Veterinary Medicines Directorate

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

Post Authorisation Assessments

Chloromed 150 mg/g Oral Powder for Calves

Vm 05150/4001

•	04 August 2021	Changes to a test procedure for the finished product. Increase in batch size (including batch size range*) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form.
•	19 May 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 January 2017	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	01 November 2016	Submission of an updated Ph. Eur. certificate of suitability. Submission of an updated Ph. Eur. certificate of suitability.
•	16 December 2014	Renewal procedure – Ireland as RMS.
•	26 March 2014	Submission of three updated Ph. Eur. Certificates of Suitability for already approved manufacturers of the active substance.
•	31 January 2014	Changes to the test limits for the active substance.
•	03 May 2012	Tightening of finished product specification limits
•	03 May 2012	Replacement of an excipient with a comparable excipient.
•	15 December 2011	To change the withdrawal period from 35 days to 10 days.
•	12 August 2011	Grouped variation to submit a new certificate of suitability from an additional manufacturer.
•	12 August 2011	Grouped variation to submit an updated certificate of suitability from an already approved manufacturer.
•	05 August 2011	To make a change to the DDPS.
•	17 February 2010	To change the shelf-life of the veterinary medicinal product as packaged for sale from 1 year to 2 years.