

Pharma Solutions

METHOCEL™ DC2 Premium Excipients

Saving the Industry Time and Money to Focus on
Life-saving Innovations



Formulate with cost efficiency in mind

METHOCEL™ DC2 Premium Excipients help you enjoy the benefits of dry powder processing techniques while maintaining consistent modified release performance. They offer the performance reliability expected from the proven family of METHOCEL™ CR excipients.

METHOCEL™ DC2 polymers are designed to offer:

- Science-based, designed morphology, enabling the switch from batch wet granulation techniques to continuous dry processing techniques, like roller compaction and direct compression
- Pure Pharmacopeial HPMC, no additives
- Demonstration of benefits using multiple model API Formulations

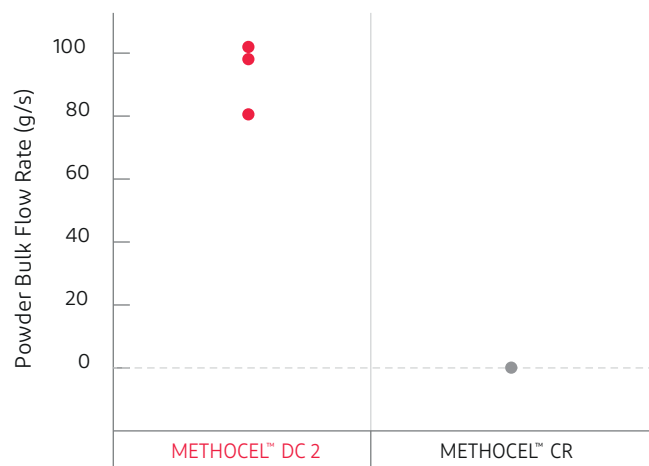
METHOCEL™ DC2 Advantages:

- Considerably improved flow properties, providing excellent processability in the industry-preferred methods of roller compaction and direct compression;
- Greater reproducibility in tablet properties, such as weight uniformity, hardness and content uniformity;
- Shortened development time and lower manufacturing costs (up to 60%) through the elimination of the wet granulation process;
- Convenience and Reliability, with low regulatory hurdles to use, as they are pure pharmacopeial HPMC;
- Better formulation option for heat- and moisture-sensitive APIs.



Formulate with cost efficiency in mind

Powder Bulk Flow Rate of METHOCEL™ DC2



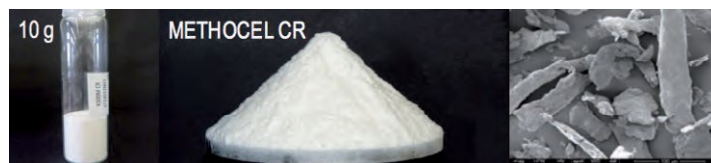
Morphology Grade Within Chemistry / MW Grade

Data is based on results from internal studies.

Differences in morphology drive the improved flow and processability.

METHOCEL™ DC2 has:

- Less fines;
- More spherical morphology.



It should be noted that METHOCEL™ DC2 is chemically identical to METHOCEL™ CR. Thus, METHOCEL™ DC2 meets all HPMC pharmaceutical requirements.

Funnel Flow Test

Screen shots of a time lapse video over 14 seconds show the difference in powder flow through a glass funnel between METHOCEL™ DC2 and METHOCEL™ CR.



Internal Test from DOW R&D, Midland, MI (2014)

Excellent processability in dry powder techniques

Such as direct compression and roller compaction

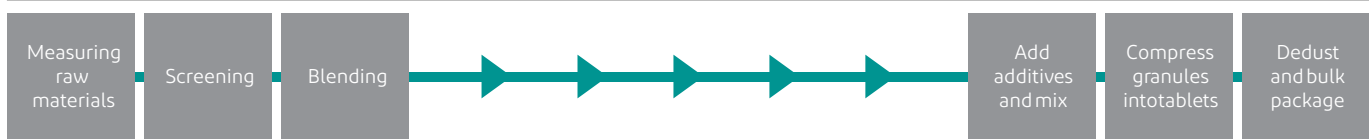
Streamline Manufacturing and Gain Efficiencies:

In the example table displayed below, a comparison between a wet granulation and direct compression process illustrates the potential for significant time and cost savings for tablet manufacturers.

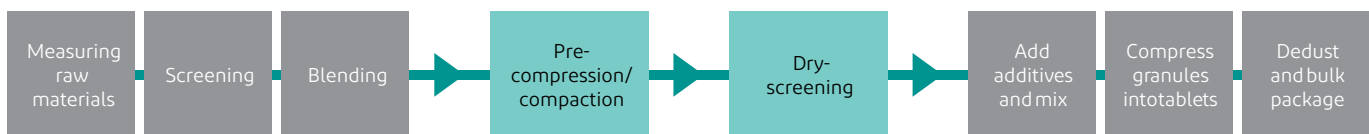
		High Shear Wet Granulation	Direct Compression
	Cost / hour	Hours	Hours
Equipment Preparation	\$150	3	1
Material Dispensing	\$120	3	3
Excipient Blend	\$160	1	1
Lubrication Blend	\$160	0.5	0.5
High Shear Granulation	\$240	1	0
Drying the Granulation	\$240	1	0
Granulation Sizing	\$120	1	0
Clean up Costs	\$120	5	1
Total Hours		15.5	6.5
Savings			~61%*

* Actual Results will vary based on formulation, manufacturing process and labor costs.

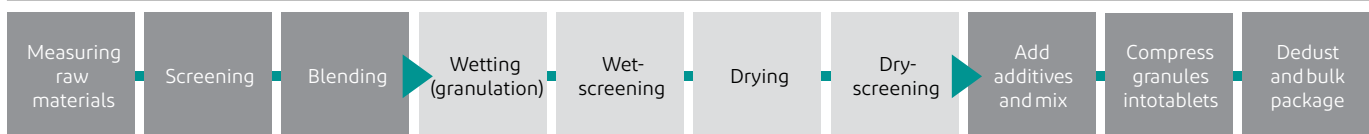
Direct Compression



Dry Granulation



Wet Granulation



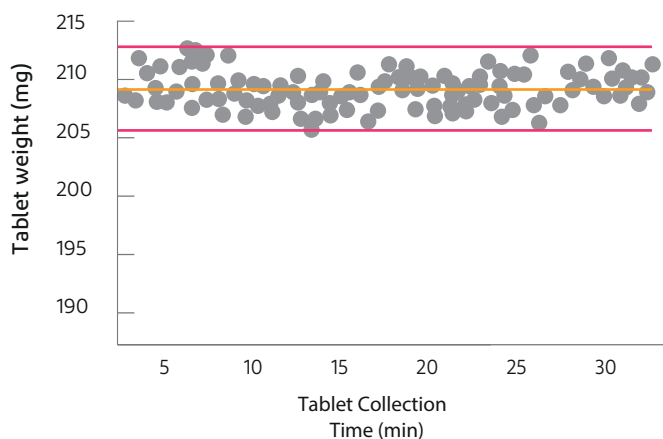
Greater reproducibility

In tablet properties

Consistency:

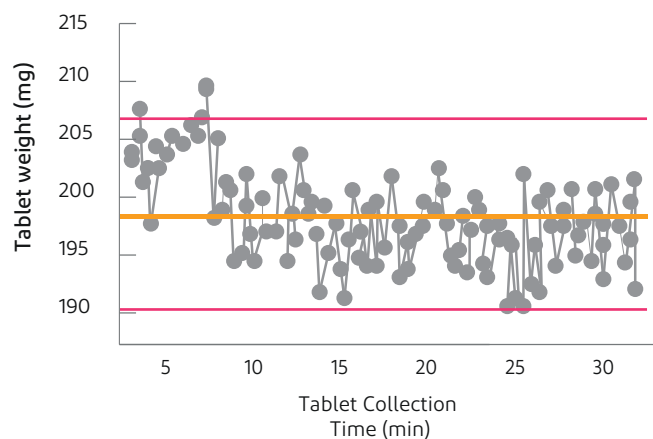
The figures below illustrate that METHOCEL™ DC2 facilitates higher reproducibility in weight and content uniformity when used for direct compression.

METHOCEL™ DC2 Control Chart: Tablet Weight



UCL = 213.31 CpK: 3.397
 Avg = 209.43 Sigma Level: 10 σ
 LCL = 205.55

METHOCEL™ CR Control Chart: Tablet Weight



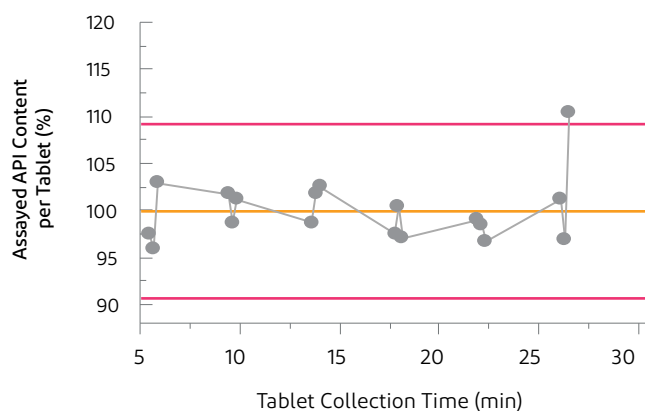
UCL = 207 CpK: 1.594
 Avg = 198.73 Sigma Level: 4 σ
 LCL = 190.46

Results from internal studies carried out in 2013 using a gliclazide model formulation.

Uniformity:

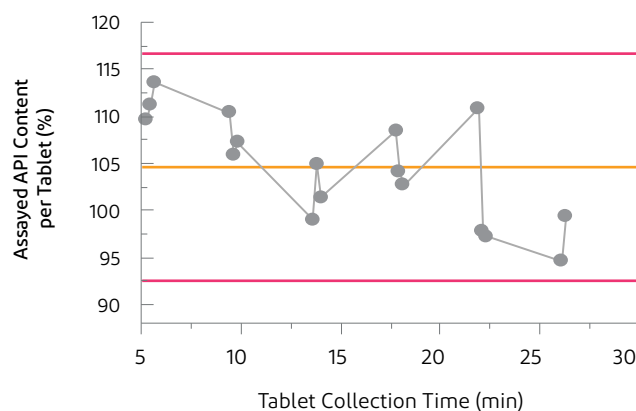
API Content Uniformity remained consistent with METHOCEL™ DC2, but showed signs of API segregation over the duration of the direct compression trial with METHOCEL™ CR.

METHOCEL™ DC2 Run Chart: API Content per Tablet



UCL = 109.09
 Avg = 99.61
 LCL = 90.13

METHOCEL™ CR Run Chart: API Content per Tablet



UCL = 116.77
 Avg = 104.69
 LCL = 92.61

Metformin HCl formulation

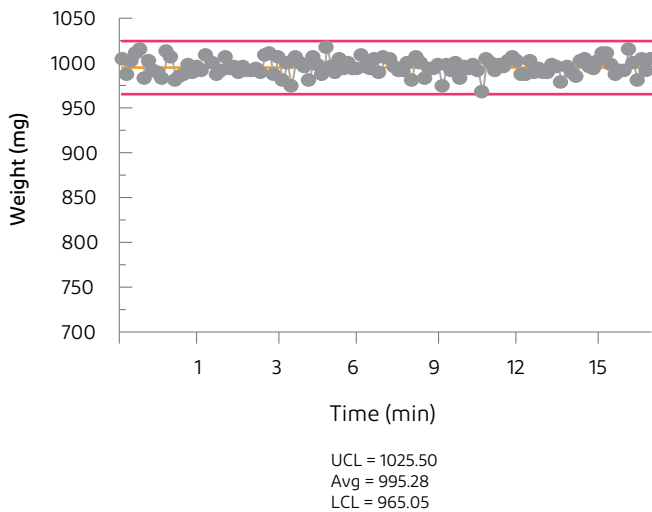
Roller compaction

The following charts show the results from an internal study of a Metformin HCl formulation, produced using dry granulation/roller compaction. When using dry powder processing techniques, like Roller Compaction, formulators can achieve a more reproducible tablet with METHOCEL™ DC2.

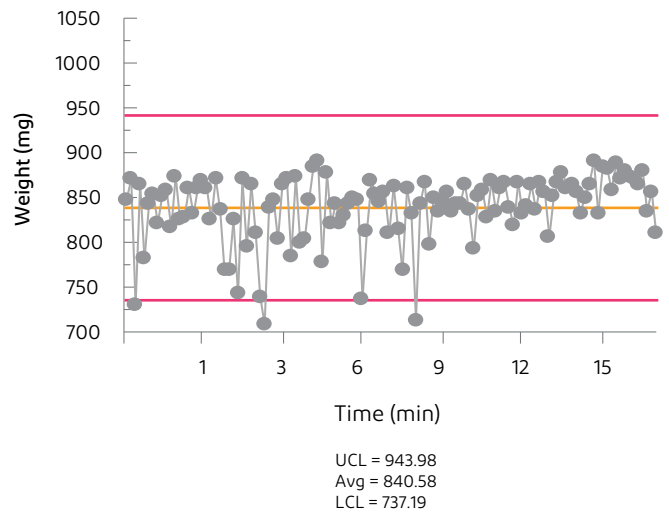
Tablet Weight

The tablets produced with METHOCEL™ DC2 showed less tablet-to-tablet weight variation than METHOCEL™ CR. Both grades exhibited similar modified release profiles, matching the control (commercially available tablet).

METHOCEL™ DC2

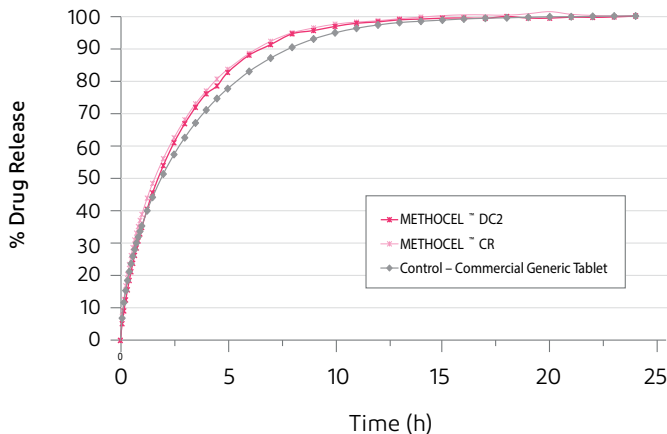


METHOCEL™ CR



Metformin Release Profiles

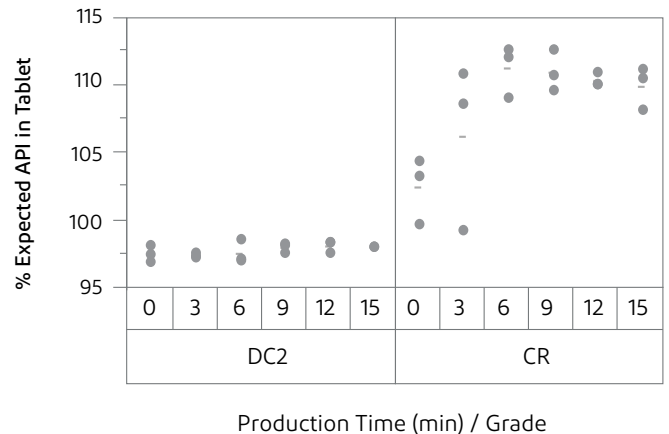
METHOCEL™ DC2 polymers deliver the expected modified release performance and consistent behavior across length of run.



Tablet Assays – Roller Compacted Material

An assay of the tablets shows greater API content uniformity when using METHOCEL™ DC2.

- Assays measured on individual tablets
- % API based on expected content per tablet weight







Our Direct Compression Portfolio

Three direct compression grades are currently available: METHOCEL™ K100LV Premium DC2, METHOCEL™ K4M Premium DC2 and METHOCEL™ K100M Premium DC2. These polymers have been developed to optimize dry powder processability while maintaining the same viscosities, degrees of methyl and hydroxypropyl substitution, and other important properties as the corresponding Controlled Release (CR) grades. The DC2 grades are chemically identical to original METHOCEL™ Premium products. The DC2 grades meet US Pharmacopoeia, European Pharmacopoeia and Japanese Pharmacopoeia monograph.

Colorcon/DuPont Controlled Release Alliance Support

- DuPont polymer chemistry expertise and manufacturing capability
- Colorcon dedicated team provides formulation expertise
- Starter formulations available through Colorcon HyperStart formulation service
- Colorcon local technical support for trials, scale-up and troubleshooting
- Colorcon global supply and logistics

Unique Together



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