Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911 Fax +44 (0)1932 336618

Post Authorisation Assessments

Baycox 2.5% w/v Oral Solution

•	19 July 2016	Minor changes to an approved test procedure for an intermediate material used in the manufacturing process of the active substance Minor changes to an approved test procedure for a starting material used in the manufacturing process of the active substance Minor changes to an approved test procedure for a starting material used in the manufacturing process of the active substance Minor changes to an approved test procedure for a starting material used in the manufacturing process of the active substance Minor changes to an approved test procedure for an intermediate material in the manufacturing process of the active substance Other changes to a test procedure for a reagent used in the manufacturing process of the active substance. Tightening of the specification limits for the active substance. Tightening in the specification parameters of an intermediate used in the manufacturing process of the active substance. Change in the specification parameters of an intermediate used in the manufacturing process of the active substance. Deletion of non-significant specification parameters of a starting material used in the manufacturing process of the active substance. Addition of a test procedure for a starting material used in the manufacturing process of the active substance Addition of a test procedure for a starting material used in the manufacturing process of the active substance Replacement of a test procedure for a starting material used in the manufacturing process of the active substance
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	28 July 2015	Addition of a new IPC test.
•	17 March 2015	Addition of a test procedure for the finished product.

•	17 March 2015	Change to the specification parameter for an excipient.
•	03 April 2014	Changes to in-process tests applied during the manufacture of the active substance. Changes to the manufacturing process of the active substance.
•	09 February 2011	Change of distributor
•	09 December 2009	Submission of an updated part 2 of the dossier
•	23 January 2009	Renewal
•	22 December 2008	Deletion of 'repeated treatment' from clinical particulars
•	22 July 2008	Referral
•	19 March 2008	Change in specification of finished product
•	13 August 2007	Batch control
•	21 March 2007	Change of legal category from POM to POM-V Changes to SPC and Product Literature to bring in line with new legislation
•	18 March 2005	Corrections/text changes to SPC and Product Literature
•	28 January 2005	Corrections/text changes to SPC and Product Literature
•	06 April 2004	Change of MAH