Veterinary Medicines Directorate

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Post Authorisation Assessments

Supaverm Oral Suspension

Vm 00879/4181

•	07 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	22 March 2023	Change(s) in the SPC, labelling or package leaflet to section 4.5.
•	17 November 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 July 2021	Change in the address of a manufacturer of the finished product, also responsible for batch release.
•	01 October 2020	Change of Marketing Authorisation Holder from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	19 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 December 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	07 July 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	15 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability.
•	20 June 2013	Variation to update the SPC and Product Literature in line with the Commission Decision regarding an Article 35 referral.
•	10 January 2013	Grouped variation to update Certificates of Suitability for the active substances.
•	29 May 2012	Grouped variation to change the Marketing Authorisation Holder.
•	14 March 2012	Grouped variation to change a distributor.
•	09 December 2011	Grouped variation to submit an updated Certificate of

		Suitability for an active substance.
•	30 March 2011	Variation to change the composition of the finished product, and the excipient specifications.
•	02 March 2011	Variation to change the specification parameters for the active substance.
•	23 February 2011	Variation to remove a storage condition.
•	09 February 2011	Submission of an updated Certificate of Suitability for an active substance.
•	09 February 2011	Minor change in the manufacturing process of the finished product.
•	09 February 2011	Addition of an in-process test during the manufacture process.
•	19 January 2011	Addition of a storage condition.
•	05 January 2011	Variation to make a minor change to the finished product test procedure.
•	29 December 2010	Variation to tighten the in-process control limits.
•	02 June 2010	Variation to replace a manufacturer of the active ingredient.
•	02 June 2010	Amendment to the SPC and subsequently the product literature.
•	27 May 2010	Deletion of a manufacturer/assembler of the dosage form.
•	07 October 2009	Variation to make a change to Part II of the dossier.
•	11 March 2009	Variation to change the finished product withdrawal period.
•	14 October 2008	Change in the shape and dimensions of the container.
•	04 September 2008	Increase of the withdrawal period.
•	21 August 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	07 March 2008	Variation to change the address of the Marketing Authorisation Holder.
•	21 November 2007	Renewal.
•	07 December 2006	Variation to amend the finished product specification.
•	14 November 2006	Submission of a Certificate of Suitability for the active substance.
•	27 September 2006	Variation to make minor changes to the manufacturing process.
•	21 September 2006	Change to the qualitative and quantitative composition of the immediate packaging material.
•	30 August 2006	Variation to amend the specification of the active substance.
•	30 August 2006	Variation to amend the specification of an intermediate.
•	30 August 2006	Change in the test procedure for an active substance.
•	30 August 2006	Variation to amend the specification of an active substance.
•	30 August 2006	Variation to amend the specification of an active substance.
•	30 August 2006	Deletion of an in-process control test.
•	15 August 2006	Change in the test procedure for a starting material.
•	15 August 2006	Change in a test method for a starting material.
•	17 March 2005	Change in the name of the manufacturer/assembler.

•	23 January 2004	Renewal.
•	30 December 2003	Addition of a batch size.
•	28 November 2003	Addition of a manufacturer/assembler of the finished product.
•	21 November 2003	Change to the specification of the active substance.
•	21 November 2003	Change to the test methods for the finished product.
•	21 November 2003	Change to the manufacturing process of the active substance.
•	30 July 2001	Change to the secondary assembler of the dosage form.
•	08 November 1999	Variation to update licence particulars.
•	15 April 1999	Renewal.
•	31 March 1998	Change to the manufacturer of the active substance.
•	12 November 1997	Addition of a pack type.
•	18 August 1997	Change of Monograph.
•	04 September 1996	Change of an excipient.
•	10 January 1996	Addition of a manufacturer/assembler of dosage form.
•	21 August 1995	Variation concerning the Importer.
•	03 April 1995	Change to the name and address of the licence holder.
•	03 April 1995	Change to the finished product safety warnings.