

Evonik receives EXCiPACT™ certification for EUDRAGIT®

July 10, 2014

Evonik has received EXCiPACT™ certification for its EUDRAGIT® products produced in Darmstadt. The EXCiPACT™ certificate confirms that EUDRAGIT® is produced and sold in conformity with the EXCiPACT™ guidelines for good manufacturing practice (GMP).

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Thanks to the EXCiPACT™ certification, Evonik's customers can rest assured that the EUDRAGIT® products are of the highest quality. "This certification shows that we are investing in product safety and cost-efficiency for our customers," notes Dr. Jean-Luc Herbeaux, head of the Health Care Business Line at Evonik. Evonik will ensure the consistent safety and quality of EUDRAGIT® products by undergoing recertification every three years and monitoring audits annually.

On an increasing basis, both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are requiring that pharmaceutical manufacturers provide proof that the excipients used in their products are of GMP-compliant quality. This requires an increasing number of audits of excipient suppliers, which involves correspondingly high investments in cost and time. In these cases, EUDRAGIT® customers can use the audit report that is part of the EXCiPACT™ certification.

The EXCiPACT™ standard was developed with input from industry experts from all of the leading international pharmaceutical excipients manufacturers and from pharmaceutical companies. It complements the ISO 9001 norm and contains specific requirements for the manufacture of excipients.

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Company information

Evonik, the creative industrial group from Germany, is one of the world leaders in specialty chemicals. Profitable growth and a sustained increase in the value of the company form the heart of Evonik's corporate strategy. Its activities focus on the key megatrends health, nutrition, resource efficiency and globalization. Evonik benefits specifically from its innovative prowess and integrated technology platforms.

Registered office Essen
Registered court
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Evonik is active in over 100 countries around the world. In fiscal 2013 more than 33,500 employees generated sales of around €12.7 billion and an operating profit (adjusted EBITDA) of about €2.0 billion.

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