Veterinary Medicines Directorate

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Post Authorisation Assessments

Coxi Plus, Sulfadimethoxine Sodium Anhydrous 25% w/w Powder for Oral Solution

Vm 13058/4002

•	07 November 2022	Change in test procedure for the finished product to comply with Ph. Eur general monograph. Change in test procedure for the multi-dose finished product to comply with Ph. Eur general monograph. Change from batch size to batch range up to 10-fold increase. Replacement of manufacturer responsible for batch release and batch control testing. Replacement of manufacturer responsible for primary packaging of finished product. Replacement of manufacturer responsible for secondary packaging of finished product.
•	12 August 2022	Change in HPLC test procedure to follow Ph. Eur. monograph HPLC method for the active substance. Replace the ID test procedures for the finished product with an alternative HPLC DAD procedure. Minor changes to manufacturing process for the finished product. Inclusion of related substance specification to finished product specifications. Replacement of manufacturing site responsible for manufacture of the finished product.
•	23 October 2008	Change of legal category from POM to POM-V.
•	04 September 2007	Change of address of MAH.
•	12 January 2007	Renewal
•	22 November 2002	Renewal
•	30 May 2001	Change of shelf life from 48 to 60 months.
•	30 June 2000	Change of shelf life from 24 to 48 months.
•	24 February 1998	Additional pack size – 120g sachet.