PRESS RELEASE

NITIKA PHARMACEUTICAL SPECIALITIES SITE IN NAGPUR, INDIA RECEIVES EXCiPACT GMP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

Brussels, 30 April 2019

EXCiPACT asbl is pleased to announce that the **Nitika Pharmaceutical Specialities Pvt. Ltd. site in Nagpur, India** has recently been awarded an EXCiPACT GMP Certificate from **SGS**, one of EXCIPACT's internationally-recognised Certification Bodies. The Certificate demonstrates that this site manufactures pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers manufacture of mineral salts, stearates, cellulose and oxide-based compounds, fumarates, carbonates, phosphates, hydroxides, starch, talc, glycols, simethicone citrates, sulphates and croscarmellose sodium used in pharmaceutical products.

Both **SGS** and their auditors had to undergo a rigorous assessment process in order 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. In addition, their auditors have successfully completed the 2-day EXCiPACT Auditor Training Course and post-course written examination followed by an independently witnessed audit to verify that their competency is to the required standard. **SGS** also had to have their auditor's report verified by an independent certification board prior to issuing the certificate.

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.

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 the 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 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 has been considerable interest among pharmaceutical excipient suppliers, customers and regulators. For further information see www.excipact.org or contact info@excipact.org