Veterinary Medicines Directorate

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Post Authorisation Assessments

Felimazole 5 mg Coated Tablets for Cats

Vm 50406/3045

June 2026	Deletion of a non-significant specification parameter for an excipient.
08 May 2026	Updated CEP for an active substance. Deletion of an obsolete test parameter from the specification of the active substance.
24 February 2026	Changes in the composition (excipients) of the finished product.
05 August 2025	Deletion of obsolete tests. Deletion of obsolete tests. Deletion of obsolete tests.
09 July 2025	Change of Marketing Authorisation Holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
05 June 2025	Deletion of obsolete tests. Deletion of obsolete tests. Deletion of obsolete tests. (GB).
22 May 2025	One-off alignment of the product information with version 9.0* of the QRD template.
15 April 2025	Change to quality testing arrangements for a finished product. (GB)
19 March 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
19 February 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB).
19 January 2025	Minor changes to an approved test procedure for the finished product (NI).
25 November 2024	Minor changes to an approved test procedure for the finished product. (GB)
01 September 2021	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant specification parameter of an

	excipient. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Replacement to a test procedure for the finished product.
15 July 2020	Change in the specification limits of the finished product.
18 February 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
17 December 2019	Deletion of manufacturing site where batch control takes place for the finished product.
18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
12 April 2019	Deletion of manufacturing site for the finished product
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
01 August 2018	Change in the RMS from UK to IE.
21 May 2018	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
09 February 2018	Repeat Use application to add 5 new member states
25 October 2017	Addition of a new container for the finished product.
08 September 2016	Minor changes to an approved test procedure. Minor changes to an approved test procedure.
13 April 2016	Updated labels and package leaflet approved.
19 November 2015	Addition of a site where batch testing takes place.
19 July 2012	Grouped variation to amend the excipients of the tablet coating, amend the excipients, and increase the batch size.
07 March 2012	Significant changes to the SPC.
09 February 2012	Variation to change a test method used in the manufacturing process.
24 February 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
15 December 2010	Change of distributor.
16 September 2010	Changes in the composition (excipients) of the finished product.
16 September 2010	Submission of a new/updated Ph. Eur Certificate of Suitability.
10 September 2010	Change in the shelf-life or storage conditions of the finished product.
25 June 2010	Renewal.
1 July 2009	Dosage instructions.
24 April 2009	Minor changes in manufacturing process of active.
30 September 2008	Change of Marketing Authorisation Holder.
19 October 2006	Correction/ simple text changes to SPC and /or product literature.
23 June 2006	Change of distributor.
26 May 2005	MRP.
04 July 2003	Change to the finished product shelf life.
17 December 2002	Change to the indications.