



Post Authorisation Assessments

Antirobe Capsules 300 mg Vm 42058/4004

•	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.
•	01 December 2010	Submission of updated Ph. Eur. Certificate of Suitability for an excipient.
•	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 of legal category from POM to POM-V. Changes to SPC and Product Literature to bring in line with new legislation.
•	01 August 2007	Renewal.
•	10 May 2007	Change of MAH.
•	09 November 2006	Addition of a manufacturer responsible for assembly and batch release. Change in specification of the finished product. Change in test procedure on the finished product. Minor change in the manufacturing process of the finished product.
•	16 August 2006	Change in the source of an excipient. Change in the printing on the capsules. Addition of a site for batch release.
•	07 July 2005	Change of distributor.

•	10 December 2004	Change in name of manufacturer of the active substance.
•	29 September 2004	Submission of updated TSE Certificate.
•	20 August 2004	Change in colouring system of the finished product.
•	29 August 2003	Change of distributor.