Veterinary Medicines Directorate

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Post Authorisation Assessments

Synuclav 250 mg Tablets for Dogs

Vm 02000/5014

•	May 2024	New CEP submitted for the manufacture of an active substance.
•	28 April 2024	Minor change in the test procedure for determination of the Total Aerobic Microbial Count, the Total Combined Yeast and Mould Count and an Absence of Escherichia coli in 1 gram for the finished product.
•	21 December 2023	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	15 February 2022	Deletion of a non-significant specification parameter of an excipient.
•	10 December 2019	Addition of a secondary packaging site 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.
•	29 November 2019	Minor change in the manufacturing process of an immediate release solid oral dosage form. Qualitative / quantitative changes to the excipients.
•	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.
•	03 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	14 January 2019	Change in RMS from UK to ES.
•	04 January 2019	Update of the test procedure to comply with the updated general Ph. Eur monograph. Changes to a test procedure for the finished product.
•	30 August 2018	Changes to the labelling.
•	21 May 2018	Change in distributor details. From MiGroup, 12b Progress Way, Mid-Suffolk Business Park Eye, IP23 7HU, United Kingdom to MiGroup, CVS House, Owen Road, Diss, Norfolk, IP22 4ER, United Kingdom.
•	03 May 2016	Change in pack size of the finished product
•	23 March 2016	Submission of a new or updated Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of

		suitability Submission of a new or updated Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability Deletion of a Ph. Eur. certificate of suitability Submission of a new or updated Ph. Eur. certificate of suitability
•	10 September 2015	Change in product name
•	28 November 2014	Update to the DDPS.
•	06 November 2014	Change in product name.
•	06 November 2014	Change to the name and address of the distributor on the package leaflet, and remove reference to the distributor on the carton and label.
•	03 January 2014	Submission of European Pharmacopoeia Certificates of Suitability.
•	24 November 2011	Changes (Safety/Efficacy) to human and veterinary medicinal products.
•	27 April 2011	Deletion of a manufacturing site.
•	09 August 2010	Repeat use – To add Iceland as a CMS.
•	11 June 2009	Submission of a new/updated European Pharmacopoeia Certificates of Suitability.
•	25 April 2008	Change in composition of the immediate packaging.
•	09 April 2008	Change shelf life of finished product as packaged for sale.
•	17 April 2007	New/updated Ph. Eur Certificates of Suitability.
•	21 March 2007	Lateral transfer of legal category.
•	20 February 2007	Correction/simple text changes to SPC and/or product literature.
•	28 October 2005	Change shelf life of finished product as packaged for sale.
•	27 June 2003	Additional pack type.