Introduction
Roller compaction has a long history as a valuable tool for conducting dry granulations. In the past, controlled release matrix tablets have been produced using roller compaction as a method for obtaining quality ribbons with minimum compression force. This led to the following conditions:
- Pressure: 2 tons
- Roll Speed: 3.1 rpm
- Screw Speed: 12.7 rpm

In our work, we have evaluated the use of roller compaction to dry granulate polyethylene oxide (PEO) matrix tablets. As a high-swelling, hydrophilic matrix material, polyethylene oxide is often wet granulated with water and alcohol. However, with the movement away from organic solvents dry granulation could provide an alternative processing option.

Our goal was to define processing conditions suitable to a matrix system having both high drug and polymer loading. In addition, we were interested in defining the impact of roller compaction on the final tablet properties. Of special interest was the impact of tablet hardness due to the work hardening expected during the roller compaction process.

Process

- Roll and Ribbon Configuration
- Post Processing Conditions

Roller Compaction Processing
- Roller Configuration: Smooth
- Run Conditions were optimized to obtain quality ribbons with minimum compression force. This led to the following conditions:
  - Pressure: 2 tons
  - Roll Speed: 3.1 rpm
  - Screw Speed: 12.7 rpm

Materials
- POLYOX™ WSR Coag NF, The Dow Chemical Company, Midland, MI
- Acetaminophen, Spectrum Chemicals Mfg. Corp., Gardena, CA
- PROSOLV® SMCC 90, JRS Pharma LP, Patterson, NY 12563
- Magnesium Stearate, Mallinckrodt Pharmaceuticals, Hobart, NY

Tablet Hardness

Results
Direct compression (DC) tablets were produced to develop baseline data. Direct compression tablets produced from a 1:1 ratio of POLYOX™ WSR Coag NF and acetaminophen produced tablets with a hardness of 7.2 kP and friability of 0.15%. When this same formulation is produced via roller compaction the hardness value drops to 4.0 kP while the friability increase to 0.44%. This loss of tablet hardness after roller compaction is to be expected for a material like PEO which has a low yield strength (ref AAPS poster).

To address this loss of tablet strength we evaluated the use of PROSOLV® which is known to improve the physical properties of tablets (ref from web). As a screening tool the PROSOLV® was processed using DC. In this case the tablet hardness increase to 7.8 kP. Extending this approach to roller compaction PROSOLV® was added to the powder blend prior to the roller compaction step. This did not improve the tablet properties of the finished tablets with showed hardness and friability values of 3.6 and 0.38, respectively.

Addition of the PROSOLV® to the formulation after the roller compaction step did improve the physical properties of the final tablets leading to hardness and friability values of 4.7 kP and 0.25%, respectively.

The dissolution properties of the finished tablets did not show any significant correlation to the processing conditions. Our prior experience with POLYOX™ has indicated that the dissolution rate is not strongly coupled to tablet hardness. This enables the formulator to optimize tablet physical properties without impacting the dissolution profile of the matrix tablet.

Conclusions
- Roller compaction is a viable dry granulation process for POLYOX™ WSR controlled release matrix tablets.
- Drug dissolution is not impacted by the processing conditions employed in this study.
- Roller Compaction leads to a loss in tablet hardness and an increase in friability for POLYOX™ WSR based systems as compared to direct compression processing.
- Addition of PROSOLV® ex-granules improves the tablet hardness and friability

References