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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Nobilis IB Primo QX

Vm 01708/5042

27 July 2026	To add the use of recombinant trypsin in the manufacture of the Byco-C hydrolysed gelatin, to ensure uninterrupted supply.
08 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
07 July 2025	Change in outer part of the primary packaging material not in contact with the finished product.
01 December 2024	Change in test procedure for intermediate used in the manufacturing process of the active substance. Change in the storage conditions of the finished product. Change to in-process tests applied during the manufacture of the active substance. Minor changes in the manufacturing process of the active substance.
02 September 2024	One-off alignment of the product information with version 2 of the GB SPC and QRD templates.
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.
06 May 2022	Approval of Mock-ups.
26 February 2021	Grouped variation: Addition of a manufacturing site for the finished product, change in the specification limits of the finished product, change to in-process tests or limits applied during the manufacture of the finished product, change in storage conditions of the active substance, change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product, increase in batch size of the finished product, change in test procedure for the finished product, change in test procedure for the finished product, change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product, change in the number of units in a pack outside the range of the currently approved pack sizes of the finished product, addition of a secondary packaging site of the finished product, addition of new tests and limits applied during the manufacture of the finished product, change in the number of units in a pack within the range of the currently approved pack sizes of the finished product and change in any part of the (primary) packaging material not in contact with the finished product formulation - Other variation