Veterinary Medicines Directorate

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Post Authorisation Assessments

Florocol Premix for Medicated Feeding Stuff 500mg/g for Atlantic Salmon

Vm 01708/4591

•	13 April 2024	Deletion of manufacturing site responsible for batch control of the finished product. Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	13 April 2024	Change in the test procedure for the finished product. Change in the specification parameters of the immediate packaging of the finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
•	06 July 2023	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) 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.
•	08 July 2021	Editorial changes to the SPC and QRD text.
•	12 February 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	21 April 2020	Addition of a site where batch control/testing takes place.
•	17 May 2019	Addition of a manufacturer responsible for batch release. Deletion of manufacturing site for the finished product.
•	29 June 2016	Change in the manufacturer of a starting material used in the manufacturing process.
•	08 July 2015	Change in batch size of the active substance. Change to the address of the ASMF holder. Tightening of specification limits. Change in test procedure. Change to the re-test period of the active substance. Changes to the manufacturing process of the active substance.
•	30 March 2015	Deletion of a manufacturing site.
•	29 April 2014	Change of manufacturing authorisation holder.
•	25 February 2014	Change to the name of the manufacturer of the finished product.
•	23 April 2013	Changes to the manufacturing process of the active substance
•	29 May 2012	Change of MAH Addition of a distributor Removal of a manufacturer of the active substance

		Removal of an assembler of the dosage form
•	18 April 2012	Change to manufacturing process of the finished product
•	09 November 2011	Change of specification of the finished product
•	19 January 2011	Addition of a manufacturer of the active substance
•	02 September 2009	Change of legal category from MFS to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	17 April 2007	Renewal
•	25 October 2005	Change in batch size Change of manufacturer responsible for batch release
•	30 July 2004	Addition of a manufacturing site for assembly of the dosage form
•	31 October 2003	Change of manufacturer of the active substance
•	12 April 2002	Change of shelf life from 24 months to 36 months
•	14 February 2000	Change in wording of indications