Veterinary Medicines Directorate

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

Post Authorisation Assessments

Stomorgyl 20 Film-coated Tablets

Vm 08327/5066

27 October 2025	Deletion of a non-significant specification parameter for an active substance. Deletion of non-significant specification parameters for finished product excipients.
10 March 2025	Change in the specification for spiramycin assay at release.
04 May 2024	Addition of very rare digestive tract adverse reactions.
13 March 2024	CEP Updated for the manufacture of an active substance.
11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
16 November 2021	Addition of a site where batch control/testing takes place.
16 November 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
28 May 2020	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
03 May 2019	Submission of an updated Ph. Eur. certificate of suitability from an already approved manufacturer
November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
09 May 2018	Change in the specification limits of the finished product.
23 August 2017	Deletion of a manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
22 October 2015	Replacement of a test procedure for the finished product. Changes in the specification parameters and limits of the finished product.
14 May 2015	Minor change in the manufacturing process of the finished product.
30 July 2014	Approval of amended mock-ups.
17 January 2012	Variation to register a new active substance manufacturer via the submission of a new European Pharmacopoeia Certificate of Suitability.
29 September 2011	Variation to tighten the specification limit for a manufacturing test.
24 August 2011	Variation to make minor changes to the manufacturing process of the finished product.
09 June 2011	Submission of an updated Certificate of Suitability.
09 June 2011	Submission of a new Certificate of Suitability.

09 June 2011	Submission of a new Certificate of Suitability.
18 November 2007	Renewal.
13 November 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
20 September 2007	Variation to update parts IIB, IIC, and IIE of the dossier.
27 August 2004	Renewal.
30 September 2003	Addition of a manufacturer.
24 July 2003	Variation to change the name of an active substance manufacturer.
07 September 1998	Renewal.
08 February 1995	Variation to change the site of assembly.