Veterinary Medicines Directorate

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Post Authorisation Assessments

Linco-Spectin 100, 222/444.7 mg/g Powder for Use in Drinking Water for Pigs and Chickens

Vm 42058/3039

•	29 February 2024	Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for a finished product.
•	21 December 2023	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the 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.
•	27 June 2023	Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance: - Other changes to a test procedure for the active substance or a starting material/intermediate.
•	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.
•	28 March 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer.
•	16 March 2023	Addition of an alternative test procedure for active substance.
•	16 March 2023	Deletion of a manufacturing site for an active substance. Deletion of a manufacturing site for a finished product.
•	15 March 2023	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active.
•	26 May 2022	Addition of a new manufacturer of an active substance supported by a Ph.Eur certificate of suitability.
•	28 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 March 2021	Addition of a site where batch control/testing takes place.
•	15 June 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).
•	21 October 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.
•	07 August 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	25 September 2018	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 March 2018	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.
•	13 January 2017	Variation to achieve joint-labelling with Ireland.
•	09 November 2016	Changes to SPC and product literature following the outcome of a referral procedure.
•	20 September 2016	Addition of a primary packaging manufacturing site for the finished product. Addition of a manufacturing site of the finished product.
•	25 May 2016	Submission of an Updated Certificate of Suitability.
•	14 January 2015	Harmonisation of the batch release site.
•	15 December 2014	Submission of a new Ph. Eur. Certificate of Suitability for an active substance.
•	11 December 2014	Changes to the product literature to harmonise product information across Europe. Updates to the quality dossier as a result of a referral procedure. Increase in the shelf-life of the finished product after first opening the immediate packaging, from 28 days to 6 months.
•	01 July 2014	Deletion of a manufacturer of the active substance.
•	08 August 2013	Transfer of Marketing Authorisation Holder. Change in the name of the Manufacturer of the finished product. Addition of an alternative site for batch release. Change in the name of the site of batch testing.
•	16 May 2013	Variation to update the test procedure for the finished product.
•	09 January 2013	Variation concerning the removal of a Manufacturing and batch release site. Removal of a batch testing site.
•	20 November 2012	Update the Certificate of Suitability for the Active Substance.
•	15 December 2009	Variation to submit a new European Pharmacopeia Certificate of Suitability for Active Substance for a new supplier. Deletion of a supplier of the API. Addition of an Active Substance Manufacturer.
•	09 December 2009	Variation to submit an updated European Pharmacopoeia Certificate of Suitability.
•	03 April 2009	Variation to seek approval for a new site of QA testing.
•	05 February 2009	Variation in order to comply with the new European Pharmacopoeia monograph for API.
•	09 October 2007	Variation to change the Active Substance Manufacturer.
•	31 August 2007	Renewal
•	20 June 2007	Variation to bring the SPC/Labelling in line with the

		Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	10 May 2007	Addition of a Manufacturer/Assembler of Dosage Form.
•	30 March 2007	Change in the batch size of the finished product.
•	30 March 2007	Change to batch release and quality control arrangements.
•	27 June 2005	Change of distributor.
•	22 June 2005	Replacement of an excipient with a comparable excipient.
•	04 March 2005	Change of name and address of Marketing Authorisation Holder.
•	09 December 2004	Change of name of the Active Substance Manufacturer.
•	18 November 2004	Renewal.
•	15 November 2004	Increase product withdrawal period for poultry.
•	28 August 2003	Addition of a distributor.
•	28 June 2002	Variation concerning the use of product in an additional species.
•	23 August 2001	Change in the name and address of the Marketing Authorisation/ATC Holder.
•	02 September 1999	Change in the name of the Manufacturing site.
•	22 February 1998	Renewal.
•	20 June 1997	Additional Active Substance Manufacturer.
•	21 April 1997	Variation concerning a Manufacturer/Assembler of Dosage Form.