Veterinary Medicines Directorate

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Post Authorisation Assessments

Pracetam 200 mg/ml Solution for Use in Drinking Water for Pigs

Vm 15052/5049

•	18 March 2024	One-off alignment of the product information with version 9.0 of the QRD templates.
•	16 June 2023	Deletion of a Ph. Eur. CEP for an active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance. (GB)
•	16 June 2023	Deletion of a secondary packaging site. Deletion of a batch release site. (GB)
•	01 March 2023	Change in the 1 L and 5 L container closure of immediate packaging of the finished product.
•	12 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road Amersham, Buckinghamshire HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire HP10 0HH, United Kingdom.
•	11 June 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 June 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.
•	23 May 2019	Replacement of a site where batch control/testing takes place
•	19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 July 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	16 February 2017	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	02 February 2017	Change in shape or dimensions of the container or closure (immediate packaging).

		Minor change in the manufacturing process of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Addition of a manufacturer responsible for batch release of the finished product. Addition of a manufacturing site for part of the manufacturing process of the finished product. Replacement of a manufacturing site for part of the manufacturing process of the finished product. Addition of a manufacturing site for part of the manufacturing process of the finished product.
•	12 January 2017	Increase in the shelf life of the finished product from 24 months to 36 months
•	09 November 2016	Change in the name of the manufacturer of the finished product including manufacturer responsible for batch release.
•	06 October 2016	Approval of mock-ups following change of design/layout.
•	29 June 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	14 June 2016	Change of MAH, from Sogeval to Ceva Animal Health Ltd and Change of Distributor to Ceva Animal Health Ltd.
•	09 October 2015	Repeat Use.
•	05 June 2015	Renewal – UK as CMS.
•	10 April 2015	Submission of updated Ph. Eur. Certificates of Suitability.
•	20 December 2011	To add a batch size of the finished product and to add a new filtration step prior to packaging.
•	08 March 2011	Changes to submit new labels.
•	30 September 2010	To add two additional tests on the active substance.
•	10 August 2010	Submission of a new or updated Ph. Eur. certificate of suitability.