



Post Authorisation Assessments

Clavaseptin 750 mg Palatable Tablets for Dogs Vm 08007/5010

17 March 2025	Change in the specification parameters or limits of an excipient - addition of a new specification parameter to the specification with its corresponding test method. Change in the specification parameters or limits of an excipient- tightening of specification limits. Deletion of a non-significant specification parameter in the specification parameters or limits of an excipient. Minor changes to an approved test procedure for an excipient.
04 December 2024	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.
23 November 2024	Submission of a new CEP for a new active substance manufacturer.
23 November 2024	Introduction of a retest period of the active substance where none is specified in the Ph. Eur. Certificate of Suitability.
14 December 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
25 July 2023	Changes to the labelling of the finished product.
30 June 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Change in the holding time of an intermediate or bulk product (if applicable).
24 March 2023	Minor changes to an approved test procedure the finished product.