

Post Authorisation Assessments

Baycox 50 mg/ml Oral Suspension

•	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.
•	8 December 2015	Addition of a secondary packaging site
•	14 June 2013	Renewal.
•	02 March 2011	To change the distributor.
•	27 October 2009	To update the carton and package leaflet text (dosage instructions) to be consistent with the SPC.