

## Evonik launches new formulation technology for the development of alcohol resistant drug products

Evonik has developed a formulation technology, which offers a novel approach to developing alcohol resistant oral drug products with delayed or sustained release profiles. EUDRATEC™ ADD delivers a solution to the problem of alcohol-induced dose dumping of modified release dosage forms and enables the pharmaceutical industry to be in accordance with the sharpened requirements of the US-FDA.

If patients take oral drugs, designed with a modified release (MR) profile, together with alcohol, the potential exists for an increased and/or uncontrolled release of the drug's active ingredient (dose dumping) in the stomach, as current tablet coating systems dissolve in alcohol. The resulting release burst and associated high concentration of the active ingredient has the potential to be harmful to patients. For example, in the case of sustained release opioids designed to treat pain for 12 hours, patients may be subjected to a 12-hour dose in a matter of minutes.

Recognizing the problem, regulatory agencies have issued guidelines for the evaluation of MR formulations through in vitro alcohol testing. These guidelines pose significant technological challenges to formulators as current drug coating formulations do not perform in the presence of alcohol.

Acknowledging the need for new solutions, Evonik has developed EUDRATEC™ ADD, a new formulation technology consisting of a bilayer coating with EUDRAGIT® polymers, which allow formulators to achieve the same release profiles in a 40% alcoholic medium (equivalent to pure whisky or vodka) as in an aqueous medium. EUDRATEC™ ADD is patent protected and has demonstrated its effectiveness for use with drugs designed for both, targeted or sustained release profiles.

"EUDRATEC™ ADD is a great demonstrator of Evonik's innovation power in oral drug product formulation", states Dr. Jean-Luc Herbeaux, Head of the Health Care Business Line of Evonik. He expects, that this new technology will generate new EUDRAGIT® product and service sales as well as licensing revenues in the next

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**Contact Person Specialized Press  
Dr. Jürgen Krauter**

Vice President Communications  
Nutrition & Care  
Phone +49 6181 59-6847  
Fax +49 6181 59-76847  
juergen.krauter@evonik.com

**Contact Partner Specialized Press  
Hannah Rausche**

Communications  
Health Care  
Phone +49 6151 18-3567  
hannah.rausche@evonik.com

**Evonik Nutrition & Care GmbH**

Rellinghauser Straße 1-11  
45128 Essen  
Phone +49 201 177-01  
Fax +499 201 177-3475  
Germany

[www.evonik.com](http://www.evonik.com)

**Supervisory Board**

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years. “EUDRATEC™ ADD has created a lot of interest at pharma companies since it was first introduced in tradeshow late last year.” Adds Herbeaux.

EUDRATEC® ADD will be available in all formulation centers of Evonik around the world. It is the first technology of the new EUDRATEC™ technology platform. The platform will be further expanded to address unmet customer formulation needs in the oral drug space.

#### **Company information**

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals, operating in the Nutrition & Care, Resource Efficiency and Performance Materials segments. The company benefits from its innovative prowess and integrated technology platforms. In 2015 more than 33,500 employees generated sales of around €13.5 billion and an operating profit (adjusted EBITDA) of about €2.47 billion.

#### **About Nutrition & Care**

The Nutrition & Care segment is led by Evonik Nutrition & Care GmbH and contributes to fulfilling basic human needs. That includes applications for everyday consumer goods as well as animal nutrition and health care. This segment employed about 7,000 employees, and generated sales of around €4.9 billion in 2015.

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