

LYOPHILIZATION VERSUS ELECTROSTATIC DRYING

CASE STUDY

FEASIBILITY COMPARISON USING BOVINE SERUM ALBUMIN (BSA)

OVERVIEW

This study compared lyophilization versus electrostatic drying (ESD) techniques using BSA (bovine serum albumin) and trehalose solutions. Formulations were prepared by drying the samples using both techniques and comparing the product characteristics. Stability studies were performed to determine which technique is more viable on an industrial scale.

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HIGHLIGHTS

Electrostatic drying is an equivalent alternative to lyophilization.

Processing times and throughputs are faster with ESD.

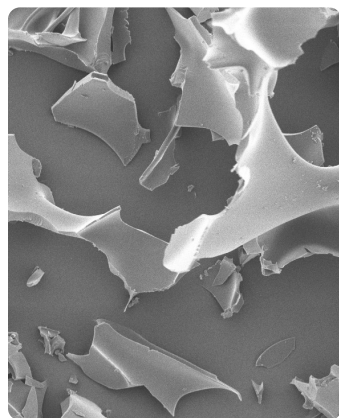
ESD improved capacity at the production level.

ESD gives a powder-like consistency for the product. Particle formation can be achieved and manipulated, to an extent.

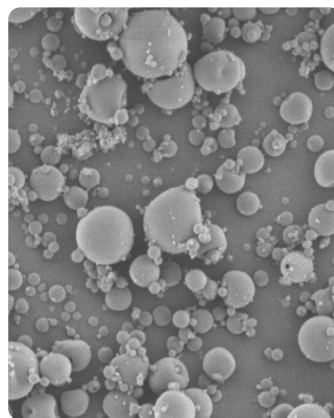
PROCESS TIME & THROUGHPUT

Drying Process:	Lyophilization	PolarDry ESD
Process Time:	70 h	4 h
Feedstock Quantity:	0.2 L	1 L
Solids Content:	10%	10%

PARTICLE FORMATION & CHARACTERISTICS



A. No particle formation in lyophilization



B. Discrete particles from ESD



C. Powder cake from lyophilization



D. Free-flowing powder from ESD

CONCLUSIONS

Based on solid-state NMR studies, it was concluded that the ESD and lyophilized powders have similar T1 relaxation times, as seen in Figure H. According to Figures E-G, the SEC-HPLC stability study shows ESD and lyophilized powders have comparable and similar stability patterns at 4°C and 20°C. At 50°C, degradation was slower for ESD BSA powders.

Pure BSA from the ESD method appears more stable than lyophilized powders through 12 weeks. Comparing the physical form of both techniques, lyophilization forms a cake-like structure while ESD gives a powder-like consistency for the product (Figures C-D). Particle formation (Figures A-B) can be achieved and manipulated, to an extent, in ESD whereas in lyophilization, the product characteristics are controlled indirectly by the process parameters such as the shelf temperature, chamber pressure, etc.

It was inferred that electrostatic drying is an equivalent alternative to lyophilization according to the preliminary study and that the processing times and throughputs are faster with ESD. This may mean an improved capacity at the production level. Lower wait time between runs is also advantageous during the drug-development stage.



PolarDry® Model 0.1



PolarDry® Model 001

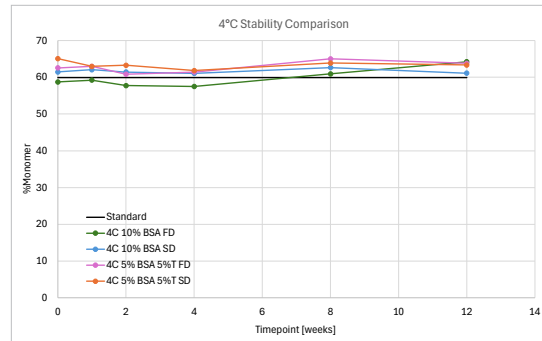


Figure E

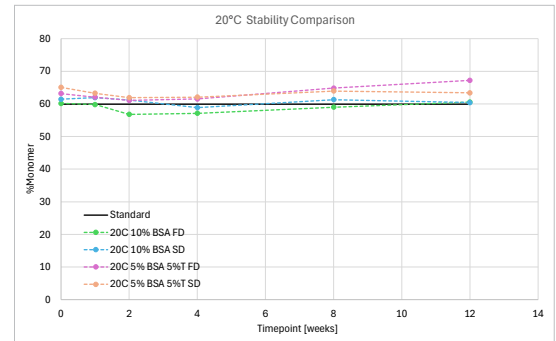


Figure F

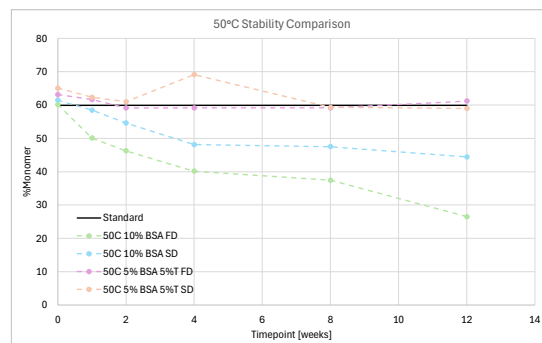


Figure G

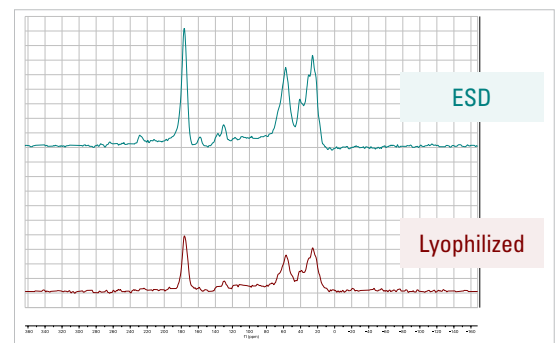


Figure H



E-G: Stability studies of BSA powders from lyophilization and ESD at 4°C, 20°C and 50°C

H: Solid-state NMR T1 relaxation times of lyophilized and ESD BSA powders

