

VPA10988/082/001

Borgal 24% Solution for Injection

Variation	Summary	Date
Vet - F.III.1 a) 1.	VRA-S - Vet - F.III.1 a) 1. - a) European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph. 1. New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free - F.III.1 a) 1. Quality Changes - CEP/TSE/MONOGRAPHS - Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: -For an active substance -For a starting material/reagent/intermediate used in the manufacturing process of the active substance -For an excipient European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate for a non-sterile active substance that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free	11/09/23
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	25/05/23
Vet - B3 a)	VNRA - Vet - B3 a) - a) Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier) - B3 a) Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	25/05/23
Vet - F.I.a.1 z)	VRA-R - Vet - F.I.a.1 z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.a.1 z) - 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	10/11/22

	<p>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 - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021</p>	
--	---	--