

# Crystallization of Polyethylene Glycol (PEG) from PEGylated protein-Sucrose Solutions During Freeze-Drying

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NNIN Facility utilized: Characterization Facility

## RESEARCH DESCRIPTION

- Crystallization of ice, drug, or non-drug components during freezing-drying can impact product appearance, stability, and performance.
- The goal of the ongoing research is to investigate the impact of processing and formulation variables on PEG crystallization during freeze-drying of a PEGylated protein and sucrose system.

## MAJOR OBSERVATIONS

- PEG crystallization was observed during freezing and drying (Fig. 1) using a variable temperature X-ray diffractometer (**Scintag XDS 2000**).
- PEG-Sucrose solutions – An increase in the sucrose concentration to 5% w/v inhibited PEG crystallization (Fig. 2).
- PEGylated protein-Sucrose solutions - PEG crystallization remained unchanged in the presence of 2 – 10% w/v sucrose (Fig. 2), suggesting **phase separation** in the freeze-dried cake.

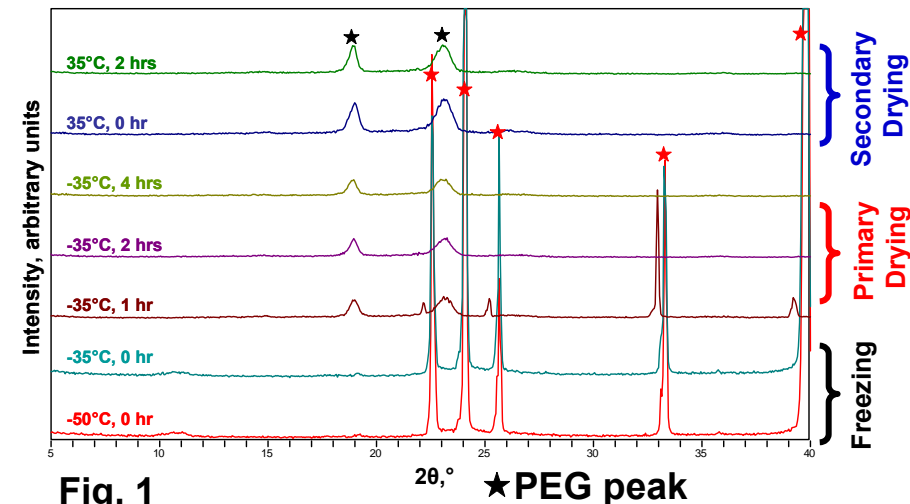


Fig. 1

★ PEG peak  
★ Hexagonal Ice peak

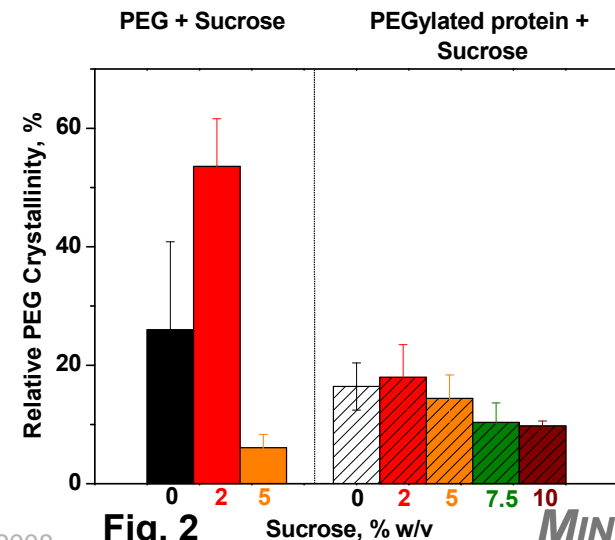


Fig. 2

Sucrose, % w/v

MINNESOTA