

VPA10987/039/001

Bovex 2.265%

Variation	Summary	Date
Vet - B49 b)	VNRA - Vet - B49 b) - b) Addition of a new specification parameter to the specification with its corresponding test method - B49 b) Changes to the quality part of the dossier: Change in specification parameters or limits of a measuring or administration device: — addition of a new specification parameter to the specification with its corresponding test method	15/09/22
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)	15/09/22
Vet - B44	VNRA - Vet - B44 - Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance, starting material, reagent or intermediate, excipient - B44 Changes to the quality part of the dossier: Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	15/09/22
Vet - B47 b)	VNRA - Vet - B47 b) - b) Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State - B47 b) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	15/09/22
Vet - F.I.d. z)	VRA-R - Vet - F.I.d. z) - z) Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - F.I.d. z) Quality Changes - Active Substance - Stability - Other changes under this code level, e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	14/09/22
Vet - E.z	VRA-R - Vet - E.z - Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021 - E.I - Administrative Changes - Other changes under this code level e.g. variations outlined in section 6 and 7 of EMA/CMDv/7381/2021	14/09/22