

Post Authorisation Assessments

Coldostin, 4800000 IU/g, Powder for Use in Drinking Water/Milk Vm 28365/4010

•	15 September 2023	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	15 June 2023	Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile.
•	28 April 2023	Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile.
•	28 April 2023	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier.
•	09 December 2021	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	10 September 2021	Renewal – UK as CMS.
•	07 July 2020	Addition of a new container for the finished product. Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	26 October 2018	Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Introduction of a re-test period of the active substance.
•	20 December 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.