Random Field Radio Frequency Lyophilization

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There has recently been a surge in the demand for lyophilized injectable products. The rapidly expanding portfolio of new biologics, particularly in the aftermath of the COVID-19 pandemic, highlighted the challenges associated with freeze-drying since such a process is very time-consuming, taking anywhere from days to weeks. Toward that end, this random field radio frequency lyophilization system addresses these shortcomings by applying highly controllable volumetric heating capable of accelerating freeze-drying processes and improving batch homogeneity while retaining products' physical and chemical properties. **Figure 1** shows the current experimental setup and a block diagram of the proposed lyophilization system, enabling both open-loop and closed-loop (highlighted in green) lyophilization processes.

Figure 2 summarizes the primary drying time of different formulations to verify the effectiveness of the proposed system. The primary drying time is proportional to the applied RF power. Such behavior is attributed to the increased electric field intensity (E) inside the chamber, allowing for an increased absorbed power density by the products.

Additionally, batch homogeneity, measured through residual moisture content, is improved using the proposed microwave system. To get batch homogeneity comparable to that obtained with the proposed system, secondary drying, which increases the total drying time, is needed in conventional freeze drying.

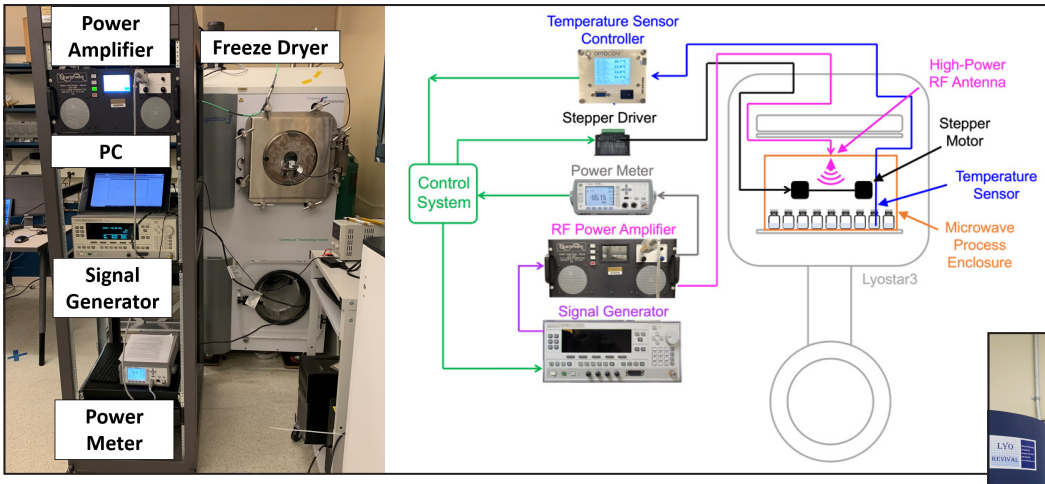


Figure 1: *Random field radio frequency lyophilization experimental setup (left) and block diagram (right).*

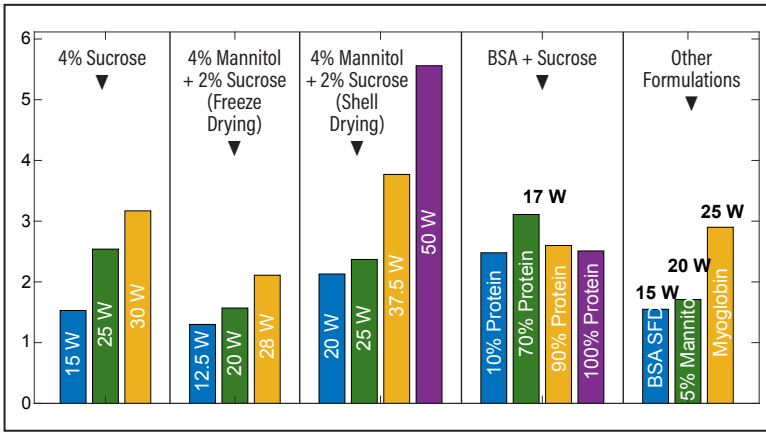
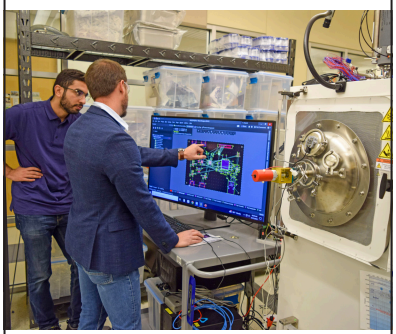


Figure 2: *Freeze drying process acceleration of the proposed heating unit relative to conventional freeze drying.*

FD Process	Avg Moisture Content (%)	Std of Moisture Content
Conventional (without SD)	7.41	0.55
Conventional (with SD)	0.19	0.13
RF (without SD)	0.84	0.15

Table 1: *Summary of residual moisture content for 5% BSA cycles.*



Top photo: *2021 RF set up*
Bottom photo: *2023 RF set up*