



## Post Authorisation Assessments

### Antirobe Capsules 25 mg Vm 42058/4003

•	27 July 2023	Submission of an updated Ph. Eur. TSE CEP for a non-sterile: – active substance, – starting material, reagent, intermediate used in the manufacturing process of the active substance, or – excipient. Submission of a new Ph. Eur. TSE CEP for a non-sterile: – active substance, – starting material, reagent, intermediate used in the manufacturing process of the active substance, or – excipient.
•	28 April 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: active substance.
•	21 August 2020	Change in the address of the MAH, from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London, EC4A 3AE to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	22 June 2020	Submission of an updated certificate of suitability. Deletion of a certificate of suitability. Submission of an updated certificate of suitability. Deletion of a certificate of suitability. Submission of an updated certificate of suitability.
•	16 January 2019	Changes in imprints including replacement, or addition of inks used for product marking.
•	28 June 2018	Submission of a new Ph. Eur. TSE certificate of suitability for a starting material from a new manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. TSE certificate of suitability for a starting material. Deletion of Ph. Eur. TSE certificate of suitability for a starting material. Deletion of Ph. Eur. TSE certificate of suitability for a starting material. Deletion of Ph. Eur. TSE certificate of suitability for a starting material.
•	20 July 2016	Submission of a new TSE Certificate of Suitability from a new supplier. Submission of a new TSE Certificate of Suitability from a

		<p>new supplier.  Submission of a new TSE Certificate of Suitability from a new supplier.  Submission of an updated TSE Certificate of Suitability from an already approved supplier.  Removal of a current supplier for gelatin</p>
•	11 April 2016	Changes in imprints * / bossing* / other markings* including replacement, or addition of inks used for product marking.
•	06 May 2015	Submission of an updated certificate of suitability.
•	06 May 2015	Submission of a new certificate of suitability.
•	19 December 2014	Change in the name of the manufacturer of the finished product, also responsible for batch release.
•	10 September 2014	Changes to test procedures for the finished product. Changes in the specifications parameters and limits of the finished product.
•	18 September 2013	Grouped variation to transfer the MAH, to change the distributor, to delete a manufacturer/assembler of the dosage form, and to delete a site of batch release.
•	08 January 2013	Submission of two Ph. Eur. Certificates of Suitability for an excipient.
•	28 December 2011	Submission of ten Ph. Eur. Certificates of Suitability for excipients.
•	19 December 2011	Change in the contact details for the QPPV for an existing pharmacovigilance system.
•	30 November 2010	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance or a starting material/reagent/intermediate involved in the manufacture of the active substance.
•	07 September 2009	Submission of a new/updated Ph. Eur. Certificate of Suitability for an active substance or a starting material/reagent/intermediate involved in the manufacture of the active substance.
•	31 March 2009	Submission of two new/updated Ph. Eur. Certificates of Suitability for an active substance or a starting material/reagent/intermediate involved in the manufacture of the active substance
•	02 October 2007	Submission of two new/updated Ph. Eur. Certificates of Suitability for an active substance or a starting material/reagent/intermediate involved in the manufacture of the active substance.
•	09 August 2007	Change in legal category from POM to POM-V Changes to SPC and Product Literature to bring in line with new legislation.
•	10 May 2007	Change of MAH.
•	25 October 2006	Replacement of a manufacturing site for the finished product. Change to manufacturing process. Change to specification of the finished product. Change in test procedure for the finished product
•	08 August 2006	Addition of a site for batch release. Change of source of an excipient. Change in batch size of finished product. Change to colouring system of the finished product. Change of printing on capsules

•	16 December 2005	Renewal.
•	07 July 2005	Change of distributor.
•	10 December 2004	Change in the name of a manufacturer for the active substance.
•	29 September 2004	Submission of an updated TSE Certificate.
•	28 August 2003	Change of distributor.
•	23 August 2001	Change in name and address of MAH.
•	28 January 2000	Renewal.
•	31 August 1999	Change in name and address of MAH.
•	30 July 1999	Change in manufacturer of the dosage form. Change in assembler of the dosage form. Change in finished product specification.
•	04 June 1998	Change in shelf life.
•	17 February 1998	Change in manufacturer of dosage form.
•	15 March 1996	New indications and dosing regimen.