

VPA10987/099/001

**Topimec Super Solution for Injection**

<b>Variation</b>	<b>Summary</b>	<b>Date</b>
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