



Post Authorisation Assessments

Slice 2 mg/g Premix for Medicated Feeding Stuff

Vm 01708/5090

•	18 October 2023	Change in shape or dimensions of the container or closure of a non-sterile finished product.
•	04 October 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Change in the holding time of an intermediate or bulk product.
•	07 June 2023	Change in batch size of the finished product.
•	18 April 2023	Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes.
•	09 March 2023	Change in batch size of the finished product.
•	28 February 2023	Increase of the batch size of the finished product.
•	02 November 2021	Addition of a manufacturing site of the finished product. Change in shape or dimensions of the container or closure (immediate packaging). Decrease in batch size range of the finished product. Minor change in the manufacturing process of the finished product. Tightening of in-process limits applied during the manufacture of the finished product. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	02 March 2021	Minor change in the manufacturing process of the active substance.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	10 October 2018	Change in RMS from UK to IE.
•	27 September 2018	Repeat use application to add one new member state.
•	13 September 2016	To add a wet particle size determination test method to the active substance specification. To add Catalent-Micron Technologies, USA as an alternative site for particle size determination analysis.
•	02 July 2016	Change to an approved stability protocol. Addition of a new specification parameter. Change in a test procedure. Deletion of a non-significant specification parameter.
•	28 March 2014	Change to the name of the manufacturing site of the finished product.
•	06 October 2011	Grouped variation concerning the addition of an active

		substance manufacturer, including a change to the manufacturing process, the in-process controls, the active substance specifications, the test methods for the starting material, the specification limits, and the test procedures for the active substance.
•	04 August 2011	Grouped variation to change the site of manufacture, packaging, testing, and release, with consequential changes to the manufacturing process, batch size, and packaging dimensions.
•	27 July 2011	Variation to replace the batch testing and release sites of the finished product.
•	24 May 2011	Renewal (UK as RMS)
•	24 March 2011	Variation to change the name of the Marketing Authorisation Holder.
•	23 October 2009	Variation to change the finished product specification.
•	19 February 2009	Variation to replace a manufacturer.
•	30 December 2008	Variation to delete a manufacturer.
•	30 December 2008	Addition of a quality control and testing site for the finished product.
•	24 April 2007	Renewal.
•	13 March 2007	Variation to update a finished product test procedure.
•	07 December 2006	Variation to change the address of the Marketing Authorisation Holder.
•	19 May 2004	MRP Repeat Use – UK as RMS.
•	09 January 2003	Change to the therapeutic indications and overdose warning.
•	18 December 2002	Variation to increase the batch size.
•	18 December 2002	Variation to increase shelf life.
•	22 September 2000	MRP (UK as RMS).