

## **NEWS RELEASE**

## BCN TRASVASES, S.L. SPANISH SITE RECEIVES EXCIPACT GMP CERTIFICATION AS PHARMACEUTICAL EXCIPIENT SUPPLIERS

## Brussels, 26 July 2016

EXCIPACT asbl is delighted to announce that **BCN Trasvases S.L. Spanish site** has recently been awarded an EXCIPACT Certificate from AENOR, one of EXCIPACT's internationally-recognised Certification Bodies.

The Certificate demonstrates that **BCN Trasvases S.L. site in Santa Perpetua de Mogoda** (**Barcelona**), **Spain**, **manufactures** pharmaceutical excipients according to the EXCiPACT Good Manufacturing Practice (GMP) Certification Standard. Its scope covers the packaging of calcium carbonate to be used as pharmaceutical excipient. For full details of all sites certified to date in Canada, China, Belgium, France, Germany, The Netherlands, India, Israel, Saudi Arabia, Singapore, Spain, Switzerland, UK and USA, see <a href="http://www.excipact.org/certification/certificates/">http://www.excipact.org/certification/certificates/</a>

Both AENOR 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. AENOR 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 independent, 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 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 <a href="https://www.excipact.org">www.excipact.org</a> or contact <a href="mainto:info@excipact.org">info@excipact.org</a>. **EXCIPACT is a registered trademark.** 

minimize risks, maximize benefits

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