



Post Authorisation Assessments

Alamycin 100mg/ml Solution for Injection

•	30 July 2019	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.
•	05 January 2016	Submission of a new Ph. Eur. certificate of suitability.
•	07 February 2014	Renewal.
•	05 December 2012	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
•	03 April 2012	Change in distributor address.
•	28 December 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
•	09 February 2011	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
•	02 December 2009	Addition of manufacturing site for finished product package assembly.
•	23 October 2008	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance.
•	28 February 2008	Changes to SPC and labels to bring in line with new legislation.
•	24 January 2007	Change in legal category from POM to POM-V.
•	19 July 2005	Review.