



Post Authorisation Assessments

HY-50 Vet 17 mg/ml Solution for Injection Vm 50406/5037

23 March 2026	One-off alignment of the product information with version 3 of the GB QRD templates.
03 December 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
03 December 2025	Correction of typographical errors and minor changes to Sections 2A and 2B of the dossier.
29 August 2025	Correction of typographical errors and minor changes to Section 2C2 of the dossier.
25 April 2025	Change of Marketing Authorisation Holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
26 March 2025	Change to quality testing arrangements for the finished product.
26 March 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (NI).
26 March 2025	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB).
03 March 2025	Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter in the specification parameters of the finished product. (NI).
03 March 2025	Changes to the quality part of the dossier: Deletion of – a non-significant specification parameter in the specification parameters of the finished product. (GB).
12 May 2022	Addition of a site for microbiological testing for the finished product.
09 November 2020	Addition of a site where batch control/testing takes place.
07 May 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
18 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
25 April 2018	Deletion of manufacturing site for the finished product.
07 December 2017	Addition of a site where batch control/testing takes place.
25 August 2016	Addition of a manufacturing site for secondary packaging.
19 April 2016	Updated labels and package leaflet approved.
02 March 2016	A change in the address of the Marketing Authorisation Holder

	from Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, ST7 1XW UK to Snaygill Industrial Estate, Keighley Road, Skipton North Yorkshire, BD23 2RW.
07 May 2015	Change to comply with an update of the Ph. Eur. Submission of an updated Ph. Eur. Certificate of Suitability.
23 April 2014	Change in control of the excipients.
09 April 2014	Changes to the manufacturing process of the active substance and changes to the specification parameters of the active. Addition of a supplier of the active.
23 December 2013	Change to an in-process test and limits applied during the manufacturing process.
01 October 2013	Variation to change the importer of the final dosage form (from outside the EU).
30 August 2013	Addition of a site for batch analysis.
22 April 2013	Change in the finished product test procedure.
05 February 2013	Variation to change the name of an excipient supplier.
05 February 2013	Change to a test method used in the manufacturing process.
19 December 2012	Grouped variation concerning the submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer, and the update of a related test method.
20 November 2012	Addition of a source of a packaging component.
25 April 2012	Variation to change the distributor.
14 March 2012	Variation to change the Marketing Authorisation Holder.
06 January 2012	Variation to change the manufacturer responsible for batch release.
07 January 2009	Addition of a new route of administration.
07 January 2009	EU Renewal.
03 March 2006	Change in the batch size of the finished product.
28 January 2005	Renewal.
11 June 2004	Change in the shelf life.
09 January 2004	Change in the address of the Marketing Authorisation Holder.
04 February 2003	New EUDE Marketing Authorisation (UK as CMS).