Veterinary Medicines Directorate

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Post Authorisation Assessments

Ivermectin Pour-on Solution for Cattle 5 mg/ml Virbac

Vm 05653/4149

•	12 June 2020	Submission of a new Ph. Eur. certificate of suitability for an excipient from a new manufacturer
•	14 January 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 July 2019	Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter).
•	18 December 2018	Minor change to an approved test procedure for an excipient. Increase in batch size (including batch size range) of the finished product. Change in manufacturing process of the finished product
•	23 December 2016	Change in shape or dimensions of the container or closure for non-sterile medicinal products. Change in shape or dimensions of the container or closure for non-sterile medicinal products. Change in shape or dimensions of the container or closure for non-sterile medicinal products. Change in shape or dimensions of the container or closure for non-sterile medicinal products.
•	02 September 2015	Submission of a new certificate of suitability.
•	30 April 2015	Change in product name from Premadex Pour-On Solution for Cattle 5 mg/ml to Ivermectin Pour-On Solution 5 mg/ml Virbac
•	11 July 2013	Change in Distributor details
•	10 July 2013	Renewal.
•	03 January 2013	To update a Ph. Eur. Certificate of suitability from an already approved manufacturer.
•	19 September 2012	To add an additional manufacturer of an excipient.
•	07 July 2010	To add an additional site for manufacturer/assembler of dosage form.
•	23 June 2010	Variation to add an additional manufacturer responsible for batch release.