Veterinary Medicines Directorate

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Post Authorisation Assessments

Mebadown Super Oral Suspension

•	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.
•	13 March 2014	Submission of a new Ph. Eur. Certificate of Suitability for a new manufacturer of the active and submission of two updated Ph. Eur. Certificates of Suitability for already approved manufacturer of the active substances.
•	20 June 2013	Updates to the SPC and Product Literature
•	10 January 2013	Submission of updated Ph. Eur. Certificates of Suitability for an active substance
•	29 May 2012	Change of MAH
•	07 March 2012	Change of distributor details
•	09 December 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance Change to specification parameters for an active substance
•	30 March 2011	Change to specification of the excipient Change to specification of the finished product
•	02 March 2011	Change to specification of an active substance
•	23 February 2011	Removal of a storage condition
•	02 February 2011	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance Minor change to manufacturing process of the finished product Addition of a new in-process test performed during the manufacture of the finished product
•	19 January 2011	Change to storage conditions of an active substance to 'Do not store above 25˚C'
•	05 January 2011	Change of test procedure performed on the finished product
•	29 December 2010	Change of in-process test limits performed during the manufacture of the finished product
•	02 June 2010	Change of manufacturer of an active substance Updates to section 4.9 of the SPC
•	27 May 2010	Removal of a manufacturer and assembler of the dosage form
•	07 October 2009	Submission of an updated Ph. Eur. Certificate of Suitability for an active substance Submission of a new Ph. Eur. Certificate of Suitability for an active susbtance

		Registration of a retest period for an active substance Change to the specification of the finished product Change of test limits for test performed on intermediate products Changes to test performed on the finished product
•	18 March 2009	Change of packaging design
•	12 March 2009	Change of withdrawal period from 64 days to 65 days
•	14 October 2008	Change of design of a packaging component
•	03 September 2008	Change of withdrawal period from 42 days to 64 days
•	21 August 2008	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
•	07 March 2008	Change of address of the MAH
•	11 January 2008	Change of name of manufacturer of the finished product
•	08 December 2006	Change to specification of the finished product
•	14 November 2006	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
•	27 September 2006	Minor change to the manufacture of the finished product
•	21 September 2006	Change of composition of the immediate packaging
•	30 August 2006	Change to specification of an active substance Change to the specification of an intermediate produced during the manufacture of an active substance Changes to test procedures performed on a starting material used in the manufacture of the active substance Change to test procedure performed on a reagent used in the manufacture of an active substance Deletion of a test procedure
•	15 August 2006	Change to test procedures performed on a starting material used in the manufacture of the active substance
•	28 July 2006	Renewal
•	10 September 2004	Addition of a manufacturing site for the finished product Addition of a new batch size Change to test method performed on the finished product Change to specification of the finished product
•	21 November 2003	Changes to the manufacturing process of the active substance
•	25 July 2003	Renewal
•	29 August 2001	Change to assembly site of the dosage form
•	31 March 1998	Change to manufacturer of the active substance
•	12 November 1997	Change of size of non-sterile containers
•	18 August 1997	Change to specification of the active substance