PRESS RELEASE

MCEPHARMA SITE IN FULNEK, CZECH REPUBLIC RECEIVES EXCiPACT GMP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIER

Brussels, 17 December 2021

EXCiPACT is pleased to announce that the **mcePharma s.r.o. site in Fulnek, Czech Republic** has recently been awarded an EXCiPACT GMP Certificate from **AJA**, one of EXCIPACT's internationally recognised Certification Bodies.

The Certificate demonstrates that this site **manufactures pharmaceutical excipients by blending, mixing, and packaging of mono-excipients in powder (non-sterile excipients)** according to the 2017 EXCiPACT Good Manufacturing Practice (GMP) Certification Standard.

Both **AJA** and their auditors had to undergo a rigorous assessment process to be EXCiPACT Registered. Both have satisfied the additional EXCiPACT competency requirements set out in the EXCiPACT annex to the ISO/IEC 17021-1:2015 standard. These include completion of the EXCiPACT Auditor Training Course, post-course written examination and independently witnessed audit to verify their competency to the required standard. **AJA** also had to have their auditor's report verified by their independent certification board prior to issuing the certificate.

For full details of all sites that have been EXCiPACT certified to date in 22 Countries (Austria, Belgium, Canada, China, Czech Republic, Finland, France, Germany, India, Indonesia, Israel, Italy, Japan, Mexico, Romania, Saudi Arabia, Singapore, Spain, Switzerland, The Netherlands, UK and USA), see http://www.excipact.org/certificate-holders.html.

EU and U.S. pharmaceutical regulations require drug manufacturers to conduct either their own or third-party physical risk assessment 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 voluntary, 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 product quality.

Notes for the Editor

EXCiPACT provides management oversight for the voluntary, independent, high quality 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 ensures 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 is now considerable interest among pharmaceutical excipient suppliers, customers, and regulators. For further information see www.excipact.org or contact info@excipact.org