PRESS RELEASE

KaiXin Certification (KCB) now registered as an EXCiPACT Certification Body

Brussels, 03 March 2023

As part of its programme to extend access to the EXCiPACT GMP Certification scheme, EXCiPACT is pleased to announce that **KaiXin Certification (KCB)** has recently been registered to conduct audits and issue EXCiPACT GMP, GDP and/or GWP Certificates for pharmaceutical excipient suppliers on behalf of EXCiPACT.

KaiXin Certification was founded in 1998, and it is a service partner for over 15,000 customers in multi-industry sectors including quality, sustainability, food safety, agri-products, and consumer products. KCB through its mission in the highly dynamic environment of China, aims to support continuous improvement in quality, traceability, and reliability by providing a comprehensive range of system certification and product certification services.

Both **KCB** 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 examinations and independently witnessed audits to verify their competency to the required standard. Also, **KCB must** have their auditors' reports verified by their independent certification board prior to issuing the certificates.

For full details of EXCiPACT Registered Certification Bodies and their geographical coverage for EXCiPACT see: https://www.excipact.org/certification-bodies.html

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EU and US 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, EXCiPACT's voluntary, independent, high quality Certification Scheme helps pharmaceutical excipient users and their suppliers to

demonstrate their commitment to GMP/GDP, reducing their audit burden and costs, to assure product quality.