

EDQM Grants C² PHARMA CEP Approval for Commercial Sale of Cyclopentolate Hydrochloride

Ireland, 27th June 2023 - [C² PHARMA](#), the global leader in manufacturing and supplying ophthalmic active pharmaceutical ingredients (APIs), is pleased to confirm approval for a Certificate of Suitability (CEP) for Cyclopentolate Hydrochloride by the Quality of Medicines & Health Care (EDQM). This is the second ever CEP granted by the European Directorate for Cyclopentolate Hydrochloride, allowing C² PHARMA to make the API commercially accessible to customers throughout Europe, Southeast Asia, Oceania and beyond.

“[Cyclopentolate Hydrochloride](#) is used to dilate (enlarge) the pupil of the eye and to temporarily paralyze the lens for eye diagnostics. Classed as an antimuscarinic agent, the API is immediately available for commercial supply globally from our warehouse location in Frankfurt, Germany” said Dr. James Lawler, General Manager. “With this approval, C² PHARMA is ready to provide the reliable and high-quality API our ophthalmic customers have come to expect from us”

The synthesis of the API was developed by a C² PHARMA affiliate, [ASM Research Chemicals](#), in Hannover, Germany. The manufacturing process was documented by ASM in a [development pack \(dev-pack\)](#) and transferred to Indian manufacturing partners, [Laurus Labs Limited](#), to leverage their state-of-the-art GMP manufacturing facilities and their operational excellence.

“A thorough review by the European Agency has confirmed compliance with the strictest quality standards and this CEP complements our US-DMF for Cyclopentolate Hydrochloride and guarantees a global availability of the API,” stated Katrien Oosterom, Vice President of Regulatory Affairs. “Working throughout the challenging times of COVID, our team was fortunate to receive an expedited approval process. From the early development work at ASM to receiving the CEP approval took only 3.5 years. Our CEP approval was obtained on the 5th of June 2023 and is now published on the EDQM website. The API has also been listed as a reference for drug product applications in the United States since the 21st of January 2002.”

Meet the C² PHARMA team in Bangkok at [CPHI Southeast Asia](#) from the 12th to the 14th of July 2023. To learn more or book an in-person meeting, email us at info@c2pharma.

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