PRESS RELEASE

FOUR DOW USA SITES RECEIVE EXCiPACT GMP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 11 December 2018

EXCiPACT asbl is pleased to announce that **four Dow USA sites** have each been awarded an EXCiPACT Certificate from SGS, one of EXCIPACT's internationally-recognised Certification Bodies. The Certificates demonstrate that the

- **Dow Midland Ethocel Operations site in Midland, Michigan, USA**, manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers manufacturing of ethylcellulose (EC).
- **Dow Midland Methocel Operations site in Midland, Michigan, USA**, manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers manufacturing, testing and release of methylcellulose (MC) and hydroxypropyl methylcellulose (HPMC) for use as pharmaceutical excipients.
- **Dow Polyox site in Institute, West Virginia, USA**, manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers manufacturing of water-soluble polyethylene oxide polymers.
- **Dow LA Methocel operations site in Plaquemine, Louisiana, USA**, manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers manufacturing of water-soluble methylcellulose and hydroxypropyl methylcellulose polymers for use as pharmaceutical excipient.

For full details of all sites that have been EXCiPACT certified to date in **16 Countries** (Canada, China, Belgium, France, Germany, India, Israel, Italy, Japan, Saudi Arabia, Singapore, Spain, Switzerland, The Netherlands, UK and USA), see http://www.excipact.org/certificate-holders.html.

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 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 require drug manufacturers to conduct either their own or commission third-party physical audits of all their starting material suppliers to demonstrate GMP and/or GDP compliance thus increasing the audit burden. However, using GMP and GDP standards designed specifically for pharmaceutical excipients, the independent, high quality EXCiPACT Certification Scheme helps pharmaceutical excipient users and their suppliers to demonstrate their commitment to GMP/GDP, to reduce their audit burden, to save costs and to assure quality.

Notes for the Editor

EXCiPACT asbl provides management oversight for a high quality, voluntary international EXCiPACT Certification Scheme that provides for independent 3rd party GMP and/or GDP 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 has been operational since early 2013 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.