



Post Authorisation Assessments

Florocol Premix for Medicated Feeding Stuff 500mg/g for Atlantic Salmon Vm 01708/4591

•	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