Veterinary Medicines Directorate

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Post Authorisation Assessments

Octacillin 697 mg/g Powder for Use in Drinking Water for Pigs

Vm 16849/4030

•	02 July 2024	Minor changes to an approved test procedure for the active substance.
•	15 September 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph. Deletion of manufacturing site for an active substance. Deletion of manufacturing site for an active substance.
•	15 July 2021	Approval of mock ups.
•	06 May 2021	Update to the SPC and PIL texts according to the latest QRD template.
•	23 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	06 May 2020	Repeat Use application to add 11 new member states.
•	15 August 2019	Changes to the DDPS.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 September 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Introduction of a re-test period of the active substance.
•	01 August 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	01 August 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 June 2018	Deletion of manufacturing site for an active substance manufacturer.
•	24 May 2018	Changes to an existing pharmacovigilance system as described in the DDPS.
•	21 March 2018	Minor change in the manufacturing process of the finished product. Submission of an updated Ph.Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 April 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	28 September 2016	Mock-ups approved. Change in distributor details
•	06 August 2013	Submission of a new Ph. Eur. Certificate of Suitability

•	12 June 2013	Change of name and contact details for QPPV
•	12 October 2012	Changes in the immediate packaging of the finished product.
•	13 June 2012	Submission of an updated certificate of suitability for an already approved manufacturer.
•	26 January 2012	Renewal – UK as CMS