



## Post Authorisation Assessments

### Zoletil 100 (50 mg/ml+50 mg/ml) Lyophilisate and Solvent for Solution for Injection for Dogs and Cats Vm 05653/4194

•	14 September 2023	Change in the specification parameters or limits of the finished product. Change in the specification parameters or limits of the finished product. Change in the specification parameters or limits of the immediate packaging of the finished product. Change to importer, batch control arrangements and quality testing. Changes to the quality part of the dossier. Minor changes to an approved test procedure for the finished product. (NI)
•	2 June 2023	Change in the specification parameters or limits of the finished product:– addition of a new specification parameter to the specification with its corresponding test method. Change in the specification parameters or limits of the finished product:– update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product. Deletion of - a non-significant specification parameter for the finished product.
•	2 June 2023	Change in the specification parameters or limits of the finished product:– addition of a new specification parameter to the specification with its corresponding test method.
•	2 June 2023	Change in the specification parameters of the finished product - addition of a new specification parameter to the specification with its corresponding test method.
•	19 April 2023	Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method.
•	19 April 2023	Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method.
•	19 April 2023	Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method.
•	19 April 2023	Minor changes: – to an approved test procedure for

		active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device.
•	19 April 2023	Change in the specification parameters or limits of the finished product: – update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product.
•	19 April 2023	Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product.
•	19 April 2023	Change in the specification parameters or limits of the finished product: – update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product.
•	19 April 2023	Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method.
•	19 April 2023	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g., deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product.
•	19 April 2023	Change in the specification parameters or limits of the immediate packaging of the finished product: – addition of a new specification parameter to the specification with its corresponding test method.
•	19 April 2023	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter (e.g., deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product.
•	19 April 2023	Changes in the manufacturing process of the solvent. Change in shape or dimensions of the container or closure (immediate packaging): - Sterile medicinal products. Change in supplier of packaging components or devices (when mentioned in the dossier): - Other changes. Change in test procedure for the finished product. Change in the batch size (including batch size ranges) of the finished product: - Other changes. Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - After dilution or reconstitution (supported by real time data) Change in the specification parameters and/or limits of the finished product: - Other changes. Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range. Changes in the composition (excipients) of the finished product: - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a

		significant impact on the safety, quality, or efficacy of the veterinary medicinal product.
•	09 March 2023	Minor changes to an approved test procedure for the finished product.
•	23 December 2020	Renewal - UK as CMS
•	23 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 January 2018	Replacement of a supplier of packaging components or devices. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	24 May 2016	Addition of a manufacturing site. Addition of a new shape of container. Addition of a new batch size. Replacement of a manufacturing site.