VPA10987/099/001

Topimec Super Solution for Injection

Variation	Summary	Date
Vet - G.I.18	VRA-S - Vet - G.I.18 - - Vet - G.I.18 - One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	20/08/26
Vet - A2	VNRA - Vet - A2 - - Vet - A2 Administrative changes - Change in the (invented) name of the veterinary medicinal product	15/12/25
Vet - B9 a)	VNRA - Vet - B9 a) - - Vet - B9 a) - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance up to 10-fold increase compared to the originally approved batch size	29/07/25
Vet - F.I.f.1	VRA-S - Vet - F.I.f.1 - 1. Substantial changes in the updated version of the ASMF or the active substance part of the dossier - F.I.f.1 Quality Changes - Active Substance - Other changes to the active substance - Substantial changes in the updated version of the ASMF or the active substance part of the dossier	14/02/23
B.I.a.3.a	IA - B.I.a.3.a - a) Up to 10-fold increase compared to the originally approved batch size - B.I.a.3.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - Up to 10-fold increase compared to the originally approved batch size	29/03/22
B.I.a.1.a	IAin - B.I.a.1.a - a) The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer - B.I.a.1.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	29/03/22