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

Post Authorisation Assessments

Poulvac Bursine 2 Lyophilisate for Suspension for Spray Vaccination or for use in Drinking Water for Chickens

Vm 42058/4099

July 2023 Addition of test procedure for the finished product. (NI) Addition of test procedure for the finished product. (GB) 28 July 2022 To replace the current pharmatone-based stabiliser with the SPA stabiliser. 08 March 2022 Update of the quality dossier. 10 September 2020 Renewal – UK as CMS. 12 November 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. O6 November 2018 Change of a test procedure for the finished product. September 2018 Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the RMS from UK to HU. 20 September 2017 Change of a test procedure for the finished product. 25 August 2017 Introduction of updated mock ups. Addition of an alternative test method. One February 2016 Change in the name of a manufacturer of the active substance. Change in the name of a manufacturer of the finished product. Change in the name of a manufacturer of the active substance. Change in test procedure for active substance. Change in test procedure for active substance. Variation to replace test methods recommended in the Ph. Eur. Monograph 5.2.2. Variation to replace test methods recommended in the Ph. Eur. Monograph 5.2.2. Variation of an alternative site for batch release. O2 September 2011 Addition of an alternative site for batch release. O2 September 2011 Addition of an alternative site for CC testing, importer of final dosage form (from outside EU), site			
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	•	02 September 2011	Addition of a site of labelling.
	•	02 September 2011	

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		for QC retesting if imported from outside the EU.
•	13 June 2011	Addition of a supplier of a starting material.
•	18 January 2011	Grouped variation to change the name of the
		manufacturer of the active substance, site for
		blending, filliang and assembly, site for QC testing,
		stie for labelling, site for batch release, importer of
		the final dosage form outside EU, and the site of QC
		testing from outside the EU.
•	23 November 2010	Variation to change the name of the active
		substance manufacturer.
•	16 June 2010	Variation to change the Marketing Authorisation
		Holder and Distributor.
•	15 October 2008	Renewal.
•	27 August 2008	Alignment of the SPC and Product Literature
		between IE and UK.
•	15 July 2008	Addition of a testing site and site of QP release.
•	09 June 2006	Variation to change the currently approved
		extraneous agents testing.
•	16 July 2004	Renewal.
•	14 June 2002	Variation to make minor changes to the labels,
		carton, and datasheet for the product.
•	19 April 2002	Additional pack type (finished product).
•	08 March 2002	Variation to change the dosage form assembly site.
•	17 March 2000	Renewal.
•	12 March 1998	Change of Assembler.
•	12 March 1998	Production transfer.
•	03 February 1998	Change to name of Marketing Authorisation Holder.
•	19 September 1996	Change to a QC procedure.
•	19 September 1996	Change in the name of the medicinal product.