efficient tablet binding for superior strength, low friability, and cost savings

tough formulating challenges require tough tablet binders

From chipping and breaking to time and cost constraints, developing a nutraceutical tablet can be a challenge. With Klucel NutraTM modified cellulose, Ashland can help solve these challenges by enabling more robust tablets and cost savings. With the addition of as little as 1%, Klucel Nutra modified cellulose performs efficiently to provide tablet hardness with low friability, which not only greatly reduces tablet chipping during the manufacturing process, but also reduces tablet damage during shipping.

benefits

- Reduce defects with unsurpassed tablet hardness and friability
- Produce smaller tablets and improve consumer usability
- Save costs through improving yields and reducing the amount of other additives
- Excellent formulation performance for both direct compression and wet granulation

improve the usability of your nutraceutical tablet

As solvers, we at Ashland know that the success of your nutraceutical product is based not only on its effectiveness, but also its ease of use for consumers. For this, Klucel Nutra has allowed many of our customers to significantly reduce their final tablet size, often by as much as 20%. The visual difference of such a reduction is shown in Figure 1.

Smaller tablets often lead to increased consumer acceptance and can thereby create opportunity for greater market penetration of your final nutraceutical product.



Figure 1. Lower binder use levels enable approximately 20% size reduction in final tablet size

Smaller tablets can also lead to greater batch throughput. For a similar comparison, a tablet that is 20% smaller yields approximately 20% more tablets for a given batch. This would eliminate the production of one in five batches with the obvious savings of time, fixed costs, and quality control.

Friability results for all formulations in Table 1 are shown in Figure 2. Removing the 20% microcrystalline cellulose and adding 2% of Klucel Nutra D modified cellulose to the formulation reduces tablet size while maintaining comparable friability at common compression forces.

Lower friability not only greatly reduces tablet chipping during the coating process, but also reduces tablet damage during shipping of the final product.

Table 1. Example direct-compression formulations incorporating Klucel Nutra modified cellulose

	Tablet Weight (mg)			
	1188	1049	1074	980
Ingredients	% w/w	% w/w	% w/w	% w/w
Glucosamine	42.0	47.6	46.5	52.1
Chondroitin	33.7	38.1	37.2	41.6
Microcrystalline cellulose	20.0	10.0	10.0	0.0
Klucel Nutra™ D modified cellulose	0.0	0.0	2.0	2.0
Polyplasdone™ XL crospovidone	2.7	2.7	2.7	2.7
Stearic acid	0.8	0.8	0.8	0.8
Fumed silica	0.5	0.5	0.5	0.5
Magnesium stearate	0.3	0.3	0.3	0.3

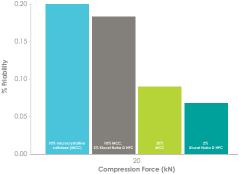


Figure 2. Removing 20% of microcrystalline cellulose and adding 2% of Klucel Nutra D modified cellulose to the formulation reduces friability



efficacy usability allure integrity profitability™





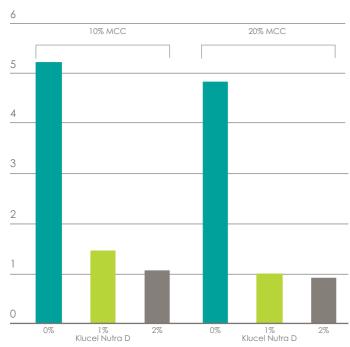
test results

1. High-Dose Herbal Tablet Dry / Direct Compression: Improve a marginal formulation with 1% added binder for tablet friability near 1%.

Formulations	%	%	
St. John's Wort (Raw Powder)	85.5-87.5	75.5-77.5	
Microcrystalline Cellulose MCC (Binder/Filler)	10	20	
Klucel Nutra D modified cellulose	0, 1 or 2	0, 1 or 2	
Croscarmellose Sodium (Disintegrant)	2	2	
Magnesium Stearate (Lubricant)	0.5	0.5	

Friability, % 15kN Compression Force

(

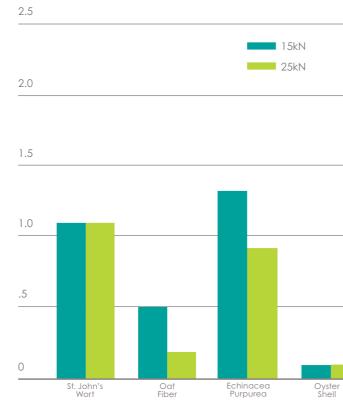


Addition of 1% Klucel Nutra D resulted in a more robust product that does not require expensive and time-consuming rework.

2. Very High-Dose Nutritional Dry / Direct Compression: Use a single-binder system for 93% raw-powder nutritional tablets with tablet friability near 1%.

Formulations	%
Candidate Nutritionals	
St. John's Wort, Oat Fiber, Echinacea Purpurea, Oyster Shell (All Raw Powders)	93.5
Klucel Nutra D modified cellulose	4
Croscarmellose Sodium (Disintegrant)	2
Magnesium Stearate (Lubricant)	0.5

Friability, % 15kN vs. 25kN Compression Force

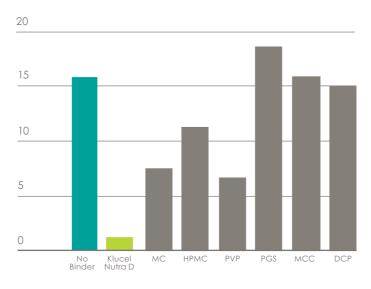


Very high-dose nutritional tablets formulated with 4% Klucel Nutra D gave excellent friability performance near 1% or less.

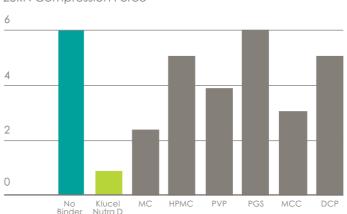
3. Very High-Dose Herbal Dry / Direct Compression: Compare common 4% binder performance for 93% dose raw-powder herbal tablet.

Formulations	%
Echinacea Purpurea	93.5
Binder Candidates	
Klucel Nutra D modified cellulose, Methylcellulose (MC), Hydroxypropylmethyl cellulose (HPM), Polyvinylpyrrolidone (PVP), Pregelantinized Starch (PGS),	4
Microcrystalline Cellulose (MCC), Dicalcium Phosphate (DCP)	
Croscarmellose Sodium (Disintegrant)	2
Magnesium Stearate (Lubricant)	0.5

Friability, % 15kN Compression Force



Friability, % 25kN Compression Force

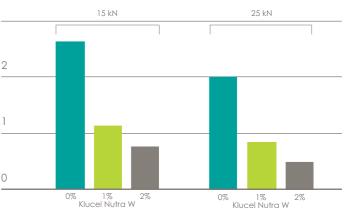


4% Klucel Nutra D outperformed every other examined candidate binder for this very high-dose herbal

4. Very High-Dose Herbal Wet Granulation 70/30 **Isopropanol / Water:** Improve a marginal formulation with 1-2% added binder for tablet friability near 1%.

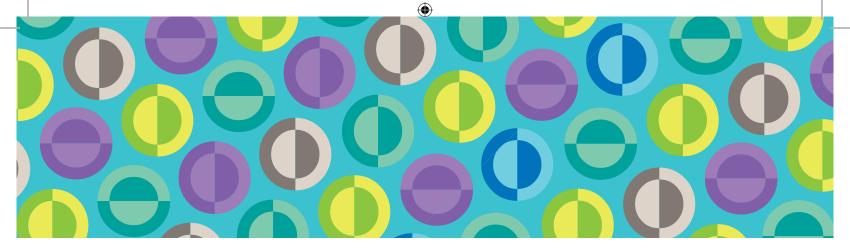
Formulation	%
Siberian Ginseng Root Powder	95.5-97.5
Klucel Nutra W modified cellulose	0, 1 or 2
Croscarmellose Sodium (Disintegrant)	2
Magnesium Stearate (Lubricant)	0.5

Friability, % 15kN vs. 25kN Compression Force



Addition of 1 to 2% Klucel Nutra W resulted in the wet granulation formulation performance saving reformulation time and expense.





Helping to ensure the integrity of your product

Klucel Nutra modified cellulose conforms to the monograph requirements for Hydroxypropyl Cellulose in the Food Chemicals Codex and to the purity criteria of E463 in the Annex of EC Directive 98/86/EC.

Solutions to meet your processing needs

For easy incorporation into your manufacturing process, Klucel Nutra modified cellulose supports both dry and wet processing and is available in two types:

- D for dry processing, with fine particle size ideal for direct compression, roller compaction, and dry granulation.
- W for wet processing, where regular particle size is best for wet granulation in water or alcohol.





lacktriangle

North America — Wilmington, DE USA Tel: +1 877 546 2782

Europe — Switzerland Tel: +41 52 560 55 00

India — Maharashtra Tel: +91 22 61489696

Asia Pacific — Singapore Tel: +65 6775 5366 Middle East, Africa — Dubai, U.A.E. Tel: +971 4 3818515

Latin America — Mexico Tel: +52 55 52 76 6121

ashland.com/contact

®Registered trademark, Ashland or its subsidiaries, registered in various countries

™Trademark, Ashland or its subsidiaries, registered in various countries ©2018, Ashland / PHA18-110 The information contained in this brochure and the various products described are intended for use only by persons having technical skill and at their own discretion and risk after they have performed necessary technical investigations, tests and evaluations of the products and their uses. Certain end uses of these products may be regulated pursuant to rules or regulations governing medical devices, drug uses, or pesticidal or antimicrobial uses. It is the end user's responsibility to determine the applicability of such regulations to its products.

All statements, information, and data presented herein are believed to be accurate and reliable, but are not to be taken as a guarantee of fitness for a particular purpose, or representation, express or implied, for which seller assumes legal responsibility. No freedom to use any patent owned by Ashland, its subsidiaries, or its suppliers is to be inferred.

