Veterinary Medicines Directorate

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Post Authorisation Assessments

Calciject 40 CM Solution for Injection

Vm 02000/4125

•	31 July 2024	Change in test procedure for the finished product.
•	01 June 2023	Deletion of a supplier of bromobutyl bung.
•	26 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.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, BT35 6QQ, Co. Down, Northern Ireland.
•	03 November 2021	Addition of a supplier of packaging components or devices.
•	26 October 2021	Tightening of in-process limits applied during the manufacture of the finished product. Increase in batch size (From – 1000 L To – 1000 L and 4000 L) of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	19 August 2021	Submission of a new certificate of suitability for an active substance. Submission of a new certificate of suitability for an active substance.
•	16 July 2021	Minor changes to an approved test procedure of the finished product.
•	24 March 2020	Change in test procedure for the finished product
•	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.
•	13 June 2017	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	07 April 2014	Deletion of a manufacturer and change of name of a manufacturer.
•	02 November 2011	Change of distributor
•	04 May 2011	Change in test procedure performed on the finished product
•	05 December 2008	Renewal

•	29 May 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	07 February 2007	Change of legal category from POM to POM-VPS
•	11 August 2005	Addition of a site of assembly
•	19 July 2004	Renewal
•	17 October 2002	Change of shelf life from 12 months to 18 months
•	15 June 2001	Change of type of sterile container
•	31 January 2001	Renewal
•	09 September 1998	Change of manufacturing site of the dosage form
•	22 August 1995	Change of specification of the finished product
•	19 April 1995	Additional presentation