Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Poulvac IBMM + ARK Lyophilisate for Suspension for Spray Administration for Chickens

Vm 42058/3033

•	09 March 2022	Change in the composition (excipients) of the finished product.
•	24 October 2019	Change in the address of the marketing authorisation holder from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	05 September 2019	Harmonisation of the product information with the QRD template.
•	06 November 2018	Change of a test procedure for the finished product.
•	23 October 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	20 April 2018	Change in the RMS from UK to NL.
•	23 March 2018	Renewal – UK as RMS.
•	20 September 2017	Change of a test procedure for the finished product.
•	21 November 2016	Change in test procedure for the finished product.
•	12 February 2016	Change in the name of a manufacturer of the active substance. Change in the name of a manufacturer of the finished product.
•	7 January 2016	Change in test procedure for the finished product.
•	05 May 2015	Change to QPPV contact details.
•	22 November 2013	Variation to a test procedure following method recommended by the EP Monograph 5.2.2. or Multiplexed Fluorescent ImmunoAssay (MFIA).
•	25 October 2013	Variation to transfer Marketing Authorisation Holder and change the distributor.
•	11 October 2013	Grouped variation to change the name of the name of the active substance manufacturer, change the name of the manufacturer responsible for batch release, change the name of the finished product manufacturer, and to change the QPPV details.
•	11 October 2013	Variation to change the name and address of the Marketing Authorisation Holder in AT, BE, and LU only.
•	05 September 2013	Deletion of a manufacturer.
•	04 July 2013	MRP (UK as RMS).
•	16 July 2012	To replace test methods recommended in the Ph. Eur. monograph.
•	13 June 2012	Introduction of a new pharmacovigilance system.

•	23 January 2012	Change in the specification for a component of the product.
•	15 September 2011	Replacement/addition of a manufacturing site for finished product.
•	07 July 2011	Change in name/address of manufacturers of the finished product and change in name/address of manufacturer or supplier of active substance.
•	13 June 2011	Change in manufacturer.
•	14 April 2010	Variation to change the Marketing Authorisation Holder.
•	03 March 2010	Variation to update the extraneous agents testing in line with the European Pharmacopoeia.
•	10 December 2009	Renewal procedure – UK as RMS.
•	17 December 2008	Change in finished product testing site.
•	09 October 2003	Mutual recognition procedure.
•	16 December 2002	Submission of a study report.
•	14 June 2002	Minor change to Marketing Authorisation Holder address.
•	22 May 2002	Variation to make an amendment to test method for finished product, and the submission of four study reports.
•	22 May 2002	Changes to the QC Procedures.
•	22 May 2002	Changes to the composition of the finished product.
•	23 April 2002	Addition of manufacturer of dosage form.
•	16 February 2001	Manufacture of dosage form.