



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Porcilis ColiClos

Vm 01708/5053

• 26 February 2024	The variation is to mention the use of animal derived trypsin in the manufacture of the Byco-C hydrolysed gelatin provided by Croda and to declare a change in the hydrolysis step of the gelatin (excipient) by replacing porcine trypsin by the use of either porcine or bovine trypsin.
• 09 February 2024	Alignment to new GB PL template version 1.
• 19 September 2023	Addition of alternative sterilisation method of the immediate packaging of the finished product.
• 04 May 2022	Replacement of a test procedure for the finished product.
• 06 April 2022	Changes to the labelling.
• 23 July 2021	Addition of a site where batch control/testing takes place.