Provepharm's Proveblue® Methylene Blue drug substance achieves full compliance with the latest US and European pharmacopoeial standards

USP & Ph. Eur. Methylene Blue standards for medicinal applications are updated

Marseille, France, November 21, 2016 – Provepharm, a company specializing in the development of pharmaceutical products, today announces that its Proveblue® Methylene Blue active pharmaceutical ingredient (API) is fully compliant with most recent pharmacopoeial standards on Methylene Blue. Pharmaceutical standards assure the identification, quality and purity of medicines.

On November 1, 2016, the United States Pharmacopeial Convention (USP) published a revision of the monograph for Methylene Blue as API, as part of the USP 40 edition. This revised USP Methylene Blue API monograph will be enforceable in the US on May 1, 2017. www.usp.org

Based on Provepharm being granted a New Drug Approval by the FDA on April 8, 2016 for ProvayBlue™ (methylene blue) Injection, the USP issued a pending monograph for Methylene Blue Injection drug products, which became an enforceable status on November 1, 2016.

On January 1, 2016, the European Directorate for the Quality of Medicines (EDQM) also enforced a revised monograph on Methylene Blue API under No. 01/2016:1132 of the European Pharmacopoeia 8.6. (Ph. Eur.). www.edqm.eu

These latest USP and Ph. Eur. standards incorporate modern analytical methods and acceptance criteria in line with the most recent Guidelines on Impurities in New Drugs Substances and New Drug Products from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Provepharm's in-depth knowledge of Methylene Blue contributed to the technical revisions of the monographs related to that substance.

"We are proud to have played an instrumental role at both the USP and the EDQM in setting up the Methylene Blue API standards at the highest level," said Michel Féraud, CEO of Provepharm. "Like us and our in-house projects, our partners in the pharmaceutical industry will benefit from the new restrictive standards and from the fully compliant Proveblue® Methylene Blue drug substance produced in cGMP conditions."

About Provepharm

Provepharm is a company specializing in the development and commercialization of innovative healthcare products from designed and patented active pharmaceutical ingredients (APIs). Anticipating the pharmaceutical industry's needs, Provepharm adopted a strategy of repositioning and rehabilitating known

compounds in new indications. This strategy was designed to cater to the growing demand for APIs that must comply with current quality demands. Provepharm is present in 20 countries across the world.
www.provepharm.com

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