



Post Authorisation Assessments

Florolab 100 mg/ml Solution for Use in Drinking Water for Pigs Vm 32112/4002

05 February 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
21 December 2022	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
21 December 2022	Change in the pharmacovigilance system master file (PSMF) location.
15 November 2022	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier: - Introduction of a manufacturer of the active substance supported by an ASMF.
06 July 2022	Update of the ASMF for active substance manufacturer.
21 June 2022	Changing from a batch size to a batch range more than 10-fold increase compared to originally approved batch size for the finished product.
17 December 2021	Change in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning a Periodic Safety Update Report.
14 October 2021	Change in the specification limits of the finished product.
07 April 2020	Introduction of a new pharmacovigilance system.
23 December 2019	Mock-ups approved.
03 October 2019	Change of MAH from Vetpharma Animal Health, S.L to Labiana Life Sciences S.A.