

Post Authorisation Assessments

Poulvac IB Primer Vm 42058/5191

31 March 2026	To include Eurofins PROXY Laboratories B.V., Darwinweg 24, Leiden, 2333 CR, Netherlands as an additional finished product quality control testing site.
01 September 2025	Submission of updated mock ups.
23 April 2025	Change of Marketing Authorisation Holder to Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Dublin 18, D18 T3Y1, Ireland (NI only).
31 January 2025	Update of section 4.8 of the SPC which now includes information on associated use of Poulvac IB QX and Poulvac IB Primer.
18 January 2025	Addition of the coulometric method as alternative residual moisture test. Addition of Zoetis Manufacturing & Research Spain, S.L as manufacturing site for the active substance and final product. Deletion of extraneous agents tests on the finished product based on assessment conducted in accordance with Ph. Eur. 5.2.5. Update of Part 2 in order to align with current manufacturing practices at the currently approved sites, and to harmonise Part 2, including replacement of the method for visual inspection by AQL with visual appearance, adjustment of the SPF eggs pre-incubation conditions, reference to gelatin as Ph. Eur. grade material, inclusion of gentamicin as a starting material of fish origin, removal of EA testing in WS according to Ph Eur 5.2.5, and other minor discrepancies. Introduction of the 7 ml vial and stopper as result of the site addition.
19 August 2022	Replacement of the current biochemical identification method with an alternative identity test based on mass spectroscopy.
14 August 2020	Change in the address of the marketing authorisation holder 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.
15 May 2019	-Change in shape or dimensions of the container or closure -Change in the batch size of the finished product.
11 February 2019	Change in the SPC and package leaflet due to new data.
06 November 2018	Change of a test procedure for the finished product.
20 September 2017	Change of a test procedure for the finished product.
21 November 2016	Change in test procedure for the finished product.
7 January 2016	Change in test procedure for the finished product
23 October 2015	Change in name of manufacturer of the active substance. Change in name of manufacturer of the finished product.
20 October 2015	Change in name of manufacturer.

06 June 2014	Deletion of a manufacturing site.
28 May 2014	Changes to the manufacturing process of the active substance.
26 March 2014	Change in test procedure for the finished product.
22 November 2013	Change in the test procedure for an active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance.
27 June 2013	Grouped variation to change the Marketing Authorisation Holder and Distributor. Change the name of the manufacturer of active substance, blending, filling and assembly. Change the name and address of the site for QC testing, and the site for labelling and batch release. Editorial change to remove an importer of dosage form from outside the EU.
16 July 2012	Variation to replace a test method recommended in the Ph. Eur. Monograph 5.2.2.
01 February 2012	Variation to provide clarification for the release testing, secondary labelling/packaging, and batch release site.
27 July 2011	Variation to change the name of the manufacturing site which is currently approved for QC testing, labelling, and batch release.
13 June 2011	Addition of a manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance.
16 December 2010	Variation to change the name of the manufacturer of active substance, site for blending, filling and assembly, site for QC testing, site for labelling and batch release.
23 November 2010	Variation to change the name of a manufacturer of active substance.
20 August 2010	Renewal.
21 April 2010	Change of Marketing Authorisation Holder and distributor.
09 February 2010	Variation to update the extraneous agents testing in line with the Eu. Ph. 6 th Edition.
13 May 2009	Addition of a site for testing and QP release.
27 July 2007	Variation to update part I and II of the Addendum.
12 July 2007	Extension of the finished product shelf-life.
06 March 2006	Change in the shape and or dimension of the container or closure.
18 April 2005	Marketing Authorisation Conversion.
30 June 2004	Renewal.
30 June 2004	Renewal.
30 June 2004	Renewal.
30 June 2004	Renewal.
30 June 2004	Renewal.
12 November 2002	Renewal.
03 February 1998	Change of Marketing Authorisation Holder
24 April 1997	Renewal.