



Post Authorisation Assessments

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

•	22 September 2021	Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for an active substance.
•	09 February 2021	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	05 October 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 April 2019	Changes to a test procedure for the finished product.
•	24 January 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	09 October 2018	Change in RMS from UK to BE.
•	30 August 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. Addition of a re-test period of the active substance.
•	31 May 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. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 April 2017	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Replacement of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	05 August 2016	Change in distributor details.
•	26 July 2013	New Ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer. Change to specification of a former non Pharmacopoeial active substance to comply with Ph. Eur.
•	26 April 2013	Change in name and address of QPPV.
•	07 September 2012	Change in immediate packaging.
•	08 July 2011	Renewal.
•	09 December 2009	Change of distributor.
•	20 November 2009	New/updated Ph. Eur. Certificate of Suitability for an active substance.
•	17 January 2006	Change of distributor.
•	30 June 2005	Change of distributor.

•	11 February 2005	Storage conditions (product).
---	------------------	-------------------------------