



international excipients
certification



NEWS RELEASE

CAPSUGEL® SITE RECEIVES EXCiPACT™ CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 23rd September, 2014:

EXCiPACT asbl is delighted to announce that **Capsugel Belgium bvba** has recently received an EXCiPACT™ Certificate from SGS France, one of EXCiPACT's internationally-recognised Certification Bodies.

The Certificate demonstrates that the **Capsugel** site at Bornem, Belgium manufactures pharmaceutical excipients according to the EXCiPACT™ Good Manufacturing Practice (GMP) Certification Standard.

The Bornem site is the first Belgium site to receive Certification and it is the 12th site to be Certified globally to date. The others sites are in Canada, France, Germany, The Netherlands, Spain and Saudi Arabia - see <http://www.excipact.org/certification/certificates/>

Both SGS and their auditors had to undergo a rigorous assessment process in order to be EXCiPACT™ Registered. This required the successful completion of the formal EXCiPACT™ Training Programme and Examination and an independently witnessed audit to verify that their competency was at the required standard.

EU and U.S. pharmaceutical excipient regulations now require drug manufacturers to do either their own or 3rd party physical audits of all their starting material suppliers to demonstrate GMP and/or GDP compliance. The audit burden is huge. Using GMP and GDP standards designed for excipients, the new, high quality 3rd Party EXCiPACT™ Certification Scheme is already helping excipient users and suppliers to reduce their audit burden, save costs and ensure quality.

Notes for the Editor

EXCiPACT asbl provides management oversight for a high quality, voluntary international scheme that provides for independent 3rd party certification of manufacturers, suppliers and distributors of pharmaceutical excipients worldwide. The Scheme will ensure patient safety through supplier quality while minimising the overall costs for assessing the excipient supply chain. It was launched in January 2012 since when there has been considerable interest among pharmaceutical excipient suppliers, customers and regulators. For further information see www.excipact.org or contact info@excipact.org.

minimize risks, maximize benefits

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