News Release

Ashland to showcase new pharmaceutical oral solid dose excipients at CPHI and AAPS

Wilmington, Del., Oct. 2, 2024 – Ashland is showcasing two new life sciences products during upcoming tradeshows, CPHI Milan, October 8-10 (booth 6D20) and AAPS PharmSci 360 in Salt Lake City, UT, October 20-23 (booth 1903).

As part of Ashland's pharmaceutical portfolio, the company offers an array of oral solid dose (OSD) ingredients that improve, protect, and moderate the delivery of medicines. These ingredients include both time controlled- and immediate-release agents, as well as film coatings.

At the upcoming events, Ashland will introduce **klucel ls™ low-substituted hydroxypropyl cellulose (hpc)**, the latest excipient addition to their OSD portfolio and the first in a series of low-substituted products to come. Klucel ls™ low-substituted hpc is a multifunctional binder and disintegrant, ideal for the formulation of smaller tablets.

Klucel ls™ low-substituted hpc offers quick disintegration and rapid dissolution, anti-capping effect, ease of adoption as a monographed ingredient and enhanced stability due to non-ionic nature and low nitrite levels. It is also a biodegradable, non-microplastic disintegrant.

Because this new low-substituted hpc is developed and delivered by Ashland, it is backed by strong knowledge, expertise, experience, and global supply to support it. As the inventors of hpc chemistry, Ashland has the manufacturing and global technical expertise needed to minimize supply chain and formulation development issues while helping customers develop their optimal formulation.

"As a company rooted in science and innovation, the drive to find ingenious solutions applied to chemistry is in our DNA," said Deneen Law, Global Strategic Marketing Director – Klucel, Ashland. "We thrive on developing solutions to complex problems through a collaborative approach that offers the features and benefits our customers require, with the dependability and quality they demand. The removal of single-source global supply for low-substituted hpc, and the production of consistent, high-quality products are just a few reasons why Ashland's customer-centric approach is driving success across diverse industries."

"Klucel™ hpc formed the basis of a new generation of oral pharmaceutical dosage forms, and the scientists at Ashland continue to innovate and develop new hpc products to meet the needs of the pharmaceutical industry. While klucel ls™ low-substituted hpc is part of the klucel brand family, it is not the same as klucel™ hpc," Deneen Law, concluded.

During the shows, Ashland will highlight the differences, including how klucel ls™ low-substituted hpc conforms to the requirements of the low-substituted hpc monograph, and has fewer hydroxypropoxy groups on the cellulose backbone. This lower substitution results in physical chemical properties that differ from traditional klucel™ grades, including insolubility in water (as Klucel ls™ low-substituted hpc absorbs water and substantially swells in volume enabling rapid tablet disintegration—unlike klucel™, which is soluble in water and used primarily as a binder in oral solid dosage forms).

Ashland's **klucel™ hpc for pharmaceuticals** portfolio is ever-expanding, and currently includes a complete range of hpc grades covering various applications:

binders
- klucel™ ef hpc
- klucel™ elf hpc
- klucel™ exf hpc
- klucel™ exf ultra hpc

melt binder
- klucel fusion™ hpc

multifunctional binder & disintegrant
- klucel ls™ low-substituted hpc

CR polymers
- klucel™ gxf hpc
- klucel™ hf hpc
- klucel™ hxf hpc
- klucel™ lf hpc
- kucel™ lxf hpc
- klucel™ mxf hpc
- klucel™ xtend hpc

Ashland is also continuing to lead the industry with the reintroduction of the newly-improved **polyplasdone™ LN superdisintegrant**, a high-purity crospovidone with low and controlled nitrite specification to manage nitrosamines challenges effectively.

Polyplasdone™ LN grades maintain the renowned performance and reliability of the polyplasdone™ brand. Featuring significantly reduced nitrite levels, polyplasdone™ LN is the optimal solution for pharmaceutical companies aiming to minimize the risk of N-nitrosamine formation in oral solid dose formulations containing crospovidone. Polyplasdone™ LN comes with a certificate of analysis specifying nitrite levels at no more than 100 ppb.

In response to growing demands for high-purity excipients, Ashland's new feature in the polyplasdone™ LN product profile aims to support the industry in developing a comprehensive nitrite control strategy. By openly declaring nitrite levels as part of the Certificate of Analysis, Ashland is taking a proactive step to mitigate the formation of nitrosamines to support the evolution of safe and effective medicines and maintain Ashland leadership in excipients. This pioneering move underscores Ashland's unwavering commitment to quality and addresses industry concerns regarding nitrosamine formation.

"We are thrilled to lead the industry with this significant advancement, our commitment to quality and safety is at the forefront of everything we do," said Alejandra Alvarez, Global Strategic Marketing Director – Vinyl Pyrrolidone and Derivatives, Ashland. "By providing detailed nitrite specifications, we are empowering our customers to make informed decisions and enhance their own quality control measures."

This initiative is part of Ashland's broader strategy to foster collaboration and innovation within the industry. By setting a new standard for transparency, Ashland hopes to inspire other suppliers to follow suit, ultimately contributing to a safer and more reliable supply chain.

Ashland solvers are known as the expert's expert, helping customers solve tomorrow's challenges today. With R&D centers of excellence in every world region, an iSolve℠ digital portal that puts information at your fingertips, regulatory expertise to support our customers across all world regions, in-house manufacturing, backward integration, sourcing, and delivery in 93 countries, the company is responsibly solving for healthier lives, everywhere.

To learn more or to request a meeting at the shows, visit our **CPHI overview** or our **AAPS overview**. For more information on klucel ls™ low-substituted hpc LS™-11 or future grades, or polyplasdone™ LN crospovidone contact your Ashland sales representative.

About Ashland
Ashland Inc. (NYSE: ASH) is a global additives and specialty ingredients company with a conscious and proactive mindset for environmental, social and governance (ESG). The company serves customers in a wide range of consumer and industrial markets, including architectural coatings, construction, energy, food and beverage, personal care and pharmaceutical. Approximately 3,800 passionate, tenacious solvers – from renowned scientists and research chemists to talented engineers and plant operators – thrive on developing practical, innovative and elegant solutions to complex problems for customers in more than 100 countries.

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