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MilliporeSigma Launches Parateck[®] MXP Excipient for Increased Solubility

- **Enhances solubility of active pharmaceutical ingredients with poor bioavailability**
- **Enables higher amount of API loading with excellent stability**

Billerica, Massachusetts, December 2, 2016 — [MilliporeSigma](#), a leading science and technology company, today introduced [Parateck[®] MXP](#), a polyvinyl alcohol-based excipient that enhances solubility of a wide range of active pharmaceutical ingredients (APIs) with poor bioavailability.

Parateck[®] MXP excipient maintains stability at temperatures above 200 degrees Celsius, making it well-suited for hot melt extrusion (HME), a process used by drug manufacturers to enhance the solubility and bioavailability of APIs. The new excipient can achieve drug loads of 30 percent or more, while other excipients may be limited to 10-15 percent in HME. Drug load is a measure of the amount of API by weight that can be combined with the excipient.

“More than 90 percent of drugs in the pharmaceutical pipeline have solubility issues that lead to poor bioavailability, a key factor in the success of a drug candidate,” said Andrew Bulpin, Head of Process Solutions Strategic Marketing & Innovation, MilliporeSigma. “Parateck[®] MXP excipient is the latest addition to our comprehensive excipients portfolio and allows our customers to address solubility challenges that otherwise might have prevented promising and potentially life-changing drug candidates from progressing through the pipeline.”



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The new excipient has been successfully tested on eight commonly used and poorly soluble APIs, including ibuprofen, indomethacin and itraconazole, and can be used in formulations for both immediate and sustained release.

In contrast with more complex excipients, Parateck[®] MXP excipient uses simple chemistry, potentially streamlining regulatory processes. The polymer used in Parateck[®] MXP is generally recognized as safe (GRAS)ⁱ by the U.S. Food and Drug Administration and complies with U.S. Pharmacopeia, European Pharmacopeia and Japanese Pharmacopeia for excipient monographs.

Parateck[®] MXP excipient is an expansion of MilliporeSigma's portfolio of products that enhance bioavailability by improving poor aqueous solubility and controlled release. After rigorous testing, Parateck[®] MXP excipient will also be incorporated into the company's Emprove[®] program. Using this program, customers have instant, online access to regulatory and technical information about the excipient, more than 400 other chemicals, filters and single-use components to facilitate risk assessment and qualification processes.

ⁱ <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153970.htm>

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About the Life Science Business of Merck KGaA, Darmstadt, Germany

The life science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has 19,000 employees and 65 manufacturing sites worldwide, with a portfolio of more than 300,000 products enabling scientific discovery. Udit Batra is the global chief executive officer of MilliporeSigma.

Merck KGaA, Darmstadt, Germany completed its \$17 billion acquisition of Sigma-Aldrich in November 2015, creating a leader in the \$125 billion global life science industry.

Merck KGaA of Darmstadt, Germany is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of €12.85 billion in 2015. Around 50,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges.

Merck KGaA, Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company



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to this day. The company holds the global rights to the name and the trademark "Merck" internationally except for the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.