



Post Authorisation Assessments

Syncaïne 1000 mg/g Powder for Solution for Fish Treatment

Vm 41203/4000

•	May 2024	Downscaling of batch size for the active substance. Downscaling of batch size for the finished product.
•	10 May 2024	Tightening of specification limits of an active substance. Tightening of specification limits of a starting material. Tightening of specification limits of the finished product.
•	12 March 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	04 October 2023	Minor changes to the manufacturing process of the active substance.
•	25 August 2023	Change of Distributor, from Elara Pharmservices Limited, Iron Farm, 7 Grimesgate, Diseworth, Derby, DE74 2QD to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ United Kingdom.
•	13 June 2023	Replacement of a quality control testing site.
•	16 March 2023	Change in the specification limits of an active substance.
•	18 January 2023	Change in the specification parameters and/or limits of an active substance, starting material/intermediate/reagent used in the manufacturing process of the active substance.
•	20 December 2022	Change in the manufacturing process of the active substance - Other changes.
•	10 November 2022	Change in legal entity from Callisto Regulatory Consulting Ltd, Iron Farm, 7 Grimes Gate, Diseworth, Derby, DE74 2QD, United Kingdom to Elara Pharmservices Limited, Iron Farm, 7 Grimes Gate, Diseworth, Derby, DE74 2QD, United Kingdom.
•	18 October 2022	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.