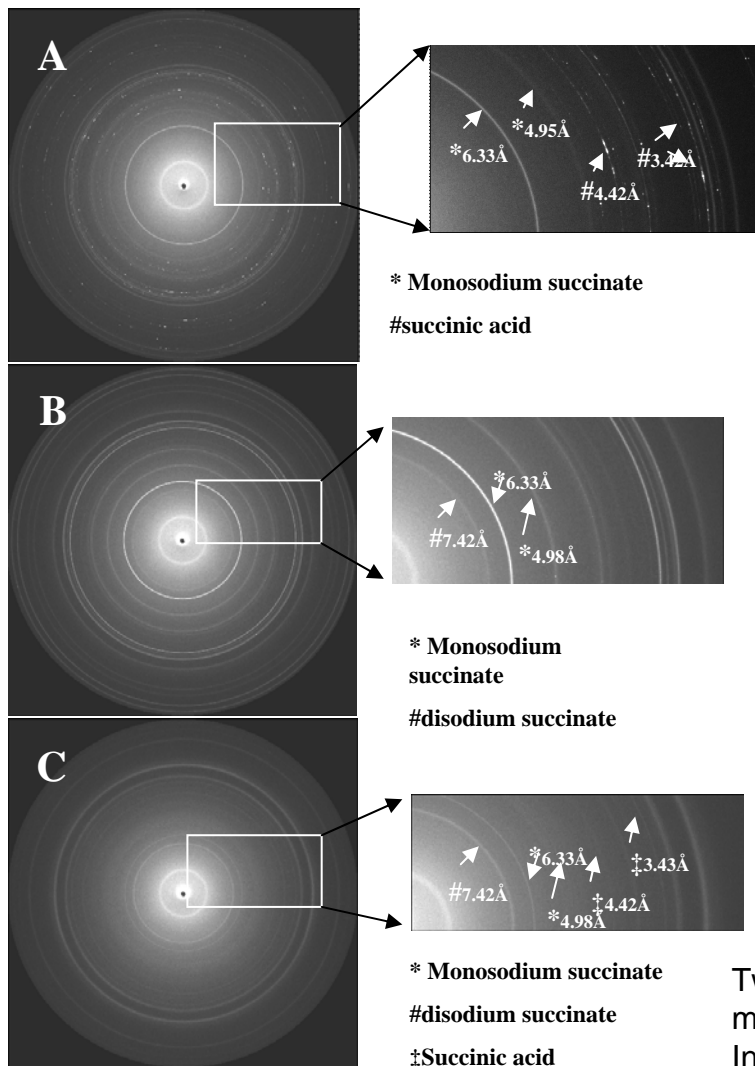


Buffer Crystallization During Freezing and Freeze Drying

Raj Suryanarayanan (PI) & Prakash Sundaramurthi

Department of Pharmaceutics, University of Minnesota

NNIN Facility utilized: Characterization Facility



- Selective crystallization of one of the buffer components can occur during the freezing stage of the freeze drying cycle.
- Selective crystallization of buffer component results in pH shifts.
- Conventional techniques (low temperature DSC and XRD) require a very high concentration (100 – 250 mM) of initial buffer salt to characterize the buffer salt crystallization in frozen systems.
- SXRD was used to characterize buffer crystallization at pharmaceutically relevant concentrations.

Two dimensional SXR patterns of the final lyophilized cake from 10 mM succinate buffer solution with initial pH values of A) 4, B) 5, C) 6. Inset: Debye rings unique to each component have been pointed out.