ADVANCED DRUG PRODUCT CHARACTERIZATION TECHNIQUES
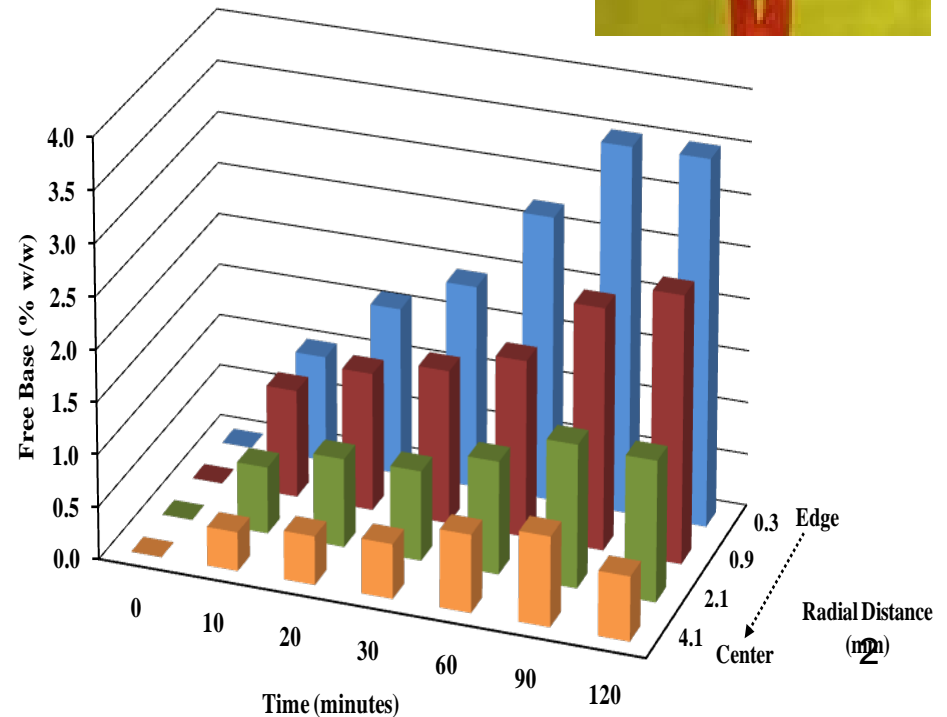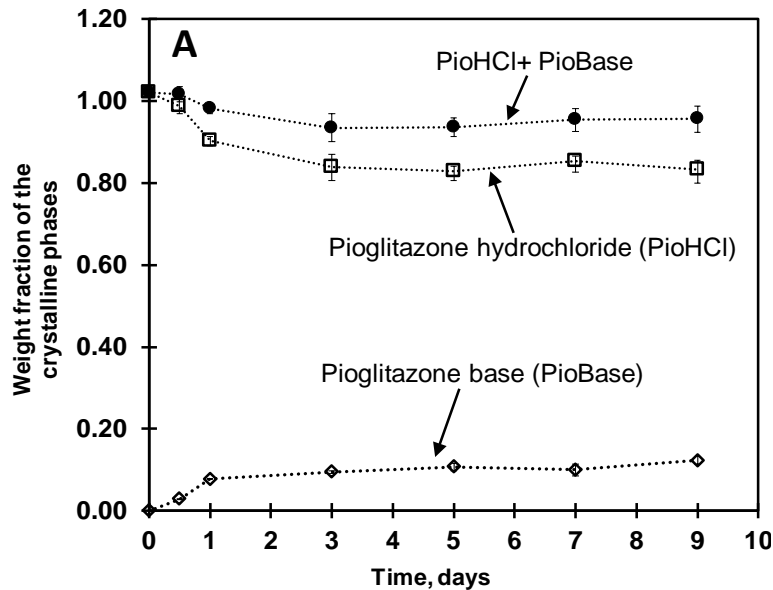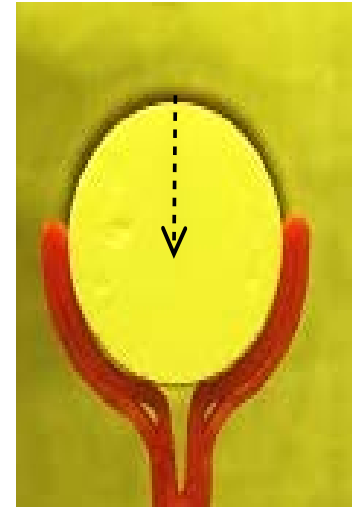
Ken Morris, Eric Munson and Raj Suryanarayanan (Sury) Long Island University, University of Kentucky and University of Minnesota

Salt Disproportionation

There is spatial heterogeneity in salt disproportionation in tablets.

Disproportionation reaction is initiated at the tablet surface and progresses towards the tablet core

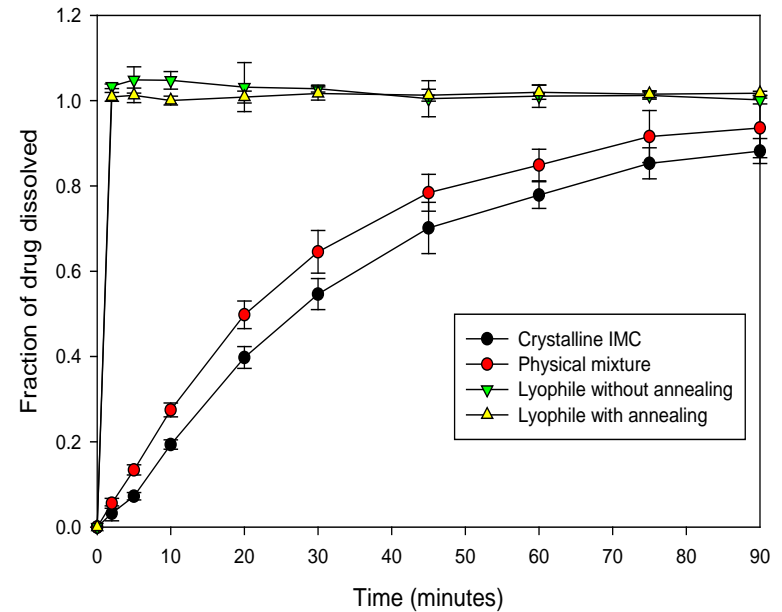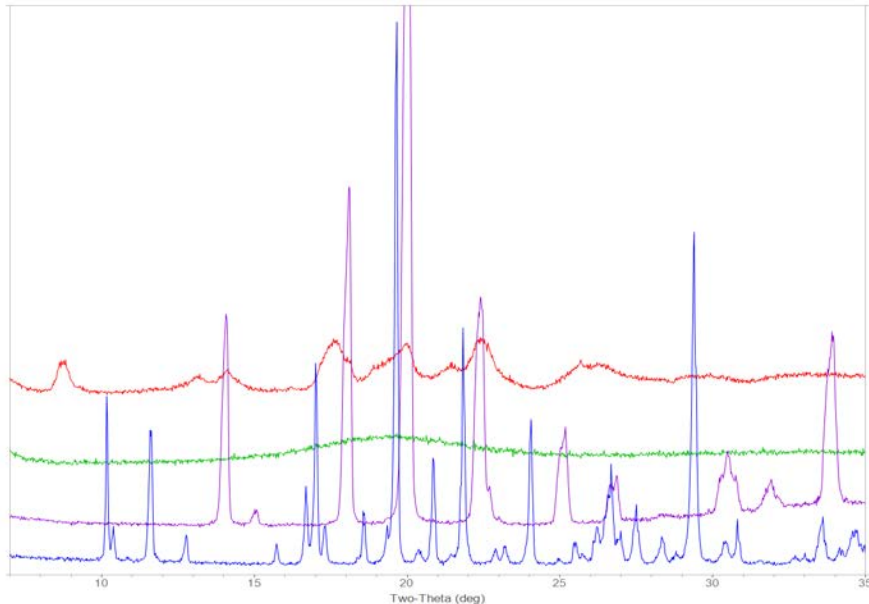Simultaneously monitor loss of salt (reactant) and appearance of free base (product)

Figure A: Weight fraction of the crystalline phases vs Time, days — PioHCl+ PioBase, Pioglitazone hydrochloride (PioHCl), Pioglitazone base (PioBase)

Figure: Free Base (% w/w) vs Time (minutes) and Radial Distance (mm) — Edge to Center

2

In situ salt formation (during freeze-drying)
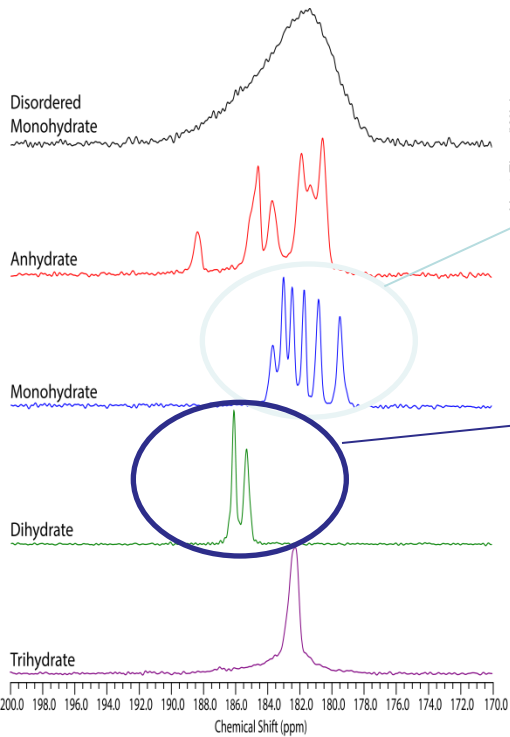## Pronounced effect on dissolution rate

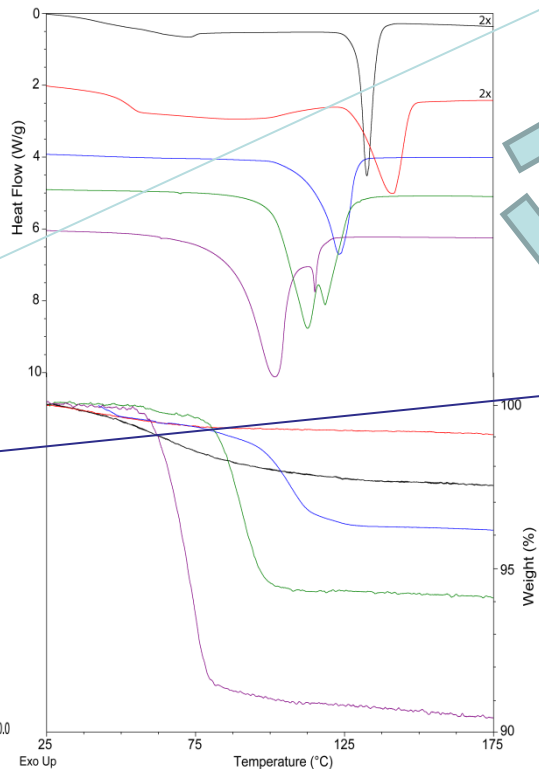Indomethacin (IMC) with tris as counter ion

0.1 M IMC in 0.15 M tris

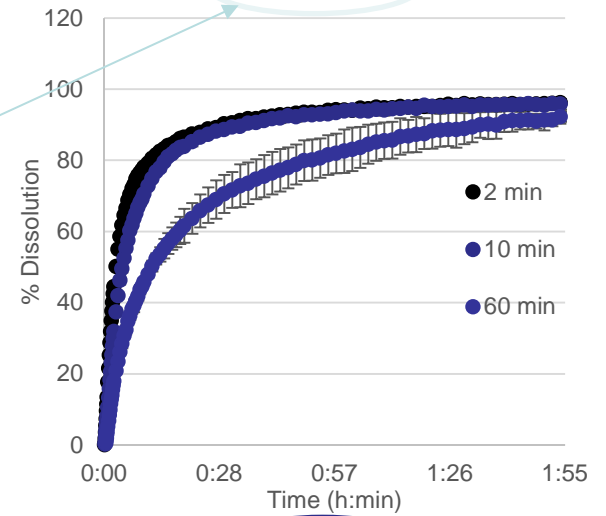# Structure/Function Relationship for Magnesium Stearate - Dissolution