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Post Authorisation Assessments

Enrotron Flavour 150 mg Tablets for Dogs Vm 24745/4011

• 08 December 2020	Change to in-process tests or limits applied during the manufacture of the finished product.
• 09 January 2020	Changes to the labelling
September 2017	Minor change in the manufacturing process of the finished product. Tightening of in-process limits applied during the manufacture of the finished product
• 02 March 2017	Replacement of a manufacturing site for secondary packaging.
• 27 April 2016	Renewal - UK as CMS
• 27 April 2016	Submission of a new Ph. Eur. certificate of suitability.
17 September 2015	Replacement or addition of a site where batch control/testing takes place. Replacement or addition of a secondary packaging site of the finished product. Replacement or addition of a primary packaging site of the finished product. Replacement or addition of a secondary packaging site of the finished product. Replacement or addition of a manufacturing site of the finished product.
• 28 November 2012	To change the QPPV.
• 24 February 2011	Changes to an existing pharmacovigilance system as described in the DDPS.