



international excipients  
certification



## NEWS RELEASE

### ASHLAND U.S. SITE RECEIVES EXCiPACT™ GMP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

**Brussels, 12<sup>th</sup> January, 2016:**

EXCiPACT asbl is delighted to announce that **Ashland Specialty Ingredients ISP Chemicals LLC** has recently been awarded an EXCiPACT™ Certificate from SGS ICS France, one of EXCiPACT's internationally-recognised Certification Bodies.

The Certificate demonstrates that the **Ashland Specialty Ingredients ISP Chemicals site in Calvert City, Kentucky** manufactures pharmaceutical excipients according to the EXCiPACT™ Good Manufacturing Practice (GMP) Certification Standard. **This is the first site in the U.S. to receive EXCiPACT Certification.** Its scope covers the manufacturing, testing and packaging of PVP and PVPP used as pharmaceutical excipients. For full details of all 26 sites certified to date in Canada, China, Belgium, France, Germany, The Netherlands, Saudi Arabia, Spain, UK and USA, see <http://www.excipact.org/certification/certificates/>

Both SGS ICS France and their auditors had to undergo a rigorous assessment process in order to be EXCiPACT™ Registered. This required the successful completion of the EXCiPACT™ Training Programme and post-course examination followed by an independently witnessed audit to verify that their competency was to the required standard. SGS also had to have their auditor's report verified by an independent certification board prior to issuing the certificate.

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

#### Notes for the Editor

EXCiPACT asbl provides management oversight for a high quality, voluntary international scheme that provides for independent 3<sup>rd</sup> 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](http://www.excipact.org) or contact [info@excipact.org](mailto:info@excipact.org).

minimize risks, maximize benefits

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