



Post Authorisation Assessments

Coldostin, 480000 IU/g, Powder for Use in Drinking Water/Milk Vm 28365/4010

11 February 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
18 May 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (NI)
15 September 2023	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB)
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.