

**Superior Performance and Versatility
Make Ac-Di-Sol® Superdisintegrant
a First Choice**



Nutrition & Biosciences

After decades in the pharmaceutical industry, we continue to put DuPont products and solutions to test – both in customer formulations and against competitive products. Our ‘Quality by Design’ experts want to know about every additive, not just DuPont products, so we are better prepared to help you increase the efficiency of new formulation development, reduce complexity and lower your manufacturing costs. That’s why we conducted a recent benchmarking study comparing a variety of cross-linked carboxymethyl cellulose (XL-CMC) disintegrants for critical material attributes such as purity, moisture, and water uptake mechanism, resulting in superior disintegration and dissolution properties.

Spoiler Alert: Ac-Di-Sol® SD-711 croscarmellose sodium showed superior performance in all categories, proving itself a ‘first-choice’ superdisintegrant for standard and challenging formulations.

What does that mean for Manufacturers?

Quality products with potentially lower cost and working capital requirements for a range of formulations, processes and actives.

What does it mean for Formulation Developers?

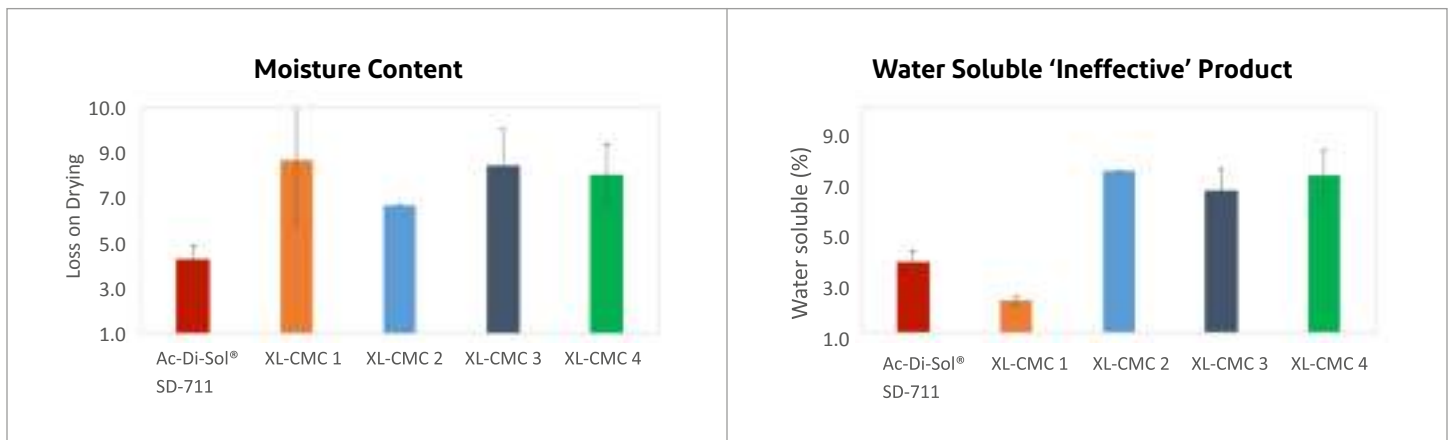
One less question to ask and challenge to navigate when advancing API efficacy and safety.

Why Choosing Ac-Di-Sol® SD-711 is a First Choice

Ac-Di-Sol® SD-711 is an internally cross-linked sodium carboxymethyl cellulose (XL-CMC) that aids in the disintegration and dissolution of pharmaceutical and dietary supplement tablets, capsules, and granules. Ac-Di-Sol® SD-711 provides consistent and faster disintegration and dissolution at low use levels, demonstrating functionality suitable for the most challenging formulations and cost equations.

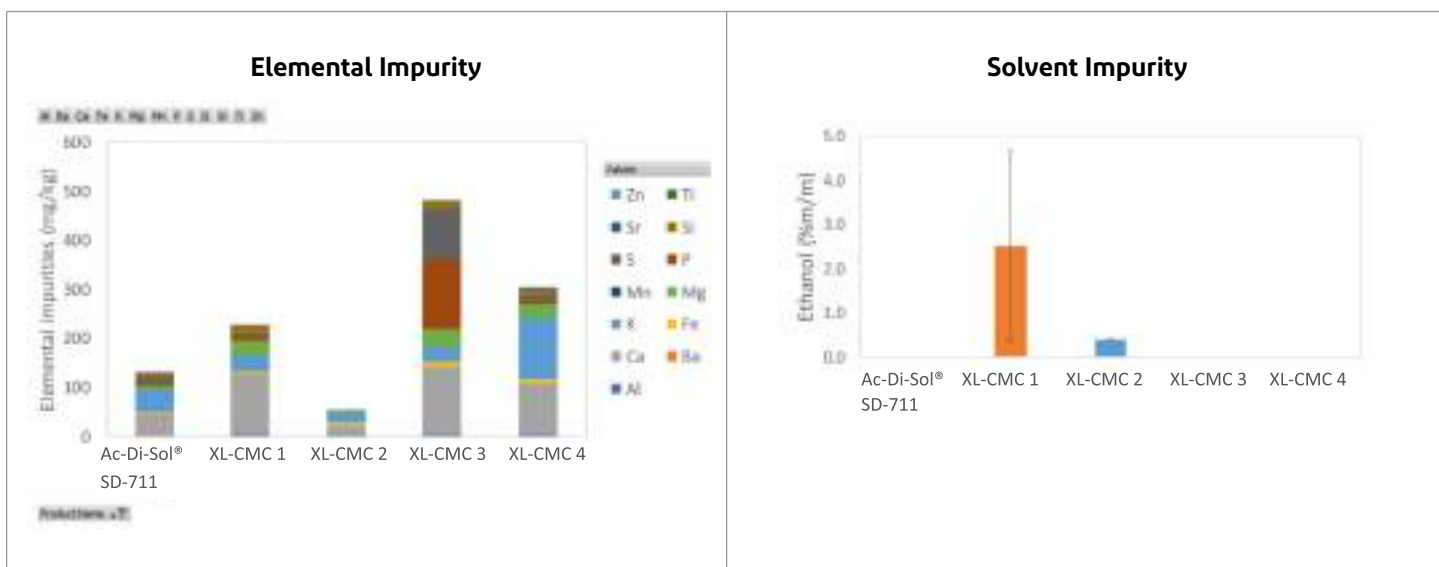
Quality that Delivers

Gram for gram, you get more of the functionality you are paying for with Ac-Di-Sol® SD-711. Suited for direct compression as well as wet and dry granulation, Ac-Di-Sol® SD-711 demonstrated substantially lower moisture and impurities such as water soluble, non-functional materials when compared to other croscarmellose suppliers. You can trust that the Ac-Di-Sol® SD-711 added will deliver the functionality intended, reliably and consistently every time.



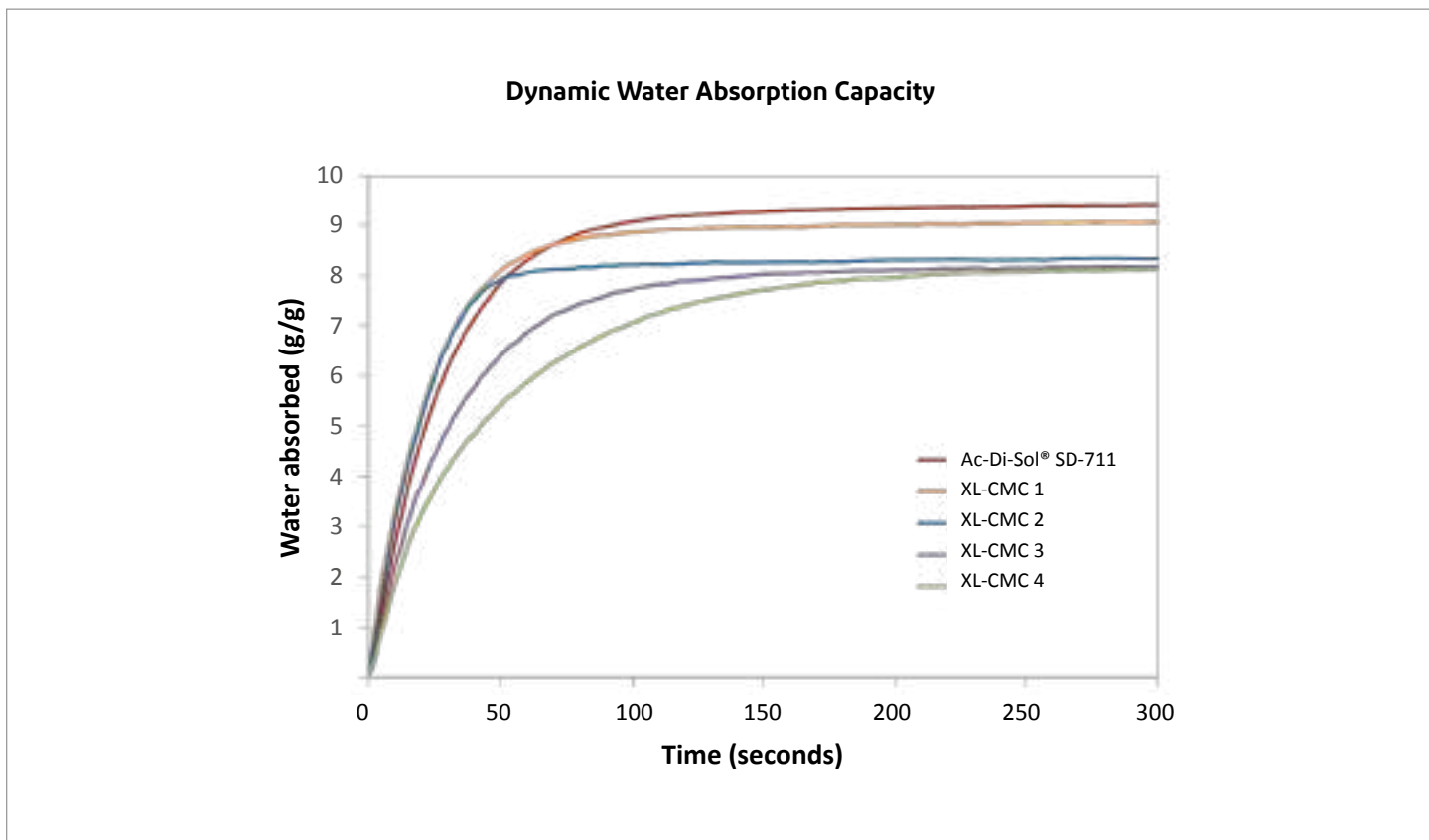
Purity that Protects APIs

Active pharmaceutical ingredients (APIs) are generally the costliest component of a formulation and they could be reactive or interactive with impurities. The efficacy of APIs and safety of drug products can therefore be affected by undesired, reactive impurities in formulation components, especially over time. The benchmarking study compared various impurity levels among competitive XL-CMC products. All products showed very high purities, as would be expected, all falling within the compendial range. However, Ac-Di-Sol® SD-711 showed either the lowest or near lowest levels of elemental and ethanol impurities. Ac-Di-Sol® SD-711 offers the consistently high purity needed for sensitive APIs and demanding formulation requirements. If your API has a specific sensitivity, we have a portfolio of solutions that can help.



Superior Functionality for Effective Dissolution of APIs

Ac-Di-Sol® SD-711 was compared to competitive XL-CMCs in regard to water uptake rate and capacity. As these materials quickly absorb water, their burst swelling power help to disintegrate the tablet and facilitate dissolution of the API. Gram-for-gram, Ac-Di-Sol® SD-711 absorbed the greatest amount of water, indicating superior intrinsic disintegration power and the potential to reduce the quantity of disintegrant required to achieve the desired dissolution performance.



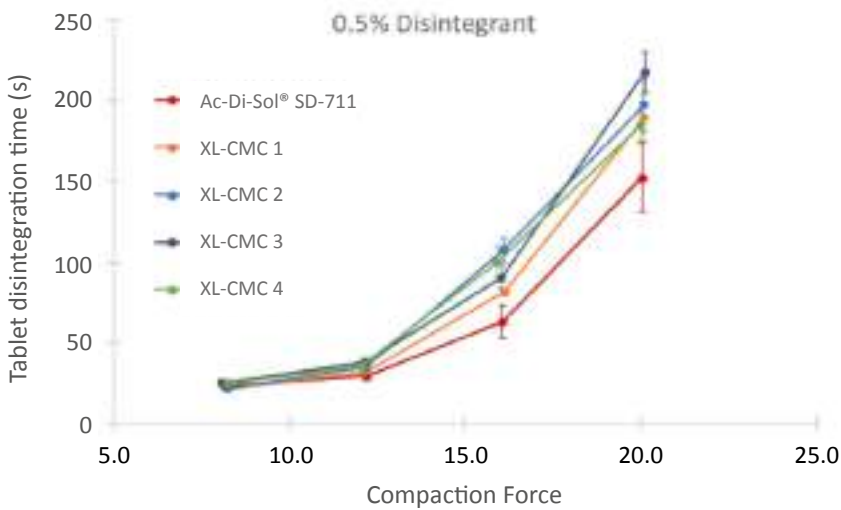
Versatility that can Reduce Complexity

Ac-Di-Sol® SD-711 demonstrates more consistent disintegration and dissolution across wider formulation and process ranges. Both direct compression (DC) and wet granulation (WG) formulations were tested with Ac-Di-Sol® SD-711 and competitive products using the APIs Theophylline and Chlorpheniramine Maleate (CPM), respectively.

Direct Compression

Keeping all tableting parameters constant except compaction force, formulations with 0.5%, 2% and 5% disintegrant were evaluated. At 0.5% disintegrant, Ac-Di-Sol® SD-711 demonstrated statistically superior disintegration performance while maintaining similar or superior tablet friability and hardness. Differences in disintegration performance were less pronounced at the 2% and 5% concentrations, which are less attractive from a cost perspective. When you use Ac-Di-Sol® SD-711, you get the support you need to optimize your formulation to deliver both the performance and cost objectives you are targeting.

Dynamic Water Absorption Capacity



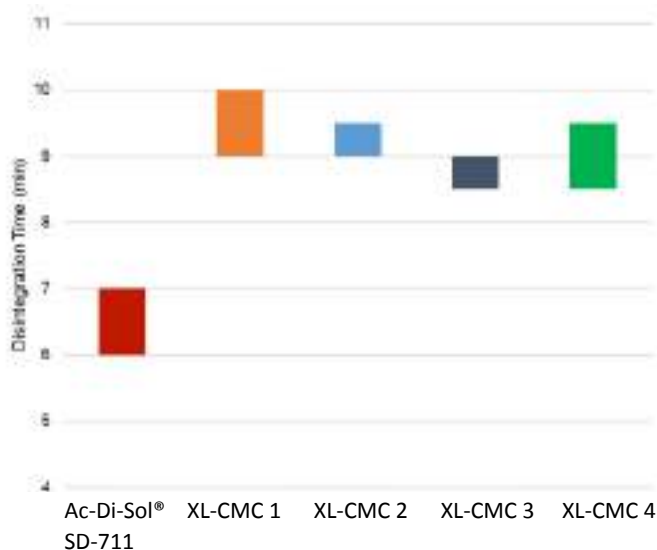
Ingredient	F1 (%)	F2 (%)	F3 (%)
SUPERTAB 11SD®	86.0	84.5	81.5
Theophylline	12.5	12.5	12.5
Disintegrant	0.5	2	5
Alubra®	1	1	1
Total (%)	100	100	100

High-Shear Wet Granulation

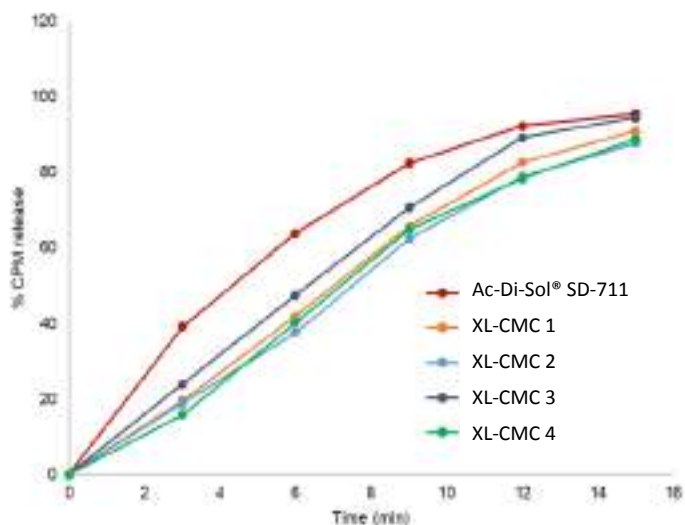
Keeping all tableting conditions constant, disintegration and dissolution times were measured for tablets made using a high-shear wet granulation process and different XL-CMC products. Ac-Di-Sol® SD-711 exhibited superior disintegration functionality and dissolution, ensuring the API is released quickly and effectively. Our Quality by Design experts are ready to work with customers to increase efficiency and reduce complexity.

Ingredients	%	Tablet Properties	%
Chlorpheniramine Maleate	3.34	Wt. of tablets (mg)	120
Lactose	59.46	Hardness (N)	107-118N
Avicel® PH-101	27.2		
METHOCEL™ E15 (Intra-granular)	2.5		
METHOCEL™ E15 (Binder)	2.5		
Disintegrant (XL-CMC)	4		
Mg. stearate/Alubra®	0.5		
Aerosil	0.5		
Total	100		

Disintegration Time



Dissolution Time

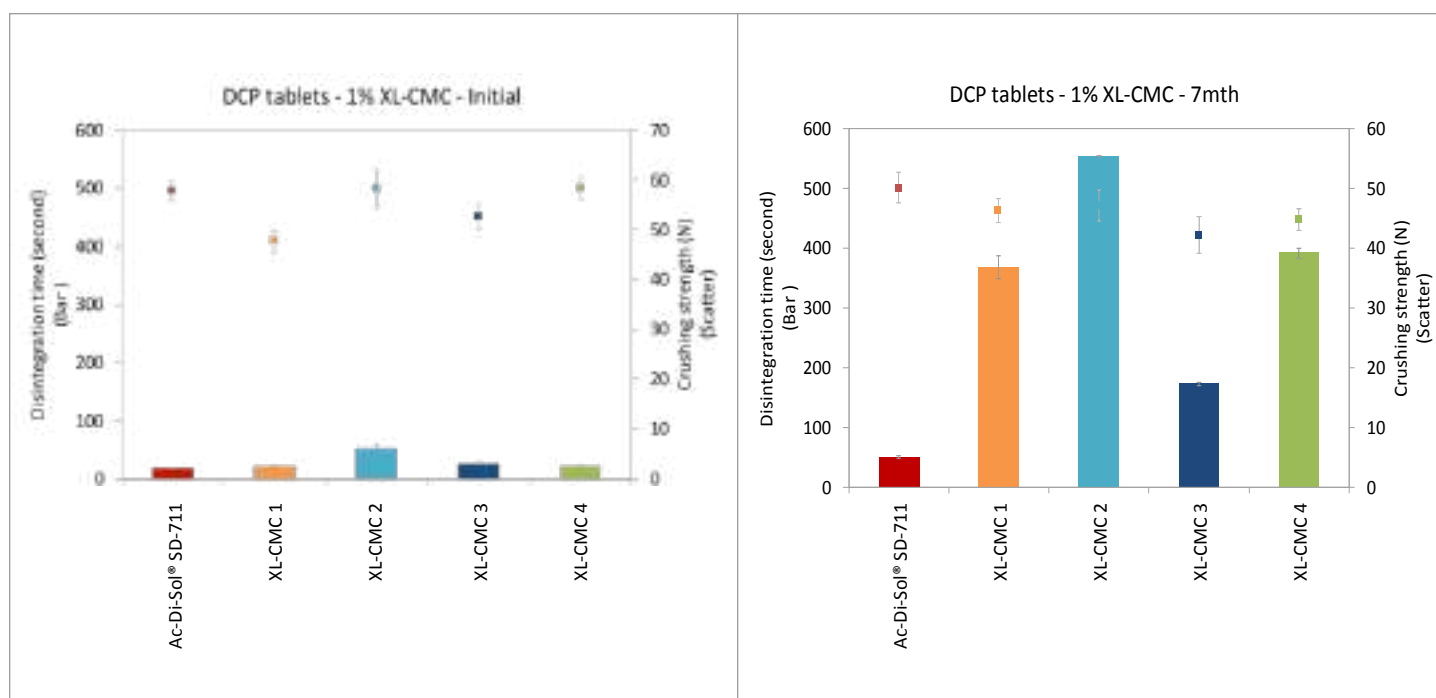


Stability that Preserves Product Quality

You only get one chance to make a good first impression and a single disappointment can deteriorate customer loyalty. That's why preserving product quality is something we take very seriously. Keeping all parameters constant, tablets using direct compression were created using different XL-CMCs. The tablets were then kept under ambient conditions in a sealed plastic bag for seven months. Tablets made using Ac-Di-Sol® SD-711 demonstrated consistently superior disintegration functionality and crushing strength before and after storage.

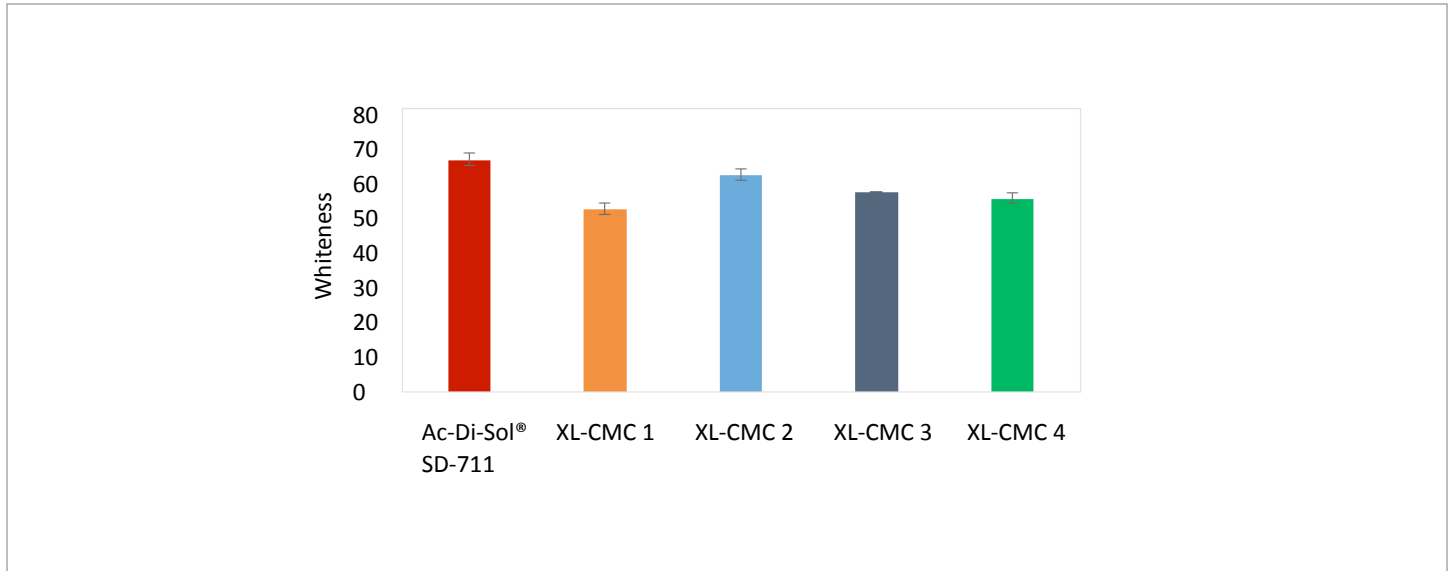
Ingredients	F1 (%)
Dicalcium Phosphate, Anhydrous	97.0
Disintegrant	1.0
Alubra®	2.0
Total	100

Direct Compression: Disintegration Time and Crushing Strength Over Period of 7 Months



Color that Outshines the Competition

Bright, white, consistent Ac-Di-Sol® SD-711 can make your tablets, capsules, and granules stand out while improving the disintegration performance of typical and advanced formulations. With similar apparent appearances, Ac-Di-Sol® SD-711 gives your product an edge when it comes to more consistent whiteness.



Make Ac-Di-Sol® SD-711 your First and only Disintegrant Choice

DuPont's portfolio of Pharma solutions and formulation and process expertise drive improved product, process and cost performance based on real-world experience. Using Ac-Di-Sol® SD-711 at lower levels and earlier in the development process can help reduce cost, complexity, and working capital by streamlining the number of disintegrants used.

Whatever your goal – formulation optimization, new APIs with yet-to-be-discovered sensitivities, novel formulation, or process consistency driven by simplicity – Ac-Di-Sol® SD-711 and DuPont formulation experts can help find that sweet spot. Our targets are your goals – avoiding formulations that are overdesigned, under-performing or have no degrees of freedom. Find out what the purity, functionality, versatility and support of Ac-Di-Sol® SD-711 can do for you.



Nutrition & Biosciences

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