

C² PHARMA Receives Approval for Digoxin China DMF, Becoming China's Only European Supplier of This API

Ireland, 14 June 2023 – [C² PHARMA](#), the global leader in manufacturing and supplying ophthalmic and niche active pharmaceutical ingredients (APIs), proudly announces the approval of a C-DMF for Digoxin, an API manufactured by our Polish manufacturing partner Nobilus Ent. This milestone comes after a challenging three-year journey, due to global disruptions caused by the Covid pandemic.

The approval covers both Digoxin and Digoxin micronized. It supports different dosage forms i.e., oral and injectable drug product formulations. Digoxin is derived from the leaves of the Digitalis lanata plant and as a cardiac glycoside, it is commonly used in clinical practice for the treatment of mild to moderate heart failure.

“As a result of this approval, we can now commercialize Digoxin in China. The Chinese customers that have received samples or quantities for exhibit batches of Digoxin can now apply using the API for their finished dosage form,” said Katrien Oosterom, Vice President of Regulatory Affairs. “For China, this implies that another international source of Digoxin will now enter the market and C² PHARMA now holds the registration of the only European manufactured Digoxin, an achievement that not only expands our global reach, but also marks a stride towards providing access to high-quality medication for local patients.”

This filing approval process required rigorous stages of reviews and constant communication with the local Chinese authorities and demonstrates we are fully compliant with Chinese quality standards. The support of manufacturing partner and our local Chinese agent were critical to our success. “Made in EU- sold in China is now a reality!”, says Regulatory Manager Anastasia Motorina. Our official approval was obtained on May 26th, 2023, and is now published on the CDE website.

The news arrives at an opportune moment on the eve of CPHI Shanghai from the 19th to the 21st of June 2023. Mitch Denny, our Senior Vice President of Business Development, Asia Pacific, will be representing C² PHARMA at this year's event.

About C² PHARMA

C² PHARMA is a pharmaceutical group established in 2014. It manufactures and distributes active pharmaceutical ingredients (APIs) and complex chemical compounds obtained from synthetic and natural origins. We reach more than 200 pharmaceutical companies across the world. Customized GDP cold-chain logistics solutions are offered through our specialized affiliate, [Logistics4Pharma](#). R&D-scale contract synthesis services, analytical services, phytochemical profiling, and impurities manufacturing are provided via our affiliate, [ASM Research Chemicals](#).

For more information visit: c2pharma.com

