Veterinary Medicines Directorate

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Post Authorisation Assessments

Lincocin Soluble Powder, 400 mg/g Powder for Use in Drinking Water

Vm 42058/5143

•	28 April 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	06 July 2023	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier: - Extension or introduction of a re-test period/storage period supported by real time data.
•	12 June 2023	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier: - Extension or introduction of a re-test period/storage period supported by real time data.
•	14 March 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer.
•	08 February 2023	Changes to the quality part of the dossier: Deletion of - a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient. Changes to the quality part of the dossier: Deletion of - a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient.
•	06 February 2023	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.
•	20 December 2022	Updated certificate of suitability from an already approved manufacturer.
•	29 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 July 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Change in shape or dimensions of the container or closure (immediate packaging).
•	03 December 2019	Change in the address of the marketing authorisation holder from: Zoetis UK Limited, 5th Floor, 6 St. Andrew

		Street, London, EC4A 3AE to: Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	31 July 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance (used in manufacturing process of active) / excipient from a new manufacturer.
•	27 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 April 2018	Update of the quality dossier intended to implement the outcome of a Union referral procedure.
•	17 April 2018	Changes to the SPC/product labelling/package leaflet following an Article 34 referral. Change in the invented name of the veterinary medicinal product in Germany only
•	24 February 2017	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	12 January 2017	Addition of a primary packaging site of the finished product. Addition of a manufacturing site of the finished product
•	24 May 2016	Deletion of a manufacturing site.
•	27 April 2016	Submission of an updated certificate of suitability.
•	13 November 2014	Submission of a new and an updated Ph. Eur. Certificate of Suitability.
•	01 July 2014	Deletion of a manufacturer of the active substance.
•	08 August 2013	Transfer of Marketing Authorisation Holder (including a change in Distributor). Change in the name of the Manufacturer of the finished product. Addition of an alternative site for batch release for the finished product.
•	16 May 2013	Update test procedure for the finished product.
•	09 January 2013	Deletion of two Manufacturing sites, deletion of a batch testing site.
•	20 November 2013	Variation to update a Certificate of Suitability for the Active Substance.
•	15 December 2009	Variation to submit a new European Pharmacopeia Certificate of Suitability for an additional supplier for the Active Substance.
•	09 December 2009	Variation to submit an updated European Pharmacopoeia Certificate of Suitability.
•	08 July 2009	Variation to make a change in the test procedure of the finished product.
•	23 April 2009	Variation to seek approval for the addition of a new site for QA testing.
•	09 October 2007	Variation to change the Active Substance Manufacturer.
•	02 August 2007	Renewal.
•	16 May 2007	Addition of a manufacturing site for the finished product.
•	16 May 2007	Change in the test procedure of the finished product.

•	11 May 2007	Change in the batch size of the finished product.
•	11 May 2007	Addition of a site of batch release.
•	28 March 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	13 December 2006	Variation to change qualitative composition of the immediate packaging details.
•	30 June 2005	Variation to add a Distributor.
•	04 March 2005	Change of Marketing Authorisation Holder's name and address.
•	30 December 2004	Renewal.
•	10 December 2004	Variation to change the name/address of an Active Substance Manufacturer.
•	29 August 2003	Variation concerning the addition of a Distributor.
•	28 January 2003	Change of product withdrawal period.
•	30 August 2001	Variation to change the name and address of the Marketing Authorisation Holder.
•	12 October 1999	Renewal.
•	20 June 1997	Additional Active Substance Manufacturer.
•	12 May 1997	Change in the packaging details.
•	12 May 1997	Additional Manufacturer/Assembler of Dosage Form.