## Summary of changes

Hybrid **CEP 2.0** Old CEP Paper document with wet Electronic document with electronic signature **Format** signature 2-block code 3-block code Numbering R0-CEP 20XX-XXX-Rev 00 CEP 20XX-XXX-Rev 00 Information on Name and address of Name and address of the holder and production sites completed by SPOR OMS LOC &ORG ID companies holder and production sites Inclusion of the approved specification and Limits for additional impurities and inclusion of tests used in Technical information (Chemical and herbal description of additional addition to the Ph. Eur. monograph tests, required to control CEP) methods required to control the substance the substance No reference to a validity date of 5 years (renewal due date, Yes reference to expiry Expiry date available on public database) date (before renewal) Box/Letter of access Letter of access (template on EDQM website) Box of access on CEP Issue date Until 31 August 2023 After 1 September 2023

