

Post Authorisation Assessments

Pracetam 10% Premix for Medicated Feeding Stuff for Pigs Vm 15052/5035

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•	23 June 2023	Deletion of a manufacturing site. Deletion of a manufacturing site for a finished product, packaging site and a batch release site. 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.
•	11 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.
•	08 July 2022	To change the batch size of the finished product at the additional manufacturing site in Italy. Addition of a new manufacturing site responsible for batch release and batch testing. Addition of a new manufacturing site responsible for the primary packaging of the finished product. Addition of a new manufacturing site responsible for the secondary packaging of the finished product. Addition of a new manufacturing site responsible for the manufacturing site responsible of all manufacturing operations of the finished product.
•	30 March 2020	Change in control of excipients in the finished product. Addition to a test procedure for an excipient.
•	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. 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
•	18 October 2018	Replacement of a manufacturer responsible batch release of the finished product.
•	16 July 2018	Change in specification parameter of an excipient
•	19 June 2018	Deletion of a non-significant specification parameter of
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