Veterinary Medicines Directorate

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Post Authorisation Assessments

Combinex Cattle Oral Suspension

Vm 00879/4083

•	20 June 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	10 March 2023	New certificate of suitability from a new manufacturer.
•	17 November 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph. Deletion of a non-significant specification parameter of the finished product.
•	03 June 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 September 2020	Change in the address of the MAH from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood, Business Park, Hook, RG27 9XA, United Kingdom.
•	12 August 2020	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Deletion of manufacturing site for an active substance.
•	15 August 2019	Introduction of a re-test period of the 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.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	13 May 2019	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
•	19 February 2019	Change in the address of a manufacturer used in the manufacture of the active substance.
•	06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	06 July 2017	Addition of a new specification parameter with its corresponding test method of the 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. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	08 November 2016	Change of MAH and Distributor, from Novartis Animal Health UK Limited to Elanco Europe Ltd.
•	04 October 2016	Change in batch size of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	06 April 2016	Change in the manufacturer of the active substance
•	05 November 2015	Change of specifications of active substance to comply with the Ph.Eur.
•	20 June 2013	Update of sections 4.7 and 4.11 of the SPC
•	26 April 2011	Change in composition of the finished product
•	24 August 2010	Deletion of a manufacturing site of an active substance Change of name of manufacturer of an active substance
•	03 November 2009	Changes to the layout of the product literature
•	25 January 2009	Change of name of manufacturer of the active substance
•	11 June 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	12 December 2007	Change of MAH address Change of distributor address
•	03 May 2006	Addition of 2 pack sizes – 12L and 21L
•	22 February 2006	Update to Part II of the Dossier
•	13 February 2006	Change of legal category from PML to POM-VPS
•	02 February 2006	Renewal
•	12 May 2005	Addition of manufacturer of the dosage form
•	20 April 2005	Deletion of a manufacturing site of the dosage form
•	21 January 2005	Increase of withdrawal period for meat to 56 days Renewal
•	29 July 2003	Update of Active Substance Master File (ASMF)
•	11 July 2003	Addition of a new manufacturer of an active substance
•	15 December 1999	Change of manufacturer of an active substance
•	22 March 1999	Change of manufacturer of the dosage form
•	17 June 1997	Renewal
•	24 April 1997	Change in size of sterile containers
•	15 March 1996	Change in dosage particulars