Dry Granulation Process

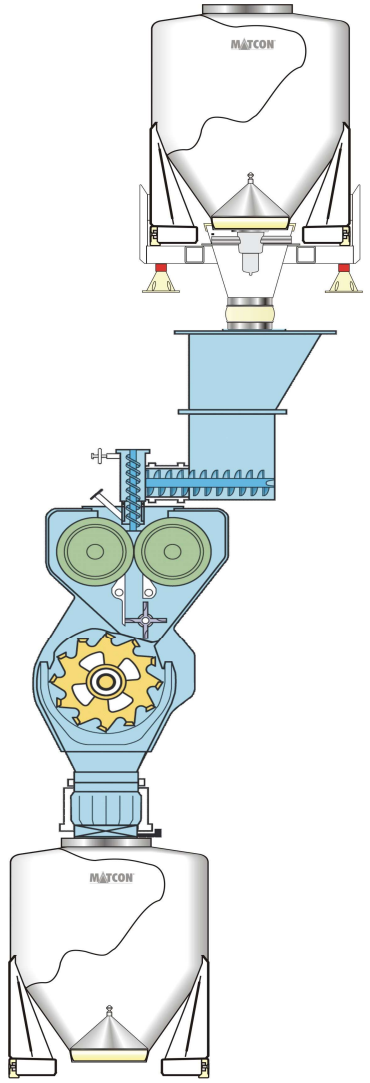
- Drug Formulation is initially blended
- Material is fed to the compression rolls and sized in-line to the desired particle distribution
- Final blend may include ingredients such as a lubricant

Initial powder (poor flowing)

Compacted sheet (roll compaction)

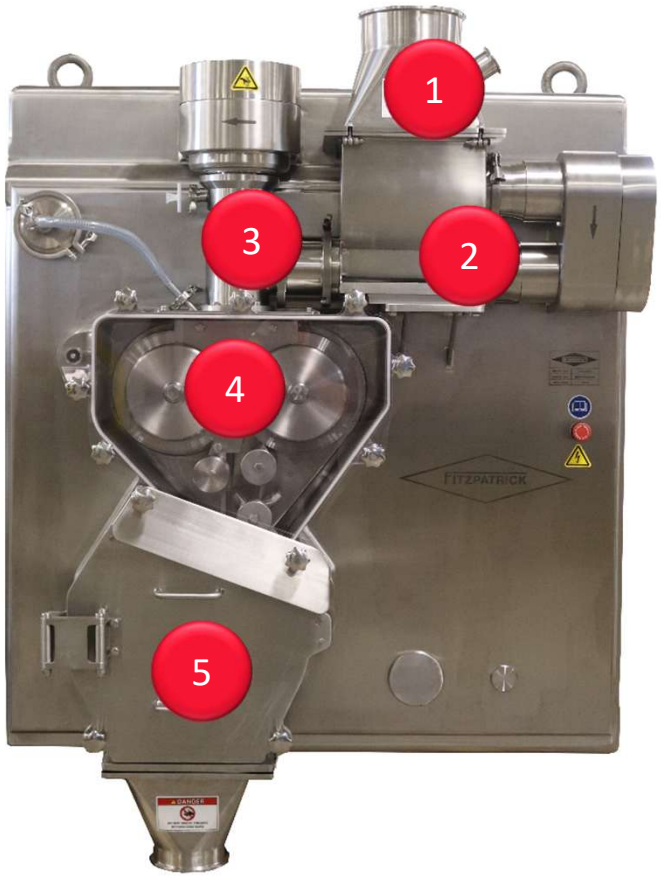
Granulate (mill ribbons)

To Tablet Press



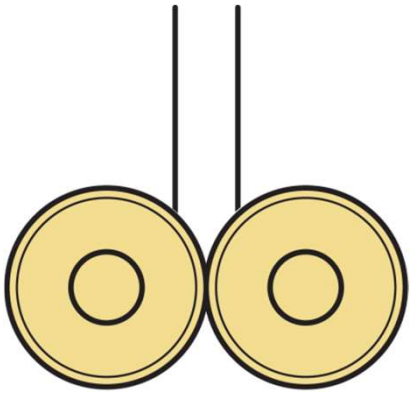
Roll Compaction Core Elements

1. Feed Hopper
2. Feed System (Horizontal Feed Screw)
3. Pre-compression for natural deaeration (Vertical Feed Screw)
4. Compaction via roll pressure with constant gap control (consistently produces ribbons/compacts with uniform density)
5. Mill granulates ribbons to ideal PSDs for improved material flow to tablet press

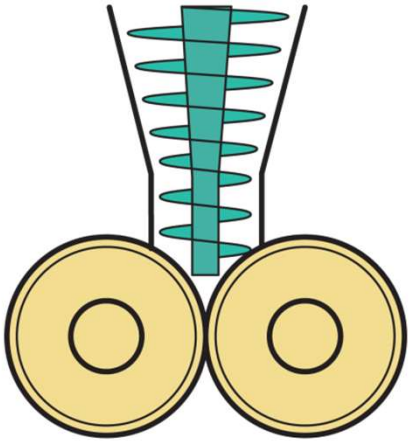


Feed system affects compaction

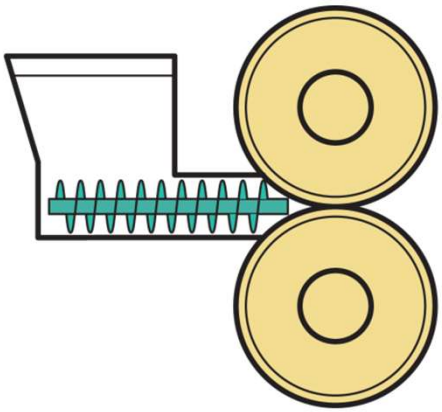
- Pre-compression
- Deaeration
- Roll Gap Control



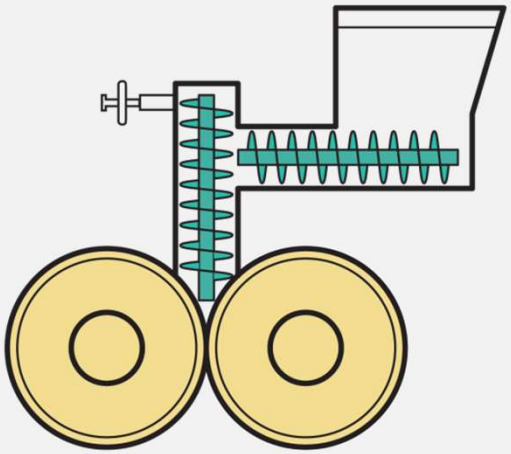
Gravity feed



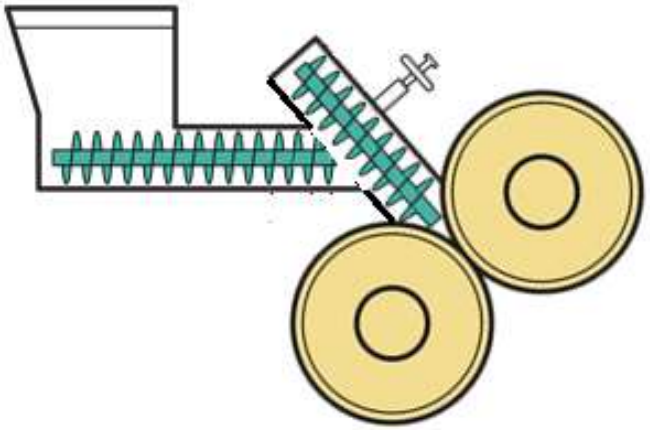
Slow speed conical feed screw



Slow speed horizontal feed screw



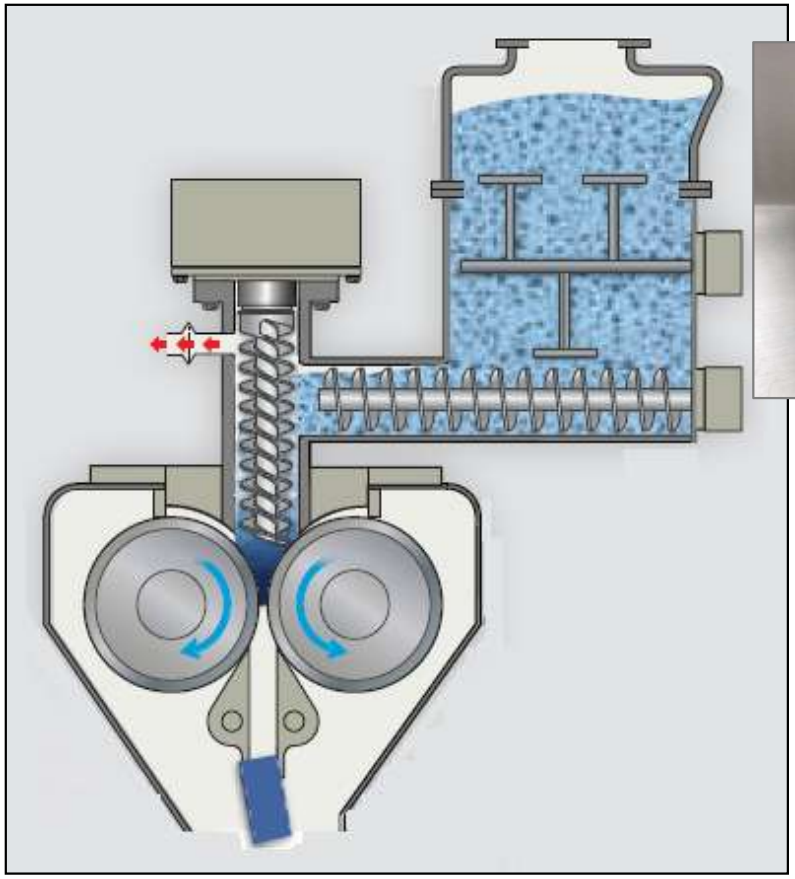
Slow speed metering screw feeding separately controlled high speed Pre-compression and de-aeration screw



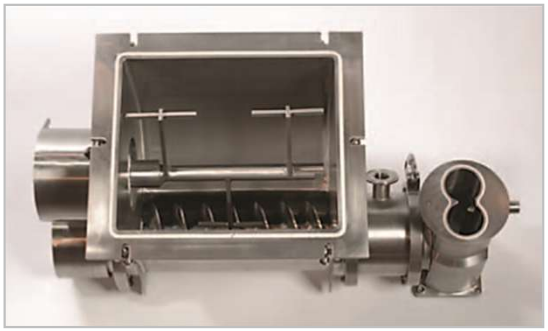
Slow speed metering screw feeding slow speed Pre-compression screw

A. HFS Consistent Volumetric Feeding (Horizontal Feed Screw)

- Controls volumetric capacity
- Roll gap controls HFS speed (RPM)
- RPM varies in increments of 0.1 RPM via PLC feedback control
- Excel Reporter trends gap vs. HFS data
- Agitator in feed hopper assists product flow

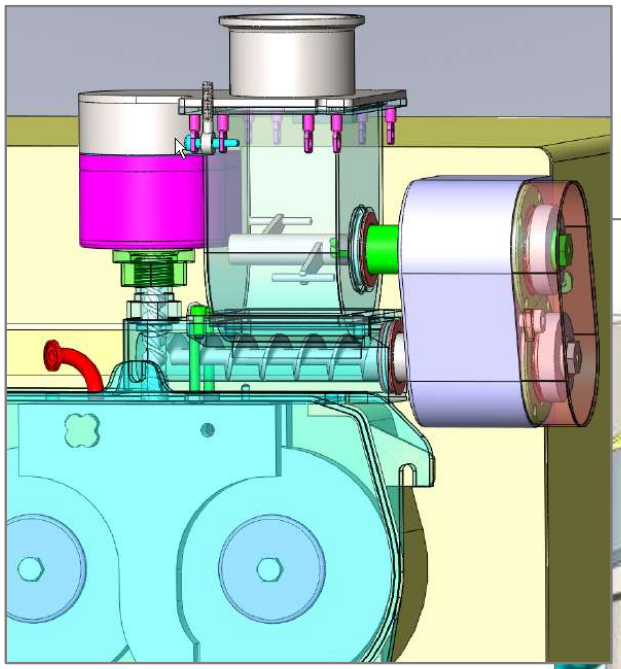


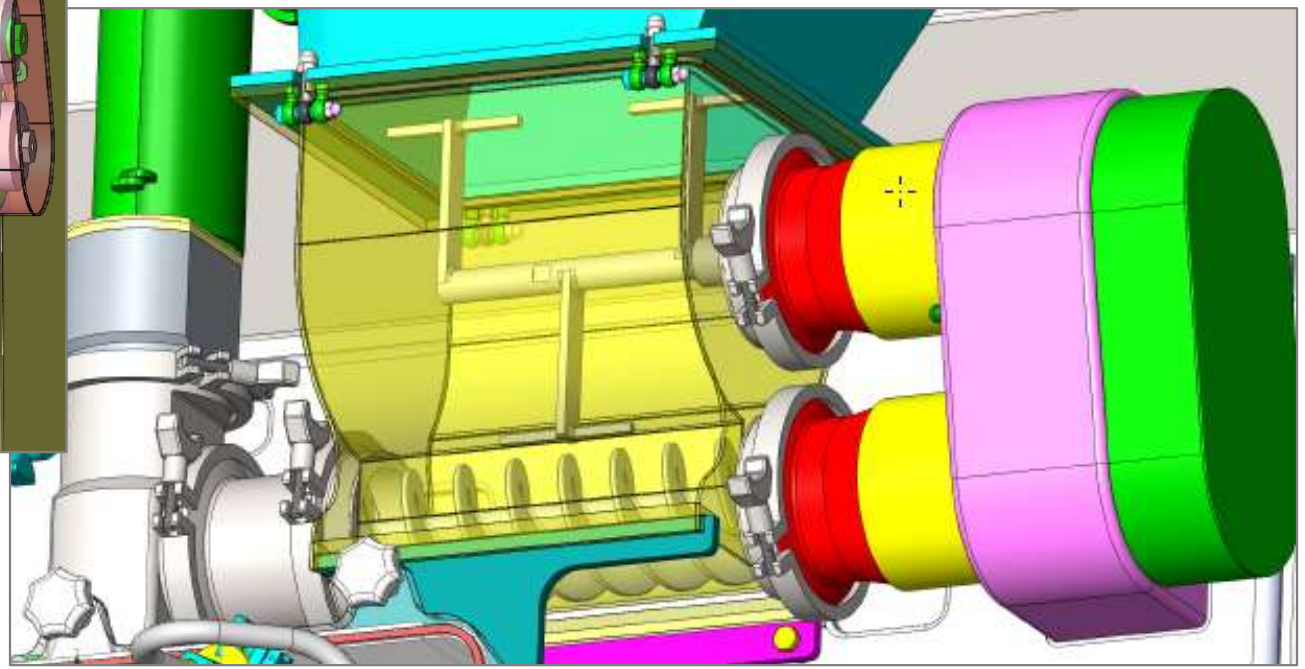
Screw efficiency will vary based upon powder processed (anticipate 85%-90% efficiency)



Process Efficiency and Uniform Quality

Feed hopper has externally driven agitator for feeding a wide variety of difficult products





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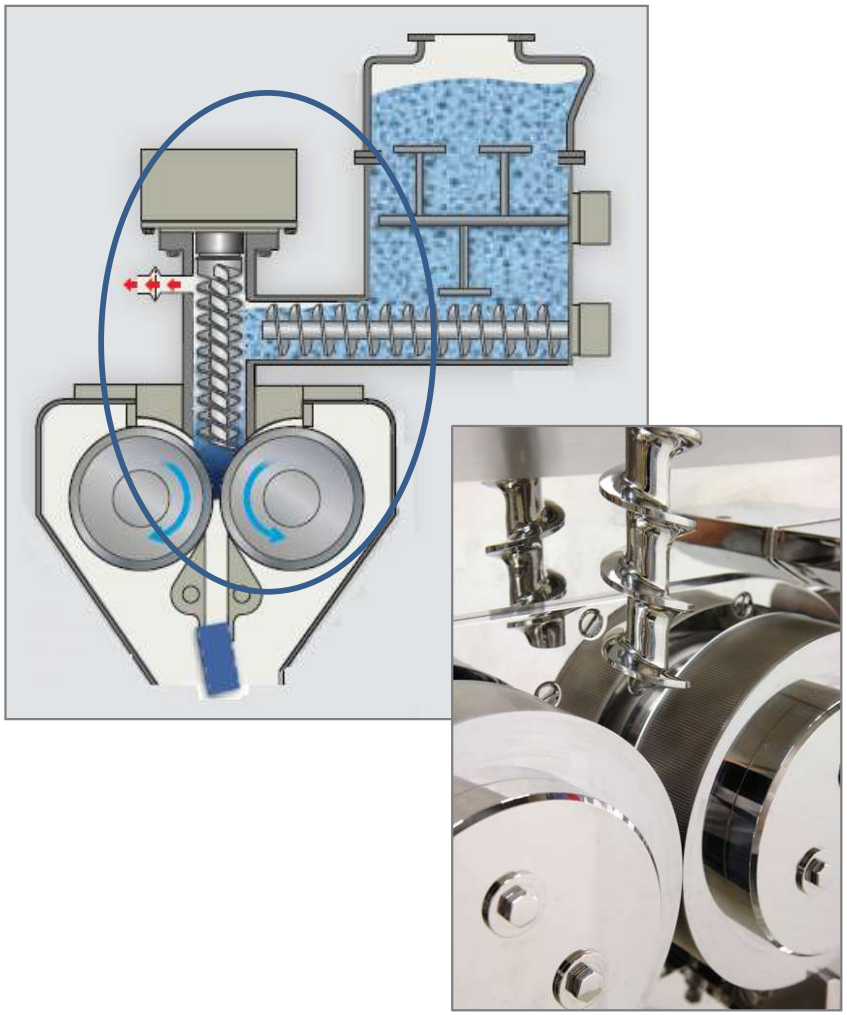
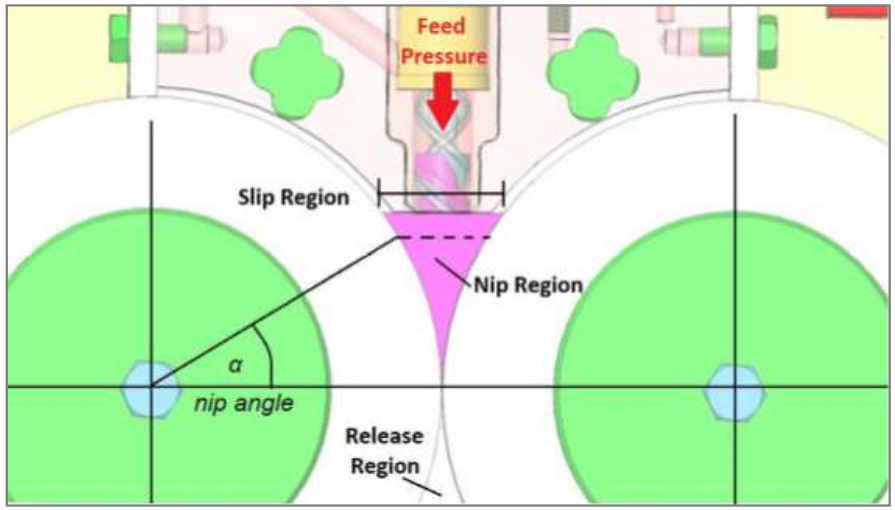
B. Pre-Compression VFS (Vertical Feed Screw)

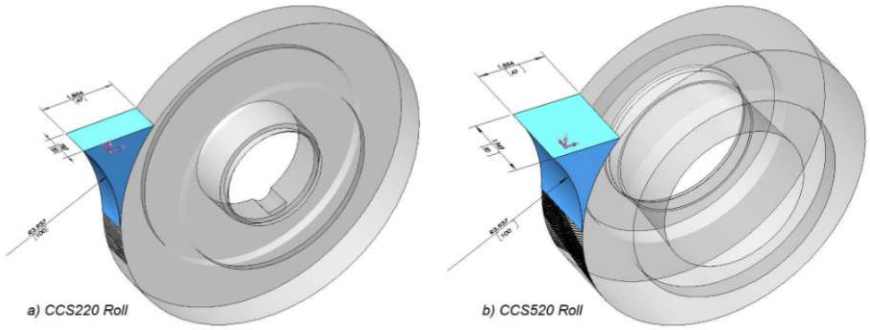
- Controls feed to roll nip
- Pre-compresses powder to deaerate and minimize slip on rolls
- Forced vacuum de-aeration adds complexity which is NOT Lean
- Feed powder bulk density dictates VFS speed
- Double flight feed screw



B. Pre-Compression VFS (Vertical Feed Screw)

- Material pre-compressed with VFS, limits slip in nip region.
- Powder compaction begins at nip angle.
- Minimal slip with proper roll surface configuration.
- Constant and consistent operating roll gap will determine degree of densification.

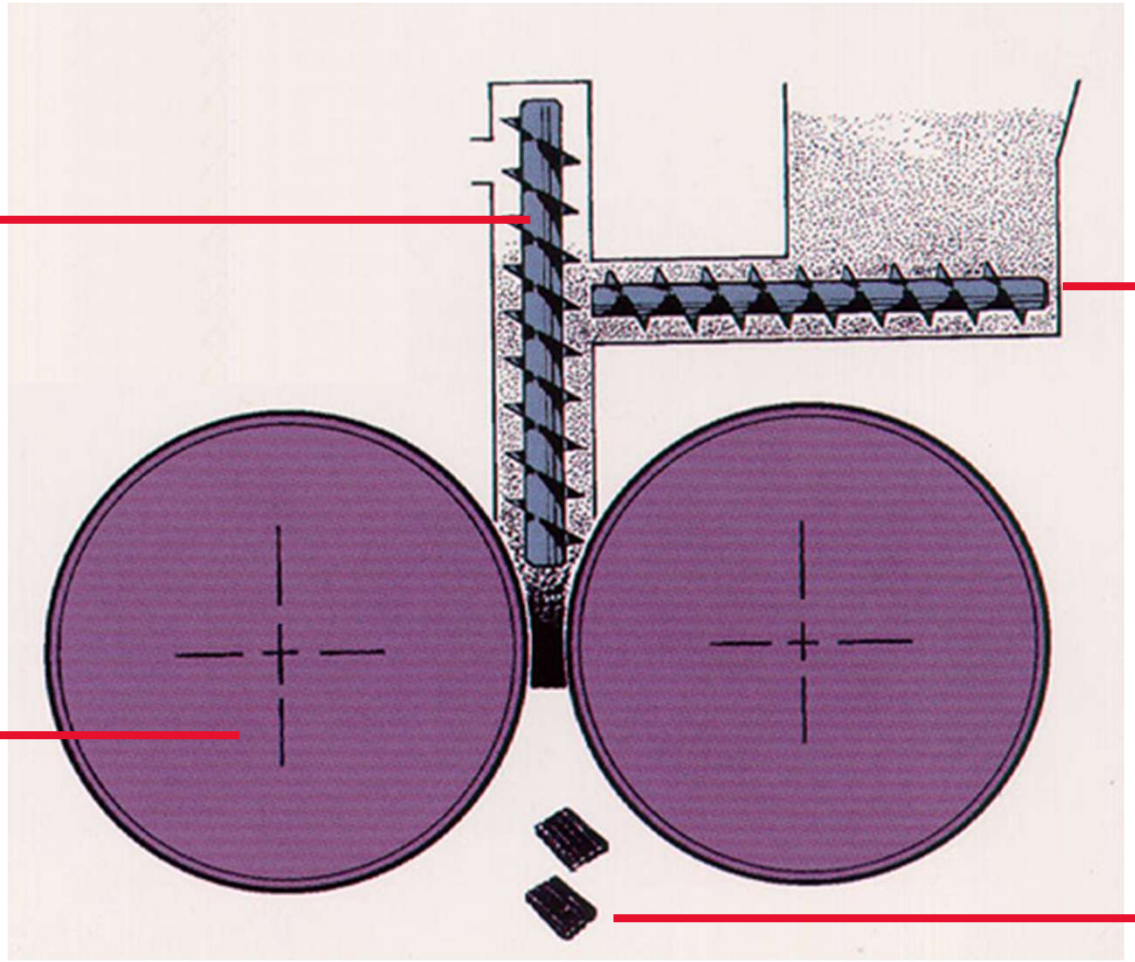




Product Feed

High speed pre-compression screw helps remove entrained air and forces product between rolls

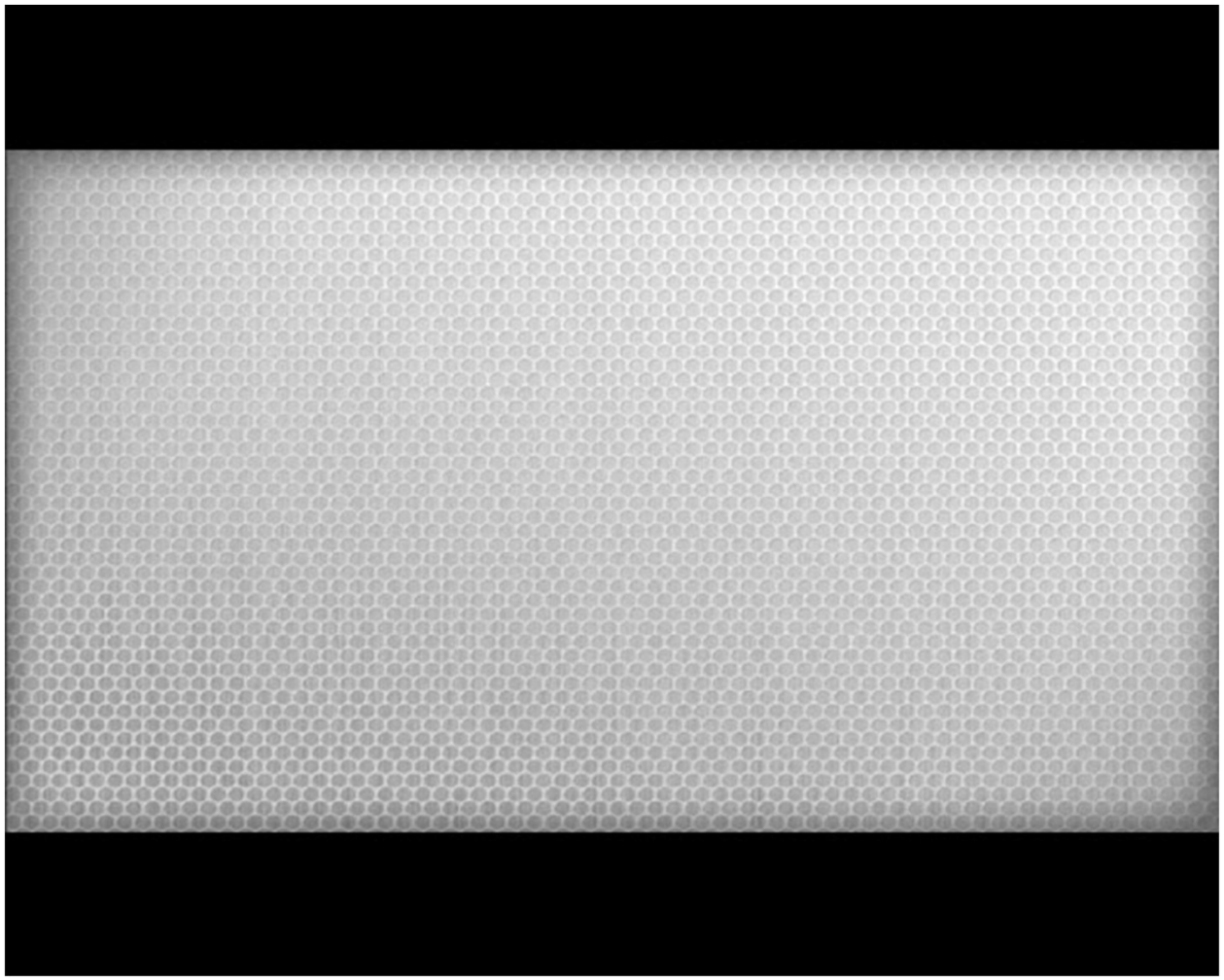
Metering screw controls amount of product fed to rolls

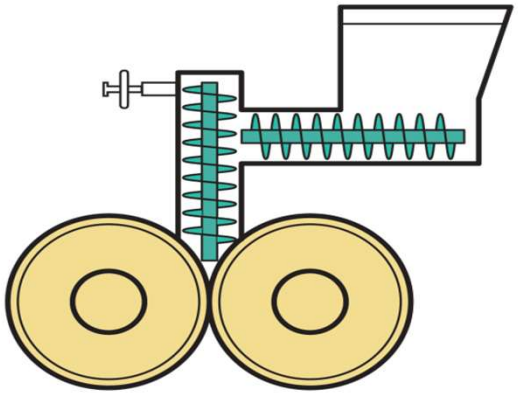


Counter rotating rolls

Compacted Material

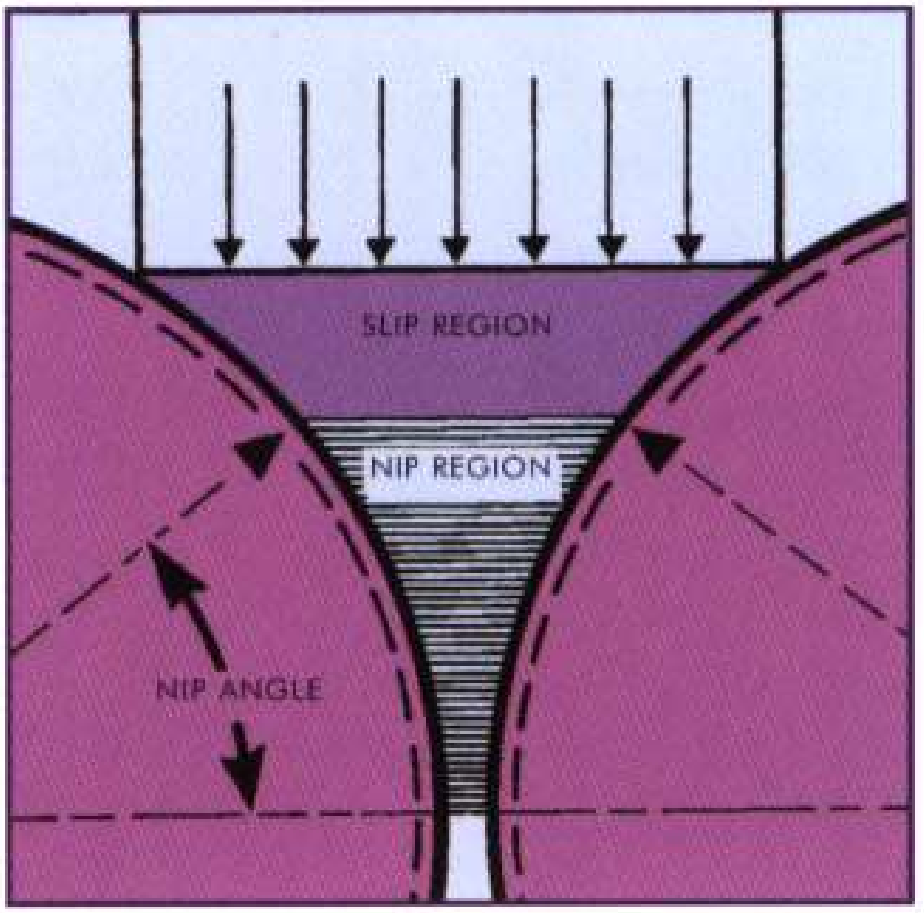
Why Separate Feeding from Pre-Compression





Nip Angle and Roll Gap influenced by:

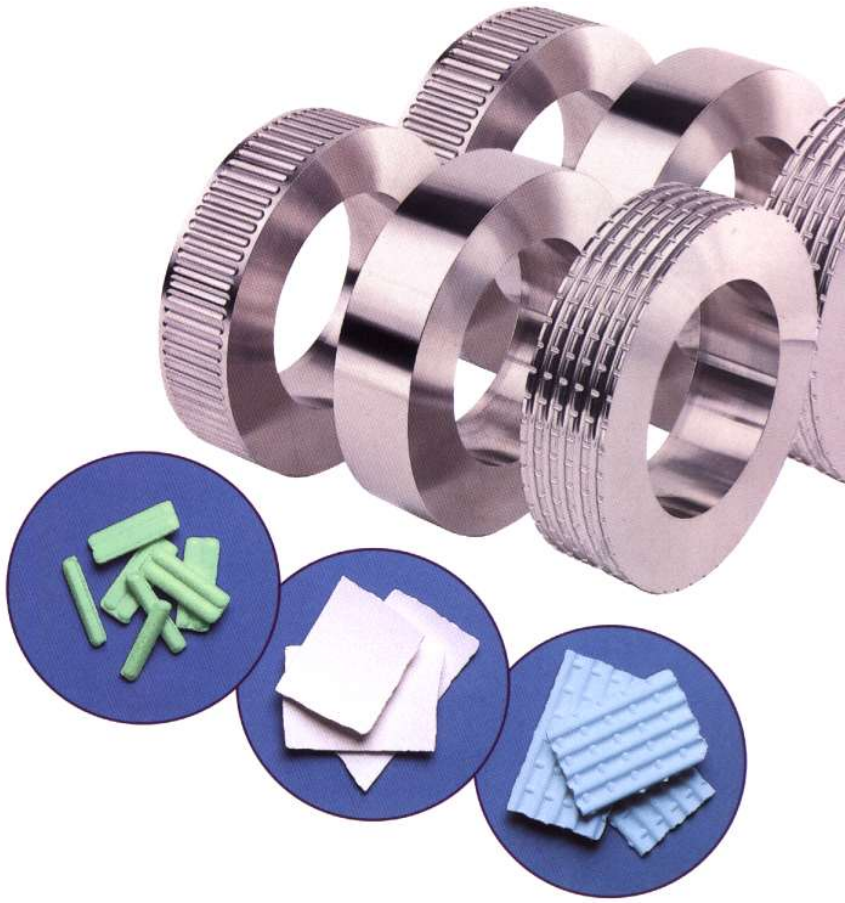
- Pressure
- Roll diameter
- Roll surface
- Pre-compression force
- Roll speed
- Roll gap



- Minimal slip will occur with proper roll surface configuration.
- Maintaining constant and consistent gap is vital to product quality and reproducibility.

C. Rolls

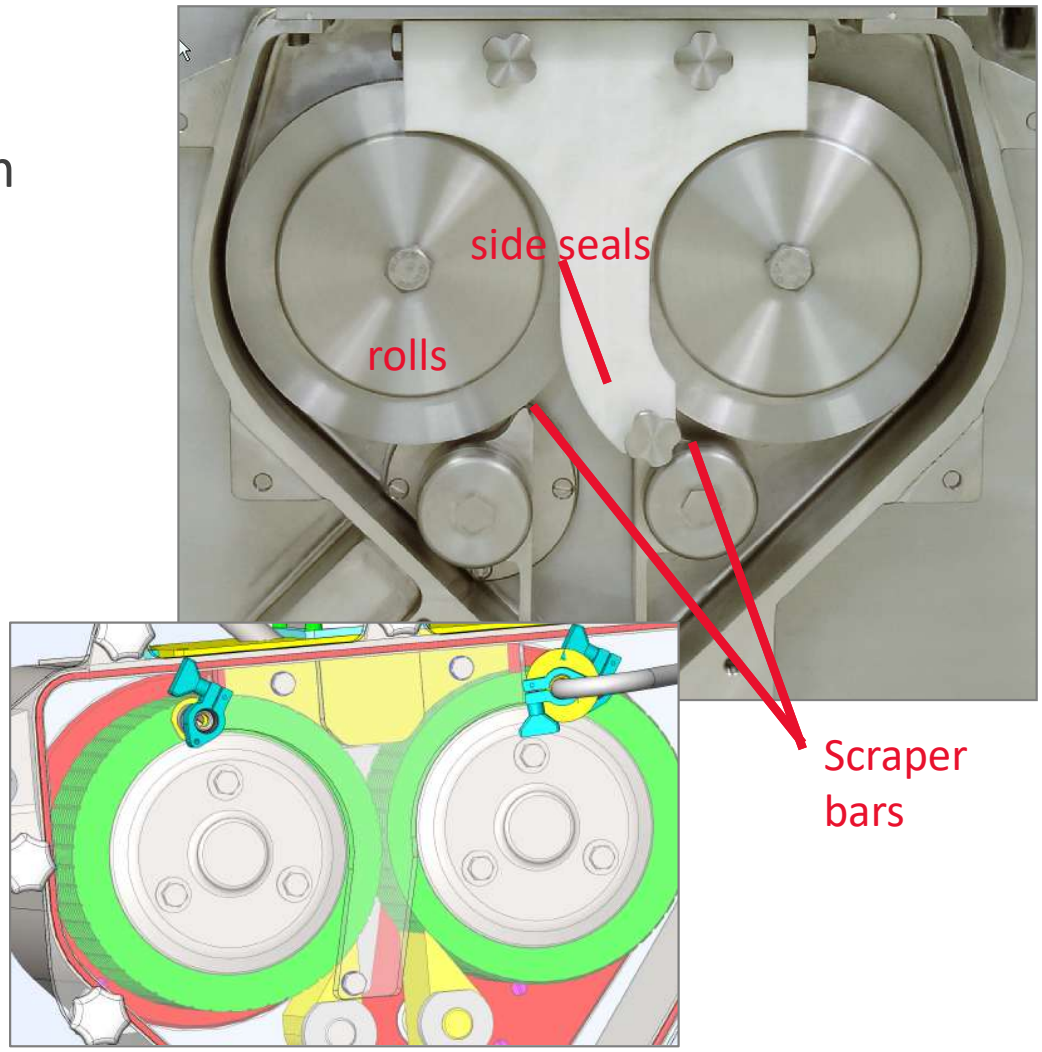
- Rolls horizontally oriented to assist de-aeration and pre-compression
- Surface establishes friction required between roll and product.
- One fixed, one floating, hydraulically controlled
- Roll surface selection is product dependent



Can be cooled for heat sensitive products

Roll Design Efficiency

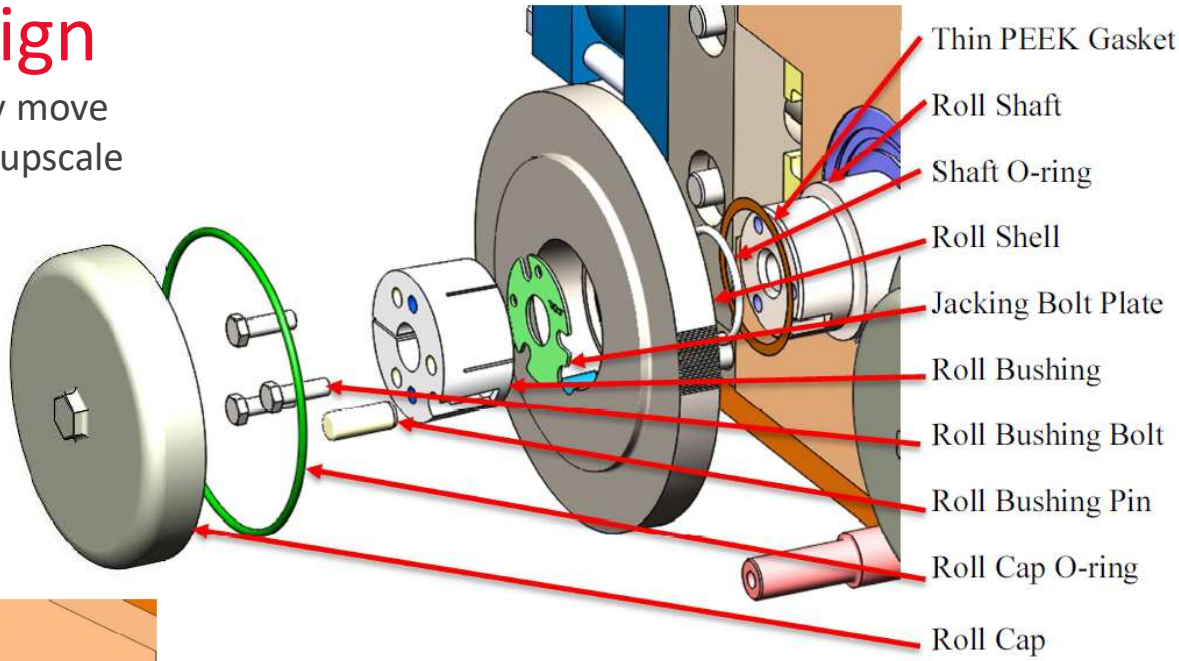
- Top and side seal assembly maintains compression, preventing material from bypassing the roll nip area
- Cantilevered rolls hygienic configuration for easier cleaning
- Scraper bars guide ribbons into size reduction unit.
- Scraper bars remove potential for compact sticking to rolls

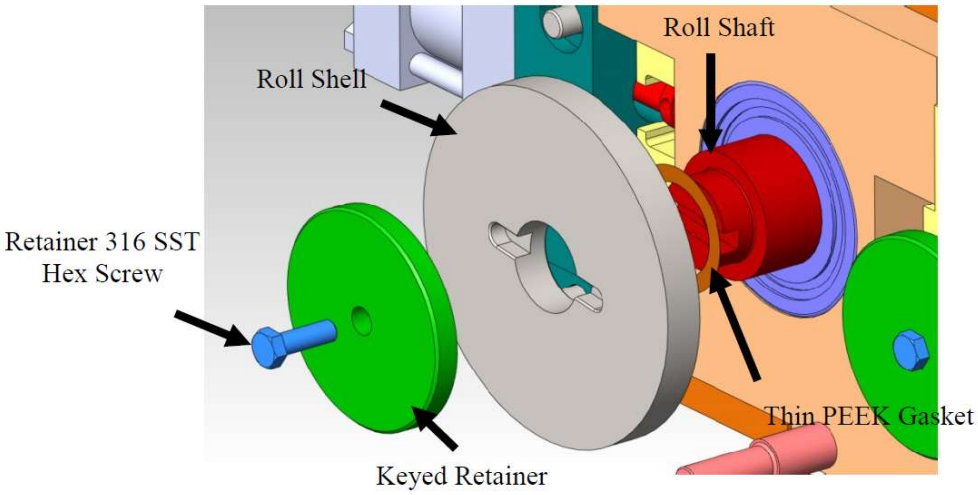


Roll Design Efficiency

New Design

Allows us to easily move from CCS220 and upscale to CCS320



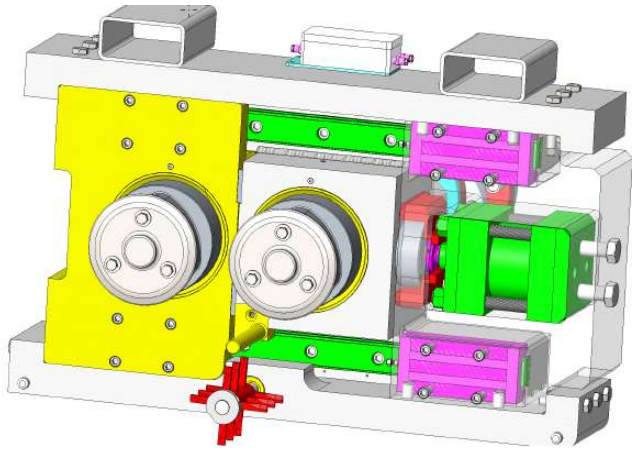


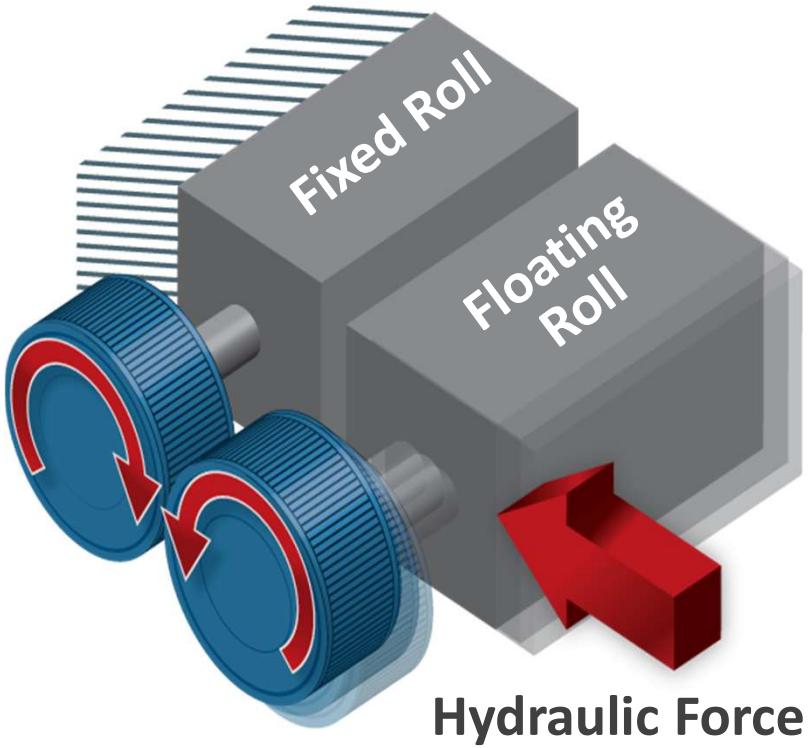
Old design

More difficult to assemble

D. Applied Roll Force (Pressure) | Speed

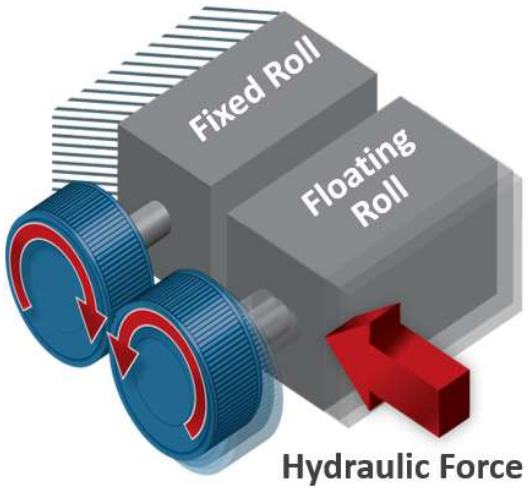
- Two pressures in Compactor
- System Hydraulic Pressure (bar)
- Pressure between roll faces (kN/cm)
- Dual hydraulic system ensures “floating” roll’s precise force for uniform compacts
- Roll speed (“ideal” dwell time) improves efficiency & reduces heat
- Precise parallel roll forces are achieved using linear bearings

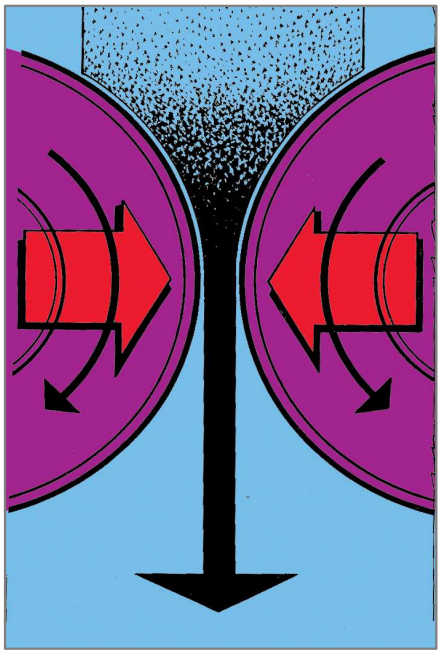




E. Roll Gap

- Roll gap function of amount of material and roll pressure
- Optimized for capacity, density and higher granule quality
- Pharma: 1.0 to 2.5 mm depending on model size
- Roll gap monitored via LVDT (Linear Variable Differential Transducer) for a +/- 0.06 mm tolerance





Process Efficiency and Uniform Quality

- Low speed horizontal feed screw meters material to the process. (10-80 RPM, in 0.1 RPM increments)
- High speed Vertical Screw pre-compresses and deaerates material as it is forced between the counter rotating rolls (50-450 RPM) - typically double flight for more uniform pressure in roll nip
- Over 90% of applications are most efficiently processed on this standard feed system
- Forced vacuum deaeration improves processing for certain types of products