



Post Authorisation Assessments

Pracetam 400 mg/ml Solution for Use in Drinking Water for Pigs Vm 15052/4130

•	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.
•	25 June 2021	Renewal – UK as CMS.
•	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 May 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. Replacement of a manufacturer responsible for importation / batch release of the finished product. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of an excipient. Addition of a manufacturing site of the finished product.
•	10 November 2016	Change in name / address of a manufacturer of the

		finished product. Change in name / address of a manufacturer of the finished product. Change in name / address of a manufacturer of the finished product.
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