Veterinary Medicines Directorate

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Post Authorisation Assessments

Somulose Solution for Injection

Vm 10434/4010

•	04 May 2024	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	11 July 2023	Minor changes to approved test procedure for the finished product.
•	11 May 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	14 November 2022	Change in the storage condition of the finished product. Change in the assay shelf-life specification of the finished product.
•	19 October 2022	Minor changes to the manufacturing process of the active substance (Secobarbital sodium, intermediate product manufacture)
•	13 January 2021	Update of Summary of Product Characteristics and product literature in relation to safety data.
•	18 December 2020	Change in the specification limits of the finished product.
•	27 October 2020	Minor change in the manufacturing process of the finished product.
•	26 August 2020	Deletion of a non-significant parameter used in the manufacturing process of the active substance. Changes to a test procedure for the active substance. Minor change in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	01 October 2019	Submission of an updated Ph. Eur. certificate of

		suitability for an active substance from an already approved manufacturer.
•	03 May 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	29 December 2017	Change in the address of a manufacturer used in the manufacture of the active substance. Minor update to 3.2.S.4.4. Minor update to 3.2.S.6. Additional stability information provided in 3.2.S.7.1. Additional stability data provided in 3.2.S.7.3.
•	22 July 2016	Submission of an update Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	11 March 2015	Changes to the packaging, not connected with the SPC.
•	08 January 2015	Change of address of the MAH.
•	21 May 2014	Change to an excipient, test procedure and specification parameters of the finished product. Extension of in-use shelf life from 28 days to 60 days.
•	19 November 2013	Variation to change an API manufacturer.
•	15 December 2010	Variation to change the distributor.
•	18 January 2010	Renewal.
•	18 December 2009	Variation to widen the shelf life specifications for the active substance, and to reduce the finished product shelf life.
•	15 December 2009	Variation to change the manufacturing process of the active substance.
•	31 July 2008	Variation to correct/make minor changes to the withdrawal period information on the SPC and in the Product Literature.
•	02 March 2007	Harmonisation of the SPC with Ireland.
•	30 November 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	20 October 2006	Change in the name of an active substance manufacturer.
•	20 October 2006	Change in the name of an active substance manufacturer.
•	11 October 2006	Change of the Marketing Authorisation Holder.
•	06 March 2006	Variation to reduce the shelf life of the finished product.
•	27 May 2004	Variation to change the product name.