Veterinary Medicines Directorate

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Post Authorisation Assessments

Virbamec Pour-on Solution for Cattle 5 mg/ml

Vm 05653/5061

•	17 July 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	22 August 2019	Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
•	11 December 2018	Minor change to an approved test procedure for an excipient. Change in batch size (including batch size range) of the finished product. Minor change in the manufacturing process of the finished product.
•	24 July 2018	Change in the RMS from UK to IE.
•	25 January 2017	Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging). Change in shape or dimensions of the container or closure (immediate packaging)
•	09 December 2015	Change in legal entity of the MAH, from 'Virbac de Portugal Laboratórios Lda' to 'Virbac, France'.
•	07 March 2012	Introduction of an alternative manufacturer of an excipient. Change to SPC and Part II dossier to include the chemical name in addition to the commercial name.
•	01 March 2012	Replacement of an Active Substance Master File with an EDQM certificate of suitability for an active substance.
•	25 February 2011	Change to Sections 4.4 and 4.9 of the SPC, change to shape/dimensions of the 500ml bottle, change in address of MAH, deletion of a manufacturer for the finished product.
•	11 March 2010	Addition of a site for batch release including batch control/testing.
•	07 January 2010	Addition of a site of manufacture of the finished product.
•	03 December 2009	Change in shape/dimensions of the 1 litre container.
•	27 September 2007	Renewal.
•	27 February 2007	Harmonisation of SPC with original CMS.
•	27 February 2007	Repeat Use (add BE, ES, NL).
•	11 March 2004	Repeat Use (add FR).