bispecific molecule of at least about 10 mg/ml in a vial exposed to a first temperature of about -18° C to about -10° C for about 60 minutes to about 270 minutes; (b) exposing the vial of (a) to a second temperature of about -25° C to -50° C for about 1 hour to about 5 hours; and (c) drying the composition of (b) at a third temperature of about -5° C to -25° C for about 25 hours to about 70 hours, and (d) further drying the composition of (c) at a fourth temperature of about 25°C to about 50°C for about 4 hours to about 12 hours, resulting in a vial comprising a lyophilized bispecific molecule composition having a percent content of high molecular weight species (HMWS) of less or equal about 1.5% (mA). The disclosure further provides a lyophilized bispecific molecule composition prepared via the method described herein.

[Continued on next page]

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